

ETHICON Wound Closure Manual

ETHICON WOUND CLOSURE MANUAL	1
WOUND HEALING	5
<i>Wound Closure Manual</i>	5
THE WOUND	7
WOUND HEALING	8
<i>Wound Healing</i>	8
<i>Patient Factors That Affect Wound Healing</i>	9
<i>Surgical Principles</i>	11
CLASSIFICATIONS OF WOUNDS	12
TYPES OF WOUND HEALING	14
<i>Types of Wound Healing</i>	14
<i>Healing By First Intention</i>	15
<i>Healing by Second Intention</i>	17
<i>Healing by Third Intention</i>	18
COMPLICATIONS IN WOUND HEALING.....	19
IN THE NEXT SECTION.....	20
REFERENCES	21
THE SUTURE	22
WHAT IS A SUTURE?	22
PERSONAL SUTURE PREFERENCE.....	22
SUTURE CHARACTERISTICS	24
<i>Suture Characteristics</i>	24
<i>Size and Tensile Strength</i>	25
<i>Monofilament vs. Multifilament Strands</i>	26
<i>Absorbable vs. Nonabsorbable Materials page 1 of 2</i>	27
<i>Absorbable vs. Nonabsorbable Materials page 2 of 2</i>	29
SPECIFIC SUTURING MATERIALS	29
<i>Specific Suturing Materials</i>	29
<i>Absorbable Sutures</i>	30
<i>Synthetic Absorbable Sutures</i>	31
<i>Nonabsorbable Sutures page 1 of 2</i>	33
<i>Nonabsorbable Sutures page 2 of 2</i>	34
<i>Synthetic Nonabsorbable Sutures</i>	35
<i>Suturing Options: Materials, Characteristics and Applications Table Part 1</i>	36
<i>Suturing Options: Materials, Characteristics and Applications Table Part 2</i>	38
<i>Suturing Options: Materials, Characteristics and Applications Table Part 3</i>	40
COMMON SUTURING TECHNIQUES.....	42
<i>Ligatures</i>	42
<i>The Primary Suture Line</i>	43
<i>The Secondary Suture Line</i>	46
<i>Stitch Placement</i>	47
KNOT TYING TECHNIQUES.....	48
<i>General Principles of Knot Tying</i>	48
<i>Suture Characteristics and Knot Security</i>	49
<i>Knot Tying Techniques Most Often Used</i>	49
<i>Endoscopic Knot Tying Techniques</i>	52
<i>Cutting Sutures</i>	53
SUTURE REMOVAL.....	54
SUTURE HANDLING TIPS.....	55
SUTURE SELECTION BY PROCEDURE	56
<i>Principles of Suture Selection</i>	56
<i>Surgery Within the Abdominal Cavity</i>	57
<i>Closing the Abdomen page 1 of 3</i>	60
<i>Closing the Abdomen page 2 of 3</i>	62

<i>Closing the Abdomen page 3 of 3</i>	64
<i>Suture Needs in Other Body Tissues page 1 of 5</i>	65
<i>Suture Needs in Other Body Tissues page 2 of 5</i>	67
<i>Suture Needs in Other Body Tissues page 3 of 5</i>	69
<i>Suture Needs in Other Body Tissues page 4 of 5</i>	70
<i>Suture Needs in Other Body Tissues page 5 of 5</i>	71
<i>Closing Contaminated or Infected Wounds</i>	73
IN THE NEXT SECTION	74
REFERENCES	75
THE SURGICAL NEEDLE	76
DESIRABLE NEEDLE CHARACTERISTICS	76
ELEMENTS OF NEEDLE DESIGN	77
PRINCIPLES OF CHOOSING A SURGICAL NEEDLE	79
THE ANATOMY OF A NEEDLE	80
<i>The Anatomy of a Needle</i>	80
<i>The Needle Eye</i>	80
<i>The Needle Body</i>	83
<i>The Needle Point</i>	85
TYPES OF NEEDLES	87
<i>Cutting Needles</i>	87
<i>Taper Point Needles</i>	90
<i>TAPERCUT Surgical Needles</i>	91
<i>Blunt Point Needles</i>	92
<i>ETHICON needle codes and their meaning Part 1</i>	93
<i>ETHICON needle codes and their meaning Part 2</i>	95
NEEDLE HOLDERS	96
NEEDLE HOLDERS	96
<i>Needle Holders</i>	96
<i>Needleholder Use</i>	97
<i>Placing the Needle in Tissue</i>	99
NEEDLE HANDLING TIPS	100
NEEDLE HANDLING TIPS	100
IN THE NEXT SECTION	101
REFERENCES	102
PACKAGING	103
AN INTEGRAL PART OF THE PRODUCT	103
RELAY SUTURE DELIVERY SYSTEM	104
<i>Relay Suture Delivery System</i>	104
<i>Modular Storage Racks</i>	105
<i>Dispenser Boxes</i>	105
<i>Primary Packets Page 1</i>	107
<i>Primary Packets Page 2</i>	109
E-PACK PROCEDURE KIT	110
EXPIRATION DATE	111
SUTURE STERILIZATION	112
ANTICIPATING SUTURE NEEDS	112
<i>Anticipating Suture Needs</i>	112
<i>Sterile Transfer of Suture Packets</i>	114
<i>Suture Preparation in the Sterile Field</i>	115
<i>Suture Handling Technique</i>	118
OTHER SURGICAL PRODUCTS	121
HEMOSTASIS PRODUCTS	122
<i>Hemostasis Products</i>	122
<i>Mechanical Method</i>	123
<i>Electrical Method</i>	124
<i>Topical Agents</i>	124

LOOPEd SUTURE.....	126
RETENTION SUTURE DEVICES.....	127
TISSUE ADHESIVES	129
TAPES	130
<i>Skin Closure Tapes</i>	130
<i>Polyester Fiber Strip</i>	132
<i>Umbilical Tape</i>	133
SURGICAL MESH.....	134
<i>Surgical Mesh</i>	134
<i>Polyester Fiber Mesh</i>	135
<i>Polypropylene Mesh</i>	136
<i>Polyglactin 910 Mesh</i>	137
TENDON REPAIR KITS	138
TEMPORARY CARDIAC PACING WIRE	139
IN THE NEXT SECTION.....	140
REFERENCES	141
RESEARCH AND DEVELOPMENT.....	142
AN ONGOING PROCESS OF CHANGE AND IMPROVEMENT.....	142
PRECLINICAL ASSESSMENT.....	143
CLINICAL ASSESSMENT	146
RESULTS	147
REFERENCES	148
PRODUCT TERMS AND TRADEMARKS	149
PRODUCT TERMS AND TRADEMARKS: ABS - DEC	149
PRODUCT TERMS AND TRADEMARKS: DEH - HEM	150
PRODUCT TERMS AND TRADEMARKS: HEM - MON	151
PRODUCT TERMS AND TRADEMARKS: MON-POW	152
PRODUCT TERMS AND TRADEMARKS: PRE-STE.....	153
PRODUCT TERMS AND TRADEMARKS: STE-TUB	154
PRODUCT TERMS AND TRADEMARKS: UMB-WOU	155
REFERENCES.....	156
PRODUCT INFORMATION	158
SURGICAL GUT SUTURE.....	158
FAST ABSORBING SURGICAL GUT (PLAIN)	160
COATED VICRYL RAPIDE (POLYGLACTIN 910) BRAIDED COATED SYNTHETIC ABSORBABLE SUTURE, UNDYED	162
COATED VICRYL (POLYGLACTIN 910) SUTURE.....	165
MONOCRYL VIOLET MONOFILAMENT (POLIGLECAPRONE 25) SUTURE.....	168
MONOCRYL (POLIGLECAPRONE 25) SUTURE	171
PDS II (POLYDIOXANONE) SUTURE DYED AND CLEAR MONOFILAMENT	174
PANACRYL SUTURE	177
PERMA-HAND SILK SUTURE.....	180
SURGICAL STAINLESS STEEL SUTURE.....	182
ETHILON NYLON SUTURE.....	184
NUROLON NYLON SUTURE.....	186
MERSILENE POLYESTER FIBER SUTURE.....	188
ETHIBOND EXCEL POLYESTER SUTURE.....	190
PROLENE POLYPROPYLENE SUTURE	192
PRONOVA POLY (HEXAFLUOROPROPYLENE-VDF) SUTURE.....	195
PROLENE POLYPROPYLENE HERNIA SYSTEM	197
PROLENE POLYPROPYLENE MESH	199
VICRYL (POLYGLACTIN 910) KNITTED MESH.....	201
VICRYL (POLYGLACTIN 910) WOVEN MESH.....	203
MERSILENE POLYESTER FIBER MESH	205
DERMABOND TOPICAL SKIN ADHESIVE PAGE 1 OF 3	207

DERMABOND TOPICAL SKIN ADHESIVE PAGE 2 OF 3	210
DERMABOND TOPICAL SKIN ADHESIVE PAGE 3 OF 3	211
SURGICEL, SURGICEL FIBRILLAR, AND SURGICEL NU-KNIT ABSORBABLE HEMOSTATS PAGE 1 OF 2.....	214
SURGICEL, SURGICEL FIBRILLAR, AND SURGICEL NU-KNIT ABSORBABLE HEMOSTATS PAGE 2 OF 2.....	217
INSTAT COLLAGEN ABSORBABLE HEMOSTAT.....	219
INSTAT MCH MICROFIBRILLAR COLLAGEN HEMOSTAT.....	222
THROMBIN, TROPICAL USP THROMBOGEN (BOVINE ORIGIN)	225
POWERSTAR BIPOLAR SCISSORS	228

Wound Healing

Wound Closure Manual



This manual has been prepared for the medical professional who would like to learn more about the practice of surgery -- the dynamics of tissue healing, the principles of wound closure, and the materials available to today's practitioners. Most important, it touches upon some of the critical decisions which must be made on a daily basis to help ensure proper wound closure.

At ETHICON, Inc. we have the utmost respect for the life-saving work of surgical practitioners everywhere -- in major medical centers and in small hospitals and clinics alike -- and we take great pride in assisting them. We hope that this manual will answer many of your questions. But, above all, we hope that it reflects our high regard for the men and women who have chosen the medical profession as a career.

The Wound

On a playground, a 6-year-old boy has fallen on a jagged rock and torn his knee. It will require 10 stitches to close the laceration.

In an operating room, a surgeon has made a precise incision on the abdomen of a 70-year-old woman with cancer. As disparate as these two scenes may seem on the surface, the boy and the woman share a common experience. They have both sustained *wounds* that must be mended.

Whether inflicted by chance, or sustained during a surgical procedure, every wound is simply a disruption of the normal continuity of tissue.¹ When tissue has been disrupted so severely that it cannot heal naturally (without complications or possible disfigurement) it must be held in apposition until the healing process provides the wound with sufficient strength to withstand stress without mechanical support. A wound may be approximated with sutures, staples, clips, skin closure strips, or topical adhesives.

Tissue may be defined as a group or layer of similarly specialized cells which, together, perform specialized functions¹. The various kinds of tissue throughout the body have different inherent properties which determine their functions, as well as their strength and resistance to tearing. The choice of wound closure materials and the techniques of using them are prime factors in the restoration of continuity and tensile strength to the injured tissues during the healing process.

The parameters for measuring the strength of normal body tissue are:

- **TENSILE STRENGTH**--The load per cross-sectional area unit at the point of rupture² relating to the nature of the material rather than its thickness.
- **BREAKING STRENGTH**--The load required to break a wound regardless of its dimension², the more clinically significant measurement.
- **BURST STRENGTH**--The amount of pressure needed to rupture a viscus, or large interior organ.

The rate at which wounds regain strength during the wound healing process must be understood as a basis for selecting the most appropriate wound closure material.

Wound Healing

Wound Healing

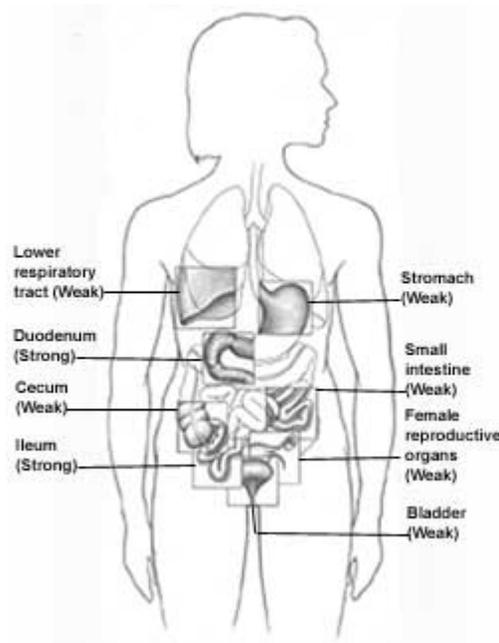
In response to injury of any kind, including surgical incision, natural defense mechanisms immediately come into play to restore the integrity and strength of the tissue involved. During the first few days, an inflammatory response causes an outpouring of tissue fluids, an accumulation of cells and fibroblasts, and an increased blood supply to the wound. Leukocytes and other cells produce proteolytic enzymes which dissolve and remove damaged tissue debris. After the debridement process is well along, fibroblasts begin to form collagen fibers in the wound. Collagen, a protein substance, is the chief constituent of connective tissue. Collagen fiber formation determines the tensile strength and pliability of the healing wound.

In time, sufficient collagen is laid down across the wound so that it can withstand normal stress. The length of this phase varies with the type of tissue involved and the stresses or tension placed upon the wound during this period. Tensile strength affects the tissue's ability to withstand injury but is not related to the length of time it takes the tissue to heal. While skin and fascia (the layer of firm connective tissue covering muscle) are the strongest tissues in the body, they regain tensile strength slowly during the healing process. The stomach and small intestine, on the other hand, are composed of much weaker tissue but heal rapidly. Variations in tissue strength may also be found within the same organ. Within the colon, for example, the sigmoid region is approximately twice as strong as the cecum--but both sections heal at the same rate.

Factors that affect tissue strength include the size, age, and weight of the patient, the thickness of tissue, the presence of edema, and induration (the degree to which the tissue has hardened in response to pressure or injury).

FIG.1

RELATIVE TISSUE STRENGTH



Patient Factors That Affect Wound Healing

The patient's overall health status will affect the speed of the healing process. The following are factors that should be considered by the surgical team prior to and during the procedure.

- **THE PATIENT'S AGE**--With aging, both skin and muscle tissue lose their tone and elasticity. Metabolism also slows, and circulation may be impaired. All of these factors lengthen healing time.
- **THE PATIENT'S WEIGHT**--In obese patients of any age, excess fat at the wound site may prevent securing a good closure. In addition, fat does not have a rich blood supply, making it the most vulnerable of all tissues to trauma and infection.
- **THE PATIENT'S NUTRITIONAL STATUS**--Deficiencies in carbohydrates, proteins, zinc, and vitamins A, B, and C can impair the healing process. Adequate nutrition is essential to support cellular activity and collagen synthesis at the wound site.
- **DEHYDRATION**--If the patient's system has been depleted of fluids, the resulting electrolyte imbalance can affect cardiac function, kidney function, cellular metabolism, oxygenation of the blood, and hormonal function. These effects will not only impact upon the patient's overall health status and recovery from surgery but may also impair the healing process.
- **INADEQUATE BLOOD SUPPLY TO THE WOUND SITE**--Oxygen is necessary for cell survival and, therefore, healing. Skin healing takes place most rapidly in the face and neck, which receive the greatest blood supply, and most slowly in the extremities. The presence of any condition that compromises the supply of blood to the wound, such as poor circulation to the limbs in a diabetic patient, will slow and can even arrest the healing process.
- **THE PATIENT'S IMMUNE RESPONSES**--Because the immune response protects the patient from infection, immunodeficiencies may seriously compromise the outcome of a surgical procedure. Patients infected with HIV, as well as those who have recently undergone chemotherapy or who have taken prolonged high dosages of catabolic steroids, may have debilitated immune systems. Some patients have allergies to specific suturing materials, metal alloys, or latex. These, on the other hand, will cause a heightened immune response in the form of an allergic reaction. This may also interfere with the healing process. Therefore, the surgeon should always check beforehand on a patient's allergies.
- **THE PRESENCE OF CHRONIC DISEASE**--A patient whose system has already been stressed by chronic illness, especially endocrine disorders, diabetes, malignancies, localized infection, or debilitating injuries will heal more slowly and will be more vulnerable to postsurgical wound complications. All of these conditions merit concern, and the surgeon must consider their effects upon the tissues at the wound site, as well as their potential impact upon the patient's overall recovery from the procedure. Malignancies, in addition, may alter the cellular structure of tissue and influence the surgeon's choice of methods and closure materials.
- **RADIATION THERAPY**--Radiation therapy to the surgical site prior to or shortly after surgery can produce considerable impairment of healing and lead to substantial wound

complications. Surgical procedures for malignancies must be planned to minimize the potential for these problems.

Surgical Principles

Many factors that affect the healing process can be controlled by the surgical team in the operating room, by the obstetrical team in labor and delivery, or by the emergency team in the trauma center. *Their first priority is to maintain a sterile and aseptic technique to prevent infection.* While organisms found within a patient's own body frequently cause postoperative infection, microorganisms carried by medical personnel also pose a threat. Whatever the source, infection will deter healing. In addition to concerns about sterility, the following must be taken into consideration when planning and carrying out an operative procedure.

1. **THE LENGTH AND DIRECTION OF THE INCISION**--A properly planned incision is just long enough to afford sufficient operating space and optimum exposure. When deciding upon the direction of the incision, the surgeon must bear the following in mind:
 - The direction in which wounds naturally heal is from side-to-side, not end-to-end.
 - The arrangement of tissue fibers in the area to be dissected will vary with tissue type.
 - The best cosmetic results may be achieved when incisions are made parallel to the direction of the tissue fibers. Results may vary depending upon the tissue layer involved.

DISSECTION TECHNIQUE--When dissecting tissue, a clean incision should be made through the skin with one stroke of evenly applied pressure on the scalpel. Sharp dissection should be used to cut through remaining tissues. The surgeon must preserve the integrity of as many of the underlying nerves, blood vessels, and muscles as possible. **TISSUE HANDLING**--Keeping tissue trauma to a minimum promotes faster healing. Throughout the operative procedure, the surgeon must handle all tissues very gently--and as little as possible. Retractors should be placed with care to avoid excessive pressure, since tension can cause serious complications: impaired blood and lymph flow, altering of the local physiological state of the wound, and predisposing to microbial colonization.

2. **HEMOSTASIS**--Various mechanical, thermal, and chemical methods are available to decrease the flow of blood and fluid into the wound site. Hemostasis allows the surgeon to work in as clear a field as possible with greater accuracy. Without adequate control, bleeding from transected or penetrated vessels or diffuse oozing on large denuded surfaces may interfere with the surgeon's view of underlying structures.

Achieving complete hemostasis before wound closure will also prevent formation of postoperative hematomas. Collections of blood (hematomas) or fluid (seromas) in the incision can prevent the direct apposition of tissue needed for complete union of wound edges. Furthermore, these collections provide an ideal culture medium for microbial growth and can lead to serious infection.

When clamping or ligating a vessel or tissue, care must be taken to avoid excessive tissue damage. Mass ligation that involves large areas of tissue may produce necrosis, or tissue death, and prolong healing time.

MAINTAINING MOISTURE IN TISSUES--During long procedures, the surgeon may periodically irrigate the wound with warm physiologic (normal) saline solution, or cover exposed surfaces with saline-moistened sponges or laparotomy tapes to prevent tissues from drying out.

REMOVAL OF NECROTIC TISSUE AND FOREIGN MATERIALS--Adequate debridement of all devitalized tissue and removal of inflicted foreign materials are essential to healing, especially in traumatic wounds. The presence of fragments of dirt, metal, glass, etc., increases the probability of infection.

CHOICE OF CLOSURE MATERIALS--The surgeon must evaluate each case individually, and choose closure material which will maximize the opportunity for healing and minimize the likelihood of infection. The proper closure material will allow the surgeon to approximate tissue with as little trauma as possible, and with enough precision to eliminate dead space. The surgeon's personal preference will play a large role in the choice of closure material; but the location of the wound, the arrangement of tissue fibers, and patient factors influence his or her decision as well.

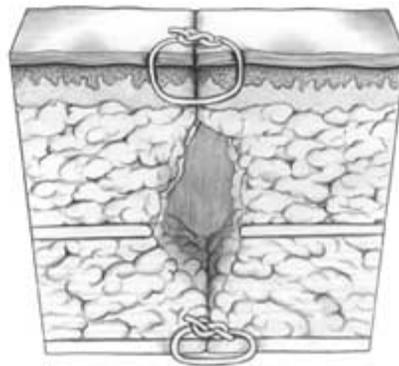
CELLULAR RESPONSE TO CLOSURE MATERIALS--Whenever foreign materials such as sutures are implanted in tissue, the tissue reacts. This reaction will range from minimal to moderate, depending upon the type of material implanted. The reaction will be more marked if complicated by infection, allergy, or trauma.

Initially, the tissue will deflect the passage of the surgeon's needle and suture. Once the sutures have been implanted, edema of the skin and subcutaneous tissues will ensue. This can cause significant patient discomfort during recovery, as well as scarring secondary to ischemic necrosis. The surgeon must take these factors into consideration when placing tension upon the closure material.

ELIMINATION OF DEAD SPACE IN THE WOUND--*This is critical to healing!* Dead space in a wound results from separation of wound edges which have not been closely approximated, or from air trapped between layers of tissue. This is especially true in the fatty layer which tends to lack blood supply. Serum or blood may collect, providing an ideal medium for the growth of microorganisms that cause infection. The surgeon may insert a drain or apply a pressure dressing to help eliminate dead space in the wound postoperatively.

FIG.2

DEAD SPACE IN WOUND



CLOSING WITH SUFFICIENT TENSION--While enough tension must be applied to approximate tissue and eliminate dead space, the sutures must be loose enough to prevent exaggerated patient discomfort, ischemia, and tissue necrosis during healing.

STRESS PLACED UPON THE WOUND AFTER SURGERY--The patient's postoperative activity can place undue stress upon a healing incision. Abdominal fascia will be placed under excessive tension after surgery if the patient strains to cough, vomit, void, or defecate. The tendons and the extremities may also be subjected to excessive tension during healing. The surgeon must be certain that the approximated wound is adequately immobilized to prevent suture disruption for a sufficient period of time after surgery.

IMMOBILIZATION OF THE WOUND--Adequate immobilization of the approximated wound, but not necessarily of the entire anatomic part, is mandatory after surgery for efficient healing and minimal scar formation.

Classifications of Wounds

Based upon a clinical estimation of microbial contamination and the risk of subsequent infection,³ operative wounds fall into four categories: clean; clean-contaminated; contaminated; and dirty and infected. A discussion of each follows.

Seventy-five percent of all wounds (which are usually elective surgical incisions) fall into the *clean wounds* category. No break in aseptic technique occurs during the procedure and the surgeon does not enter the oropharyngeal cavity, or the respiratory, alimentary, or genitourinary tracts. These elective incisions are made under sterile conditions and are not predisposed to infection. Inflammation is a natural part of the healing process and should be differentiated from infection in which bacteria are present and produce damage.

Clean wounds are closed by primary union and are not usually drained. Primary union is the most desirable method of closure, involving the simplest surgical procedures and the lowest risk of postoperative complications. Apposition of tissue is maintained until wound tensile strength is sufficient so that sutures or other forms of tissue apposition are no longer needed.

Clean-contaminated wounds have usual, normal flora without unusual contamination such as frank pus or foreign bodies. Appendectomies and vaginal operations fall into this category, as well as normally clean wounds which become contaminated by entry into a viscus resulting in minimal spillage of contents. The surgeon may enter any part of the oropharyngeal cavity, or the respiratory or alimentary tracts (as long as no significant spillage occurs). When the genitourinary or biliary tracts are entered and there is no contamination from infected urine or bile, these are considered clean-contaminated wounds.

Contaminated wounds include fresh traumatic injuries such as soft tissue lacerations, open fractures, and penetrating wounds; operative procedures in which gross spillage from the gastrointestinal tract occurs; genitourinary or biliary tract procedures in the presence of infected urine or bile; and operations in which a major break in aseptic technique has occurred (as in emergency open cardiac massage). Microorganisms multiply so rapidly that within 6 hours a contaminated wound can become infected.

Dirty and infected wounds have been heavily contaminated or clinically infected prior to the operation. They include perforated viscera, abscesses, or old traumatic wounds in which devitalized tissue or foreign material have been retained. Infection present at the time of surgery can increase the infection rate of any wound by an average of four times.⁴

Types of Wound Healing

Types of Wound Healing

The rate and pattern of healing falls into three categories, depending upon the type of tissue involved and the circumstances surrounding closure. Timeframes are generalized for well-perfused healthy soft tissues, but may vary.

Healing By First Intention

Every surgeon who closes a wound would like it to heal by primary union or first intention, with minimal edema and no local infection or serious discharge. An incision that heals by first intention does so in a minimum of time, with no separation of the wound edges, and with minimal scar formation. This takes place in three distinct phases:

- **PHASE I: INFLAMMATORY RESPONSE (DAY 1 TO DAY 5)**

Fluids containing plasma proteins, blood cells, fibrin, and antibodies flow into the wound. A scab forms on the surface to seal in the healing fluids and prevent microbial invasion. The wound is generally sealed within the first 24 hours.

Inflammation, which results from leukocyte migration to the area, occurs within a few hours causing localized edema, pain, fever, and redness around the wound site. This should not be mistaken for infection. Leukocytes break down and remove cellular debris. They also ingest microorganisms and foreign material. Monocytes, which subsequently reach the site from more distant bone marrow, become macrophages, producing proteolytic enzymes and ingesting the remaining debris. Finally, basal cells from skin edges migrate over the incision to close the surface of the wound. Simultaneously, fibroblasts located in deeper connective tissue begin reconstruction of nonepithelial tissue.

During the acute inflammatory phase, the tissue does not gain appreciable tensile strength, but depends solely upon the closure material to hold it in approximation.

- **PHASE II: MIGRATION/ PROLIFERATION (DAY 5 TO DAY 14)**

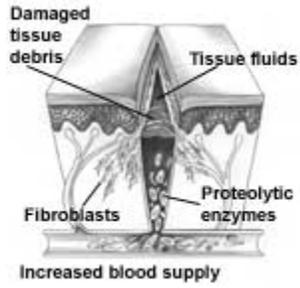
During the first or second week after surgery, fibroblasts (fibrous tissue germ cells) migrate toward the wound site. With enzymes released from the blood and cells in the surrounding tissue, fibroblasts form *collagen* and *ground substance* (fibrin, fibronectin). These substances adhere fibroblasts to the substratum. The fibroblasts contain myofibroblasts which have smooth muscle characteristics that contribute to wound contraction. Collagen deposition begins at approximately the fifth day and rapidly increases the tensile strength of the wound.

The plasma proteins support cellular activities essential to the synthesis of fibrous tissue during this stage of healing. In addition to collagen synthesis, other damaged components of connective tissue are replaced. The lymphatics recanalize, the blood vessels form buds, granulation tissue forms, and numerous capillaries develop to nourish the fibroblasts. Many of these disappear during the final stage of healing.

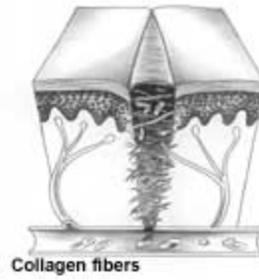
- **PHASE III: MATURATION/ REMODELING (DAY 14 THROUGH COMPLETE HEALING)**

There is no sharp distinction between Phase II and Phase III. Healing begins rapidly during Phase II, then diminishes progressively. *Tensile strength continues to increase up to 1 year postoperatively*. Skin only regains 70% to 90% of its original tensile strength, whereas the intestines may regain 100% of original strength within just 1 week.⁵ Collagen content remains constant, but tensile strength increases from the formation and cross-linking of collagen fibers. The deposition of fibrous connective tissue results in scar formation. In normal healing, wound contraction occurs over a period of weeks and months. As collagen density increases, the formation of new blood vessels decreases and the scar tissue grows pale.

Phases of Wound Healing



Phase 1--
Inflammatory response and debridement process



Phase 2--
Collagen formation (scar tissue)



Phase 3--
Sufficient collagen laid down

Healing by Second Intention

When the wound fails to heal by primary union, a more complicated and prolonged healing process takes place. Healing by second intention is caused by infection, excessive trauma, tissue loss, or imprecise approximation of tissue.

In this case, the wound may be left open and allowed to heal from the inner layer to the outer surface. Granulation tissue forms and contains myofibroblasts. These specialized cells help to close the wound by contraction. This process is much slower than first intention healing. Excessive granulation tissue may build up and require treatment if it protrudes above the surface of the wound, preventing epithelialization.

Healing by Third Intention

Also referred to as *delayed primary closure*, healing by third intention occurs when two surfaces of granulation tissue are brought together. This is a safe method of repair for contaminated, as well as dirty and infected traumatic wounds with extensive tissue loss and a high risk of infection. This method has been used extensively in the military arena and has proven successful following excessive trauma related to motor vehicle accidents, shooting incidents, or infliction of deep, penetrating knife wounds.

The surgeon usually treats these injuries by debridement of nonviable tissues, and leaves them open. The healing open wound gradually gains sufficient resistance to infection which permits an uncomplicated closure. Usually, this takes place 4 to 6 days postinjury.

This process is characterized by the development of capillary buds and granulation tissue. When closure is undertaken, skin edges and underlying tissue must be accurately and securely approximated.

Complications in Wound Healing

Whenever the integrity of tissue is disrupted by accident or dissection, the patient becomes vulnerable to infection and complications. Even though the surgical team may scrupulously adhere to proper procedure, complications still occur in some patients, delaying recovery. The two major problems the surgeon may encounter are infection and wound disruption.

Infection continues to be one of the most serious complications affecting surgical patients.⁶ An infection arises from the introduction of virulent organisms into a susceptible wound. If left untreated, prolonged illness, gangrene, or even death may result.

Postoperative infections may be classified according to the source of infection as well as the anatomical and pathophysiological changes that occur. The key to effective treatment is rapid identification of the responsible pathogens. A considerable number of infections are of mixed bacterial origin. As soon as an infection is apparent, treatment must be initiated. Direct wound treatment may consist of incision and drainage or debridement of necrotic tissue. A course of antibiotic treatment must be initiated immediately for cellulitis and fasciitis. A specimen of purulent drainage or tissue for culture is sent prior to the institution of antibiotic therapy. It is seldom possible to wait for culture and sensitivity results prior to the start of antibiotics, and empirical therapy based on suspected sensitivity may be used. Superficial wounds often do not require incision and drainage or debridement.

Fungal and viral infections may also occur. Their incidence has steadily increased with the clinical administration of steroids, immunosuppressive agents, and multiple antibiotic agents.

Wound disruption, or dehiscence, is most often seen in older or debilitated patients, but may occur at any age. It seems to affect male patients more often than female patients and most commonly occurs between the fifth and twelfth postoperative days.

The term *dehiscence* means "a splitting open." Wound dehiscence is partial or total separation of layers of tissue after closure. Dehiscence may result from too much tension placed upon the newly sutured tissue, from improper suturing technique, or from the use of inappropriate suture materials. In a great majority of instances, the cause is tissue failure rather than suture failure. When dehiscence occurs, the wound may or may not be reclosed, depending upon the extent of the disruption and the surgeon's assessment.

There is no difference in the dehiscence rate of vertical versus transverse incisions.⁷ The highest incidence occurs following gastric, biliary tract, and intra-abdominal cancer surgery. While cancer does not predispose to wound disruption, it may cause debility and hypoproteinemia, which contribute to impaired healing and subsequent disruption.

Evisceration indicates protrusion of the bowel through the separated edges of an abdominal wound closure.

Distention, nausea, and coughing after surgery increase abdominal pressure and, in turn, increase tension on the wound. These are the major causes of evisceration. *This is an emergency situation.* The surgeon must replace the bowel and reclose the wound without delay when this occurs.

In The Next Section

The materials, devices, and techniques used to repair wounded tissue will be discussed at length. As you will see, the number of options available is extensive. But no matter how many choices the surgeon has, his or her objective remains singular: to restore the patient to health with as little operative trauma as possible.

References

Taylor EJ et al (ed): Dorland's Medical Dictionary, Philadelphia: Saunders, 1988

Davis JH: Clinical Surgery, CV Mosby Co., 1987

American College of Surgeons, Altemeier WA, et al (eds): Manual on Control of Infection in Surgical Patients, Philadelphia: Lippincott, 1976

Cruse P, Foorde R: The epidemiology of wound infection, Surg Clin NA 60(1): 27-40, 1980

Gottrup F: Acta Chir Scand 149:57, 1983

Chu CC, Williams DF: Effects of physical configuration and chemical structure of suture materials on bacterial adhesion, Am J Surg 147:197-204, February 1984

Kenady DE: Management of abdominal wounds. Surg Clin NA 64(4):803-806, 1984

The Suture

What is a Suture?

The word "suture" describes any strand of material used to ligate (tie) blood vessels or approximate (bring close together) tissues. As far back as 2,000 B.C., written references have been found describing the use of strings and animal sinews for suturing. Through the centuries, a wide variety of materials--silk, linen, cotton, horsehair, animal tendons and intestines, and wire made of precious metals--have been used in operative procedures. Some of these are still in use today.

The evolution of suturing material has brought us to a point of refinement that includes sutures designed for specific surgical procedures. They not only eliminate some of the difficulties the surgeon may have previously encountered during closure but decrease the potential for infection postoperatively.

Despite the sophistication of today's suture materials and surgical techniques, closing a wound still involves the same basic procedure used by physicians to the Roman emperors. *The surgeon still uses a surgical needle to penetrate tissue and advance a suture strand to its desired location.*

Successful use of suture materials depends upon the cooperation of the suture manufacturer and the surgical team. The *manufacturer* must have a thorough knowledge of surgical procedures, anticipate the surgical team's needs, and produce suture materials that meet these stringent criteria:

- They must have the greatest tensile strength consistent with size limitations.
- They must be easy to handle and meet a minimum of resistance when introduced into tissue.
- They must be secured in packaging which presents them sterile for use, in excellent condition, and ensures the safety of each member of the surgical team.

The *nurse* must maintain the sterility of sutures when storing, handling, and preparing them for use. The integrity and strength of each strand must remain intact until it is in the surgeon's hands.

The *surgeon* must select suture materials appropriate for the procedure and must place them in the tissues in a manner consistent with the principles that promote wound healing.

With the manufacturer and surgical team working in concert, the patient reaps the final benefit...*the wound is closed in a manner that promotes optimum healing in minimum time.*

Personal Suture Preference

Most surgeons have a basic "suture routine," a preference for using the same material(s) unless circumstances dictate otherwise. The surgeon acquires skill, proficiency, and speed in handling by using one suture material repeatedly--and may choose the same material throughout his or her entire career. A number of factors may influence the choice of materials:

- His or her area of specialization.
- Wound closure experience during clinical training.
- Professional experience in the operating room.
- Knowledge of the healing characteristics of tissues and organs.
- Knowledge of the physical and biological characteristics of various suture materials.
- Patient factors (age, weight, overall health status, and the presence of infection).

Surgical specialty plays a primary role in determining suture preference. For example, obstetrician/gynecologists frequently prefer Coated VICRYL *RAPIDE* (polyglactin 910) suture for episiotomy repair and Coated VICRYL (polyglactin 910) suture and MONOCRYL (poliglecaprone 25) suture for all tissue layers except, possibly, skin. Most orthopaedic surgeons use Coated VICRYL suture, PDS II (polydioxanone) suture, and ETHIBOND *EXCEL*

polyester suture. Many plastic surgeons prefer ETHILON nylon suture, VICRYL suture, or MONOCRYL suture. Many neurosurgeons prefer Coated VICRYL suture or NUROLON braided nylon suture. *But no single suture material is used by every surgeon who practices within a specialty.*

The surgeon's knowledge of the physical characteristics of suture material is important. Because the requirements for wound support vary with patient factors, the nature of the procedure, and the type of tissue involved, the surgeon will select suture material that will retain its strength until the wound heals sufficiently to withstand stress on its own.

The surgeon knows that the nature of suture material may elicit biological responses during the first post-operative week. While most suture materials will cause a mild reaction, synthetic materials tend to be less reactive than natural fibers. In addition, some suture materials become more inert--or less reactive--than others in the later phases of healing.

Suture Characteristics

Suture Characteristics

If an ideal suture material could be created, it would be:

- Sterile.
- Nonelectrolytic, noncapillary, nonallergenic, and noncarcinogenic.
- Nonferromagnetic, as is the case with stainless steel sutures.
- Easy to handle.
- Minimally reactive in tissue and not predisposed to bacterial growth.
- Capable of holding tissue layers throughout the critical wound healing period securely when knotted without fraying or cutting.
- Resistant to shrinking in tissues.
- Absorbed completely with minimal tissue reaction after serving its purpose.

However, because the *ideal* all-purpose suture does not yet exist, the surgeon must select a suture that is at least as close to the ideal as possible and maintains the following suture qualities:

1. High uniform tensile strength, permitting use of finer sizes.
2. High tensile strength retention *in vivo*, holding the wound securely throughout the critical healing period, followed by rapid absorption.
3. Consistent uniform diameter.
4. Sterile.
5. Pliable for ease of handling and knot security.
6. Freedom from irritating substances or impurities for optimum tissue acceptance.
7. Predictable performance.

Size and Tensile Strength

Size denotes the diameter of the suture material. The accepted surgical practice is to use the smallest diameter suture that will adequately hold the mending wounded tissue. This practice minimizes trauma as the suture is passed through the tissue to effect closure. It also ensures that the minimum mass of foreign material is left in the body. Suture size is stated numerically; as the number of 0's in the suture size increases, the diameter of the strand decreases. For example, size 5-0, or 00000, is smaller in diameter than size 4-0, or 0000. The smaller the size, the less tensile strength the suture will have.

Knot tensile strength is measured by the force, in pounds, which the suture strand can withstand before it breaks when knotted. The tensile strength of the tissue to be mended (its ability to withstand stress) determines the size and tensile strength of the suturing material the surgeon selects. The accepted rule is that the tensile strength of the suture need never exceed the tensile strength of the tissue. However, sutures should be at least as strong as normal tissue through which they are being placed. If the tissue reduces suture strength over time, the relative rates at which the suture loses strength and the wound gains strength are important. If the suture biologically alters the healing process, these changes must also be understood.¹

Monofilament vs. Multifilament Strands

Sutures are classified according to the number of strands of which they are comprised. *Monofilament sutures* are made of a single strand of material. Because of their simplified structure, they encounter less resistance as they pass through tissue than multifilament suture material. They also resist harboring organisms which may cause suture line infection.² These characteristics make monofilament sutures well-suited to vascular surgery. Monofilament sutures tie down easily. However, because of their construction, extreme care must be taken when handling and tying these sutures. Crushing or crimping of this suture type can nick or create a weak spot in the strand. This may result in suture breakage.

Multifilament sutures consist of several filaments, or strands, twisted or braided together. This affords greater tensile strength, pliability, and flexibility. Multifilament sutures may also be coated to help them pass relatively smoothly through tissue and enhance handling characteristics. Coated multifilament sutures are well-suited to intestinal procedures.

Absorbable vs. Nonabsorbable Materials

page 1 of 2

Sutures are also classified according to their absorption properties. *Absorbable sutures* may be used to hold wound edges in approximation temporarily, until they have healed sufficiently to withstand normal stress. These sutures are prepared either from the collagen of healthy mammals or from synthetic polymers. Some are absorbed rapidly, while others are treated or chemically structured to lengthen absorption time. They may also be impregnated or coated with agents that improve their handling properties, and colored with an FDA-approved dye to increase visibility in tissue.

SUTURE	RAW MATERIAL	TABLE 1
Surgical Gut Plane Chromic Fast Absorbing	Submacosa of sheep intestine or serosa of beef intestine	Absorbable Sutures: Basic Raw Materials <i>Notes:</i> 1. VICRYL (polyglactin 910) Suture 2. Coated VICRYL (polyglactin 910) Suture 3. Cotaed VICRYL <i>RAPIDE</i> (polyglactin 910) Suture 4. MONOCRYL (poliglecaprone 25) Suture 5. PDS II (polydioxanone) Suture 6. PANACRYL Suture
Polyglactin 910 Uncoated ₁ Coated _{2/3}	Copolymer of glycolide and lactide with polyglactin 370 and calcium stearate, if coated	
Polyglycolic Acid	Homopolymer of glycolid	
Poliglecaprone 25 ₄	Copolymer of glycolide and epsilon-caprolactone	
Polyglyconate	Copolymer of glycolide and trimethylene carbonate	
Polydioxanone ₅	Polyester of poly (p-dioxanone)	
Poly (L-lactide/glycolide) ₆	Copolymer of lactide and glycode with caprolactone and glycolide coating	

Natural absorbable sutures are digested by body enzymes which attack and break down the suture strand. Synthetic absorbable sutures are hydrolyzed--a process by which water gradually penetrates the suture filaments, causing the breakdown of the suture's polymer chain. Compared to the enzymatic action of natural absorbables, hydrolyzation results in a lesser degree of tissue reaction following implantation.

During the first stage of the absorption process, tensile strength diminishes in a gradual, almost linear fashion. This occurs over the first several weeks post-implantation. The second stage often follows with considerable overlap, characterized by loss of suture mass. Both stages exhibit leukocytic cellular responses which serve to remove cellular debris and suture material from the line of tissue approximation.

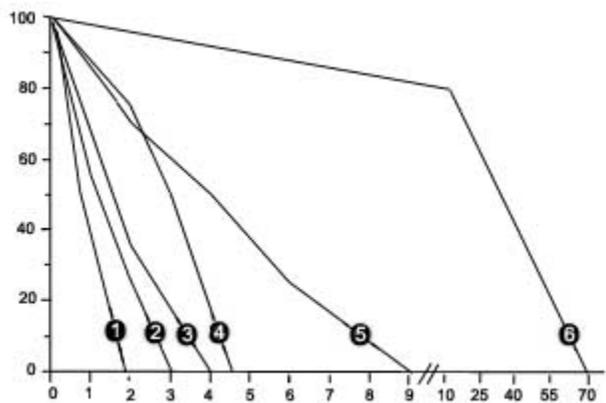
The loss of tensile strength and the rate of absorption are separate phenomena. A suture can lose tensile strength rapidly and yet be absorbed slowly--or it can maintain adequate tensile strength through wound healing, followed by rapid absorption. In any case, the strand is eventually completely dissolved, leaving no detectable traces in tissue.

Table 2 shows *in vivo* breaking strength retention of synthetic absorbable sutures.

TABLE 2

**SYNTHETIC
ABSORBABLE
SUTURES**

In vivo breaking
strength
retention
(percent
retention)



TIME (WEEKS)

Coated VICRYL *RAPIDE*
(polyglactin 910) Suture

Undyed MONOCRYL
(poliglecaprone 25) Suture

Dyed MONOCRYL (poliglecaprone
25) Suture

Coated Vicryl (poliglecaprone 910)
Suture

PDS II (polydioxanone) Suture

PANACRYL suture

Although they offer many advantages, absorbable sutures also have certain inherent limitations. If a patient has a fever, infection, or protein deficiency, the suture absorption process may accelerate, causing too rapid a decline in tensile strength. Absorption may also speed up if the sutures are placed in an area of the body cavity that is moist or filled with fluid. In addition, if the sutures become wet or moist during handling, prior to being implanted in tissue, the absorption process may begin prematurely. All of these situations predispose to postoperative complications, as the suture strand will not maintain adequate strength to withstand stress until the tissues have healed sufficiently.

Absorbable vs. Nonabsorbable Materials

page 2 of 2

Nonabsorbable sutures are those which are not digested by body enzymes or hydrolyzed in body tissue. They may be used in a variety of applications:

- Exterior skin closure, to be removed after sufficient healing has occurred.
- Within the body cavity, where they will remain permanently encapsulated in tissue.
- Patient history of reaction to absorbable sutures, keloidal tendency, or possible tissue hypertrophy.
- Prosthesis attachment (i.e., defibrillators, pacemakers, drug delivery mechanisms).

Nonabsorbable sutures are composed of single or multiple filaments of metal, synthetic, or organic fibers rendered into a strand by spinning, twisting, or braiding. Each strand is substantially uniform in diameter throughout its length, conforming to the United States Pharmacopeia (U.S.P.) limitations for each size. Nonabsorbable sutures have been classified by the U.S.P. according to their composition. In addition, these sutures may be uncoated or coated, uncolored, naturally colored, or dyed with an FDA-approved dye to enhance visibility.

SUTURE	RAW MATERIAL	TABLE 3
Surgical Silk	Raw silk spun by silkworm	NonAbsorbable Sutures: Basic Raw Materials <i>Notes:</i> 1. ETHILON [®] Nylon Suture 2. NUROLON [®] Nylon Suture 3. MERSILENE [®] Polyester Fiber Suture 4. ETHIBOND [®] EXCEL Polyester Suture 5. PROLENE [®] Polypropylene Suture 6. PRONOVA [®] Poly(hexafluoro-propylene-VDF) Suture
Stainless Steel Wire	Specially Formulated iron-chromium-nickel-molybdenum alloy	
Nylon _{1,2}	Polyamide polymer	
Polyester fiber Uncoated ₃ Coated ₄	Polymer of polyethylene terephthalate (may be coated)	
Polypropylene ₅	Polymer of propylene	
Poly(hexafluoropropylene-VDF) ₆	Polymer blend of poly(vinylidene fluoride) and poly(vinylidene fluoride-cohexafluoropropylene)	

Specific Suturing Materials

Specific Suturing Materials

The materials and products described here embody the most current advances in the manufacture of surgical sutures. They are grouped as either *absorbable* or *nonabsorbable* for easy reference.

Absorbable Sutures

SURGICAL GUT

Absorbable surgical gut is classified as either *plain* or *chromic*. Both types consist of processed strands of highly purified collagen. The percentage of collagen in the suture determines its tensile strength and its ability to be absorbed by the body without adverse reaction. Noncollagenous material can cause a reaction ranging from irritation to rejection of the suture. The more pure collagen throughout the length of the strand, the less foreign material there is introduced into the wound.

ETHICON surgical gut sutures are manufactured from between 97% and 98% pure ribbons of collagen. To meet U.S.P. Specifications, processed ribbons of the submucosa layer of sheep intestine or the serosa layer of beef intestine are electronically spun and polished into virtually monofilament strands of various sizes, with minimum and maximum limits on diameter for each size. The ETHICON exclusive TRU-GAUGING process produces a uniform diameter to within an accuracy of 0.0002 inch (0.0175mm) along the entire length of every strand, eliminating high and low spots. High and low spots can cause the suture to fray or chatter when knots are tied down, resulting in a knot that is not positioned properly or tied securely. Most protein-based absorbable sutures have a tendency to fray when tied.

TRU-GAUGING ensures that ETHICON surgical gut sutures possess uniform high tensile strength, virtually eliminating the possibility of fray or breaking. Their unexceeded strength and surface smoothness allow the surgeon to "snug down" the suture knot to achieve optimum tension.

The rate of absorption of surgical gut is determined by the type of gut being used, the type and condition of the tissue involved, and the general health status of the patient. Surgical gut may be used in the presence of infection, although it may be absorbed more rapidly under this condition.

Plain surgical gut is rapidly absorbed. Tensile strength is maintained for only 7 to 10 days postimplantation, and absorption is complete within 70 days. The surgeon may choose plain gut for use in tissues which heal rapidly and require minimal support (for example, ligating superficial blood vessels and suturing subcutaneous fatty tissue).

Plain surgical gut can also be specially heat-treated to accelerate tensile strength loss and absorption. This fast absorbing surgical gut is used primarily for epidermal suturing where sutures are required for only 5 to 7 days.

These sutures have less tensile strength than plain surgical gut of the comparable U.S.P. size. Fast absorbing plain gut is not to be used internally.

Chromic gut is treated with a chromium salt solution to resist body enzymes, prolonging absorption time over 90 days. The exclusive CHROMICIZING process used by ETHICON thoroughly bathes the pure collagen ribbons in a buffered chrome tanning solution before spinning into strands. After spinning, the entire cross section of the strand is evenly chromicized. The process alters the coloration of the surgical gut from yellowish-tan to brown. Chromic gut sutures minimize tissue irritation, causing less reaction than plain surgical gut during the early stages of wound healing. Tensile strength may be retained for 10 to 14 days, with some measurable strength remaining for up to 21 days.

Synthetic Absorbable Sutures

Synthetic absorbable sutures were developed in response to problems encountered with natural chromic gut and natural chromic collagen, specifically, suture antigenicity, tissue reaction, and unpredictable rates of absorption.³ Synthetic absorbables are the sutures of choice for a wide range of applications, from abdominal and chest wound closure to ophthalmic surgery.^{4,5}

VICRYL (POLYGLACTIN 910) SUTURE

This synthetic absorbable suture is a co-polymer of lactide and glycolide (from lactic and glycolic acid). Both are natural metabolic substances. The water-repelling quality of lactide slows water penetration into the suture filaments, thus slowing the rate of *in vivo* tensile strength loss as compared to natural absorbable sutures which are subject to enzymatic digestion. Lactides are also bulky, keeping the submicroscopic polymer chains comprising the filaments spaced apart so that absorption of the suture mass is rapid once tensile strength is lost. The combination of lactide and glycolide results in a molecular structure which maintains sufficient tensile strength for efficient approximation of tissues during the critical wound-healing period, followed by rapid absorption.⁶

VICRYL sutures (size 6-0 and larger) retain approximately 75% of original tensile strength 2 weeks after implantation. At 3 weeks, 50% of tensile strength is retained by suture sizes 6-0 and larger, and 40% by suture sizes 7-0 and smaller.

Because synthetic absorbable sutures are not digested by enzymatic activity, they exhibit a lower degree of tissue reaction than surgical gut. VICRYL suture is extruded into monofilament strands which are dyed violet to enhance visibility in tissue. They are available for use in ophthalmic surgery. Conjunctival sutures remaining in place longer than 7 days may cause localized irritation and should be removed as indicated.

COATED VICRYL (POLYGLACTIN 910) SUTURE

This material fills the need for a smoother synthetic absorbable suture that will pass through tissue readily with minimal drag. Coated VICRYL sutures facilitate easy tissue passage, precise knot placement, smooth tie down, and a decreased tendency to incarcerate tissue.³

The coating is a combination of equal parts of co-polymer of lactide and glycolide (*polyglactin 370*), plus calcium stearate which is used extensively in pharmaceuticals and food. Calcium stearate is a salt of calcium and stearic acid, both of which are present in the body and constantly metabolized and excreted. The result of this mixture is an outstandingly absorbable, adherent, nonflaking lubricant. This suture may be used in the presence of infection.⁷

At 2 weeks postimplantation, approximately 75% of the tensile strength of Coated VICRYL suture remains.

Approximately 50% of tensile strength is retained at 3 weeks for suture sizes 6-0 and larger, and 40% is retained for suture sizes 7-0 and smaller. Absorption is minimal until day 40, and essentially complete between days 56 and 70. Like the suture itself, the coating absorbs rapidly and predictably within 56 to 70 days.

Lactide and glycolide acids are readily eliminated from the body, primarily in urine. As with uncoated sutures, Coated VICRYL sutures elicit only a mild tissue reaction during absorption. Their safety and effectiveness in neural and cardiovascular tissue have not been established. Transcutaneous or conjunctival sutures remaining in place longer than 7 days may cause localized irritation and should be removed as indicated. Coated VICRYL sutures are available as braided dyed violet or undyed natural strands in a variety of lengths with or without needles.

COATED VICRYL RAPIDE (POLYGLACTIN 910) SUTURE

This braided suture is composed of the same copolymer as Coated VICRYL suture--lactide and glycolide--and is coated with a combination of equal parts of copolymer of lactide and glycolide (*polyglactin 370*) and calcium stearate. However, the absorption rate and tensile strength profile are significantly different from Coated VICRYL suture, achieved by the use of a polymer material with a lower molecular weight than Coated VICRYL suture. Coated VICRYL *RAPIDE* sutures are only available undyed.

Coated VICRYL *RAPIDE* suture is the fastest-absorbing synthetic suture and exhibits characteristics that model the performance of surgical gut suture. However, being a synthetic material, Coated VICRYL *RAPIDE* suture elicits a lower tissue reaction than chromic gut suture. Coated VICRYL *RAPIDE* suture is indicated only for use in superficial soft tissue approximation of the skin and mucosa, where only short-term wound support (7 to 10 days) is required. It is not to be used in ligation, in ophthalmic, cardiovascular, or neurological procedures, where extended approximation of tissues under stress is required, or where wound support beyond 7 days is required.

Coated VICRYL *RAPIDE* sutures retain approximately 50% of the original tensile strength at 5 days post-implantation. All of the original tensile strength is lost by approximately 10 to 14 days. Absorption is essentially complete by 42 days. Coated VICRYL *RAPIDE* suture is particularly well-suited for skin closure, episiotomy repair, and closure of lacerations under casts. In addition, since the suture begins to "fall off" in 7 to 10 days as the wound heals, the need for suture removal is eliminated.

MONOCRYL (POLIGLECAPRONE 25) SUTURE

This monofilament suture features superior pliability for easy handling and tying. Comprised of a copolymer of glycolide and epsilon-caprolactone, it is virtually inert in tissue and absorbs predictably. The surgeon may prefer MONOCRYL sutures for procedures which require high initial tensile strength diminishing over 2 weeks

postoperatively. These include subcuticular closure and soft tissue approximations and ligations, with the exception of neural, cardiovascular, ophthalmic, and microsurgical applications.

MONOCRYL suture is available dyed (violet) and undyed (natural). Dyed MONOCRYL suture retains 60% to 70% of its original strength at 7 days postimplantation, reduced to 30% to 40% at 14 days, with all original strength lost by 28 days. At 7 days, undyed MONOCRYL suture retains approximately 50% to 60% of its original strength, and approximately 20% to 30% at 14 days postimplantation. All of the original tensile strength of undyed MONOCRYL suture is lost by 21 days postimplantation. Absorption is essentially complete at 91 to 119 days.

PDS II (POLYDIOXANONE) SUTURE

Comprised of the polyester poly (p-dioxanone), this monofilament represents a significant advance in suturing options. It combines the features of soft, pliable, monofilament construction with absorbability and extended wound support for up to 6 weeks. It elicits only a slight tissue reaction. Additionally, PDS II sutures exhibit a low affinity for microorganisms.⁸ This material is well-suited for many types of soft tissue approximation, including pediatric cardiovascular, orthopaedic, gynecologic, ophthalmic, plastic, digestive, and colonic surgeries.⁹⁻¹²

Like other synthetic absorbable sutures, PDS II sutures are absorbed *in vivo* through hydrolysis. Approximately 70% of tensile strength remains 2 weeks postimplantation, 50% at 4 weeks, and 25% at 6 weeks. Absorption is minimal until about the 90th day postoperatively and essentially complete within 6 months. The safety and effectiveness of PDS II sutures in microsurgery, neural tissue, and adult cardiovascular tissue have not been established. PDS II sutures are available clear or dyed violet to enhance visibility.

PANACRYL SUTURE

This braided synthetic absorbable suture, comprised of a copolymer of lactide and glycolide and coated with a copolymer of caprolactone and glycolide, provides the extended wound support found in nonabsorbable sutures. PANACRYL suture retains approximately 80% of its original strength at 3 months and 60% of its original strength at 6 months post-implantation. It is essentially absorbed in 1.5 to 2.5 years.

PANACRYL suture is unique for its combined superior strength and absorbability. Indicated for use in general soft tissue and orthopaedic uses including tendon and ligament repairs and reattachment to bone, PANACRYL suture is useful where extended wound support up to 6 months is desirable. For example, PANACRYL suture is especially well-suited in cases involving patients with compromised wound healing resulting from the use of corticosteroids, malnourishment, obesity, and cancer. PANACRYL suture should not be used in ophthalmic, cardiovascular, or neurological tissue.

PANACRYL is only available undyed, which provides excellent visibility in the presence of blood.

Nonabsorbable Sutures

page 1 of 2

The U.S.P. classifies nonabsorbable surgical sutures as follows:

- **CLASS I**--Silk or synthetic fibers of monofilament, twisted, or braided construction.
- **CLASS II**--Cotton or linen fibers, or coated natural or synthetic fibers where the coating contributes to suture thickness without adding strength.
- **CLASS III**--Metal wire of monofilament or multifilament construction.

SURGICAL SILK

For many surgeons, *surgical silk* represents the standard of performance by which newer synthetic materials are judged, especially due to its superior handling characteristics. Silk filaments can be twisted or braided, the latter providing the best handling qualities.

Raw silk is a continuous filament spun by the silkworm larva to make its cocoon. Cream or orange-colored in its raw state, each silk filament is processed to remove natural waxes and sericin gum, which is exuded by the silkworm as it spins its cocoon. The gum holds the cocoon together, but is of no benefit to the quality of braided surgical silk sutures.

ETHICON degums the silk for most suture sizes before the braiding process. This allows for a tighter, more compact braid which significantly improves suture quality. After braiding, the strands are dyed, scoured and stretched, and then impregnated and coated with a mixture of waxes or silicone. Each of these steps is critical to the quality of the finished suture and must be carried out in precise order. Surgical silk is usually dyed black for easy visibility in tissue.

Raw silk is graded according to strength, uniformity of filament diameter, and freedom from defects. Only top grades of silk filaments are used to produce PERMA-HAND surgical silk sutures.

Surgical silk loses tensile strength when exposed to moisture and should be used dry. Although silk is classified by the U.S.P. as a nonabsorbable suture, long-term *in vivo* studies have shown that it loses most or all of its tensile strength in about 1 year and usually cannot be detected in tissue after 2 years. Thus, it behaves in reality as a very slowly absorbing suture.

Nonabsorbable Sutures

page 2 of 2

SURGICAL STAINLESS STEEL

The essential qualities of surgical stainless steel sutures include the absence of toxic elements, flexibility, and fine wire size. Both monofilament and twisted multifilament varieties are high in tensile strength, low in tissue reactivity, and hold a knot well. Provided that the sutures do not fragment, there is little loss of tensile strength in tissues. The 316L (low carbon) stainless steel alloy formula used in the manufacture of these sutures offers optimum metal strength, flexibility, uniformity, and compatibility with stainless steel implants and prostheses. Stainless steel sutures may also be used in abdominal wall closure, sternum closure, retention, skin closure, a variety of orthopaedic procedures, and neurosurgery.

Disadvantages associated with alloy sutures include difficulty in handling; possible cutting, pulling, and tearing of the patient's tissue; fragmentation; barbing; and kinking, which renders the stainless steel suture useless. When used for bone approximation and fixation, asymmetrical twisting of the wire will lead to potential buckling, wire fracture, or subsequent wire fatigue. Incomplete wire fixation under these circumstances will permit movement of the wire, resulting in postoperative pain and possible dehiscence³.

Surgical stainless steel sutures should not be used when a prosthesis of another alloy is implanted since an unfavorable electrolytic reaction may occur.

Above all, stainless steel sutures pose a safety risk. They easily tear surgical gloves when handled and may puncture the surgeon's own skin--putting both physician and patient at risk of transmitted immunodeficiency virus or hepatitis.

Many surgeons refer to wire size by the Brown & Sharpe (B & S) gauge of 40 (smallest diameter) to 18 (largest diameter). ETHICON labels surgical stainless steel with both the B & S and U.S.P. diameter size classifications. ETHICON packaging of surgical stainless steel maintains the integrity of the product by eliminating kinking and bending of strands. Just as important, it presents the strands in a safe manner for all members of the surgical team who handle them.

TABLE 4		
DIAMETER	U.S.P.	B&S
.0031 inch	6-0	40
.0040	6-0	38
.0056	5-0	35
.0063	4-0	34
.0080	4-0	32
.0100	3-0	30
.0126	2-0	28
.0159	0	26
.0179	1	25
.0201	2	24
.0226	3	23
.0253	4	22
.0320	5	20
.0363	6	19

**SURGICAL
STAINLESS
STEEL:
WIRE
GAUGE**

Synthetic Nonabsorbable Sutures

Nylon sutures are a polyamide polymer derived by chemical synthesis. Because of their elasticity, they are particularly well-suited for retention and skin closure. They may be clear, or dyed green or black for better visibility.

ETHILON NYLON SUTURE

These sutures are extruded into noncapillary single or monofilament strands characterized by high tensile strength and extremely low tissue reactivity. They degrade *in vivo* at a rate of approximately 15% to 20% per year by hydrolysis. ETHILON sutures in sizes 10-0 and 6-0 and larger are produced from a special grade of nylon 6. The medical grade polyamide nylon 6-6 is used for sizes 7-0 and finer. While both grades permit good handling, monofilament nylon sutures have a tendency to return to their original straight extruded state (a property known as "memory"). Therefore, more throws in the knot are required to securely hold monofilament than braided nylon sutures.

Monofilament nylon in a wet or damp state is more pliable and easier to handle than dry nylon. A limited line of ETHILON sutures (sizes 3-0 through 6-0) are premoistened or "pliabilized" for use in cosmetic plastic surgery. This process enhances the handling and knot tying characteristics to approximate that of braided sutures. ETHILON sutures are frequently used in ophthalmology and microsurgery procedures in very fine sizes. For this reason, sizes 9-0 and 10-0 have an intensified black dye for high visibility.

NUROLON NYLON SUTURE

This suture is composed of filaments of nylon that have been tightly braided into a multifilament strand. Available in white or dyed black, NUROLON sutures look, feel, and handle like silk. However, NUROLON sutures have more strength and elicit less tissue reaction than silk. Braided nylon may be used in all tissues where multifilament nonabsorbable sutures are acceptable. Braided nylon sutures generally lose 15% to 20% of their tensile strength per year in tissue by hydrolyzation.

Polyester fiber suture is comprised of untreated fibers of polyester (polyethylene terephthalate) closely braided into a multifilament strand. They are stronger than natural fibers, do not weaken when wetted prior to use, and cause minimal tissue reaction. Available white or dyed green, polyester fiber sutures are among the most acceptable for vascular synthetic prostheses.

MERSILENE POLYESTER FIBER SUTURE

The first synthetic braided suture material shown to last indefinitely in the body, MERSILENE sutures provide precise, consistent suture tension. They minimize breakage and virtually eliminate the need to remove irritating suture fragments postoperatively. Following ophthalmic procedures, MERSILENE sutures have also been found to cause less burning and itching.¹³ Because it is uncoated, MERSILENE suture has a higher coefficient of friction when passed through tissue.

ETHIBOND EXCEL POLYESTER SUTURE

ETHIBOND EXCEL sutures are uniformly coated with polybutylate, a biologically inert, nonabsorbable compound which adheres itself to the braided polyester fiber strand. Polybutylate was the first synthetic coating developed specifically as a surgical suture lubricant. The coating eases the passage of the braided strands through tissue and provides excellent pliability, handling qualities, and smooth tie-down with each throw of the knot. Both the suture material and the coating are pharmacologically inactive. The sutures elicit minimal tissue reaction and retain their strength *in vivo* for extended periods. ETHIBOND EXCEL sutures are used primarily in cardiovascular surgery, for vessel anastomosis, and placement of prosthetic materials.

ETHIBOND EXCEL polyester sutures are also available attached to TFE polymer felt pledgets. Pledgets serve to prevent possible tearing of adjacent friable tissue. Pledgets are used routinely in valve replacement procedures (to prevent the annulus from tearing when the prosthetic valve is seated and the sutures are tied), and in situations where extreme deformity, distortion, or tissue destruction at the annulus has occurred.

Polypropylene is an isostatic crystalline stereoisomer of a linear hydrocarbon polymer permitting little or no saturation. Manufactured by a patented process which enhances pliability and handling, polypropylene monofilament sutures are not subject to degradation or weakening by tissue enzymes. They are extremely inert in tissue and have been found to retain tensile strength for long periods of time *in vivo*.¹⁴ Polypropylene sutures cause minimal tissue reaction and hold knots better than most other synthetic monofilament materials.

PROLENE POLYPROPYLENE SUTURE

Widely used in general, cardiovascular, plastic, and orthopaedic surgery, PROLENE sutures do not adhere to tissue and are therefore efficacious as a pull-out suture. PROLENE sutures are relatively biologically inert.

PROLENE sutures are recommended for use where minimal suture reaction is desired, such as in contaminated and infected wounds to minimize later sinus formation and suture extrusion. They are available clear or dyed blue.

PRONOVA POLY (HEXAFLUOROPROPYLENE-VDF) SUTURE

This monofilament nonabsorbable suture is a polymer blend of poly (vinylidene fluoride) and poly (vinylidene fluoride-cohexafluoropropylene). This suture resists involvement in infection and has been successfully employed in

contaminated and infected wounds to eliminate or minimize later sinus formation and suture extrusion. Furthermore, the lack of adherence to tissues has facilitated the use of PRONOVA suture as a pull-out suture. This material is well-suited for many types of soft tissue approximation and ligation, including use in cardiovascular, ophthalmic and neurological procedures.

Table 5 gives an overview of the many suturing options that have been discussed in this section.

Suturing Options: Materials, Characteristics and Applications Table Part 1

SUTURE	TYPE	COLOR OF MATERIAL	RAW MATERIAL
Surgical Gut Suture	Plain	Yellowish-tan Blue Dyed	Collagen derived from serosa of beef intestine or submucosa of sheep intestine.
Surgical Gut Suture	Chromic	Brown Blue Dyed	Collagen derived from serosa of beef intestine or submucosa of sheep intestine.
Coated VICRYL RAPIDE (polyglactin 910) Suture	Braided	Undyed (Natural)	Copolymer of glycolide and lactide coated with polyglactin 370 and calcium stearate.
Coated VICRYL (polyglactin 910)Suture	Braided Monofilament	Violet Undyed (Natural)	Copolymer of glycolide and lactide coated with polyglactin 370 and calcium stearate.
MONOCRYL (poliglecaprone 25) Suture	Monofilament	Undyed (Natural) Violet	Copolymer of glycolide and epsilon-caprolactone.
PDS II (polydioxanone) Suture	Monofilament	Violet Blue Clear	Polyester polymer.
PANACRYL Suture	Braided	Undyed (Natural)	Copolymer of lactide and glycolide coated with a polymer of caprolactone and glycolide.
PERMA-HAND Silk Suture	Braided	Black White	Organic protein called fibroin.
Surgical Stainless Steel Suture	Monofilament Multifilament	Silver metallic	316L stainless steel.
ETHILON Nylon Suture	Monofilament	Black Green Undyed (Clear)	Long chain aliphatic polymers Nylon 6 or Nylon 6,6.
NUROLON Nylon Suture	Braided	Black Green Undyed (Clear)	Long-chain aliphatic polymers Nylon 6 or Nylon 6,6.
MERSILENE Polyester Fiber Suture	BraidedMonofilament	Green Undyed (White)	Poly (ethylene terephthalate).
ETHIBOND EXCEL Polyester Fiber Suture	Braided	Green Undyed (White)	Poly (ethylene terephthalate) coated with polybutilate.

PROLENE Polypropylene	Monofilament	Clear Blue	Isotactic crystalline stereoisomer of polypropylene.
PRONOVA Poly (hexafluoro-propylene- VDF) Suture	Monofilament	Clear Blue	Polymer blend of poly(vinylidene fluoride and poly (vinylidene fluoride-cohexafluoropropylene)

Suturing Options:
Materials, Characteristics and Applications Table
Part 2

SUTURE	TENSILE STRENGTH RETENTION <i>IN VIVO</i>	ABSORPTION RATE	TISSUE REACTION	CONTRAINDICATIONS
Surgical Gut Suture	Individual patient characteristics can affect rate of tensile strength loss.	Absorbed by proteolytic enzymatic digestive process.	Moderate reaction	Being absorbable, should not be used where extended approximation of tissues under stress is required. Should not be used in patients with known sensitivities or allergies to collagen or chromium.
Surgical Gut Suture	Individual patient characteristics can affect rate of tensile strength loss.	Absorbed by proteolytic enzymatic digestive process.	Moderate reaction	Being absorbable, should not be used where extended approximation of tissues under stress is required. Should not be used in patients with known sensitivities or allergies to collagen or chromium.
Coated VICRYL RAPIDE (polyglactin 910) Suture	Approximately 50% remains at 5 days. All tensile strength is lost by approximately 10-14 days.	Essentially complete by 42 days. Absorbed by hydrolysis.	Minimal to moderate acute inflammatory reaction.	Should not be used when extended approximation of tissue under stress is required or where wound support beyond 7 days is required.
Coated VICRYL (Polyglactin 910) Suture	Approximately 75% remains at 2 weeks. Approximately 50% remains at 3 weeks. (6-0 and larger)	Essentially complete between 56-70 days. Absorbed by hydrolysis.	Minimal acute inflammatory reaction	Being absorbable, should not be used where extended approximation of tissue is required.
MONOCRYL (poliglecaprone 25) Suture	Approximately 50-60% remains at 1 week (undyed); 60-70% at 1 week (dyed). Approximately 20-30% remains at 2 weeks (undyed); 30-40% at 2 weeks (dyed). Lost by 28 days.	Complete at 91-119 days. Absorbed by hydrolysis.	Minimal acute inflammatory reaction	Being absorbable, should not be used where extended approximation of tissue under stress is required. Undyed not indicated for use in fascia.
PDS II (polydioxanone) Suture	Approximately 70% remains at 2 weeks. Approximately 50% remains at 4 weeks. Approximately 25% remains at 6 weeks.	Minimal until about 90th day. Essentially complete within 6 months. Absorbed by slow hydrolysis.	Slight reaction	Being absorbable, should not be used where prolonged approximation of tissues under stress is required. Should not be used with prosthetic devices, such as heart valves or synthetic grafts.
PANACRYL Suture	Approximately 80% remains at 3 months. Approximately 60% remains at 6 months.	Essentially complete in 1.5 to 2.5 years.	Minimal inflammatory reaction	Being absorbable, should not be used where extended approximation of tissue

				beyond 6 months is required.
PERMA-HAND Silk Suture	Progressive degradation of fiber may result in gradual loss of tensile strength over time.	Gradual encapsulation by fibrous connective tissue.	Acute inflammatory reaction	Should not be used in patients with known sensitivities or allergies to silk.
Surgical Stainless Steel Suture	Indefinite.	Nonabsorbable.	Minimal acute inflammatory reaction	Should not be used in patients with known sensitivities or allergies to 316L stainless steel, or constituent metals such as chromium and nickel.
ETHILON Nylon suture	Progressive hydrolysis may result in gradual loss of tensile strength over time.	Gradual encapsulation by fibrous connective tissue.	Minimal acute inflammatory reaction	Should not be used where permanent retention of tensile strength is required.
NUROLON Nylon Suture	Progressive hydrolysis may result in gradual loss of tensile strength over time.	Gradual encapsulation by fibrous connective tissue.	Minimal acute inflammatory reaction	Should not be used where permanent retention of tensile strength is required.
MERSILENE Polyester Fiber Suture	No significant change known to occur in vivo.	Gradual encapsulation by fibrous connective tissue.	Minimal acute inflammatory reaction	None known.
ETHIBOND EXCEL Polyester Fiber Suture	No significant change known to occur in vivo.	Gradual encapsulation by fibrous connective tissue.	Minimal acute inflammatory reaction	None known.
PROLENE Polypropylene	Not subject to degradation or weakening by action of tissue enzymes.	Gradual encapsulation by fibrous connective tissue.	Minimal acute inflammatory reaction	None known.
PRONOVA Poly (hexafluoropropylene-VDF) Suture	Not subject to degradation or weakening by action of tissue enzymes.	Gradual encapsulation by fibrous connective tissue.	Minimal to mild inflammatory reaction	None known.

Suturing Options:
Materials, Characteristics and Applications Table
Part 3

SUTURE	FREQUENT USES	HOW SUPPLIED	COLOR CODE
Surgical Gut Suture	General soft tissue approximation and/or ligation, including use in ophthalmic procedures. Not for use in cardiovascular and neurological tissues.	7-0 thru 3 with and without needles, and on LIGAPAK dispensing reels 0 thru 1 with CONTROL RELEASE needles	Yellow
Surgical Gut Suture	General soft tissue approximation and/or ligation, including use in ophthalmic procedures. Not for use in cardiovascular and neurological tissues.	7-0 thru 3 with and without needles, and on LIGAPAK dispensing reels 0 thru 1 with CONTROL RELEASE needles	Beige
Coated VICRYL RAPIDE (polyglactin 910) Suture	Superficial soft tissue approximation of skin and mucosa only. Not for use in ligation, ophthalmic, cardiovascular, or neurological procedures.	5-0 thru 1 with needles	Violet and Red
Coated VICRYL (Polyglactin 910) Suture	General soft tissue approximation and/or ligation, including use in ophthalmic procedures. Not for use in cardiovascular and neurological tissues.	8-0 thru 3 with and without needles, and on LIGAPAK dispensing reels 4-0 thru 2 with CONTROL RELEASE needles 8-0 with attached beads for ophthalmic use	Violet
MONOCRYL (poliglecaprone 25) Suture	General soft tissue approximation and/or ligation. Not for use in cardiovascular and neurological tissues, microsurgery, or ophthalmic surgery.	6-0 thru 2 with and without needles 3-0 thru 1 with CONTROL RELEASE needles	Coral
PDS II (polydioxanone) Suture	All types of soft tissue approximation, including pediatric cardiovascular and ophthalmic procedures. Not for use in adult cardiovascular tissue, microsurgery and neural tissue.	9-0 thru 2 with needles (violet) 4-0 thru 1 with CONTROL RELEASE needles (violet) 9-0 thru 7-0 with needles (blue) 7-0 thru 1 with needles (clear)	Silver
PANACRYL Suture	General soft tissue approximation and/or ligation. Not for use in ophthalmic, cardiovascular or neurological tissues.	3-0 thru 2 with CONTROL RELEASE needles or without needles	Plum
PERMA-HAND Silk Suture	General soft tissue approximation and/or ligation, including cardiovascular, ophthalmic and neurological procedures.	9-0 thru 5 with and without needles, and on LIGAPAK dispensing reels 4-0 thru 1 with CONTROL RELEASE needles	Light Blue

Surgical Stainless Steel Suture	Abdominal wound closure, hernia repair, sternal closure, and orthopaedic procedures including cerclage and tendon repair.	10-0 thru 7 with and without needles	Yellow-Ochre
ETHILON Nylon suture	General soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurological procedures.	11-0 thru 2 with and without needles	Mint Green
NUROLON Nylon Suture	General soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurological procedures.	6-0 thru 1 with and without needles 4-0 thru 1 with CONTROL RELEASE needles	Mint Green
MERSILENE Polyester Fiber Suture	General soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurological procedures.	6-0 thru 5 with or without needles 10-0 and 11-0 for ophthalmic (green monofilament) 0 with CONTROL RELEASE needles	Turquoise
ETHIBOND EXCEL Polyester Fiber Suture	General soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurological procedures.	7-0 thru 5 with or without needles 4-0 thru 1 with CONTROL RELEASE needles-various sizes attached to TFE polymer pledgets	Orange
PROLENE Polypropylene Suture	General soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurological procedures.	7-0 thru 2(clear) with and without needles 10-0 thru 8-0 and 6-0 thru 2(blue) with and without needles 0 thru 2 with CONTROL RELEASE needles-various sizes attached to TFE polymer pledgets	Deep Blue
PRONOVA Poly (hexafluoropropylene-VDF)Suture	General soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurological procedures.	6-0 thru 2 (clear) with needles 10-0 thru 8-0 and 6-0 thru 2 (blue) with needles 7-0 are U.S.P. except for diameter 0 thru 2 with CONTROL RELEASE needles	Cranberry

Common Suturing Techniques

Ligatures

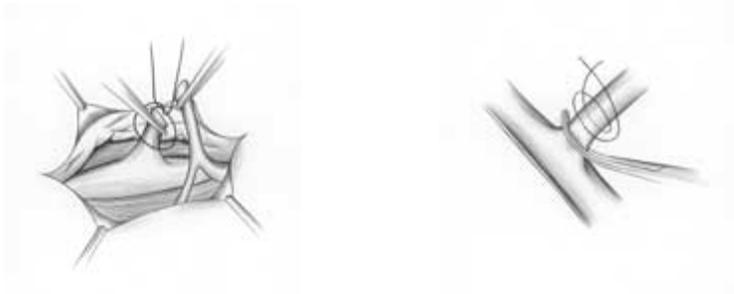
A suture tied around a vessel to occlude the lumen is called a *ligature* or *tie*. It may be used to effect hemostasis or to close off a structure to prevent leakage. There are two primary types of ligatures.

Free tie or freehand ligatures are single strands of suture material used to ligate a vessel, duct, or other structure. After a hemostat has been placed on the end of the structure, the suture strand is tied around the vessel under the tip of the hemostat. The hemostat is removed after the first throw and the surgeon tightens the knot using his or her fingertips, taking care to avoid instrument damage to the suture. Additional throws are added as needed to secure the knot.

Stick tie, suture ligature, or transfixion suture is a strand of suture material attached to a needle to ligate a vessel, duct, or other structure. This technique is used on deep structures where placement of a hemostat is difficult or on vessels of large diameter. The needle is passed through the structure or adjacent tissue first to anchor the suture, then tied around the structure. Additional throws are used as needed to secure the knot.

FIG.1

Ligatures



Free Tie

Stick Tie

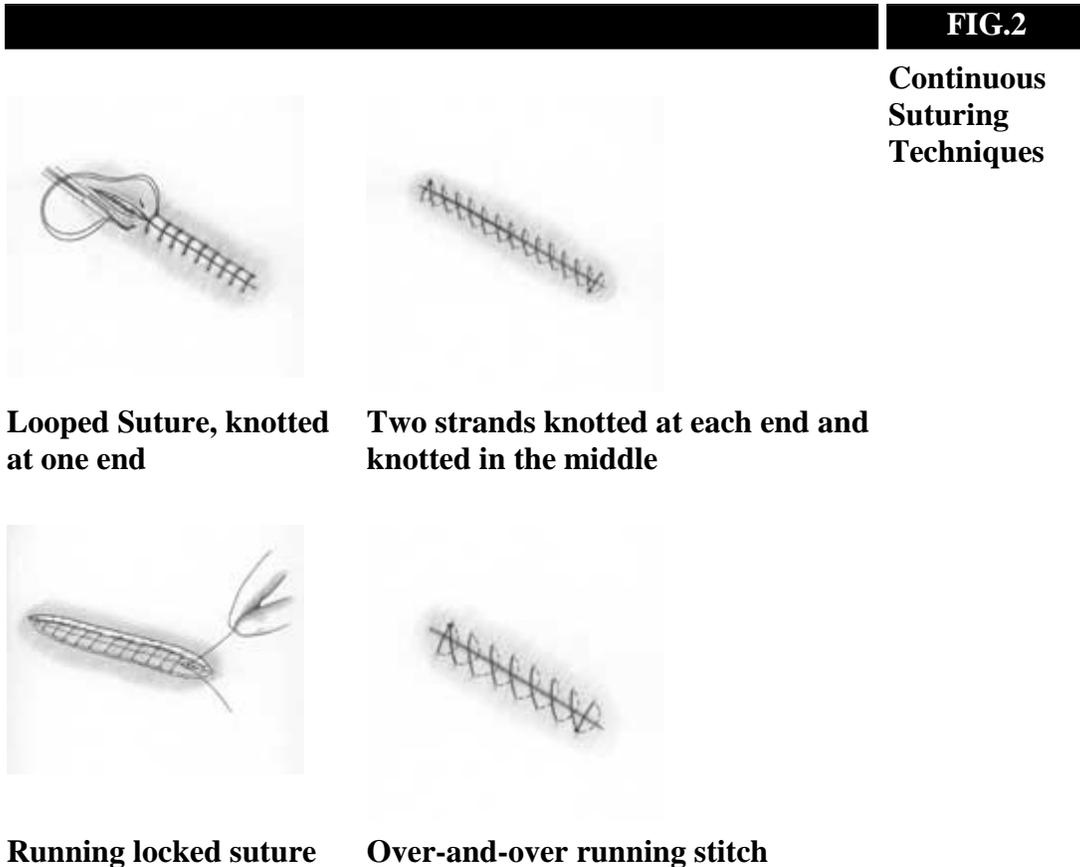
The Primary Suture Line

The *primary suture line* is the line of sutures that holds the wound edges in approximation during healing by first intention. It may consist of a continuous strand of material or a series of interrupted suture strands. Other types of primary sutures, such as deep sutures, buried sutures, purse-string sutures, and subcuticular sutures, are used for specific indications. Regardless of technique, a surgical needle is attached to the suture strand to permit repeated passes through tissue.

CONTINUOUS SUTURES

Also referred to as *running stitches*, continuous sutures are a series of stitches taken with one strand of material. The strand may be tied to itself at each end, or looped, with both cut ends of the strand tied together. A continuous suture line can be placed rapidly. It derives its strength from tension distributed evenly along the full length of the suture strand. However, care must be taken to apply firm tension, rather than tight tension, to avoid tissue strangulation. Overtensioning and instrument damage should be avoided to prevent suture breakage which could disrupt the entire line of a continuous suture.

Continuous suturing leaves less foreign body mass in the wound. In the presence of infection, it may be desirable to use a monofilament suture material because it has no interstices which can harbor microorganisms. This is especially critical as a continuous suture line can transmit infection along the entire length of the strand. A continuous one-layer mass closure may be used on peritoneum and/or fascial layers of the abdominal wall to provide a temporary seal during the healing process.



INTERRUPTED SUTURES

Interrupted sutures use a number of strands to close the wound. Each strand is tied and cut after insertion. This provides a more secure closure, because if one suture breaks, the remaining sutures will hold the wound edges in approximation.

Interrupted sutures may be used if a wound is infected, because microorganisms may be less likely to travel along a series of interrupted stitches.



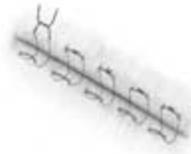
Techniques



Simple interrupted



**Interrupted vertical
mattress**



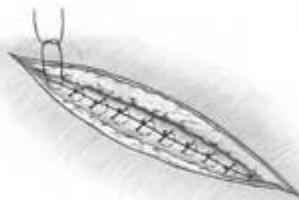
**Interrupted
horizontal mattress**

DEEP SUTURES

Deep sutures are placed completely under the epidermal skin layer. They may be placed as continuous or interrupted sutures and are not removed postoperatively.

FIG.4

**Deep
Sutures**



Interrupted technique

BURIED SUTURES

Buried sutures are placed so that the knot protrudes to the inside, under the layer to be closed. This technique is useful when using large diameter permanent sutures on deeper layers in thin patients who may be able to feel large knots that are not buried.

PURSE-STRING SUTURES

Purse-string sutures are continuous sutures placed around a lumen and tightened like a drawstring to invert the opening. They may be placed around the stump of the appendix, in the bowel to secure an intestinal stapling device, or in an organ prior to insertion of a tube (such as the aorta, to hold the cannulation tube in place during an open heart procedure).

FIG.5

**Purse-
String
Sutures**



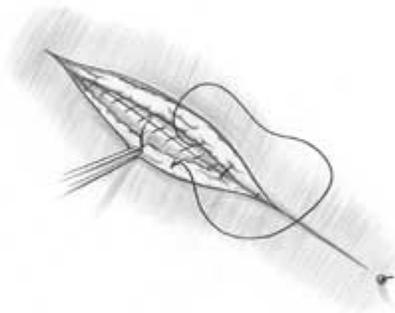


SUBCUTICULAR SUTURES

Subcuticular sutures are continuous or interrupted sutures placed in the dermis, beneath the epithelial layer. Continuous subcuticular sutures are placed in a line parallel to the wound. This technique involves taking short, lateral stitches the full length of the wound. After the suture has been drawn taut, the distal end is anchored in the same manner as the proximal end. This may involve tying or any of a variety of anchoring devices. Subcuticular suturing may be performed with absorbable suture which does not require removal, or with monofilament nonabsorbable suture that is later removed by simply removing the anchoring device at one end and pulling the opposite end.

FIG.6

Subcutaneous Sutures



The Secondary Suture Line

A secondary line of sutures may be used:

- To reinforce and support the primary suture line, eliminate dead space, and prevent fluid accumulation in an abdominal wound during healing by first intention. When used for this purpose, they may also be called *retention*, *stay*, or *tension* sutures.
- To support wounds for healing by second intention.
- For secondary closure following wound disruption when healing by third intention.

NOTE: If secondary sutures are used in cases of nonhealing, they should be placed in opposite fashion from the primary sutures (i.e., interrupted if the primary sutures were continuous, continuous if the primary sutures were interrupted).

Retention sutures are placed approximately 2 inches from each edge of the wound. The tension exerted lateral to the primary suture line contributes to the tensile strength of the wound. *Through-and-through* sutures are placed from inside the peritoneal cavity through all layers of the abdominal wall, including the peritoneum. They should be inserted before the peritoneum is closed using a simple interrupted stitch. The wound may be closed in layers for a distance of approximately three-fourths its length. Then the retention sutures in this area may be drawn together and tied. It is important that a finger be placed within the abdominal cavity to prevent strangulation of the viscera in the closure. The remainder of the wound may then be closed. Prior to tightening and tying the final retention sutures, it is important to explore the abdomen again with a finger to prevent strangulation of viscera in the closure. The remainder of the wound may then be closed.

Retention sutures utilize nonabsorbable suture material. They should therefore be removed as soon as the danger of sudden increases in intra-abdominal pressure is over-- usually 2 to 6 weeks, with an average of 3 weeks.

FIG.7

**Retention
Suture
Bolster**



Stitch Placement

Many types of stitches are used for both continuous and interrupted suturing. In every case, equal "bites" of tissue should be taken on each side of the wound. The needle should be inserted from 1 to 3 centimeters from the edge of the wound, depending upon the type and condition of the tissue being sutured. The distance from suture to suture should be approximately equal to the distance from the edge of the wound to the suture.¹⁵

Most tissues heal when the edges are held in apposition. In some instances, the tissues should be either inverted or everted to affect healing. For example, mucosa is inverted in a sutured gastrointestinal anastomosis, apposing serosa to serosa. Skin edges may be everted prior to the placement of sutures.

		Table 6
CONTINUOUS SUTURE	INTERRUPTED SUTURE	Commonly Used Types of Stitches
To appose skin and other tissue		
Over-and-over Subcuticular	Over-and-over Vertical mattress Horizontal mattress	
To invert tissue		
Lembert Cushing Connell	Lembert Halsted Purse-String	
To evert tissue		
Horizontal mattress	Horizontal mattress	

Knot Tying Techniques

General Principles of Knot Tying

Of the more than 1,400 knots described in the *Encyclopedia of Knots*, only a few are used to secure sutures or to ligate blood vessels. The type of knot tied will depend upon the material used, the depth and location of the incision, and the amount of stress that will be placed upon the wound postoperatively. Multifilament sutures are generally easier to handle and tie than monofilament sutures.

The surgeon must work slowly and meticulously. Speed in knot tying frequently results in less than perfect placement of the strands. When tying a knot, the surgeon must consider the amount of tension he or she is placing upon the incision and must allow for post-operative edema. The general principles of knot tying which apply to all suture materials are:

1. The completed knot must be firm to virtually eliminate slippage. The simplest knot for the material used is the most desirable.
2. Tie the knot as small as possible and cut the ends as short as possible. This helps to prevent excessive tissue reaction toward absorbable sutures and to minimize foreign body reaction to nonabsorbable sutures.
3. Avoid friction. "Sawing" between strands may weaken suture integrity.
4. Avoid damage to the suture material during handling, especially when using surgical instruments in instrument ties.
5. Avoid excessive tension which may break sutures and cut tissue. Practice will lead to successful use of finer gauge materials.
6. Do not tie sutures used for tissue approximation too tightly, as this may contribute to tissue strangulation. *Approximate-- do not strangulate.*
7. Maintain traction at one end of the strand after the first loop is tied to avoid loosening of the throw.
8. Make the final throw as nearly horizontal as possible.
9. Do not hesitate to change stance or position in relation to the patient in order to place a knot securely and flat.
10. Extra throws do not add to the strength of a properly tied knot, only to its bulk.

Some procedures involve tying knots with the fingers, using one or two hands; others involve tying with the help of instruments. Perhaps the most complex method of knot tying is done during endoscopic procedures, when the surgeon must manipulate instruments from well outside the body cavity.

Suture Characteristics and Knot Security

Suture materials manufactured by ETHICON have been designed to provide the optimum combination of strength, uniformity, hand, and extensibility (where appropriate).

Hand is the most subtle of all suture qualities, relating literally to the way the suture handles--the smoothness with which it passes through tissue and ties down, the way in which knots can be set and snugged down, and most of all, to the firmness or body of the suture. *Extensibility* relates to the way the suture stretches slightly and then recovers during knot tying. It also denotes whether or not a good deal of tension can be placed on the strand before it breaks. The coefficient of friction in *monofilament sutures* is relatively low. (The coefficient of friction affects the tendency of the knot to loosen after it has been tied; more friction results in a more secure knot.) Most surgeons have had the experience of discovering that a carefully tied knot in monofilament nylon had eventually loosened. In larger sizes, monofilament nylon suture is the most likely to slip. However, PROLENE suture is preferred for cardiovascular bypass surgery because it exhibits a small degree of plasticity. If it is tied carefully and the knots set firmly, a flattening occurs where the strands cross which helps to lock polypropylene knots. Surgeons suggest that the stretching characteristics of PROLENE suture provide the signal to the surgeon at the precise moment when the knot is snug. The key to the proper use of these materials is meticulous technique in laying flat knots and setting each knot as it is tied.

One drawback of monofilament synthetic polymeric sutures is their *memory*. This is the tendency not to lay flat, but to return to a given shape set by the material's extrusion process or the suture's packaging. Packaging can also play a role in helping sutures to lay flat. Packages such as the RELAY and straight pack suture delivery systems deliver sutures with minimal package memory due to their unique package design.

When knot security is critical, synthetic *multifilament or braided sutures*, usually polyesters, are used. Additional knots are usually tied to maximize knot security. With multifilament absorbable sutures, particularly Coated VICRYL sutures, silk, and cotton, the knots do not tend to slip. This is because the nature of the material and its braided or twisted construction provide a high coefficient of friction. The knots remain as they were laid down. However, variability in knot strength among multifilament sutures might arise from the technical aspects of the braiding or twisting process.

Although various suturing materials react in specific ways while being tied, perhaps the greatest factor affecting knot security is the *human factor*. Herrman concluded: "Knot security proved to be a much more variable characteristic than breaking strength (of suture material). In addition to the variable inherent in the material itself, considerable variation was found between knots tied by different individuals and even between knots tied by the same individual on different occasions."¹⁶

Knot Tying Techniques Most Often Used

An important part of good suturing technique is the method of knot tying. A see-saw motion (where one strand saws down over the other until the knot is formed) may weaken suture material to the point that it may break when the next throw is made, or worse, in the postoperative period when the suture is further weakened by increased tension or motion or decreasing tensile strength. If the two ends of the suture are pulled in opposite directions with uniform rate and tension, the knot will be tied more securely. Following are the most frequently used knot tying techniques with accompanying illustrations of finished knots.

SQUARE KNOT

The two-handed square knot is the easiest and most reliable for tying most suture materials. Standard technique of flat and square ties with additional throws if indicated by the surgical circumstance and the experience of the operator should be used to tie plain and chromic surgical gut, Coated VICRYL *RAPIDE* suture, Coated VICRYL suture, MONOCRYL suture, PDS II suture, PANACRYL suture, ETHIBOND *EXCEL* suture, ETHILON suture, PERMA-HAND suture, PROLENE suture, PRONOVA suture, and stainless steel suture. Whenever possible, this technique is performed using two hands. The square knot may also be tied using one hand.

CAUTION: If the strands of a square knot are inadvertently incorrectly crossed, a granny knot will result. Granny knots are not recommended because they have a tendency to slip when subjected to increased stress.



FIG.8a

**FINISHED
SUTURE
TIES**

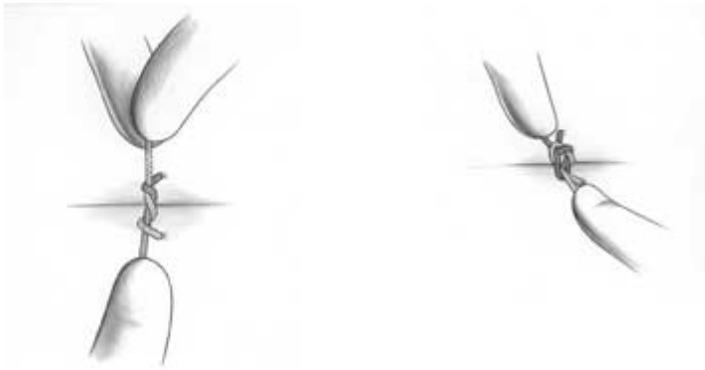


Square Knot

SURGEON'S KNOT

The surgeon's knot, or friction knot, is recommended for tying Coated VICRYL suture, ETHIBOND *EXCEL* suture, ETHILON suture, MERSILENE suture, NUROLON suture, and PROLENE suture.

FIG.8b, c



**FINISHED
SUTURE
TIES**

Surgeon's Knot-first throw

Surgeon's Knot-second throw

DEEP TIE

Tying deep in a body cavity can be difficult. The square knot must be firmly snugged down. However, upward tension which may tear the tissue must be avoided.

FIG.8d



**FINISHED
SUTURE
TIES**

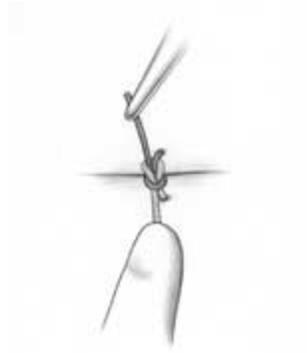
Deep tie

INSTRUMENT TIE

This tie is useful when one or both ends of the suture material are short. Care must be taken not to crush the suture material, especially for monofilament sutures which are prone to instrument damage.

FIG.8e

**FINISHED
SUTURE
TIES**



Instrument tie

LIGATION AROUND A HEMOSTATIC CLAMP

This procedure may be needed to ligate a clamped vessel or tissue.

Endoscopic Knot Tying Techniques

During an endoscopic procedure, a square knot or surgeon's knot may be tied either outside the abdomen and pushed down into the body through a trocar (extracorporeal) or directly within the abdominal cavity (intracorporeal).

In *extracorporeal knot tying*, the suture appropriately penetrates the tissue, and both needle and suture are removed from the body cavity, bringing both suture ends outside of the trocar. Then a series of half-hitches are tied, each one being pushed down into the cavity and tightened with an endoscopic knot pusher.

Intracorporeal knot tying is performed totally within the abdominal cavity. After the suture has penetrated the tissue, the needle is cut from the suture and removed. Several loops are made with the suture around the needleholder, and the end of the suture is pulled through the loops. This technique is then repeated to form a surgeon's knot, which is tightened by the knot pusher.

In both extracorporeal and intracorporeal knot tying, the following principles of suture manipulation on tissue should be observed.

1. Handle tissue as gently as possible to avoid tissue trauma.
2. Grasp as little tissue as possible.
3. Use the smallest suture possible for the task.
4. Exercise care in approximating the knot so that the tissue being approximated is not strangulated.
5. Suture must be handled with care to avoid damage.

Cutting Sutures

Once the knot has been securely tied, the ends must be cut. Before cutting, make sure both tips of the scissors are visible to avoid inadvertently cutting tissue beyond the suture.

Cutting sutures entails running the tip of the scissors lightly down the suture strand to the knot. The ends of surgical gut are left relatively long, approximately 1/4" (6mm) from the knot. Other materials are cut closer to the knot, approximately 1/8" (3mm), to decrease tissue reaction and minimize the amount of foreign material left in the wound. To ensure that the actual knot is not cut, twist or angle the blades of the scissors prior to cutting.

Make certain to remove the cut ends of the suture from the operative site.

Suture Removal

When the wound has healed so that it no longer needs the support of non-absorbable suture material, skin sutures must be removed. The length of time the sutures remain in place depends upon the rate of healing and the nature of the wound. Sutures should be removed "...before the epithelium has migrated into deeper parts of the dermis. To prevent widening of the scar, the wound edges must be taped...."¹⁷ General rules are as follows:

Sutures should be removed using aseptic and sterile technique. The surgeon uses a sterile suture removal tray prepared for the procedure. The following steps are taken:

- **STEP 1**--Cleanse the area with an antiseptic. Hydrogen peroxide can be used to remove dried serum encrusted around the sutures.
- **STEP 2**--Pick up one end of the suture with thumb forceps, and cut as close to the skin as possible where the suture enters the skin.
- **STEP 3**--Gently pull the suture strand out through the side opposite the knot with the forceps. To prevent risk of infection, the suture should be removed without pulling any portion that has been outside the skin back through the skin.

NOTE: Fast absorbing synthetic or gut suture material tend to lose all tensile strength in 5 to 7 days and can be removed easily without cutting. A common practice is to cover the skin sutures with PROXI-STRIP skin closures during the required healing period. After the wound edges have regained sufficient tensile strength, the sutures may be removed by simply removing the PROXI-STRIP skin closures.

Table 7

Suture Location	Time For Suture Removal
Skin on the face and neck	2 to 5 days
Other skin sutures	5 to 8 days
Retention sutures	2 to 6 weeks

**Suture
Removal**

Suture Handling Tips

These guidelines will help the surgical team keep their suture inventory up to date and their sutures in the best possible condition.

1. Read labels.
2. Heed expiration dates and rotate stock.
3. Open only those sutures needed for the procedure at hand.
4. Straighten sutures with a gentle pull. Never crush or rub them.
5. Don't pull on needles.
6. Avoid crushing or crimping suture strands with surgical instruments.
7. Don't store surgical gut near heat.
8. Moisten--but never soak-- surgical gut.
9. Do not wet rapidly absorbing sutures.
10. Keep silk dry.
11. Wet linen and cotton to increase their strength.
12. Don't bend stainless steel wire.
13. Draw nylon between gloved fingers to remove the packaging "memory."
14. Arm a needleholder properly.

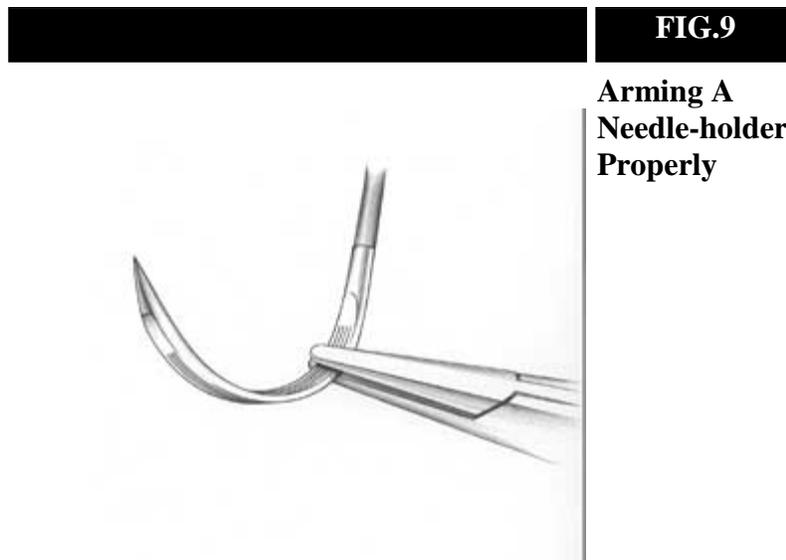


FIG.9

**Arming A
Needle-holder
Properly**

Grasp the needle one-third to one-half of the distance from the swaged end to the point.

Suture Selection By Procedure

Principles of Suture Selection

Among the many decisions that face the surgeon in the operating room, suture selection for the procedure at hand may be one of the most critical. Personal preference will, of course, play a role. But the final choice will depend upon various patient factors that influence the healing process, the characteristics of the tissues involved, and potential post-operative complications.

The wide variety of suturing materials available can make it difficult to choose the most appropriate suture for a given task. The following principles are offered as a guide to selecting suture materials:

When a wound reaches maximal strength, sutures are no longer needed. Therefore:

- a. Close slow-healing tissues (skin, fascia, tendons) with nonabsorbable sutures or a long-lasting absorbable suture.
- b. Close fast-healing tissues (stomach, colon, bladder) with absorbable sutures.

Foreign bodies in potentially contaminated tissues may convert contamination into infection. Therefore:

- a. Avoid multifilament sutures which may convert a contaminated wound into an infected one.
- b. Use monofilament sutures or absorbable sutures which resist harboring infection.

Where cosmetic results are important, close and prolonged apposition of tissues and avoidance of irritants will produce the best results. Therefore:

- a. Use the smallest inert monofilament suture materials (nylon, polypropylene).
- b. Avoid using skin sutures alone. Close subcuticularly whenever possible.
- c. Use sterile skin closure strips to secure close apposition of skin edges when circumstance permits.

Foreign bodies in the presence of fluids containing high crystalloid concentrations may cause precipitation and stone formation. Therefore:

- a. Use absorbable sutures in the urinary and biliary tracts.

Regarding suture size:

- a. Use the finest size suture commensurate with the natural strength of the tissue to be sutured.
- b. Use retention sutures to reinforce appropriately sized primary sutures if the patient is at risk of producing sudden strains on the suture line post-operatively. Remove the retention sutures as soon as that risk is reduced.

Surgery Within the Abdominal Cavity

Going in, the surgeon will need to seal subcutaneous blood vessels immediately after the incision is made, using either an electro-surgical unit designed for this purpose or free ties (ligatures). Use of the ETHICON POWERSTAR bipolar scissors, which simultaneously cuts and coagulates tissue in open surgery, may reduce the need for ligatures. If ligatures are used, an absorbable suture material is generally preferred. When preparing the ties, the scrub person often prepares one strand on a needle for use as a suture ligature should the surgeon wish to transfix a large blood vessel. Once inside, the type of suture selected will depend upon the nature of the operation and the surgeon's technique.

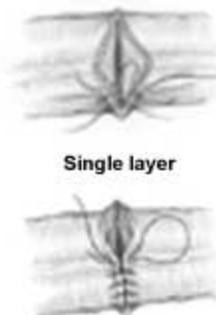
THE GASTROINTESTINAL TRACT

Leakage from an anastomosis or suture site is the principal problem encountered in closing wounds of the gastrointestinal tract. This problem can lead to localized or generalized peritonitis. Sutures should not be tied too tightly in an anastomotic closure. Wounds of the stomach and intestine are rich in blood supply and may become edematous and hardened. Tight sutures may cut through the tissue and cause leakage. A leak-proof anastomosis can be achieved with either a single- or double-layer closure.

For a single-layer closure, interrupted sutures should be placed approximately 1/4" (6mm) apart. Suture is placed through the submucosa, into the muscularis and through the serosa. Because the submucosa provides strength in the gastrointestinal tract, effective closure involves suturing the submucosal layers in apposition without penetrating the mucosa. A continuous suture line provides a tighter seal than interrupted sutures. However, if a continuous suture breaks, the entire line may separate.

FIG.10a

Anastomotic Closure Technique

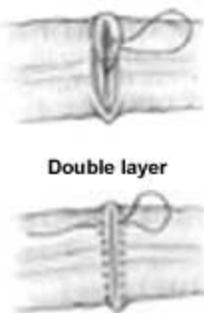


Single layer

Many surgeons prefer to use a double-layer closure, placing a second layer of interrupted sutures through the serosa for insurance. *Absorbable VICRYL sutures, or chromic gut sutures* may be used in either a single- or double-layer closure. Surgical silk may also be used for the second layer of a double-layer closure.

FIG.10b

Anastomotic Closure Technique

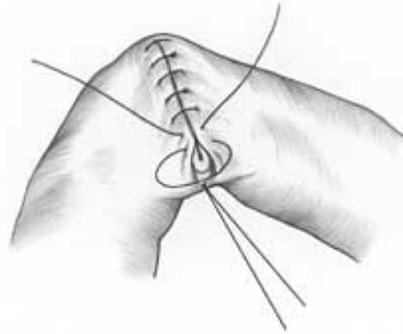


Double layer

Inverted, everted, or end-to-end closure techniques have all been used successfully in this area, but they all have drawbacks. The surgeon must take meticulous care in placing the sutures in the submucosa. Even with the best technique, some leakage may occur. Fortunately, the omentum usually confines the area, and natural body defenses handle the problem.

FIG.11

Inverted Closure Technique



THE STOMACH--For an organ that contains free hydrochloric acid and potent proteolytic enzymes, the stomach heals surprisingly quickly. Stomach wounds attain maximum strength within 14 to 21 days postoperatively, and have a peak rate of collagen synthesis at 5 days.

Absorbable sutures are usually acceptable in the stomach, although they may produce a moderate reaction in both the wound and normal tissue. *Coated VICRYL sutures* are most commonly used. *PROLENE sutures* may also be used for stomach closure.

THE SMALL INTESTINE--Closure of the small intestine presents the same considerations as the stomach. Proximal intestinal contents, primarily bile or pancreatic juices, may cause a severe chemical (rather than bacterial) peritonitis.

If using an inverted closure technique, care must be taken to minimize the cuff of tissue which protrudes into the small sized intestinal lumen in order to avoid partial or complete obstruction. *Absorbable sutures* are usually preferred, particularly because they will not permanently limit the lumen diameter. A *nonabsorbable suture* may be used in the serosal layer for added assurance.

The small intestine heals very rapidly, reaching maximal strength in approximately 14 days.

THE COLON--The high microbial content of the colon once made contamination a major concern. But absorbable sutures, once absorbed, leave no channel for microbial migration. Still, leakage of large bowel contents is of great concern as it is potentially more serious than leakage in other areas of the gastrointestinal tract.

The colon is a strong organ--approximately twice as strong in the sigmoid region as in the cecum. Yet, wounds of the colon gain strength at the same rate regardless of their location. This permits the same suture size to be used at either end of the colon. The colon heals at a rate similar to that of the stomach and small intestine. A high rate of collagen synthesis is maintained for a prolonged period (over 120 days). The entire gastrointestinal tract exhibits a loss of collagen and increased collagenous activity immediately following colon anastomosis. Both *absorbable* and *nonabsorbable sutures* may be used for closure of the colon. Placement of sutures in the submucosa, avoiding penetration of the mucosa, will help prevent complications.

THE RECTUM--The rectum heals very slowly. Because the lower portion is below the pelvic peritoneum, it has no serosa. A large bite of muscle should be included in an anastomosis, and the sutures should be tied carefully to avoid cutting through the tissues. *Monofilament sutures* reduce the risk of bacterial proliferation in the rectum.

THE BILIARY TRACT

THE GALLBLADDER--Within the gallbladder, the cystic and common bile ducts heal rapidly. Their contents present special considerations for suture selection. The presence of a foreign body such as a suture in an organ that is prone to crystal formation may precipitate the formation of "stones." Multifilament sutures should probably not be used because it is not always possible to prevent exposure of a suture in the ducts. The surgeon should choose an *absorbable suture* in the finest size possible that leaves the least surface area exposed.

PARENCHYMATOUS ORGANS

THE SPLEEN, LIVER, AND KIDNEY--On occasion, a surgeon may be called upon to repair a laceration of one of these vital organs. If large vessels, particularly arteries, within these organs have been severed, they must be located and ligated before attempting to close the defect. Otherwise, hematomas or secondary hemorrhage may occur.

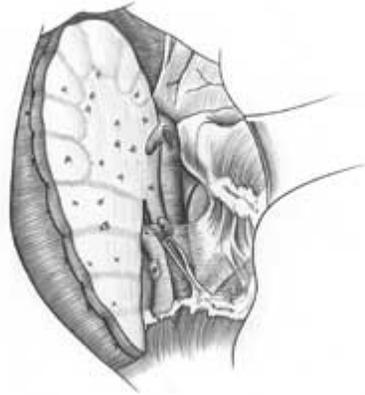
Because these organs are composed chiefly of cells with little connective tissue for support, attempts must be made to coapt the outer fibrous capsule of the torn tissue. In the absence of hemorrhage, little tension is placed on the suture line and only small size sutures need to be used. If the tissue cannot be approximated, tacking a piece of

omentum over the defect will usually suffice to provide closure. Sutures do not need to be placed close together or deeply into the organ.

Lacerations in this area tend to heal rapidly. New fibrous tissue will usually form over the wound with 7 to 10 days. In a liver resection, suturing of the wedges in a horizontal through-and-through fashion should hold the tissue securely. Large vessels should be tied using VICRYL sutures or silk. Raw surfaces can be closed or repaired using VICRYL (polyglactin 910) mesh.

FIG.12

**Liver
Resection**



Closing the Abdomen

page 1 of 3

When closing the abdomen, the closure technique may be more important than the type of suture material used.

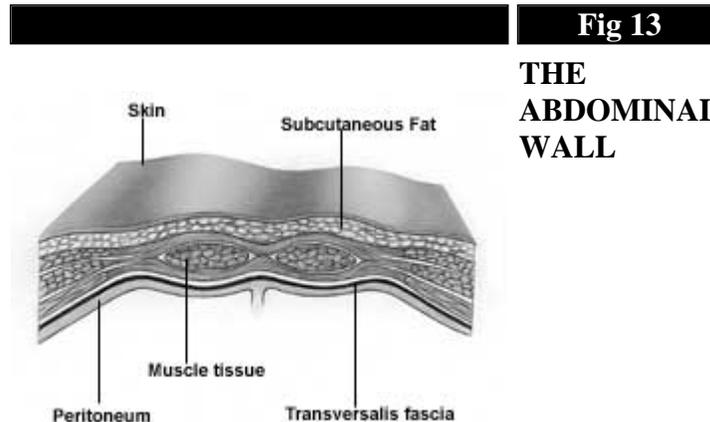


Fig 13

THE ABDOMINAL WALL

THE PERITONEUM

The peritoneum, the thin membranous lining of the abdominal cavity, lies beneath the posterior fascia. It heals quickly. Some believe that the peritoneum does not require suturing, while others disagree. If the posterior fascia is securely closed, suturing the peritoneum may not contribute to the prevention of an incisional hernia. Among surgeons who choose to close the peritoneum, a continuous suture line with *absorbable suture material* is usually preferred. Interrupted sutures can also be used for this procedure.

FASCIA

This layer of firm, strong connective tissue covering the muscles is the main supportive structure of the body. In closing an abdominal incision, the fascial sutures must hold the wound closed and also help to resist changes in intra-abdominal pressure. Occasionally, synthetic graft material may be used when fascia is absent or weak. *PROLENE polypropylene mesh* may be used to replace abdominal wall or repair hernias when a great deal of stress will be placed on the suture line during healing. *Nonabsorbable sutures* such as PROLENE suture may be used to suture the graft to the tissue. Fascia regains approximately 40% of its original strength in 2 months. It may take up to a year or longer to regain maximum strength. Full original strength is never regained. The anatomic location and type of abdominal incision will influence how many layers of fascia will be sutured. The posterior fascial layer is always closed. The anterior layer may be cut and may also require suturing. Mass closure techniques are becoming the most popular. Most suture materials have some inherent degree of elasticity. If not tied too tightly, the suture will "give" to accommodate post-operative swelling that occurs. Stainless steel sutures, if tied too tightly, will cut like a knife as the tissue swells or as tension is placed upon the suture line. Because of the slow healing time and because the fascial suture must bear the maximum stress of the wound, a moderate size *nonabsorbable suture* may be used. An *absorbable suture* with longer lasting tensile strength, such as PDS II sutures or PANACRYL sutures, may also provide adequate support. PDS II sutures are especially well-suited for use in younger, healthy patients. PANACRYL sutures are appropriate for patients with compromised wound healing due to its extended wound support.

Many surgeons use an interrupted technique to close fascia. In the absence of infection or gross contamination, the surgeon may choose either *monofilament* or *multifilament sutures*. In the presence of infection, a *monofilament absorbable material* like PDS II sutures or inert *nonabsorbable sutures* like stainless steel or PROLENE sutures may be used.

MUSCLE

Muscle does not tolerate suturing well. However, there are several options in this area.

Abdominal muscles may be either cut, split (*separated*), or retracted, depending upon the location and type of the incision chosen. Where possible, the surgeon prefers to avoid interfering with the blood supply and nerve function by making a muscle-splitting incision or retracting the entire muscle toward its nerve supply. During closure, muscles handled in this manner do not need to be sutured. The fascia is sutured rather than the muscle.

FIG.14

SURGICAL OPTIONS

IN MUSCLE



Cutting



Splitting



Retracting

The Smead-Jones far-and-near-technique for abdominal wound closure is strong and rapid, provides good support during early healing with a low incidence of wound disruption, and has a low incidence of late incisional problems. This is a single-layer closure through both layers of the abdominal wall fascia, abdominal muscles, peritoneum, and the anterior fascial layer. The interrupted sutures resemble a "figure of eight" when placed. *Absorbable* PDS II sutures or VICRYL sutures are usually used.

Stainless steel sutures may also be used. *Monofilament* PROLENE sutures also provide all the advantages of steel sutures: strength, minimal tissue reactivity, and resistance to bacterial contamination. They are better tolerated than steel sutures by patients in the late postoperative months and are easier for the surgeon to handle and tie. However, both stainless steel and PROLENE sutures may be detectable under the skin of thin patients. To avoid this problem, knots should be buried in fascia instead of in the subcutaneous space.

SUBCUTANEOUS FAT

Neither fat nor muscle tolerate suturing well. Some surgeons question the advisability of placing sutures in fatty tissue because it has little tensile strength due to its composition, which is mostly water. However, others believe it is necessary to place at least a few sutures in a thick layer of subcutaneous fat to prevent dead space, especially in obese patients. Dead spaces are most likely to occur in this type of tissue, so the edges of the wound must be carefully approximated. Tissue fluids can accumulate in these pocket-like spaces, delaying healing and predisposing infection.

Absorbable sutures are usually selected for the subcutaneous layer. VICRYL suture is especially suited for use in fatty, avascular tissue since it is absorbed by hydrolysis. The surgeon may use the same type and size of material used earlier to ligate blood vessels in this layer.

Closing the Abdomen

page 2 of 3

SUBCUTICULAR TISSUE

To minimize scarring, suturing the subcuticular layer of tough connective tissue will hold the skin edges in close approximation. In a single-layer subcuticular closure, less evidence of scar gaping or expansion may be seen after a period of 6 to 9 months than is evident with simple skin closure. The surgeon takes continuous short lateral stitches beneath the epithelial layer of skin. Either *absorbable* or *nonabsorbable sutures* may be used. If nonabsorbable material is chosen, one end of the suture strand will protrude from each end of the incision, and the surgeon may tie them together to form a "loop" or knot the ends outside of the incision.

To produce only a hair-line scar (on the face, for example), the skin can be held in very closed approximation with skin closure tapes in addition to subcuticular sutures. Tapes may be left on the wound for an extended period of time depending upon their location on the body. When great tension is not placed upon the wound, as in facial or neck surgery, very fine sizes of subcuticular sutures may be used. Abdominal wounds that must withstand more stress call for larger suture sizes.

Some surgeons choose to close both the subcuticular and epidermal layers to achieve minimal scarring. *Chromic surgical gut* and *polymeric materials*, such as MONOCRYL suture, are acceptable for placement within the dermis. They are capable of maintaining sufficient tensile strength through the collagen synthesis stage of healing which lasts approximately 6 weeks. The sutures must not be placed too close to the epidermal surface to reduce extrusion. If the skin is nonpigmented and thin, a *clear or white monofilament suture* such as MONOCRYL suture will be invisible to the eye. MONOCRYL suture is particularly well-suited for this closure because, as a monofilament, it does not harbor infection and, as a synthetic absorbable suture, tissue reaction is minimized. After this layer is closed, the skin edges may then be approximated.

SKIN

Skin is composed of the epithelium and the underlying dermis. It is so tough that a very sharp needle is essential for every stitch to minimize tissue trauma. (*See the section on Needle Selection.*)

Skin wounds regain tensile strength slowly. If a nonabsorbable suture material is used, it is typically removed between 3 and 10 days postoperatively, when the wound has only regained approximately 5% to 10% of its strength. This is possible because most of the stress placed upon the healing wound is absorbed by the fascia, which the surgeon relies upon to hold the wound closed. The skin or subcuticular sutures need only be strong enough to withstand natural skin tension and hold the wound edges in apposition.

The use of Coated VICRYL *RAPIDE* suture, a rapidly absorbed synthetic suture, eliminates the need for suture removal. Coated VICRYL *RAPIDE* suture, which is indicated for superficial closure of skin and mucosa, provides short-term wound support consistent with the rapid healing characteristics of skin. The sutures begin to fall off in 7 to 10 days, with absorption essentially complete at 42 days.

Suturing technique for skin closure may be either continuous or interrupted. Skin edges should be everted.

Preferably, each suture strand is passed through the skin only once, reducing the chance of cross-contamination across the entire suture line. Interrupted technique is usually preferred.

If surgeon preference indicates the use of a nonabsorbable suture material, several issues must be considered. Skin sutures are exposed to the external environment, making them a serious threat to wound contamination and stitch abscess. The interstices of multifilament sutures may provide a haven for microorganisms. Therefore, *monofilament nonabsorbable sutures* may be preferred for skin closure. Monofilament sutures also induce significantly less tissue reaction than multifilament sutures. For cosmetic reasons, *nylon* or *polypropylene monofilament sutures* may be preferred. Many skin wounds are successfully closed with silk and polyester multifilaments as well. Tissue reaction to nonabsorbable sutures subsides and remains relatively acellular as fibrous tissue matures and forms a dense capsule around the suture. (Note, surgical gut has been known to produce tissue reaction. Coated VICRYL *RAPIDE* suture elicits a lower tissue reaction than chromic gut suture due to its accelerated absorption profile.) The key to success is early suture removal before epithelialization of the suture tract occurs and before contamination is converted into infection.

DERMABOND Topical Skin Adhesive (2-Octyl Cyanoacrylate), a tissue adhesive for skin closure, is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed trauma-induced lacerations.

DERMABOND adhesive can replace suture on virtually all facial and appropriate extremity and torso wounds.

However, it should not be used across areas of increased skin tension, such as knuckles, elbows, or knees, unless the joint is immobilized during the skin healing period.

The use of this topical skin adhesive has produced cosmetic results superior to those of suturing while providing patients a fast and relatively painless closure.^{18,19} (*See Chapter 5, Other Surgical Products, for more information on DERMABOND adhesive.*)

A WORD ABOUT SCARRING (EPITHELIALIZATION)

When a wound is sustained in the skin--whether accidentally or during a surgical procedure--the epithelial cells in the basal layer at the margins of the wound flatten and move into the wound area. They move down the wound edge until they find living, undamaged tissue at the base of the wound. Then they move across the wound bed to make contact with similar cells migrating from the opposite side of the wound. They move down the suture tract after it has been embedded in the skin. When the suture is removed, the tract of the epithelial cells remains. Eventually, it may disappear, but some may remain and form keratin. A punctate scar is usually seen on the skin surface and a "railroad track" or "crosshatch" appearance on the wound may result. This is relatively rare if the skin sutures are not placed with excessive tension and are removed by the seventh postoperative day.



FIG. 15

THE RAILROAD TRACK SCAR CONFIGURATION



The forces that create the distance between the edges of the wound will remain long after the sutures have been removed. Significant collagen synthesis will occur from 5 to 42 days postoperatively. After this time, any additional gain in tensile strength will be due to remodeling, or crosslinking, of collagen fibers rather than to collagen synthesis. Increases in tensile strength will continue for as long as 2 years, but the tissue will never quite regain its original strength.

Closing the Abdomen

page 3 of 3

CLOSURE WITH RETENTION SUTURES

We have already discussed the techniques involved with placing retention sutures, and using them in a secondary suture line. (See the section on *Suturing Techniques*.) Heavy sizes (0 to 5) of *nonabsorbable materials* are usually used for retention sutures, not for strength, but because larger sizes are less likely to cut through tissue when a sudden rise in intra-abdominal pressure occurs from vomiting, coughing, straining, or distention. To prevent the heavy suture material from cutting into the skin under stress, one end of the retention suture may be threaded through a short length of plastic or rubber tubing called a *bolster* or *bumper* before it is tied. A plastic bridge with adjustable features may also be used to protect the skin and primary suture line and permit postoperative wound management for patient comfort.

Properly placed retention sutures provide strong reinforcement for abdominal wounds, but also cause the patient more postoperative pain than does a layered closure. The best technique is to use a material with needles swaged on each end (*double-armed*). They should be placed from the inside of the wound toward the outside skin to avoid pulling potentially contaminated epithelial cells through the entire abdominal wall.

The ETHICON retention suture line includes ETHILON sutures, MERSILENE sutures, ETHIBOND *EXCEL* sutures, and PERMA-HAND sutures. Surgical steel sutures may also be used. Retention sutures may be left in place for 14 to 24 days postoperatively. Three weeks is an average length of time. Assessment of the patient's condition is the controlling factor in deciding when to remove retention sutures.

SUTURE FOR DRAINS

If a drainage tube is placed in a hollow organ or a bladder drain is inserted, it may be secured to the wall of the organ being drained with *absorbable sutures*. The surgeon may also choose to minimize the distance between the organ and the abdominal wall by using sutures to tack the organ being drained to the peritoneum and fascia. Sutures may be placed around the circumference of the drain, either two sutures at 12 and 6 o'clock positions, or four sutures at 12, 3, 6, and 9 o'clock positions, and secured to the skin with temporary loops. When the drain is no longer needed, the skin sutures may be easily removed to remove the drain. The opening can be left open to permit additional drainage until it closes naturally.

A drainage tube inserted into the peritoneal cavity through a stab wound in the abdominal wall usually is anchored to the skin with one or two nonabsorbable sutures. This prevents the drain from slipping into or out of the wound.

FIG.16

PLACEMENT OF SUTURES AROUND THE DRAIN



THE IMPORTANCE OF MENDING THE MESENTERY

When closing, the surgeon knows how critical it is to repair any defects that have been created during the surgical procedure in the mesentery to prevent possible hernia. The mesentery is a membranous fold that attaches the various organs to the body wall. Either a running or interrupted technique may be used, with VICRYL sutures or surgical gut.

NEUROSURGERY

Surgeons have traditionally used an interrupted technique to close the galea and dura mater.

The tissue of the galea, similar to the fascia of the abdominal cavity, is very vascular and hemostatic. Therefore, scalp hematoma is a potential problem, and the surgeon must be certain to close well.

The dura mater is the outermost of the three meninges that protects the brain and spinal cord. It tears with ease and cannot withstand too much tension. The surgeon may drain some of the cerebrospinal fluid to decrease volume, easing the tension on the dura before closing. If it is too damaged to close, a patch must be inserted and sutured in place.

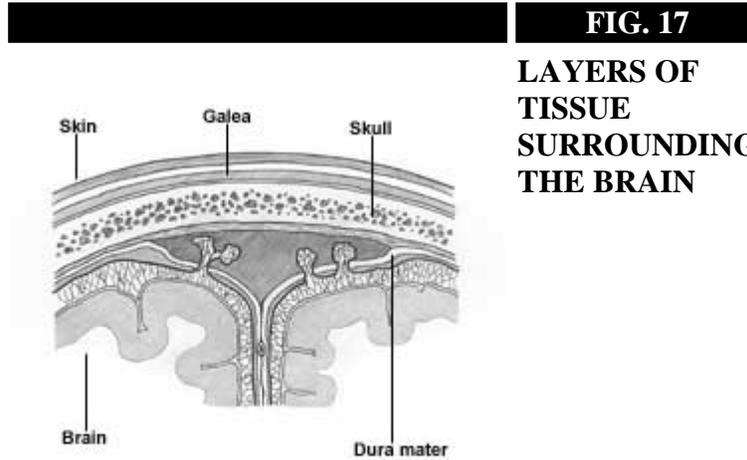


FIG. 17
LAYERS OF TISSUE SURROUNDING THE BRAIN

Surgical silk is appropriate in this area for its pliability and easy knot tying properties. Unfortunately, it elicits a significant foreign body tissue reaction. Most surgeons have switched to NUROLON sutures or Coated VICRYL sutures because they tie easily, offer greater strength than surgical silk, and cause less tissue reaction. PROLENE sutures have also been accepted by surgeons who prefer a continuous closure technique, who must repair potentially infected wounds, or who must repair dural tears.²⁰

In peripheral nerve repair, precise suturing often requires the aid of an operating microscope. Suture gauge and needle fineness must be consistent with nerve size. After the motor and sensory fibers are properly realigned, the epineurium (the outer sheath of the nerve) is sutured. The strength of sutures in this area is less of a consideration than the degree of inflammatory and fibroplastic tissue reaction. Fine sizes of *nylon*, *polyester*, and *polypropylene* are preferred.

MICROSURGERY

The introduction of fine sizes of sutures and needles has increased the use of the operating microscope. ETHICON introduced the first microsurgery sutures--ETHILON sutures--in sizes 8-0 through 11-0. Since then, the microsurgery line has expanded to include PROLENE sutures and Coated VICRYL sutures. Literally all surgical specialties perform some procedures under the operating microscope, especially vascular and nerve anastomosis.

OPHTHALMIC SURGERY

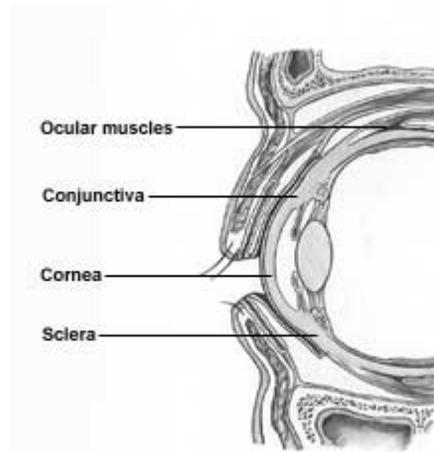
The eye presents special healing challenges. The ocular muscles, the conjunctiva, and the sclera have good blood supplies; but the cornea is an avascular structure. While epithelialization of the cornea occurs rapidly in the absence of infection, full thickness cornea wounds heal slowly. Therefore, in closing wounds such as cataract incisions, sutures should remain in place for approximately 21 days. Muscle recession, which involves suturing muscle to sclera, only requires sutures for approximately 7 days.



FIG.
18

THE EYE





Nylon was the preferred suture material for ophthalmic surgery. While nylon is not absorbed, progressive hydrolysis of nylon *in vivo* may result in gradual loss of tensile strength over time. Fine sizes of *absorbable sutures* are currently used for many ocular procedures. Occasionally, the sutures are absorbed too slowly in muscle recessions and produce granulomas to the sclera. Too rapid absorption has, at times, been a problem in cataract surgery. Because they induce less cellular reaction than surgical gut and behave dependably, VICRYL sutures have proven useful in muscle and cataract surgery.

While some ophthalmic surgeons promote the use of a "no-stitch" surgical technique, 10-0 Coated VICRYL (polyglactin 910) violet monofilament sutures offer distinct advantages. They provide the security of suturing immediately following surgery but eliminate the risks of suture removal and related endophthalmitis. Furthermore, clinical analysis has shown no significant complications relative to suture absorption.⁵

The ophthalmologist has many fine size suture materials to choose from for keratoplasty, cataract, and vitreous retinal microsurgical procedures. In addition to VICRYL sutures, *other monofilament suture materials* including ETHILON sutures, PROLENE sutures, and PDS II sutures may be used. *Braided material* such as virgin silk, black braided silk, MERSILENE sutures, and Coated VICRYL sutures are also available for ophthalmic procedures.

Suture Needs in Other Body Tissues

page 2 of 5

UPPER ALIMENTARY TRACT PROCEDURES

The surgeon must consider the upper alimentary tract from the mouth down to the lower esophageal sphincter to be a potentially contaminated area. The tract is a musculomembranous canal lined with mucus membranes. Final healing of mucosal wounds appears to be less dependent upon suture material than on the wound closure technique.

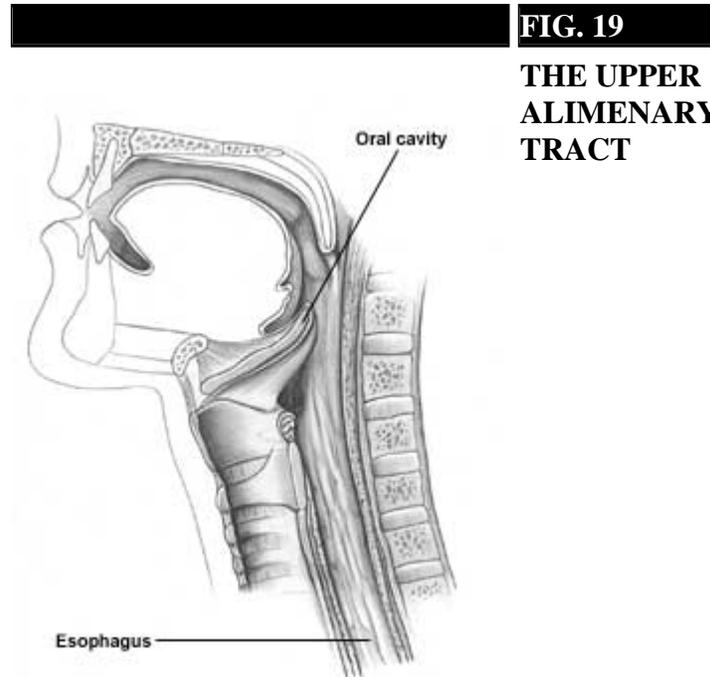


FIG. 19

THE UPPER ALIMENTARY TRACT

The oral cavity and pharynx generally heal quickly if not infected. Fine size sutures are adequate in this area as the wound is under little tension. *Absorbable sutures* may be preferred. Patients, especially children, usually find them more comfortable. However, the surgeon may prefer a *monofilament nonabsorbable suture* under certain circumstances. This option causes less severe tissue reaction than multifilament materials in buccal mucosa, but also requires suture removal following healing.

In cases involving severe periodontitis, VICRYL periodontal mesh may be used to promote tissue regeneration, a technique that enhances the regeneration and attachment of tissue lost due to periodontitis. VICRYL periodontal mesh, available in several shapes and sizes with a preattached VICRYL ligature, is woven from the same copolymer used to produce absorbable VICRYL suture. As a synthetic absorbable, VICRYL periodontal mesh eliminates the trauma associated with a second surgical procedure and reduces the risk of infection or inflammation associated with this procedure.

The esophagus is a difficult organ to suture. It lacks a serosal layer. The mucosa heals slowly. The thick muscular layer does not hold sutures well. If multifilament sutures are used, penetration through the mucosa into the lumen should be avoided to prevent infection. "A particularly high incidence of anastomosis failure has been reported in operations on the esophagus."²¹

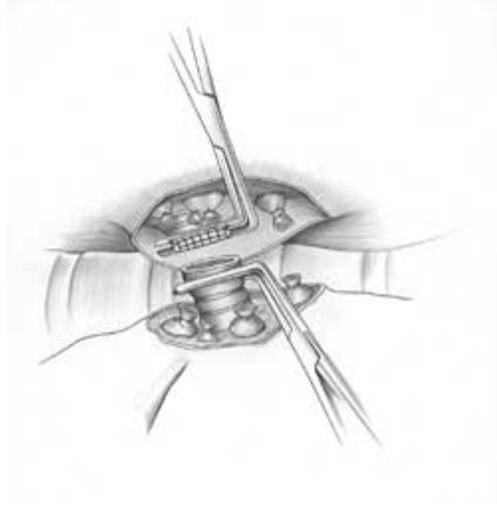
RESPIRATORY TRACT SURGERY

Relatively few studies have been done on healing in the respiratory tract. Bronchial stump closure following lobectomy or pneumonectomy presents a particular challenge. Infection, long stumps, poor approximation of the transected bronchus, and incomplete closure (i.e., air leaks) may lead to bronchopleural fistula. Avoidance of tissue trauma and maintenance of the blood supply to the area of closure are critical to healing. The bronchial stump heals slowly, and sometimes not at all. Unless it is closed tightly with strong, closely spaced sutures, air may leak into the thoracic cavity.



FIG. 20

BRONCHIAL STUMP CLOSURE



Closure is usually achieved with *mechanical devices*, particularly *staples*. When sutures are used, *polypropylene monofilament nonabsorbable sutures* are less likely to cause tissue reaction or harbor infection. *Silk suture* is also commonly used. Surgeons usually avoid absorbable sutures because they may permit secondary leakage as they lose strength.

Monofilament nylon suture should also be avoided because of its potential for knot loosening.

CARDIOVASCULAR SURGERY

Although definitive studies are few, blood vessels appear to heal rapidly. Most cardiovascular surgeons prefer to use synthetic nonabsorbable sutures for cardiac and peripheral vascular procedures. Lasting strength and leakproof anastomoses are essential. Wire sutures are used on the sternum unless it is fragile, in which case absorbable sutures can be used.

Suture Needs in Other Body Tissues

page 3 of 5

VESSELS

Excessive tissue reaction to suture material may lead to decreased luminal diameter or to thrombus formation in a vessel. Therefore, the more inert synthetics including nylon and polypropylene are the materials of choice for vessel anastomoses. Multifilament polyester sutures allow clotting to occur within the interstices which helps to prevent leakage at the suture line. The advantages of a material such as ETHIBOND EXCEL sutures are its strength, durability, and slippery surface which causes less friction when drawn through a vessel. Many surgeons find that PROLENE sutures, PRONOVA sutures, or silk are ideal for coronary artery procedures because they do not "saw" through vessels.

Continuous sutures provide a more leakproof closure than interrupted sutures in large vessel anastomoses because the tension along the suture strand is distributed evenly around the vessel's circumference. Interrupted monofilament sutures such as ETHILON sutures, PROLENE sutures, or PRONOVA sutures are used for microvascular anastomoses.

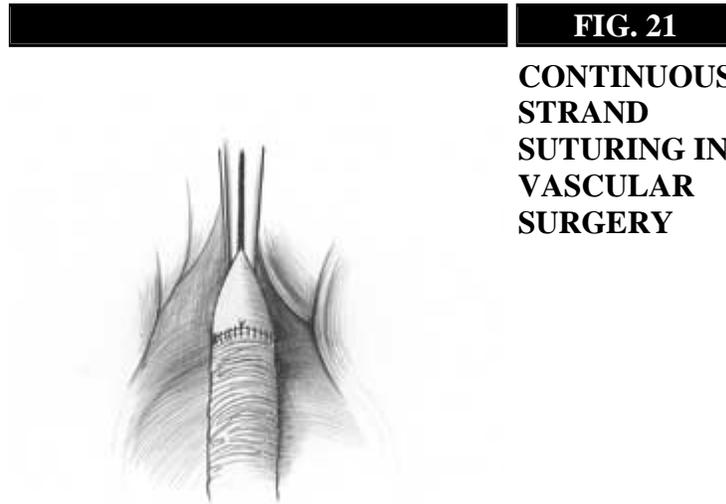


FIG. 21

CONTINUOUS STRAND SUTURING IN VASCULAR SURGERY

When anastomosing major vessels in young children, special care must be taken to anticipate the future growth of the patient. Here, the surgeon may use silk to its best advantage, because it loses much of its tensile strength after approximately 1 year, and is usually completely absorbed after 2 or more years. Continuous polypropylene sutures have been used in children without adverse effects. The continuous suture, when placed, is a coil which stretches as the child grows to accommodate the changing dimensions of the blood vessel. However, reports of stricture following vessel growth have stimulated interest in use of a suture line which is one-half continuous, one-half interrupted.

Clinical studies suggest that a prolonged absorbable suture, such as PDS II suture, may be ideal, giving adequate short-term support while permitting future growth.

Following vascular trauma, mycotic aneurysms from infection are extremely serious complications. A suture may act as a nidus for an infection. In the presence of infection, the chemical properties of suture material can cause extensive tissue damage which may reduce the tissue's natural ability to combat infection. Localized sepsis can also spread to adjacent vascular structures, causing necrosis of the arterial wall. Therefore, the surgeon may choose a monofilament suture material that causes only a mild tissue reaction and resists bacterial growth.

VASCULAR PROSTHESES

The fixation of vascular prostheses and artificial heart valves presents an entirely different suturing challenge than vessel anastomosis. The sutures must retain their original physical properties and strength throughout the life of the patient. A prosthesis never becomes completely incorporated into the tissue and constant movement of the suture line occurs. Coated polyester sutures are the choice for fixation of vascular prostheses and heart valves because they retain their strength and integrity indefinitely.

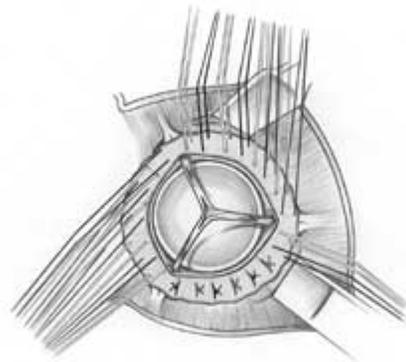
Either a continuous or interrupted technique may be used for vessel to graft anastomoses. The surgeon may opt for interrupted sutures when the graft can be held vertically, as in end-to-side aortic procedures. However, in technically

difficult areas such as the groin or popliteal fossa, continuous sutures may permit easier placement and reduce the risk of anastomotic narrowing or hemorrhage.²²

To assist in proper strand identification, many surgeons alternate green and white strands of ETHIBOND EXCEL suture around the cuff of the valve before tying the knots.

FIG. 22

**SEATING
A HEART
VALVE
WITH
ETHIBOND
EXCEL
SUTURE**



Some surgeons routinely use pledgets to buttress sutures in valve surgery. They are used most commonly in valve replacement procedures to prevent the annulus from tearing when the prosthetic valve is seated and the sutures are tied. They may also be used in heart wall closure of penetrating injuries, excising aneurysms, vascular graft surgery, and to add support when the surgeon encounters extreme deformity, distortion, or tissue destruction at the annulus.

Suture Needs in Other Body Tissues

page 4 of 5

URINARY TRACT SURGERY

Closure of tissues in the urinary tract must be leakproof to prevent escape of urine into surrounding tissues. The same considerations that affect the choice of sutures for the biliary tract affect the choice of sutures for this area. Nonabsorbable sutures incite the formation of calculi, and therefore cannot be used. Surgeons use *absorbable sutures* as a rule, especially MONOCRYL sutures, PDS II sutures, Coated VICRYL sutures, and chromic gut sutures. They are "ideally suited for closing genitourinary wounds, since these organs regain wound strength rapidly and are essentially healed by 21 days. There is no need for a suture thereafter, and the disappearance of polyglactin 910 after 56 to 70 days is just what is desired for sutures in these locations."²³

The urinary tract heals rapidly. The transitional cell epithelium migrates over the denuded surfaces quickly. Unlike other epithelium, the migrating cells in the urinary tract undergo mitosis and cell division. Epithelial migration may be found along suture tracts in the body of the bladder. The bladder wall regains 100% of its original tensile strength within 14 days. The rate of collagen synthesis peaks at 5 days and declines rapidly thereafter. Thus, sutures are needed for only 7 to 10 days.

THE FEMALE GENITAL TRACT

Surgery within this area presents certain challenges. First, it is usually regarded as a potentially contaminated area. Second, the surgeon must frequently work within a very restricted field. Endoscopic technique is frequently used in this area.

Most gynecological surgeons prefer to use *absorbable sutures* for repair of incisions and defects. Some prefer using heavy, size 1 surgical gut sutures, MONOCRYL sutures, or VICRYL sutures. However, the stresses on the reproductive organs and the rate of healing indicate that these larger-sized sutures may only be required for abdominal closure.

Handling properties, especially pliability of the sutures used for internal use, are extremely important. *Synthetic absorbable sutures* such as VICRYL sutures in size 0 may be used for the tough, muscular, highly vascular tissues in the pelvis and vagina. These tissues demand strength during approximation and healing. Coated VICRYL *RAPIDE* suture, for example, is an excellent choice for episiotomy repair.

TENDON SURGERY

Tendon surgery presents several challenges. Most tendon injuries are due to trauma, and the wound may be dirty. Tendons heal slowly. The striated nature of the tissue makes suturing difficult.

Tendon repair fibroblasts are derived from the peritendinous tissue and migrate into the wound. The junction heals first with scar tissue, then by replacement with new tendon fibers. Close apposition of the cut ends of the tendon (especially extensor tendons) must be maintained to achieve good functional results. Both the suture material and the closure technique are critical for successful tendon repair.

The suture material the surgeon chooses must be inert and strong. Because tendon ends can separate due to muscle pull, sutures with a great degree of elasticity should be avoided. *Surgical steel* is widely used because of its durability and lack of elasticity. *Synthetic nonabsorbable materials* including polyester fibers, polypropylene, and nylon may be used. In addition, PANACRYL suture, a *long-term synthetic absorbable suture* with extended wound support up to 6 months, may be used. In the presence of potential infection, the most inert monofilament suture materials are preferred.

The suture should be placed to cause the least possible interference with the surface of the tendon, as this is the gliding mechanism. It should also not interfere with the blood supply reaching the wound. Maintenance of closed apposition of the cut ends of the tendons, particularly extensor tendons, is critical for good functional results. The parallel arrangement of tendon fibers in a longitudinal direction makes permanent and secure placement of sutures difficult. Various figure-of-eight and other types of suturing have been used successfully to prevent suture slippage and the formation of gaps between the cut ends of the tendon.

Many surgeons use the Bunnell Technique. The suture is placed to be withdrawn when its function as a holding structure is no longer necessary. Referred to as a *pull-out suture*, it is brought out through the skin and fastened over a polypropylene button. The Bunnell Technique suture can also be left in place.

FIG. 23

**THE
BUNNEL
TECHNIQUE**



NUROLON sutures, PROLENE sutures, PRONOVA sutures, ETHIBOND *EXCEL* sutures, and PANACRYL sutures may be used for connecting tendon to bone. Permanent wire sutures also yield good results because healing is slow. In periosteum, which heals fairly rapidly, surgical gut or Coated VICRYL sutures may be used. In fact, virtually any suture may be used satisfactorily in the periosteum.

Suture Needs in Other Body Tissues

page 5 of 5

SUTURES FOR BONE

In repairing facial fractures, *monofilament surgical steel* has proven ideal for its lack of elasticity. Facial bones do not heal by callus formation, but more commonly by fibrous union. The suture material must remain in place for a long period of time-- perhaps months--until the fibrous tissue is laid down and remodeled. Steel sutures immobilize the fracture line and keep the tissues in good apposition.

Following median sternotomy, surgeons prefer *interrupted steel sutures* to close. Sternum closure may be difficult. Appropriate tension must be maintained, and the surgeon must guard against weakening the wire. Asymmetrical twisting of the wire may cause it to buckle, fatiguing the metal, and ultimately causing the wire to break. Motion between the approximated sides of the sternum will result, causing postoperative pain and possibly dehiscence.

Painful nonunion is another possible complication. (In osteoporotic patients, very heavy *VICRYL sutures* may be used to close the sternum securely.)

The surgeon may use a bone anchor to hold one end of a suture in place when needed (e.g., shoulder repair surgery). This involves drilling a hole in the bone and inserting the anchor, which expands once completely inside the bone to keep it from being pulled out.

OTHER PROSTHETIC DEVICES

Often, it is necessary for the surgeon to implant a prosthetic device such as an automatic defibrillator or drug delivery system into a patient. To prevent such a device from migrating out of position, it may be tacked to the fascia or chest wall with nonabsorbable sutures.

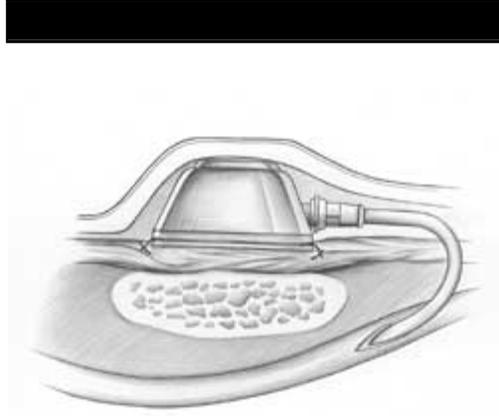


FIG. 24

**TACKING A
PROSTHETIC
DEVICE IN
POSITION
TO PREVENT
MIGRATION**

Closing Contaminated or Infected Wounds

Contamination exists when microorganisms are present, but in insufficient numbers to overcome the body's natural defenses. Infection exists when the level of contamination exceeds the tissue's ability to defend against the invading microorganisms. Generally, contamination becomes infection when it reaches approximately 10^6 bacteria per gram of tissue in an immunologically normal host. Inflammation without discharge and/or the presence of culture-positive serous fluid indicate possible infection. Presence of purulent discharge indicates positive infection.

Contaminated wounds can become infected when hematomas, necrotic tissue, devascularized tissue, or large amounts of devitalized tissue (especially in fascia, muscle, and bone) are present. Microorganisms multiply rapidly under these conditions, where they are safe from cells that provide local tissue defenses.

Some contaminated wounds may be closed following irrigation and debridement. Infected wounds should be left open to heal by second intention. Foreign bodies, including sutures, perpetuate localized infection. Therefore, the surgeon's technique and choice of suture is critical.

Nonabsorbable monofilament nylon sutures are commonly used in delayed closure of dirty and infected wounds. The sutures are laid in but not tied. Instead, the loose suture ends are held in place with PROXI-STRIP skin closures (sterile tape). The wound should be packed to maintain a moist environment. When the infection has subsided, the surgeon can easily reopen the wound, remove the packing and any tissue debris, and then close using the previously inserted monofilament nylon suture.

In The Next Section

The surgeon depends as much upon the quality and configuration of the needle used as on the suturing material itself to achieve a successful closure. The relationship between needles and sutures will be explored on the pages that follow.

References

- VanWinkle Jr W, Hastings JC: Considerations in the choice of suture material for various tissues, *Surg Gyn & Obs* 135:113-126, July 1972
- Dineen P: The effect of suture material in the development of vascular infection. *Vasc Surg* 11(1):29-32, January/February 1977
- Blaydes JE, Berry J: Comparative evaluation of coated and uncoated polyglactin 910 in cataract and muscle surgery, *Ophth Surg* 11(11):790-793, November 1980
- Murray DH, Blaisdell FW: Use of synthetic absorbable sutures for abdominal and chest wound closure, *Arch Surg* 113:477-480, April 1978
- Hunter P: 10-0 Vicryl suture offers alternative to no stitch, *Ocular Surg News* 9(16): August 15, 1991
- Craig PH, et al: A biologic comparison of polyglactin 910 and polyglycolic acid synthetic absorbable sutures, *Surg Gyn & Obs* 14(1):1-10, July 1975
- Amshel AL: The use of Vicryl (polyglactin 910) sutures in colonic and rectal surgery, *Dis Col & Rect* 20(7):635-638, October 1977
- Chu CC, Williams DF: Effects of physical configuration and chemical structure of suture material on bacterial adhesion, *Am J Surg* 147:197-204, February 1984
- Pfeffer WH: How to choose sutures for microsurgery, *Contemporary OB/GYN*:1-5, November 1983
- Chusak RB, Dibbell DG: Clinical experience with polydioxanone monofilament absorbable sutures in plastic surgery, *Plas & Recon Surg* 72(2):217-220, August 1983
- Houdart R et al: Polydioxanone in digestive surgery, *Am J Surg* 152:268-271, September 1986
- Durdey P, Bucknall TE: Assessment of sutures for use in colonic surgery: An experimental study, *J Royal Society of Med* 77:472-477, June 1984
- Lo Piccolo M (ed): Mersilene suture results found comparable to nylon, *Ophthalmology Times*:18, August 15, 1988
- Kronenthal RL: Intraocular degradation of nonabsorbable sutures, *Amer Intra-Ocular Implant Soc J*3:222-228, July/October 1977
- Nealon TF: *Fundamental Skills in Surgery*, 3d ed, Philadelphia: Saunders, 1979, p. 47
- Herrman JB: Tensile strength and knot security of surgical suture materials, *Am Surg* 37:211, April 1971
- VanWinkle Jr W: Epithelization and wound contraction, In *Symposium on Basic Science in Plastic Surgery* (Krizek TJ, Hoopes JE, eds). Mosby, St. Louis 1976, p. 87
- Quinn J, et al: A randomized trial comparing octylcyanoacrylate tissue adhesive and sutures in the management of lacerations, *J Am Med Assn* 277(19):1527-1530, May 21, 1997
- Toriumi DM, et al: Use of Octyl-2-Cyanoacrylate for Skin Closure in Facial Plastic Surgery, *Plas & Recon Surg* 102(6):2209-2219, November 1998
- Vallors B, et al: Absorbable or Nonabsorbable Suture Materials for Closure of the Dura Mater?, *Neurosurgery* 9(4):407-413, 1981
- Tera H, Aberg C: Tissue holding power to a single suture in different parts of the alimentary tract, *Acta Chir Scand* 142:343-348, 1976
- McCollum CN, Kester RC: A sliding suture technique for inaccessible arterial anastomoses, *Surg Gynecol Obstet* 153(6):907, 1981
- VanWinkle Jr W: The healing of skin and visceral wounds and the effect of suture materials, In *Symposium on Basic Science in Plastic Surgery* (Krizek TJ, Hoopes JE, eds). Mosby, St. Louis 1976, p. 135

The Surgical Needle

Desirable Needle Characteristics

While suture material will remain embedded in the patient's tissues for days or weeks after the surgical procedure, the needle will only come in contact with the patient's tissues for a matter of *seconds*. But if the needle doesn't work properly, the sutures won't work properly.

Comfort with needle security in the needleholder, the ease of passage through tissue, and the degree of trauma that it causes all have an impact upon the overall results of surgical needle performance. This is especially true when precise cosmetic results are desired.

The best surgical needles are:

- Made of high quality stainless steel.
- As slim as possible without compromising strength.
- Stable in the grasp of a needleholder.
- Able to carry suture material through tissue with minimal trauma.
- Sharp enough to penetrate tissue with minimal resistance.
- Rigid enough to resist bending, yet ductile enough to resist breaking during surgery.
- Sterile and corrosion-resistant to prevent introduction of microorganisms or foreign materials into the wound.

These desirable qualities present a real challenge to manufacturers of surgical needles.

To maintain a proper perspective, we must also remember that variations in needle geometrics are just as *important* as variations in suture sizes--and that needle dimensions must be *compatible* with suture sizes, allowing the two to work in tandem.

Elements of Needle Design

Needle design involves analyzing a surgical procedure and the density of the tissue involved in great detail. ETHICON engineers work continuously to improve upon their needle line, sometimes making subtle alterations resulting in a positive impact upon the procedure itself. The various metal alloys used in the manufacture of surgical needles determine their basic characteristics to a great degree. ETHICON stainless steel alloy needles are heat-treated to give them the maximum possible strength and ductility. ETHALLOY needle alloy (Patent No. 5,000,912) was developed for unsurpassed strength in precision needles used in cardiovascular, ophthalmic, plastic, and microsurgical procedures. It is produced economically without sacrificing ductility or corrosion resistance.

A needle's *strength* is determined by how it resists deformation during repeated passes through tissue. Tissue trauma can be induced if a needle bends during penetration and compromises tissue apposition. Therefore, greater needle strength equals less tissue trauma.¹ A weak needle that bends too easily can compromise the surgeon's control and damage surrounding tissue during the procedure. In addition, loss of control in needle placement could result in an inadvertent needlestick.

Manufacturers measure needle strength in the laboratory by bending them 90° to determine the needle's maximum strength. This is referred to as the needle's "ultimate moment," and is more important to the needle manufacturer than to the surgeon. The most critical aspect of needle strength to the surgeon is the "surgical yield" point. Surgical yield indicates the amount of angular deformation the needle can withstand before becoming permanently deformed. This point is usually 10° to 30° depending upon the material and the manufacturing process. Any angle beyond that point renders the needle useless. Reshaping a bent needle may cause it to lose strength and be less resistant to bending and breaking.

At ETHICON, the combination of alloy selection and the needle manufacturing process are carefully selected to achieve the highest possible surgical yield, which also optimizes needle strength.

Ductility refers to the needle's resistance to breaking under a given amount of bending. If too great a force is applied to a needle it may break, but a ductile needle will bend before breaking. Needle breakage during surgery can prevent apposition of the wound edges as the broken portion passes through tissue. In addition, searching for part of a broken needle can cause added tissue trauma and add to the time the patient is anesthetized. A piece that cannot be retrieved will remain as a constant reminder to both the patient and surgeon.¹ Needle bending and breakage can be minimized by carefully passing needles through tissue in the direction of the needle body. Needles are not designed to be used as retractors to lift tissue.

Needle *sharpness* is especially important in delicate or cosmetic surgery. The sharper the needle, the less scarring that will result. However, the right balance must be found. If a needle is too sharp, a surgeon may not feel he or she has adequate control of needle passage through tissue.

Sharpness is related to the angle of the point as well as the taper ratio of the needle.

Taper pointed needles usually have a ratio of taper length to needle diameter of 8:1, 12:1, etc. "Scanning electron microscopic photographs of comparable needles demonstrated that the sharpest needles had a long, thin tapered point with smooth cutting edges. In contrast, the dull needles had short, wide tapered points with serrated irregular cutting edges."²

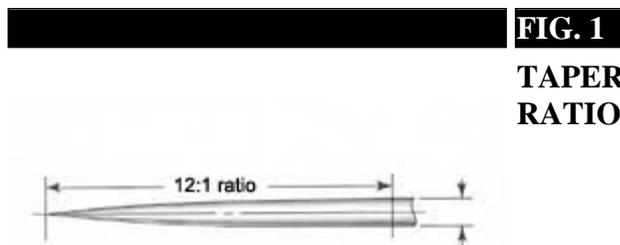


FIG. 1

**TAPER
RATIO**

The ETHICON sharpness tester incorporates a thin, laminated, synthetic membrane that simulates the density of human tissue, allowing engineers to gauge exactly how much force is required for penetration.

Most ETHICON needles have a micro-thin coating comprised of silicone or similar lubricants which significantly and measurably improves ease of needle penetration. According to laboratory tests, this coating serves several important functions:

- It reduces the force needed to make the initial penetration through tissue.
- It reduces the drag force on the needle body as it passes repeatedly through tissue.

Needle performance is also influenced by the *stability* of the needle in the grasp of a needleholder. Most curved needles are flattened in the grasping area to enhance control. All ETHICON curved needles of 22 mil wire or heavier are ribbed as well as flattened. Longitudinal ribbing or grooves on the inside or outside curvatures of curved needles provides a crosslocking action in the needleholder for added needle control. This reduces undesirable rocking, twisting, and turning in the needleholder.

FIG. 2

**ETHICON
RIBBED
NEEDLE**



Principles of Choosing a Surgical Needle

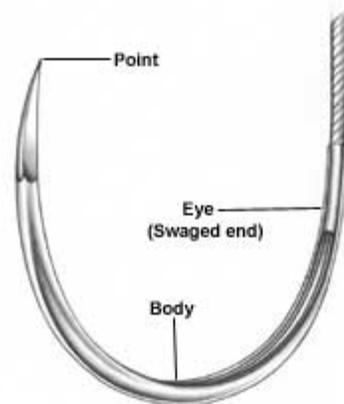
"One basic assumption must be made in considering the ideal surgical needle for a given application, namely, that the tissue being sutured should be altered as little as possible by the needle since the only purpose of the needle is to introduce the suture into the tissue for apposition."³

While there are no hard and fast rules governing needle selection, the following principles should be kept in mind. (Specific types of needles mentioned here will be described in full detail later on in this section.)

1. Consider the tissue in which the surgeon will introduce the needle. Generally speaking, taper point needles are most often used to suture tissues that are easy to penetrate. Cutting or TAPERCUT needles are more often used in tough, hard-to-penetrate tissues. When in doubt about whether to choose a taper point or cutting needle, choose the taper point for everything except skin sutures.
2. Watch the surgeon's technique closely. Select the length, diameter, and curvature of the needle according to the desired placement of the suture and the space in which the surgeon is working.
3. Consult frequently with the surgeon. Working with the same surgeon repeatedly leads to familiarity with his or her individual routine. However, even the same surgeon may need to change needle type or size to meet specific requirements.
4. When using eyed needles, try to match needle diameter to suture size. Swaged needles, where the needle is already attached to the suture strand, eliminate this concern.
5. The best general rule of thumb for the scrub person to follow is *pay attention* and *remain alert to the progress of the operation*. Observation is the best guide to needle selection if the surgeon has no preference.

FIG. 3

**NEEDLE
COMPONENTS**



The Anatomy of a Needle

The Anatomy of a Needle

Regardless of its intended use, every surgical needle has three basic components:

- The eye.
- The body.
- The point.

The measurements of these specific components determine, in part, how they will be used most efficiently. Needle size may be measured in inches or in metric units. The following measurements determine the size of a needle.

- **CHORD LENGTH**--The straight line distance from the point of a curved needle to the swage.
- **NEEDLE LENGTH**--The distance measured along the needle itself from point to end.
- **RADIUS**--The distance from the center of the circle to the body of the needle if the curvature of the needle were continued to make a full circle.

- **DIAMETER**--The gauge or thickness of the needle wire.

Very small needles of fine gauge are needed for microsurgery.

Large, heavy gauge needles are used to penetrate the sternum and to place retention sutures in the abdominal wall. A broad spectrum of sizes are available between the two extremes.

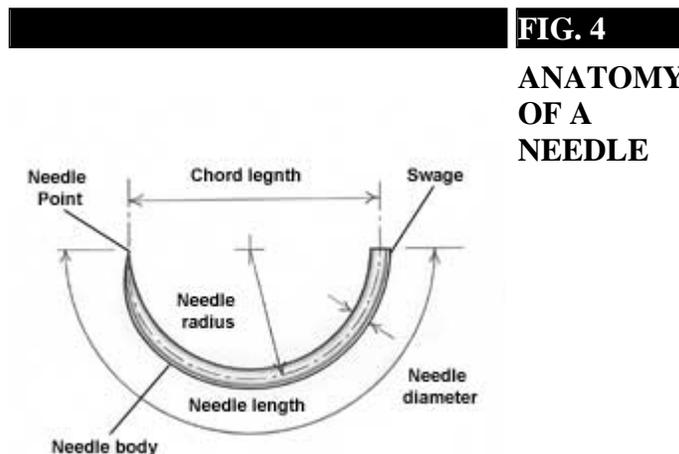


FIG. 4

ANATOMY OF A NEEDLE

The Needle Eye

The eye falls into one of three categories: closed eye, French (split or spring) eye, or swaged (eyeless).

The closed eye is similar to a household sewing needle. The shape of the eye may be round, oblong, or square.

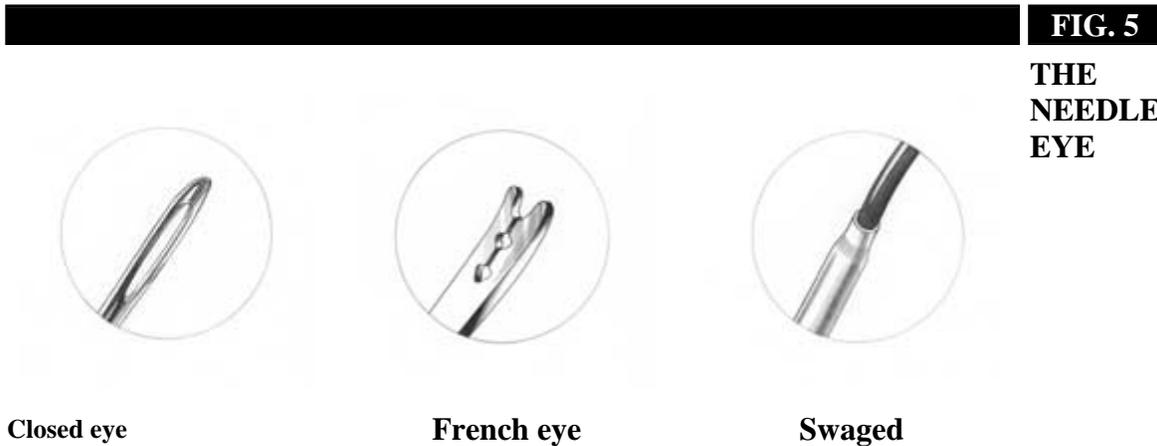
French eye needles have a slit from inside the eye to the end of the needle with ridges that catch and hold the suture in place.

Eyed needles must be threaded, a time-consuming procedure for the scrub person. This presents the disadvantage of having to pull a double strand of suture material through tissue, creating a larger hole with additional tissue disruption. In addition, the suture may still become unthreaded while the surgeon is using it. While tying the suture

to the eye may minimize this possibility, it also adds to the bulk of the suture. Another disadvantage of eyed needles is that repeated use of these needles with more than one suture strand causes the needle to become dull, thereby making suturing more difficult.

Virtually all needles used today are swaged. This configuration joins the needle and suture together as a continuous unit--one that is convenient to use and minimizes trauma. The method of attaching the suture to the needle varies with the needle diameter. In larger diameter needles, a hole is drilled in the needle end.

In smaller diameter needles, a channel is made by forming a "U" at the swage end or a hole is drilled in the wire with a laser. Each hole or channel is specifically engineered for the type and size of suture material it will hold, and crimped or closed around the suture to hold it securely. When the surgeon has finished placing the suture line in the patient's tissue, the suture may be cut, or easily released from the needle as is the case when using CONTROL RELEASE needles (Patent No. 3,980,177).



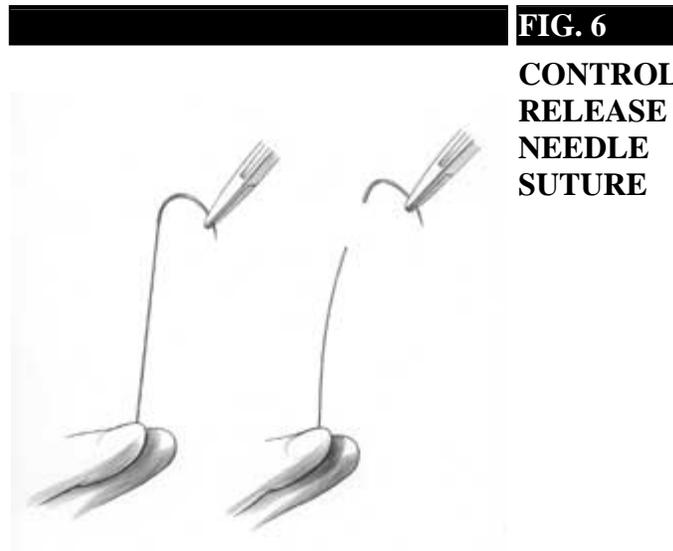
The diameter of a needle swaged to suture material is no larger than necessary to accommodate the diameter of the suture strand itself. Swaged sutures offer several advantages to the surgeon, nurse, and patient.

1. The scrub person does not have to select a needle when the surgeon requests a specific suture material since it is already attached.
2. Handling and preparation are minimized. The strand with needle attached may be used directly from the packet. This helps maintain the integrity of the suture strand.
3. Tissues are subjected to minimal trauma.
4. Tissue trauma is further reduced because a new, sharp, undamaged needle is provided with each suture strand.
5. Swaged sutures do not unthread Prematurely.
6. If a needle is accidentally dropped into a body cavity, the attached suture strand makes it easier to find.
7. Inventory and time spent cleaning, sharpening, handling, and sterilizing reusable eyed needles is eliminated, thereby reducing cost as well as risk of needle punctures.
8. CONTROL RELEASE needles allow placement of many sutures rapidly. This may reduce operating time and, ultimately, the length of time the patient is anesthetized.
9. The ATRALOC surgical needle and CONTROL RELEASE needle ensure consistent quality and performance.
10. Swaged sutures eliminate suture fraying or damage due to sharp corners in the eye of eyed needles.

11. Needles are corrosion-free.

Small diameter ETHICON taper point needles commonly used in cardiovascular surgery were compared in laboratory tests--some with "split" channels and some with laser-drilled holes. The needles with laser-drilled holes produced less drag force as they passed through a membrane that simulated vascular tissue. This could be associated with less trauma to the vessel walls.⁴

The swaged ATRALOC surgical needles made by ETHICON are supplied in a variety of sizes, shapes, and strengths. Some of them incorporate the CONTROL RELEASE needle suture principle which facilitates fast separation of the needle from the suture when desired by the surgeon. This feature allows rapid placement of many sutures, as in interrupted suturing techniques. Even though the suture is securely fastened to the needle, a slight, straight tug will release it. This needle/ suture configuration was created originally for abdominal closure and hysterectomies, but is now used in a wide variety of procedures.



Holding the needle securely in the needleholder, the suture should be grasped securely and pulled straight and taut. The needle will be released with a straight tug of the needle holder.

The Needle Body

The body of the needle is the portion which is grasped by the needleholder during the surgical procedure. The body of the needle should be as close as possible to the diameter of the suture material to minimize bleeding and leakage. This is especially true for cardiovascular, gastrointestinal, and bladder procedures.

The curvature of the needle body may come in a variety of different shapes. Each shape gives the needle different characteristics.

STRAIGHT NEEDLE

This shape may be preferred when suturing easily accessible tissue. Most of these needles are designed to be used in places where direct finger-held manipulation can easily be performed.

The Keith needle is a straight cutting needle. It is used primarily for skin closure of abdominal wounds. Varying lengths are also used for arthroscopic suturing of the meniscus in the knee.

Bunnell (BN) needles are used for tendon repair. Taper point needle variations may also be used for suturing the gastrointestinal tract.

Some microsurgeons prefer straight needles for nerve and vessel repair. In ophthalmology, the straight transchamber needle protects endothelial cells and facilitates placement of intraocular lenses.

HALF-CURVED NEEDLE

The half-curved or "ski" needle may be used for skin closure or in laparoscopy. Its low profile allows easy passage down laparoscopic trocars. Its use in skin closure is limited because, while the curved portion passes through tissue easily, the remaining straight portion of the body is unable to follow the curved path of the needle without bending or enlarging its path in the tissue.

CURVED NEEDLE

Curved needles allow predictable needle turnout from tissue, and are therefore used most often. This needle shape requires less space for maneuvering than a straight needle, but the curve necessitates manipulation with a needleholder. The curvature may be 1/4, 3/8, 1/2, or 5/8 circle.

The most common use for the 3/8 circle is skin closure. The surgeon can easily manipulate this curvature with slight pronation of the wrist in a relatively large and superficial wound. It is very difficult to use this needle in a deep body cavity or restricted area because a larger arc of manipulation is required.

The 1/2 circle needle was designed for use in a confined space, although it requires more pronation and supination of the wrist. But even the tip of *this* needle may be obscured by tissue deep in the pelvic cavity. A 5/8 circle needle may be more useful in this situation, especially in some anal, urogenital, intraoral, and cardiovascular procedures.

COMPOUND CURVED NEEDLE

The compound curved needle (Patent No. 4,524,771) was originally developed for anterior segment ophthalmic surgery. It allows the surgeon to take precise, uniform bites of tissue. The tight 80° curvature of the tip follows into a 45° curvature throughout the remainder of the body. The initial curve allows reproducible, short, deep bites into the tissue. The curvature of the remaining portion of the body forces the needle out of the tissue, everting the wound edges and permitting a view into the wound. This ensures equidistance of the suture material on both sides of the incision. Equalized pressure on both sides of the corneal-scleral junction minimizes the possibility of astigmatism following anterior segment surgery.

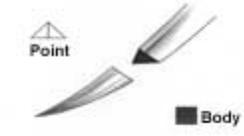
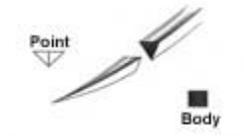
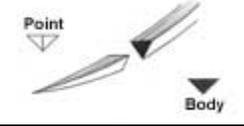
		Fig. 7
SHAPE	APPLICATION	NEEDLE SHAPES AND TYPICAL APPLICATIONS
Straight 	gastrointestinal tract, nasal cavity, nerve, oral cavity, pharynx, skin, tendon, vessels	
Half-curved 	skin (rarely used) laparoscopy	

<p>1/4 Circle</p> 	<p>eye (primary application) microsurgery</p>	
<p>3/8 Circle</p> 	<p>aponeurosis, biliary tract, cardiovascular system, dura, eye, gastrointestinal tract, muscle, myocardium, nerve, perichondrium, periosteum, pleura, skin tendon, urogenital tract, vessels</p>	
<p>1/2 Circle</p> 	<p>biliary tract, cardiovascular system, eye, fascia, gastrointestinal tract, muscle, nasal cavity, oral cavity, pelvis, peritoneum, pharynx, pleura respiratory tract, skin, subcutaneous fat, urogenital tract</p>	
<p>5/8 Circle</p> 	<p>anal (hemorrhoidectomy), nasal cavity, oral cavity, pelvis, urogenital tract (primary application)</p>	
<p>Compound Curved</p> 	<p>eye (anterior segment) laparoscopy</p>	

The Needle Point

THE NEEDLE POINT

The point extends from the extreme tip of the needle to the maximum cross-section of the body. Each needle point is designed and produced to the required degree of sharpness to smoothly penetrate specific types of tissue.

		Fig. 8
POINT/SHAPE	APPLICATION	NEEDLE POINTS AND BODY SHAPES AND TYPICAL APPLICATIONS
Conventional Cutting 	skin, sternum	
Reverse Cutting 	fascia, ligament, nasal cavity, oral mucosa, pharynx, skin, tendon sheath	
Precision Point Cutting 	skin (plastic or cosmetic)	
PC PRIME Needle 	skin (plastic or cosmetic)	
MICRO-POINT Reverse Cutting Needle 	eye	
Side-Cutting Spatula 	eye (primary application), microsurgery, ophthalmic (reconstructive)	

<p>CS ULTIMA Ophthalmic Needle</p>  <p>Point</p> <p>Body</p>	<p>eye (primary application)</p>	
<p>Taper</p>  <p>Point</p> <p>Body</p>	<p>aponeurosis, biliary tract, dura, fascia, gastrointestinal tract, laparoscopy, muscle, myocardium, nerve, peritoneum, pleura, subcutaneous fat, urogenital tract, vessels, valve</p>	
<p>TAPERCUT Surgical Needle</p>  <p>Point</p> <p>Body</p>	<p>bronchus, calcified tissue, fascia, laparoscopy, ligament, nasal cavity, oral cavity, ovary, periochondrium, periosteum, pharynx, sternum, tendon, trachea, uterus, valve, vessels (sclerotic)</p>	
<p>Blunt</p>  <p>Point</p> <p>Body</p>	<p>blunt dissection (friable tissue), cervix (ligating incompetent cervix), fascia, intestine, kidney, liver, spleen.</p>	

Types of Needles

Cutting Needles

CUTTING NEEDLES

Cutting needles have at least two opposing cutting edges. They are sharpened to cut through tough, difficult-to-penetrate tissue. Cutting needles are ideal for skin sutures that must pass through dense, irregular, and relatively thick connective dermal tissue. Because of the sharpness of the cutting edge, care must be taken in some tissue (tendon sheath or oral mucous membrane) to avoid cutting through more tissue than desired.³

CONVENTIONAL CUTTING NEEDLES

In addition to the two cutting edges, conventional cutting needles have a third cutting edge on the *inside* concave curvature of the needle. The shape changes from a triangular cutting blade to that of a flattened body on both straight and curved needles. This needle type may be prone to cutout of tissue because the inside cutting edge cuts toward the edges of the incision or wound.

The PC PRIME needle (Precision Cosmetic, Patent No. 5,030,228) is designed specifically for aesthetic plastic surgery, and has conventional cutting edges. Where cosmetic results are important, the PC PRIME needle is superior to any other for more delicate surgery, especially facial surgery. The narrow point, fine wire diameter, and fine taper ratio allow superior penetration of soft tissue. The inside and outside curvatures of the body are flattened in the needle grasping area for greater stability in the needleholder. Flattened sides reduce bending that might occur due to the fine wire diameter.

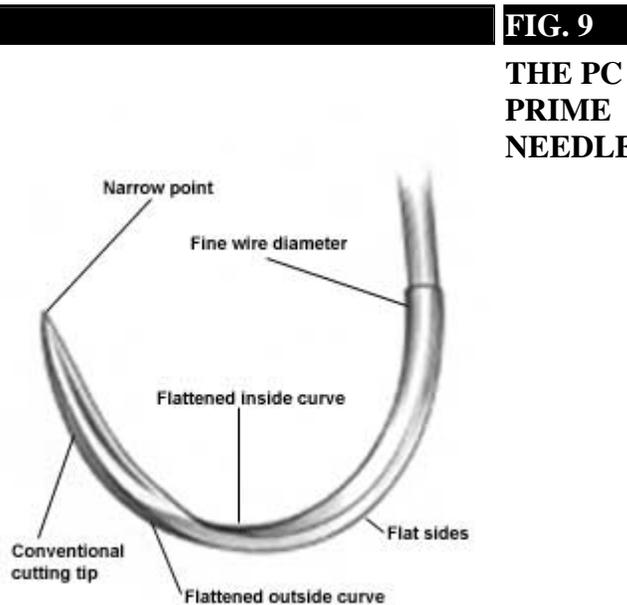


FIG. 9

THE PC PRIME NEEDLE

The tip configuration of the conventional cutting sternotomy needle is slightly altered to resist bending as it penetrates the sternum. The alloy used for this needle provides the increased strength and ductility needed for its function. The cutting edges of the point extend approximately 1/4" (6mm) from the round body and terminate in a triangular-shaped tip. This particular sternotomy needle maximizes cutting efficiency and control in the needleholder. TAPERCUT surgical needles may also be used for this procedure.

FIG. 10

STERNOTOMY NEEDLE

Conventional cutting edges (1/4 inch or 6mm)



REVERSE CUTTING NEEDLES

These needles were created specifically for tough, difficult-to-penetrate tissue such as skin, tendon sheath, or oral mucosa. Reverse cutting needles are used in ophthalmic and cosmetic surgery where minimal trauma, early regeneration of tissue, and little scar formation are primary concerns. The reverse cutting needle is as sharp as the conventional cutting needle, but its design is distinctively different. The third cutting edge is located on the *outer* convex curvature of the needle. This offers several advantages:

- Reverse cutting needles have more strength than similar-sized conventional cutting needles.
- The danger of tissue cutout is greatly reduced.
- The hole left by the needle leaves a wide wall of tissue against which the suture is to be tied.

FIG. 11

REVERSE CUTTING NEEDLE



The MICRO-POINT surgical needle for ophthalmic procedures has a smooth surface and is honed to extreme sharpness. This allows the surgeon to suture the extremely tough tissues of the eye with optimum precision and ease. A needle manufactured by the exclusive ETHICON Precision Point Process may be used for plastic or cosmetic surgery, and passes smoothly through tissue creating a minute needle path. This results in superior apposition. The bottom third cutting edge on the Precision Point needle flattens out as it transitions to the needle body for greater security in the needleholder. The OS (Orthopaedic Surgery) needles are curved, heavy bodied, reverse-cutting needles. The orthopaedic surgeon may use the OS needle for extremely tough tissue, such as cartilage, where force is required for penetration.

SIDE-CUTTING NEEDLES

Also referred to as *spatula needles*, they feature a unique design which is flat on both the top and bottom,

eliminating the undesirable tissue cutout of other cutting needles. The side-cutting edges are designed for ophthalmic procedures. They permit the needle to separate or split through the thin layers of scleral or corneal tissue and travel within the plane between them. The optimal width, shape, and precision sharpness of this needle ensure maximum ease of penetration, and gives the surgeon greater control of the needle as it passes between or through tissue layers. The position of the point varies with the design of each specific type of spatulated needle.

FIG. 12

**SPATULA
NEEDLE
CROSS-
SECTION**



The SABRELOC spatula needle has two cutting edges and a trapezoidal-shaped body.

The SABRELOC needle with the cobra-shaped tip has four equidistant defined edges.

The CS ULTIMA ophthalmic needle (Corneal-Scleral, Patent No. 5,002,564) is the sharpest needle in its category and is used for corneal scleral closure. The smaller angles and increased cutting-edge length result in superior sharpness facilitating easy tissue penetration.

The TG PLUS needle (Transverse Ground) has a long, ultra-sharp, slim tip. This needle undergoes a unique honing process which results in a sharper needle. The surgeon encounters low penetration resistance with the TG PLUS needle, and gets excellent tactile feedback. In corneal wound closure, this allows the surgeon to control the depth of each suture placement and length of each bite.⁵

Taper Point Needles

TAPER POINT NEEDLES

Also referred to as *round needles*, taper point needles pierce and spread tissue without cutting it. The needle point tapers to a sharp tip. The needle body then flattens to an oval or rectangular shape. This increases the width of the body to help prevent twisting or turning in the needleholder.

Taper point needles are usually used in easily penetrated tissue such as the peritoneum, abdominal viscera, myocardium, dura, and subcutaneous layers. They are preferred when the smallest possible hole in the tissue and minimum tissue cutting are desired. They are also used in internal anastomoses to prevent leakage which can subsequently lead to contamination of the abdominal cavity. In the fascia, taper point needles minimize the potential for tearing the thin connective tissue lying between parallel and interlacing bands of denser, connective tissue.

The Mayo (MO) needle has a taper point, but a heavier and more flattened body than conventional taper needles. This needle was designed for use in dense tissue; particularly for gynecological procedures, general closure, and hernia repair.

TAPERCUT Surgical Needles

ETHICON manufactures TAPERCUT needles which combine the features of the reverse cutting edge tip and taper point needles. Three cutting edges extend approximately 1/32" back from the point. These blend into a round taper body. All three edges are sharpened to provide uniform cutting action. The point, sometimes referred to as a *trocar point*, readily penetrates dense, tough tissue. The objective should be for the point itself not to exceed the diameter of the suture material. The taper body portion provides smooth passage through tissue and eliminates the danger of cutting into the surrounding tissue.

Although initially designed for use in cardiovascular surgery on sclerotic or calcified tissue, the TAPERCUT needle is widely used for suturing dense, fibrous connective tissue--especially in fascia, periosteum, and tendon where separation of parallel connective tissue fibers could occur with a conventional cutting needle.

ETHICON developed a modified TAPERCUT CC needle (Calcified Coronary) for anastomosis of small fibrotic and calcified blood vessels. The calcified portion of an artery requires a cutting tip only for initial penetration to avoid tearing the vessel. This needle configuration has a slimmer geometry than other TAPERCUT needles from the body through the point which facilitates penetration. It also minimizes the risk of leakage from friable vessels or vascular graft material.

Blunt Point Needles

Blunt point (BP) needles can literally dissect friable tissue rather than cutting it. They have a taper body with a rounded, blunt point that will not cut through tissue. They may be used for suturing the liver and kidney. Due to safety considerations, surgeons also use blunt point needles in obstetric and gynecological procedures when working in deep cavities which are prone to space and visibility limitations. In addition, blunt point needles for general closure are especially helpful when performing procedures on at-risk patients.

The ETHIGUARD blunt point needle combines the safety of the blunt point with the security of a ribbed and flattened design, and the convenience of a swaged needle.

ETHICON needle codes and their meaning

Part 1

CODE	MEANING
BB	Blue Baby
BIF	Blunt Intraocular Fixation
BN	Bunnell
BP	Blunt Point
BV	Blood Vessel
BVH	Blood Vessel Half
C	Cardiovascular
CC	Calcified Coronary
CCS	Conventional Cutting Sternotomy
CE	Cutting Edge
CFS	Conventional for Skin
CIF	Cutting Intraocular Fixation
CP	Cutting Point
CPS	Conventional Plastic Surgery
CPX	Cutting Point Extra Large
CS	Corneal-Scleral
CSB	Corneal-Scleral Bi-Curve
CSC	Corneal-Scleral Compound Curve
CT	Circle Taper
CTB	Circle Taper Blunt
CTX	Circle Taper Extra Large
CTXB	Circle Taper Extra Large Blunt
CV	Cardiovascular
DC	Dura Closure
DP	Double Point
EN	Endoscopic Needle
EST	Eyed Straight Taper
FN	For Tonsil

CODE	MEANING
FSLX	For Skin Large Extra
G	Greishaber
GS	Greishaber Spatula
J	Conjunctive
KS	Keith Straight
LH	Large Half (circle)
LR	Large Retention
LS	Large Sternotomy
M	Muscle
MF	Modified Ferguson
MH	Medium Half (circle)
MO	Mayo
MOB	Mayo Blunt
OPS	Ocular Plastic Surgery
OS	Orthopaedic Surgery
P	Plastic
PC	Precision Cosmetic
PS	Plastic Surgery
RB	Renal (artery) Bypass
RD	Retinal Detachment
RH	Round Half (circle)
RV	Retinal-Vitreous
S	Spatula
SC	Straight Cutting
SFS	Spatulated for Skin
SH	Small Half (circle)
SIF	Ski Intraocular Fixation
SKS	Sternotomy Keith Straight
SM	Spatulated Muscle
ST	Straight Taper

ETHICON needle codes and their meaning
Part 2

CODE	MEANING
STB	Straight Blunt
STC	Straight Cutting
STP	Straight Taper Point
TE	Three-Eighths
TF	Tetralogy of Fallot
TG	Transverse Ground
TGW	Tranverse Ground Wire
TN	Trocar Needle
TP	Taper Pericostal/Point
TPB	Taper Pericostal/Point Blunt
TS	Tendon Straight
TQ	Twisty Q
UCL	5/8 Circle Colateral Ligament
UR	Urology
URB	Urology Blunt
V	TAPERCUT Surgical Needle
VAS	Vas Deferens
X or P	Exodontal (dental)
XLH	Extra Large Half (circle)
XXLH	Extra Extra Large Half (circle)

Needle Holders

Needle Holders

The surgeon uses the needleholder to pass a curved needle through tissue. It must be made of noncorrosive, high strength, good quality steel alloy with jaws designed for holding the surgical needle securely. Needleholder jaws may be short or flat, concave or convex, smooth or serrated. Smooth jaws may allow the needle to wobble or twist. Jaws with teeth hold most securely but may damage the suture or needle if too much pressure is applied. Jaws with tungsten carbide particles embedded in them offer two advantages: one, the fine, granular jaw surface has more holding power than smooth jaws; and two, it is less apt to damage sutures or alter their breaking strength than jaws with teeth.⁶

Most, but not all, needleholders have a ratchet lock near to thumb and finger rings.

Surgical needles are designed for optimum needleholder stability. Because this tool actually drives the needle, its performance will have an impact upon the entire suturing procedure. The surgeon has maximum control only when the needle sits well in the holder without wobbling as it is passed through tissue. Needleholders, like pliers, weaken with repeated use. Therefore, the scrub person should check before each procedure to make sure that the needleholder jaws align properly and grasp securely.

When selecting a needleholder, the following should be taken into consideration:

- It must be the appropriate size for the needle selected. A very small needle should be held with small, fine jaws. The larger and heavier the needle, the wider and heavier the jaws of the needleholder should be.
- It should be an appropriate size for the procedure. If the surgeon is working deep inside the body cavity, a longer needleholder is in order.

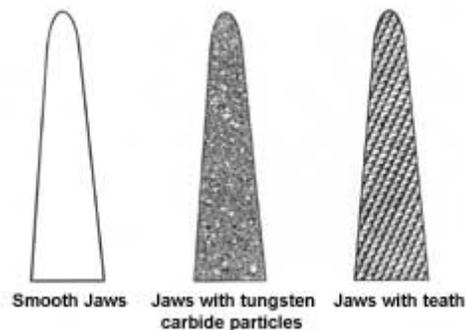


FIG. 13

**NEEDLE-
HOLDER
JAWS**

Needleholder Use

The following guidelines are offered to the scrub person for needleholder use:

1. Grasp the needle with the tip of the needleholder jaws in an area approximately one-third to one-half of the distance from the swaged end to the point. Avoid placing the holder on or near the swaged area which is the weakest part of the needle.
2. Do not grasp the needle too tightly as the jaws of the needleholder may deform, damage, or bend it irreversibly.
3. Always check alignment of the needleholder jaw to make certain the needle does not rock, twist, or turn.
4. Handle the needle and needleholder as a unit.
5. Pass the needleholder to the surgeon so that he or she will not have to readjust it before placing the suture in tissue. Make sure the needle is pointing in the direction in which it will be used and that the suture strand is not entangled.
6. Always provide a needleholder--*never a hemostat*--to pull the needle out through tissue. A hemostat or other clamp can damage the needle.
7. Immediately after use, every needle should be returned to the scrub person while clamped in a needleholder. Needles are less likely to be lost if they are passed one-for-one (one returned for each one received).

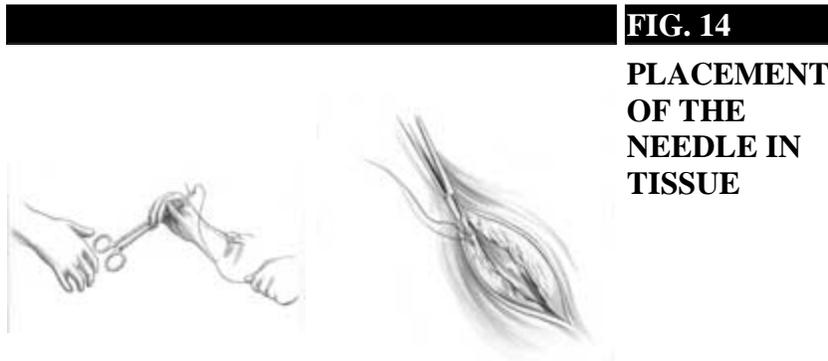
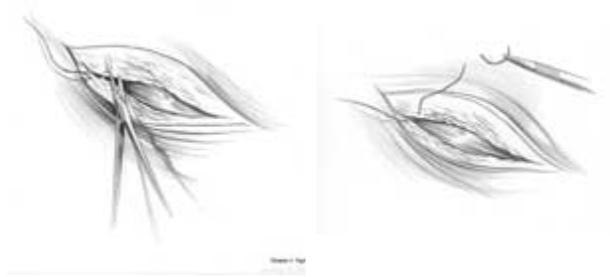


FIG. 14

PLACEMENT OF THE NEEDLE IN TISSUE

1. The surgeon receives the needleholder with the needle point toward the thumb to prevent unnecessary wrist motion. The scrub person controls the free end of the suture to prevent dragging it across the sterile field, and to keep the suture from entering the surgeon's hand along with the needleholder.
2. The surgeon begins closure with the swaged suture.



3. The needle is passed into the tissue. The surgeon releases the needle from the holder and reclaims the holder onto the body of the needle near the point end to pull the needle and strand through tissue. The needle is released or cut from the suture strand. The surgeon leaves the needle clamped in the same position and returns it to the scrub person. The scrub person immediately passes another prepared suture to the surgeon, one-for-one.

Placing the Needle in Tissue

The actual placement of the needle in the patient's tissue can cause unnecessary trauma if done incorrectly. Keep the following in mind during suturing:

1. Apply force in the tissue to be sutured in the same direction as the curve of the needle.
2. Do not take excessively large bites of tissue with a small needle.
3. Do not force a dull needle through tissue. Take a new needle.
4. Do not force or twist the needle in an effort to bring the point out through the tissue. Withdraw the needle completely and then replace it in the tissue, or use a larger needle.
5. Avoid using the needle to bridge or approximate tissues for suturing.
6. Do not damage taper points or cutting edges when using the needleholder to pull the needle through tissue. Grasp as far back on the body as possible.
7. Depending upon the patient, the tissue may be tougher or more fibrous than anticipated and require the use of a heavier gauge needle. Conversely, a smaller needle may be required when tissue is more friable than usual.
8. In a deep, confined area, ideal positioning of the needle may not be possible. Under these circumstances, proceed with caution. A heavier gauge needle or a different curvature may help.
9. If a glove is punctured by a needle, the needle must be discarded immediately and the glove must be changed for the safety of the patient, as well as the surgical team.

Needle Handling Tips

Needles should be protected from bacterial contamination and damage during handling by adhering to the following guidelines:

Open needle packets and prepare sutures carefully, protecting needle sharpness.

Make sure the needle is free of corrosion.

If using eyed needles, make sure they do not have rough or sharp edges inside the eye to fray or break suture strands.

Also check the eyes for burrs or bluntness to ensure easy penetration and passage through tissue.

If a needle is defective, discard it.

Pass needles on an exchange basis; one is passed to the surgeon for one returned.

Employ the nontransfer technique to avoid inadvertent needlesticks: the surgeon places the needle and needleholder down in a neutral area of the sterile field; the scrub person then picks up the needleholder.

Secure each needle as soon as it is used. Do not allow needles to lie loose on the sterile field or Mayo stand. Keep them away from Sponges and tapes so they will not inadvertently be dragged into the wound.

If a needle breaks, all pieces must be accounted for.

Count all needles before and after use according to hospital procedure. Retain the packets containing descriptive information on quantity and needle type for swaged needles to help determine if all are accounted for.

Follow these steps for safe needle handling:

Use sterile adhesive pads with or without magnets or disposable magnetic pads to facilitate counting and safe disposal.

Swaged needles can be inserted through or into their original packet after use. An empty packet indicates a missing needle. If using an E-PACK procedure kit, compare the count of needles used to the number preprinted on the kit label.

Return eyed needles to the needle rack. If eyed needles are to be reused, they must be cleaned and reprocessed at the end of the operation.

Do not collect used needles in a medicine cup or other container since they must then be handled individually to count them. This can potentially contaminate gloves and increase the risk of an accidental puncture.

Discard used needles in a "sharps" container.

In The Next Section

In the section that follows, the dual role that suture and needle packaging plays will be covered. Packaging does much more than keep the needle and suture sterile. Package design can help or seriously hinder the efficiency of the surgical procedure.

References

- Edlich RF et al: Scientific basis for selecting surgical needles and needle holders for wound closure, *Clin Plastic Surg* 17(3):583-601, July 1990
- Thacker JG et al: Surgical needle sharpness, *Am J Surg* 157:334-339, March 1989
- Trier WC: Considerations in the choice of surgical needles, *Surg Gynecol Obstet* 149:84, 1979
- Towler MA et al: Laser-drilled cardiovascular surgical needles, *J Appl Biomaterials* 2:183-186, 1991
- Troutman RC, McGregor W: New compound curved needle TG6-C Plus, *Ophthalmology, Instrument and Book Suppl* 92(8):84-86, 1985
- Abidin MR et al: Metallurgically bonded needle holder jaws, *Am Surg* 56(10):643-647, October 1990

Packaging

An Integral Part of the Product

The purpose of a package is to protect its contents and provide convenience to the user. ETHICON wound closure packaging is an integral part of each product. Over the past half a century, packaging has evolved from glass tubes packed in jars, to multilayered foil and paper packages, to new materials that reflect concern for both the environment and the individuals who must maintain operative sterility and efficiency. Packaging has kept pace with the technological developments of wound closure products themselves. Several factors have influenced these developments:

- Increasing product diversity.
- Technological advances in packaging materials.
- Stringent regulatory requirements.

To prevent infection in an operative wound, all instruments and supplies that come in contact with the wound must be sterile (free of living microorganisms and spores) including sutures, needles, ligating clips, and stapling instruments. High standards and criteria are set for all components in the packaging of sterile products:

1. Protect and preserve product stability and sterility from potential deterioration from outside forces such as oxygen, moisture, light, temperature, dust, and vermin.
2. Prevent product damage or microbial contamination in transit and storage.
3. Provide identifiable product information.
4. Permit convenient, safe, and sterile transfer of the product from the package to the sterile field.
5. Meet the functional needs of all members of the surgical team.

Relay Suture Delivery System

Relay Suture Delivery System

Most suture materials are packaged and sterilized by the manufacturer. They arrive ready for use in boxes which can be stored until needed. The RELAY suture delivery system, developed by ETHICON with human, clinical, and environmental factors in mind, stores and delivers sutures in a time-efficient manner and reduces unnecessary handling to access sutures. The system also provides control over suture storage, usage, inventory rotation, needle counting, and cost containment. The RELAY suture system consists of three basic, interrelated components: modular suture storage racks, dispenser boxes, and primary packets.

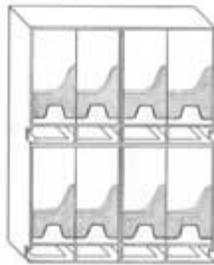
Modular Storage Racks

The modular storage racks are designed for maximum convenience and versatility to meet the individual needs of a particular specialty, nurse, surgeon, or department. Modules can be easily assembled to accommodate both vertical and horizontal suture dispenser boxes. Any number of modules can be fastened together to meet both small and large storage needs. Once assembled, the racks may be used on shelves, mounted on walls, placed on mobile carts, or connected to IV poles. Racks can also be fitted with a rotating base for more convenient access, as well as with a handle for easy carrying.

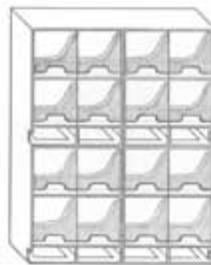
Each module has a built-in inventory control area to facilitate restocking. This feature enables unused suture packets to be systematically fed back into the proper rotational flow without mixing lots within the boxes. Sutures may be grouped within the modular system by material type or size, or by use (i.e., general closure, gastrointestinal surgery, plastic surgery, etc.).

FIG.1

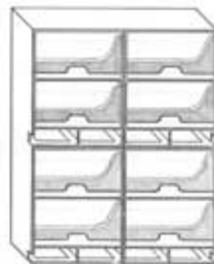
Ethicon Modular Storage Racks



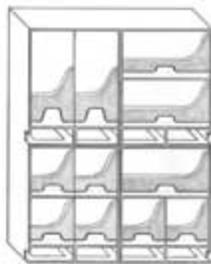
Full-vertical boxes



Half-vertical boxes



Horizontal boxes



Combination of boxes

Dispenser Boxes

Gravity-fed dispenser boxes dispense suture packets from the opening at the bottom of the box. The opening can accommodate the removal of several suture packets at one time.

All ETHICON dispenser boxes are made of recyclable paper and printed with either water- or soy-based inks. Each box provides clear product identification through streamlined graphics, product color coding, bold label copy, and descriptive symbols. The information required for quick reference and easy selection of suture materials is highlighted in a logical sequence. The three most important criteria necessary for proper identification and suture selection are:

1. Suture size.

2. Suture material.
3. Type and size of needle.

Other important product information found on all suture boxes include:

1. Surgical application.
2. Product code number.
3. Suture length and color.
4. Metric diameter equivalent of suture size and length.
5. Shape and quantity of needles (single- or double-armed, shown by silhouette).
6. Needle point geometry.
7. Lot number.
8. Expiration date.

A package insert with detailed information about the suture material is inserted in every dispenser box. Users should be familiar with this information as it contains FDA-approved indications, contraindications, and all appropriate warnings and precautionary statements for each product.

Dispenser boxes should be restocked when the last few suture packets appear in the box opening, *before* the box is completely empty. The unused packets from the previous box should be used before a new dispenser box is opened. This will help to avoid mixing lot numbers and ensure proper stock rotation. ETHICON advocates rotation of the entire dispenser box. In addition to ensuring the use of the oldest suture materials first, this helps to maintain a fresh stock of clean dispenser boxes.

Most dispenser boxes contain three dozen suture packets. Other may contain one or two dozen packets. The product code number suffix and a statement on the box indicate the quantity of suture packets in the box (product code suffix G = 1 dozen, D = 1 dozen, T = 2 dozen, H = 3 dozen). The dispenser boxes are held securely for easy dispensing by firmly pushing the box into a "lock" in the back of the rack module.

Primary Packets

Page 1

Individual sutures and multiple suture strands are supplied sterile within a primary packet. The exterior surfaces of the overwrap are not sterile. ETHICON primary packaging is designed to permit fast and easy opening in one peelable motion. The single layer overwrap of primary packaging is made of either foil *or* coated TYVEK on one side heat-sealed to polyethylene film on the other. Absorbable sutures are always encased in foil to provide a safe and durable moisture barrier and to withstand sterilization in the manufacturing process. Most nonabsorbable sutures are encased in coated TYVEK overwraps.

In a continuous effort to be more environmentally conscious, ETHICON has chosen materials in the manufacture of primary packets which generate minimal negative impact to the environment upon incineration or disposal.

Furthermore, wherever possible, the number of primary packaging layers has been reduced by as much as 50 percent, thus reducing the volume of environmental water per OR procedure.

Each primary packet provides critical product information and the same color coding as its dispenser box. The packet also identifies the product code number, material, size, needle type, and the number of needles per packet to simplify needle counts.

Table 1

Absorbable Sutures	Layers	Most Common ETHICON Suture Packaging
Surgical Gut Suture (plain and Chromic)	TYVEK overwrap, foil primary package containing one-step RELAY suture delivery system tray	
Coated VICRYL RAPIDE (polyglactin 910) Suture	TYVEK overwrap, foil primary package, paper folder	
Coated VICRYL (polyglactin 910) Suture	Peelable foil overwrap, one-step RELAY tray	
MONOCRYL* (poliglecaprone 25) Suture	Peelable foil overwrap, one-step RELAY tray	
PDS II (polydioxanone) Suture	Peelable foil overwrap, one-step RELAY tray	
Panacryl Suture	Peelable foil overwrap, one-step RELAY tray	
Non-Absorbable Sutures	Layers	
PERMA-HAND Silk Suture	TYVEK overwrap, one-step RELAY tray	
Stainless Steel Suture	TYVEK overwrap, paper folder	
ETHILON Nylon Suture	Peelable foil overwrap, one-step RELAY tray	
NUROLON Nylon Suture	TYVEK overwrap, one-step RELAY tray	
MERSILENE	TYVEK overwrap, one-step RELAY tray	
ETHIBOND EXCEL Polyester Fiber Suture	TYVEK overwrap, one-step RELAY tray	
PROLENE* Polypropylene Suture	TYVEK overwrap, one-step RELAY tray	

PRONOVA Poly
(hexafluoropropylene-VDF) Suture

TYVEK overwrap, one-step RELAY
tray

Primary packets of suture material may contain sutures in one of five styles:

1. Standard lengths of nonneeded material: 54 inches (135cm) of absorbable or 60 inches (150cm) of nonabsorbable suture, which may be cut in half, third, or quarter lengths for ligating or threading.
2. SUTUPAK pre-cut sterile suture is nonneeded material for ligating or threading. These lengths may be supplied in a multistrand labyrinth packet or in a folder packet, both of which are designed to deliver one strand at a time. SUTUPAK sutures may be removed from the packet and placed in the suture book.
3. One single strand of material with single- or double-armed swaged needle(s). Needles for one-step RELAY suture packets, microsurgery, and some ophthalmic needles are secured in a "needle park." The needle park is designed to provide a standard location for, and easy access to, the needle. All other needles are protected within an inner folder or other specific channel within a paper folder.

Most single strand needled sutures are sealed in convenient one-step RELAY delivery packages. One-step RELAY packages allow the needle to be armed in the needleholder from any angle without touching the needle. This increases the safety of handling needles intraoperatively. If it is preferred to locate the needle by hand, this can be accomplished with the one-step RELAY package by pushing up the flap behind the needle park, thereby elevating the needle so it can be grasped by hand.

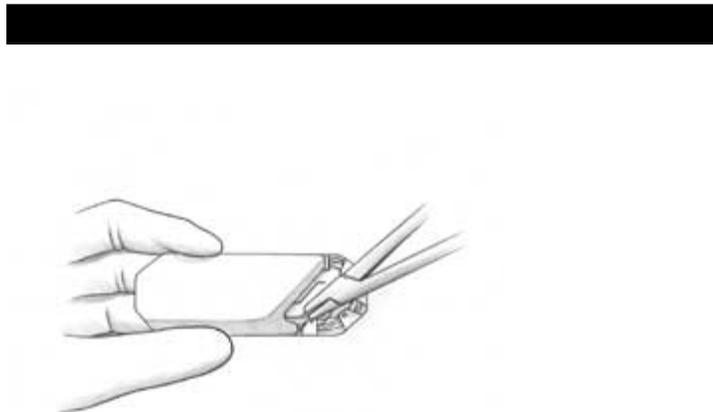


FIG.2

**Method for
Preparing
One-Step
Relay
Package
Sutures**

Arm the needle directly from the one-step RELAY tray
and deliver the single suture to the surgeon.

Primary Packets

Page 2

Multiple suture strands, either swaged to a single needle or double-armed. This type is appropriate for procedures requiring numerous interrupted sutures of the same type. It saves valuable operative time by enabling the surgeon to use one suture while the next is being armed--without delay of opening packets or threading needles.

Multistrand packets are labeled with the symbol MS/ that denotes multiple strands/number of strands of surgical needles per packet. Multistrand packets may contain 3 to 10 swaged sutures. The inner folder for these products is white.

All packets containing CONTROL RELEASE needle sutures have multiple strands (8, 5, 4, 3, or 1) and are designated CR/8, CR/5, CR/4, CR/3, or CR/1. CONTROL RELEASE sutures may be available in foil or Tyvek overwrap packets for single strand delivery. The single strand delivery *folder* is used for some Coated VICRYL (polyglactin 910) sutures, MONOCRYL (poliglecaprone 25) sutures, PDS II (polydioxanone) sutures, ETHIBOND EXCEL polyester sutures, NUROLON nylon sutures, MERSILENE polyester sutures, and PERMA-HAND silk sutures. The suture material straightens as it is delivered from the folder. Each suture may be delivered to the surgeon individually from the opening packet or removed from the folder and placed in the suture book. The inner folder for these products is either red with a black C/R symbol or white with red lettering. The safety organizer tray is used for Coated VICRYL sutures, MONOCRYL sutures, PDS II sutures, ETHIBOND EXCEL sutures, PERMA-HAND silk sutures, NUROLON nylon sutures, MERSILENE sutures, and surgical gut sutures. The safety organizer tray allows for single strand arming and dispensing. The needles are situated in individually numbered needle parks and may be armed and dispensed with little or no hand-to-needle contact.

Ligating material used as either single strand (free or freehand) ties, or as continuous ties unwound from a reel or other device. The length of single strand ties is determined by the depth of the wound. In subcutaneous tissue, quarter lengths (approximately 14 inches) are usually long enough for ligating. Deeper wounds may require single strand ties from 18 to 30 inches long. Single strand ligating material is available in pre-cut lengths or 18, 24, and 30 inch strands.

Many surgeons prefer continuous ties. Some prefer LIGAPAK ligature, which is supplied on disc like plastic radiopaque dispensing reels that are color coded by material. The size of the ligature material is indicated by the number of holes visible on the side of the reel (e.g., 3 holes = 3-0 suture). The reel is held in the palm of the hand as blood vessels are ligated. Other surgeons may prefer the ligating material rewound onto a rubber reel, gauze sponge, metal bobbin, or other device.

The number of packets of ligating material required to tie off subcutaneous vessels (bleeders) will vary with patient size and age, the amount of bleeding, the type of operation, the length of the incision, and the surgical technique. An abdominal incision 8 to 12 inches long might require one to three packets to ligate the subcutaneous blood vessels. All suture material is packaged dry with the exception of surgical gut and plibilized ETHILON sutures. Natural absorbable suture materials are packaged with a small amount of sterile fluid, usually alcohol with water, to maintain pliability. They should therefore be opened over a basin to prevent any solution from spilling onto the sterile field.

All needles should be counted after packets of swaged sutures are opened, according to established hospital procedure. The packets should be retained to facilitate verification of the final needle count after the surgical procedure.

E-PACK Procedure Kit

The E-PACK procedure kit contains numerous sutures and other products for a specific procedure, surgeon, or surgical specialty. The packaging concept saves valuable time in the OR by eliminating the need to open and coordinate multiple individual suture packages. The E-PACK procedure kit is also an effective means of reducing inventory levels of individual product codes, and providing a record for determining the suture costs associated with a given surgical procedure.

The suture packages are secured in an organizer sleeve to facilitate sterile transfer to the sterile field. The procedure kit label provides all the pertinent information regarding the number and types of needles, as well as sizes and types of suture. Suture quantities are listed on the label, making it easy to quickly determine how many needles have been used and thus simplifying needle accountability at the end of the procedure. The organizer sleeve is delivered in a Tyvek pouch.

Expiration Date

The expiration date of a product is determined by product stability studies. The Food and Drug Administration (FDA) requires that all synthetic absorbable suture products have an expiration date stamped on each dispenser box and primary packet to indicate the known shelf life of the material, provided the physical integrity of the package is maintained. Tests conducted by ETHICON show conclusively that synthetic absorbable suture products such as Coated VICRYL suture and PDS II suture continue to meet all product requirements even at five years of storage. In addition, all ETHICON nonabsorbable suture products contain a five-year expiry dating on each dispenser box and primary packet. This expiry dating is necessary to comply with various international regulatory guidelines and is an aid in inventory management.

The RELAY suture delivery system is designed as a "first-in, first-out" inventory control system. Dispenser boxes are rotated, permitting the oldest sutures to be used first. The expiration date stamped on the outside of each box and every packet clearly indicates the month and year of product expiration.

Suture Sterilization

Sutures sterilized by ETHICON are either irradiated with cobalt 60 or exposed to ethylene oxide gas. Both processes alter proteins, enzymes, and other cellular components to the extent that microorganisms are unable to survive or cause infection. Irradiation and ethylene oxide gas are considered cold sterilization processes because radiation sterilizes at room temperature and ethylene oxide gas sterilizes at much lower temperatures than other sterilization methods such as dry heat or steam under pressure.

Irradiation sterilization exposes products to ionizing radiation--either beta rays produced by high energy electron accelerators or gamma rays from radioisotopes--until absorbed in appropriate sterilizing dose. ETHICON was a pioneer in both beta and gamma irradiation and routinely sterilizes products with cobalt 60 which emits gamma rays. Cobalt 60 irradiation is the simplest of all sterilization processes.

Some suture materials cannot withstand the effects of irradiation sterilization. Instead, they are gas sterilized. Gas sterilization uses ethylene oxide gas. As an environmental measure, ETHICON replaced chlorofluorocarbons (CFCs) with more environmentally friendly replacements in all gas sterilization processes. The combination of ethylene oxide gas concentration, temperature, humidity, and exposure time must be carefully controlled to ensure reliable sterilization.

WARNING: Surgical sutures are labeled as disposable, single-use medical devices. Suture products manufactured by ETHICON are provided in easy-to-use packages designed to maintain the stability and sterility of the suture and needle materials. The component layers of packaging materials do not permit exposure to high temperatures or extremes of pressure without affecting package and product integrity. For this reason, all sterile products manufactured by ETHICON are clearly labeled, "DO NOT RESTERILIZE." Manufacturers cannot be held responsible for the quality, effectiveness, or integrity of suture materials resterilized in the hospital, office, or by outside vendors. Therefore, if customers utilize the services of a sterilization reprocessor for suture, ETHICON will disclaim any responsibility for sterilization and/or other product failures resulting from the resterilization process. The practice of resterilization is not recommended, except for ETHI-PACK pre-cut steel sutures and spools or cardreels of nonabsorbable materials supplied nonsterile.

Anticipating Suture Needs

Anticipating Suture Needs

Today's healthcare environment dictates that hospitals continue to maintain quality standards while lowering costs to remain financially viable. Through total quality management initiatives, many hospitals have identified material use as an opportunity to lower cost. To increase the efficiency of suture utilization during a surgical procedure, it is important to determine and anticipate the surgeon's needs more precisely. For this reason, a file system of preference cards for each surgeon on staff is usually maintained in the operating suite. The cards contain such information as the surgeon's "suture routine," suture materials, sizes, needles, and/or product code numbers customarily used in specific procedures.

Becoming more aware of each surgeon's routine through good communication and regularly updated preference cards can help reduce preparation time, minimize waste, and assure cost effectiveness. Prior to dispensing suture packets, the circulating nurse should have a brief discussion with the surgeon to ascertain whether a change in suture routine is anticipated due to a specific patient's needs.

While it is difficult to say precisely how many suture packets are *enough*, three major factors should be considered in deciding how many packets to open:

1. Fewer packets will be needed if products with multiple strands of suture material are used.
2. Open sufficient suture packets to prevent prolonging operative time and causing surgeon inconvenience.

3. Leftover suture on the surgical field must be discarded. Therefore, opening too many suture packets should be avoided to reduce waste and lower cost.

Although it is important to be prepared to answer requests at a moment's notice, it is not necessary to overload the table with sutures. The introduction of single-layer peelable packaging, such as one-step RELAY packaging, helps encourage less handling to access the suture, enhancing quick delivery of suture materials to the surgeon in the sterile field. Unexpected suture needs can also be obtained rapidly from the storage racks.

Sterile Transfer of Suture Packets

At some point, suture packets must cross the sterile barrier--the invisible line of demarcation between the sterile and the nonsterile. In all settings (e.g., operating room, delivery room, emergency department, or physician's office), the individual who removes the nonsterile overwrap must remember these three points about sterile transfer:

1. Outer surfaces of the overwrap are not sterile and may be handled with nonsterile hands.
2. The sterile inner packet or tray must be transferred to the sterile field without being touched or contacting any nonsterile object or surface.
3. Nonsterile hands over the sterile field violate aseptic technique.

There are two methods commonly used for achieving sterile transfer of suture packets: handing-off the sterile inner one-step RELAY tray directly to the scrub person *or* "flipping" the inner contents of the primary packet onto the sterile field. Regardless of the aseptic technique performed, all items introduced onto the sterile field should be opened, dispensed, and transferred by methods that maintain product sterility and integrity. AORN Guidelines recommend the "hand-off" method, since items tossed or flipped have a greater potential to roll off the edge of the sterile field, causing contamination or other items to be displaced.

METHOD I: STERILE TRANSFER TO THE SCRUB PERSON

Grasp the two flaps of the peelable overwrap between the knuckles of the thumbs and forefingers. With a rolling-outward motion, peel the flaps apart to approximately one third of the way down the sealed edges. Keeping the pressure between the knuckles for control, offer the sterile inner packet or tray to the scrub person, who takes it with the gloved hand or sterile instrument. Care must be taken to avoid contact with the nonsterile overwrap as the packet or tray is withdrawn.

This method *must* be used to remove paper folder packets of surgical steel and PROLENE sutures from long straight overwraps, and to remove the organizer sleeves from E-PACK procedure kits. It should also be used for transfer of flexible, lightweight, transparent packets containing microsurgery and ophthalmic products.

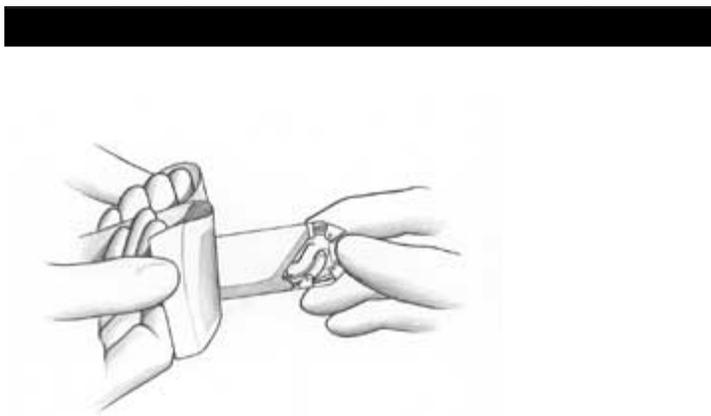


FIG.3

**Sterile
Transfer to
the Scrub
Person**

METHOD II: STERILE TRANSFER TO THE STERILE FIELD

"Flipping" is a rapid and efficient method of ejecting sterile product from its overwrap onto the sterile field without contacting the unsterile outer packet or reaching over the field. However, skill must be acquired to ensure its effective use. The circulating nurse must stand near enough to the sterile table to project the suture packet or tray onto it, but not too close as to risk contaminating the table by touching it or extending nonsterile hands over it. To accomplish this, grasp the flaps of the overwrap as described in Method I and peel the flaps apart with the same rolling-outward motion. The sterile packet or tray is projected onto the sterile table as the overwrap is completely peeled apart.

NOTE: DO NOT attempt to project the inner folder of long straight packets onto the sterile table. Instead, present them to the scrub person as outlined in Method I.

Suture Preparation in the Sterile Field

Suture preparation may be more confusing than virtually any other aspect of case preparation. Familiarity and understanding of the sequence in which tissue layers are handled by the surgeon will help to eliminate this confusion. (See the Suturing Section, Chapter 2.)

Once the suture packets are opened and prepared according to the surgeon's preference card, sutures can be organized in the sequence in which the surgeon will use them. Ligatures (ties) are often used first in subcutaneous tissue shortly after the incision is made, unless ligating clips or an electro-surgical cautery device is used to coagulate severed blood vessels.

After the ligating materials have been prepared, the suturing (sewing) materials can be prepared in the same manner. Preparing large amounts of suture material in advance should be avoided. For example, if the surgeon opens the peritoneum (the lining of the abdominal cavity) and discovers disease or a condition that alters plans for the surgical procedure and anticipated use of sutures, opened packets would be wasted. At closure following abdominal surgery, remembering the letters PFS (peritoneum, fascia, skin) will be helpful for organizing sutures.

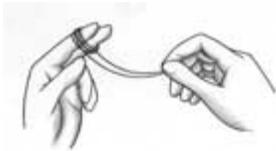
By watching the progress of the procedure closely, listening to comments between the surgeon and assistants, and evaluating the situation, suture needs can be anticipated. Free moments can be used to prepare sufficient suture material to stay one step ahead of the surgeon. The goal should be to have no unused strands at the end of the procedure.

Ligature material which remains toward the end of the procedure may be the same material and size specified by the surgeon for sutures in the subcutaneous layer of wound closure. In this case, the remaining ligating material should be used rather than opening an additional suture packet.

If the surgeon requires "only one more suture," and strands of suitable material remain which are shorter than those prepared originally, do not be reluctant to ask the surgeon if one of the strands will serve the purpose before opening a new packet. Most surgeons are cooperative in efforts to conserve valuable supplies.

FIG.4

Preparation of Standard Length Ligature Strands



1. Prepare cut lengths of ligature material, coil around fingers of left hand, grasp free ends with right hand, and unwind to full length



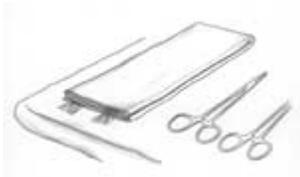
2. Maintain loop in left hand and two free ends in right hand. Gently pull the strand to straighten



3. To make 1/3 lengths: Pass one free end of strand from right to left hand. Simultaneously catch a loop around third finger of right hand. Make strands equal in thirds and cut the loops with scissors.



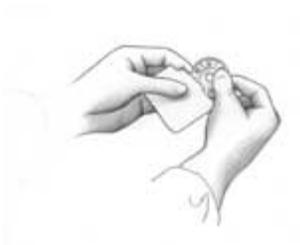
4. To make 1/4 lengths: Pass both free ends from right to left hand. Simultaneously catch a double loop around the third finger of the right hand. Cut the loops.



5. Place packets or strands in suture book (folded towel)--or under Mayo tray--with ends extended for enough to permit rapid extraction.

FIG.5

Preparation of Standard Length Ligature Strands



1. Open the packet containing appropriate material on a reel. Transfer the inner contents of the primary packet to the sterile field using aseptic technique.



2. Extend the strand end slightly for easy grasping. Place reel conveniently on the Mayo tray.



3. Hand reel to surgeon as needed, being certain that the end of the ligating material is free to grasp.



4. Surgeon holds reel in palm, feeds strand between fingers, and places around tip of hemostat.

FIG.6

Preparation of Pre-Cut sutures for ties or Ligature Sutures





1. Remove one pre-cut length of nonabsorbable suture at a time from the labyrinth packet as it is needed by the surgeon.
2. Extract pre-cut strands of SUTUPAK sterile absorbable or nonabsorbable suture. Straighten surgical gut with a gentle pull. Place strands in the suture book or under Mayo tray.



Suture Handling Technique

During the first postoperative week, the patient's wound has little or no strength. The sutures or mechanical devices must bear the responsibility of holding the tissues together during this period. They can only perform this function reliably if the quality and integrity of the wound closure materials are preserved during handling and preparation prior to use. It is therefore essential for everyone who will handle the suture materials to understand proper procedure to preserve suture tensile strength.

In general, avoid crushing or crimping sutures with surgical instruments such as needleholders and forceps, except as necessary to grasp the free end of a suture during an instrument tie. There are also specific procedures to follow to preserve suture tensile strength which depend upon whether the material is absorbable or nonabsorbable.

Table 2

1. Protect absorbable sutures from heat and moisture.
 - Store suture packets at room temperature. Avoid prolonged storage in hot areas such as near steam pipes or sterilizers.
 - Do not soak absorbable sutures. Also avoid prolonged placement of sutures in a moist suture book.
 - Surgical gut can be dipped momentarily in tepid (room temperature) water or saline to restore pliability if strands dry out before use. Surgical gut or collagen for use in ophthalmic surgery should be rinsed briefly in tepid water before use, as they are packed in a solution usually consisting of alcohol and water to maintain pliability.
 - Synthetic absorbable sutures must be kept dry. Use strands directly from packet when possible. Store sutures in a dry suture book if necessary.
2. Limit contact between rubber gloves and suture strands to an absolute minimum. Excessive handling can cause fraying.
3. Straighten strands with a gently, steady, even pull. Jerking and tugging can weaken sutures.
4. Do not "test" suture strength.
5. Do not resterilize.

**Preservation of
tensile strength:
Absorbable**

Table 3

Silk--Store strands in a dry towel. Dry strands are stronger than wet strands. Wet silk loses up to 20% in strength. Handle carefully to avoid abrasion, kinking, nicking, or instrument damage. Do not resterilize.

Surgical Stainless Steel--Handle carefully to avoid kinks and bends. Repeated bending can cause breakage. Stainless steel suture can be steam sterilized without any loss of tensile strength. However, *DO NOT* steam sterilize on spool or in contact with wood. Lignin is leached from wood subjected to high temperature and may cling to suture material. Handle carefully to avoid abrasion, kinking, nicking, or instrument damage.

Polyester Fiber--Unaffected by moisture. May be used wet or dry. Handle carefully to avoid abrasion, kinking, nicking, or instrument damage. Do not resterilize.

Nylon--Straighten kinks or bends by "caressing" strand between gloved fingers a few times. Handlerecarefully to avoid abrasion, kinking, nicking, or instrument damage.

Polypropylene--Unaffected by moisture. May be used wet or dry. Straighten strands with a gentle, steady, even pull. Handle with special care to avoid abrasion, kinking, nicking, or

**Preservation of
Tensile Strength:
Non-Absorbable
Sutures**

instrument damage.

Do not resterilize.

The following summarizes the most important points for each member of the surgical team to remember and observe in handling suture materials and surgical needles.

FIG.7

Suture Handling Technique



1. With a rolling-outward motion, peel the flaps apart to approximately one-third the way down the sealed edges. Keeping pressure between the knuckles for control, after the sterile inner RELAY tray to the scrub person.

2. Clamp the needleholder approximately one-third to one-half of the distance from the swage area to the needle point. Do not clamp the swaged area. Gently pull the suture to the right in a straight line.



3. Additional suture straightening should be minimal. If the strand must be straightened, hold the armed needleholder and gently pull the strand making certain not to disarm the needle from the suture.

FOR THE CIRCULATING NURSE

1. Consult the surgeon's preference card for suture routine.
2. Check the label on the dispenser box for type and size of suture material and needle(s). Note the number of strands per packet. Fewer packets will be needed if multistrand or CONTROL RELEASE sutures are used.
3. Estimate suture requirements accurately and dispense only the type and number of sutures required for the procedure.
4. Read the label on the primary packet or overwrap before using to avoid opening the wrong packet.
5. Use aseptic technique when peeling the overwrap. Transfer the inner contents of the primary packet to the sterile field by offering it to the scrub person or by projecting (flipping) it onto the sterile table, avoiding contamination.
6. To open long straight packets, peel overwrap down 6 to 8 inches and present to the scrub person. Do not attempt to project the inner folder of long straight packets onto the sterile table.

7. Maintain an adequate supply of the most frequently used sutures readily accessible.
8. Rotate stock using the "first-in, first-out" rule to avoid expiration of dated products and keep inventories current.
9. Suture packets identify the number of needles per packet to simplify needle counts. Retain this information during the procedure and/or until final needle counts are completed.
10. Count needles with the scrub person, per hospital procedure.

FOR THE SCRUB PERSON

1. If appropriate, remove the inner one-step RELAY tray or folder containing suture materials from the primary packet being offered from the circulating nurse.
2. Hold the one-step RELAY tray or folder in gloved hand and arm the needle using the "no-touch" technique. Gently dispense the suture.
3. Leave pre-cut suture lengths in labyrinth packet on Mayo tray. Strands can then be removed one at a time as needed.
4. Surgical gut and collagen sutures for ophthalmic use must first be rinsed briefly in tepid water to avoid irritating sensitive tissues. If the surgeon prefers to use sutures wet, dip only momentarily. Do not soak. Silk sutures should be used dry.
5. Do not pull or stretch surgical gut or collagen. Excessive handling with rubber gloves can weaken and fray these sutures.
6. Count needles with the circulating nurse, per hospital procedure.
7. Hold single strands taut for surgeon to grasp and use as a freehand tie.
8. Do not pull on needles to straighten as this may cause premature separation of CONTROL RELEASE needle suture.
9. Always protect the needle to prevent dulling points and cutting edges. Clamp the needleholder forward of the swaged area, approximately one-third to one-half the distance from the swage to the point.
10. Microsurgery sutures and needles are so fine that they may be difficult to see and handle. They are packaged with the needles parked in foam to protect delicate points and edges. The needles may be armed directly from the foam needle park. If the microsurgeon prefers to arm the needle, the removable orange-colored tab may be used to transport the needle into the microscopic field.
11. Handle all sutures and needles as little as possible. Sutures should be handled without using instruments unless absolutely necessary. Clamping instruments on strands can crush, cut, and weaken them.
12. Cut sutures only with suture scissors

Other Surgical Products

There are many surgical products available which may be used during wound closure and other operative procedures which involve suturing. Each of these products has specific indications for use.

- **HEMOSTASIS PRODUCTS**--to control bleeding in the operative site.
- **LOOPED SUTURE**--for continuous closure of the fascia in the abdominal wall.
- **RETENTION SUTURE DEVICES**-- to relieve excessive tension and prevent cutting of the skin by retention sutures.
- **TISSUE ADHESIVES**--to hold closed easily approximated skin edges from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations.
- **TAPES**--for approximating the edges of lacerations, skin closures, repair and/or support in selected operative procedures, and suspending small structures and vessels.
- **SURGICAL MESH**--for repairing abdominal wall hernias and other fascial or tissue defects.
- **TENDON REPAIR KITS**--to aid in specific tendon and ligament repair techniques.
- **TEMPORARY CARDIAC PACING WIRE**--for temporary control of arrhythmias following open heart surgery.

Hemostasis Products

Hemostasis Products

Hemostasis is a complex process that prevents or stops blood flow from vessels in the operative site. Hemostasis not only prevents loss of the patient's blood, but provides as bloodless a field as possible for accurate dissection. Various mechanical, electrical, and topical methods are used to achieve hemostasis.

Mechanical Method

ETHICON bone wax is a sterile mixture of semisynthetic beeswax and isopropyl palmitate (a wax-softening agent). It is used to control local bleeding from bone surfaces by creating a mechanical (tamponade) barrier.

Bone wax is minimally resorbable and should be used sparingly as it may inhibit osteogenesis and act as a physical barrier to the reparative process. Excess bone wax should be removed from the operative site. Bone wax should not be used where rapid osseous regeneration and fusion are desired. Mild tissue reaction adjacent to the site of bone wax use has been reported. Also, studies have suggested that bone wax acts as a foreign body and may impair the ability of cancellous bone to clear bacteria.¹ Local accumulation of foreign body giant cells has been observed in animal models. Histologic examination has revealed the appearance of macrophages and occasionally polymorphonuclear leukocytes and lymphocytes.

Bone wax is supplied sterile in 2.5 gram foil envelopes with sealed overwraps. Packets should be opened just prior to use to minimize the possibility of contamination and excessive drying and should be used immediately. Using sterile technique, the wax should be warmed to the desired consistency by manipulation with the fingers or by immersion of the unopened foil packet in warm sterile solution. Bone wax should not be resterilized or subjected to excessive heat.

Electrical Method

The ETHICON POWERSTAR bipolar scissors provide precise cutting and simultaneous coagulation in open procedures. Hemostasis is achieved through bipolar electrosurgery, or the controlled use of high frequency electric current for cutting and coagulation.

There are two types of electrosurgery: monopolar and bipolar. Both draw high voltage, high frequency current from an electrosurgical generator. The main difference between the two is the method of grounding each uses.

In monopolar electrosurgery, the active electrode is both the cutting and coagulation instrument. The patient becomes part of the return path by being connected to a return electrode in the form of a grounding pad. The patient's tissue provides the impedance in this circuit. However, although current density is diminished by both distance from the contact site and the return electrode, cutting or coagulation current can pass through the patient beyond the area of surgical concern, and may produce thermal damage in tissue surrounding the area of interest. Monopolar electrosurgery lacks a tight focus of operation in patient tissue.

In bipolar electrosurgery, both electrodes are active and are incorporated into a single instrument. Current is focused from one active electrode to the other active electrode through only the very small segment of patient tissue between them. Except for the tissue between the active and return electrodes, the patient is not part of the bipolar circuit.

Therefore, bipolar electrosurgery is highly focused with regard to the targeted tissue.

Since electrical energy delivered to tissue by means of bipolar electrosurgery is more focused than is the energy distribution produced by monopolar electrosurgery, cutting and coagulation with the

POWERSTAR bipolar scissors can be performed closer to delicate structures, such as nerves and bowel tissue. The bipolar scissors are particularly effective in cardiovascular, peripheral vascular, plastic, and ENT procedures.

However, the POWERSTAR bipolar scissors are not indicated for contraceptive coagulation of the fallopian tube, but may be used to achieve hemostasis following transection of the fallopian tube.

POWERSTAR bipolar scissors are available in a variety of styles and sizes and are compatible with most electrosurgical generators. Supplied nonsterile, the reusable POWERSTAR bipolar scissors are sterilized by steam autoclave.

Topical Agents

SURGICEL absorbable hemostat (oxidized regenerated cellulose) is a fabric made from pure alpha cellulose. It is used adjunctively in surgical procedures to assist in the control of capillary, venous, and small artery hemorrhage when ligation or other conventional methods of control are impractical or ineffective. As a result of the regeneration process, oxidized regenerated cellulose absorbs more rapidly than regular oxidized cellulose and is bactericidal.

Upon contact with blood, SURGICEL absorbable hemostat generally stops bleeding within 2 to 8 minutes by acting as a matrix for the formation of a clot. SURGICEL absorbable hemostat is generally absorbed from the site of implantation within 7 to 14 days with a minimum of tissue reaction. It is safe and reliable for use on or near vital tissue. However, SURGICEL hemostat must always be removed from the site of application when used in, around, or in the proximity of bone defects and foramina.

Uniquely, SURGICEL hemostat is bactericidal *in vitro* against a wide range of gram-positive and gram-negative organisms including aerobes and anaerobes. As such, it should not be impregnated with anti-infective agents.

Two variations on regular SURGICEL hemostat, which is a loosely knit fabric, are provided to give the surgeon superior handling qualities for specific applications. SURGICEL NU-KNIT absorbable hemostat is a more densely woven fabric that can be sutured and is especially appropriate for procedures involving solid organs, like the liver. SURGICEL fibrillar absorbable hemostat differs from standard SURGICEL and SURGICEL NU-KNIT in that it has been through a carding/fibrillation process which creates a fibrous web of ORC fibers. This process results in the product having consistency and adherence properties similar to those of cotton.

SURGICEL absorbable hemostat is available in four sizes: 2 x 14 inch (5.1 x 35.6cm), 4 x 8 inch (10.2 x 20.3cm), 2 x 3 inch (5.1 x 7.6cm), and 1/2 x 2 inch (1.3 x 5.1cm). SURGICEL NU-KNIT absorbable hemostat is available in four sizes: 1 x 1 inch (2.5 x 2.5cm), 1 x 3.5 inch (2.5 x 8.9 cm) [endoscopic size], 3 x 4 inch (7.6 x 10.2cm), and 6 x 9 inch (15.2 x 22.9cm). SURGICEL fibrillar is available in three sizes: 1 x 2 inch (2.5 x 5.1cm), 2 x 4 inch (5.1 x 10.2cm), and 4 x 4 inch (10.2 x 10.2cm). All products are supplied sterile and should not be resterilized.

INSTAT collagen absorbable hemostat, a purified and lyophilized (freeze-dried) bovine dermal collagen, is indicated in surgical procedures (other than in neurosurgery and ophthalmology) for use as an adjunct to hemostasis when the control of bleeding by ligature or other conventional methods are ineffective or impractical.

The material, prepared as a spongelike pad, combines the efficacy of collagen to control bleeding with the excellent handling properties of a sponge. INSTAT hemostat, which can be cut to size, is applied directly to the bleeding surface with pressure. Hemostasis is typically achieved in 2 to 5 minutes. INSTAT hemostat maintains its integrity in the presence of blood and is not dispersed when wet. It can be used dry or moistened with sterile saline, depending on surgeon preference.

INSTAT hemostat is supplied sterile in 1 x 2-inch (2.5 x 5.1cm) and 3 x 4-inch (7.6 x 10.2cm) peelable plastic envelopes. It is inactivated by autoclaving and, therefore, should not be resterilized.

INSTAT MCH Microfibrillar Collagen Hemostat, is a dry white absorbent hemostatic agent in microfibrillar form obtained from bovine deep flexor tendon (achilles tendon).

INSTAT MCH (other than neurological, urological, and ophthalmological) is recommended for use in surgical procedures as an adjunct to hemostasis when control of bleeding by ligature or conventional procedures is ineffective or impractical.

The microfibrillar form of the product allows the surgeon to grasp with forceps any amount of INSTAT MCH needed to achieve hemostasis at a particular bleeding site. The microfibrillar form may be more convenient than the sponge form for hard to reach or irregularly shaped bleeding sites. Although it is easy to pull the desired amount of INSTAT MCH from the entire supply, the group of selected fibers continue to cohere to one another and application to the bleeding site is easily controlled.

Topical application of INSTAT MCH effectively controls bleeding, usually within 2 to 4 minutes, when applied directly to the bleeding site. INSTAT MCH is designed to be completely absorbable if left *in situ* after hemostasis. In contact with blood, the fibers expand to become a coherent gelatinous mass that conforms to the shape of the bleeding area. If desired, removal of this mass is easily accomplished.

Sterile INSTAT MCH is supplied in 1 gram and 0.5 gram sizes. It is supplied sterile and should not be resterilized.

THROMBOGEN topical thrombin, U.S.P. is an absorbable hemostatic drug that is used in a wide variety of procedures as an aid in hemostasis whenever oozing blood from capillaries and small venules is accessible.

THROMBOGEN topical thrombin is a protein substance derived from bovine blood and is supplied as a sterile powder that has been lyophilized (freeze dried). The speed with which it will clot the blood is dependent on the concentration of thrombin and diluent. It can be used via spray, splash, powder, absorbable gelatin sponge, or collagen sponge.

Looped Suture

ETHICON looped sutures range in length up to a 60-inch strand with both ends swaged to a single taper point needle. Available in various materials and suture sizes, they provide a simple, reliable technique for continuous closure of the fascia in the abdominal wall. The needle of the looped suture is passed through the fascia from inside out at one end of the incision, then through the opposite wound edge from outside in, and then passed through the loop. The locking stitch lies beneath the wound edge. The double strand is run over and over to the other end of the incision. The final stitch is completed by passing the needle from the outside in, cutting one strand, and passing the needle through the opposite wound edge from the outside in. The needle is then cut off and the loose suture ends tied together, leaving the knot inverted under the fascia.

Retention Suture Devices

Retention sutures, if not placed carefully without excessive tension, can cut the skin. Devices such as bolsters and bridges are used to prevent such complications and eliminate pressure. However, care should also be taken in the use of these devices.

Retention suture bolsters are sterile 2 1/2-inch (6cm) lengths of 3/16-inch (0.48cm) diameter surgical latex tubing with a 1/32-inch (0.08cm) wall. The suture is threaded through the bolster and tied. Sutures sheathed in this manner can cause "a severe inflammatory response with reaction both at the site of the suture exit from the skin and along the entire length of the suture itself."² Also, the skin may become necrotic beneath the bolsters if the sutures are too tight.

The *retention suture bridge* is a strong plastic truss that can be adjusted to relieve the pressure of the retention suture on the skin during, and subsequent to, initial suture placement. After the desired number of sutures is placed in the wound, a sterile bridge is positioned over each retention suture. Each side of the bridge has six holes spaced 1/4 inch (0.64cm) apart to accommodate many patient sizes. The ends of the sutures are passed through the appropriate holes and tied loosely over the bridge. The suture strand is then slipped into the capstan located in the middle of the bridge, and the capstan is rotated to apply the desired tension before locking into place. The bridge permits easy tension readjustment by raising and rotating the capstan to compensate for postoperative wound edema, and again when the edema subsides. The suture remains elevated away from the skin while the bridge has contact along its entire 4 3/8-inch (11cm) length. Pressure is evenly distributed over the area, and the transparent bridge facilitates complete visualization of the wound. In reported studies, both the suture exits and the skin underlying the bridge show no inflammatory reaction other than the slight depression of the device on the skin.²

FIG.1

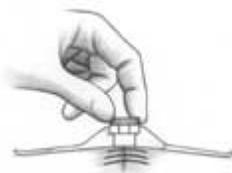
Adjustment of Retention Suture Bridge



1. Pass the retention suture through appropriate holes in the bridge



2. Place the suture with tension over the slit in the capstan, and tie.



2. To adjust tension, lift capstan.



4. Rotate capstan until desired tension is attained



5. To lock, press capstan down into bridge.

Tissue Adhesives

Wound closure should be simple, rapid, inexpensive, and painless, and should achieve optimal cosmetic results.³ The ideal surgical adhesive would be safe for topical application, easy to apply, polymerize rapidly, support the approximated skin edges and maintain the skin edge eversion necessary for maximum wound healing and acceptable cosmesis, and eliminate the need for suture removal.⁴

Tissue adhesives offer many of the advantages of the ideal wound closure devices. They have been shown to be inexpensive and painless, and have antimicrobial activity against gram-positive organisms. They have a low rate of dehiscence and a low infection rate, and provide excellent cosmetic results.³

The use of DERMABOND* Topical Skin Adhesive (2-Octyl Cyanoacrylate) significantly decreases the time of treatment for wound closure and eliminates the need for postoperative suture removal. And, although 5- to 7-day follow-up visits may still be necessary, patients will not experience the anxiety and discomfort often associated with suture removal. Additional benefits of DERMABOND adhesive include ease of use, formation of its own protective barrier, eliminating the need for additional bandages, and excellent cosmetic outcome.⁴

Although tissue adhesives have many advantages, successful incorporation into surgical use depends on an understanding of the indications, contraindications, and proper method of application. (*See instructions on next page and Package Insert on pages 118-121.*)

FIG.2

A Guide For Using Dermabond Adhesive



1. Clean and debride the wound and establish hemostasis. Be sure wound edges and surrounding skin are dry, to assure direct tissue contact and prevent premature polymerization of DERMABOND adhesive.



Use subcutaneous sutures as needed. DERMABOND adhesive should not be used as a replacement for proper subcutaneous closure. MONOCRYL* (poliglecaprone 25) suture would be an excellent choice for subcutaneous closure.

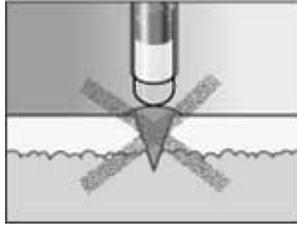


2. Remove applicator from packaging and hold with tip pointed upward. Apply pressure at the midpoint of the ampule, crushing the inner glass ampule. Invert applicator and gently squeeze to express the liquid through the applicator tip. After crushing the inner glass ampule, use DERMABOND adhesive immediately.



3. To prevent inadvertent run-off of DERMABOND adhesive, position the wound in a horizontal plane. Manually approximate the wound edges with forceps or gloved fingers. Use gentle brushing strokes to apply a thin film of liquid to the approximated wound edges, and maintain proper eversion of skin edges as you apply DERMABOND adhesive. The adhesive should extend at least 1/2 centimeter on each side of the apposed wound edges. Apply DERMABOND adhesive from above the wound.

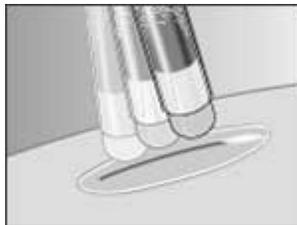
Avoid seepage into the wound as it may delay healing.



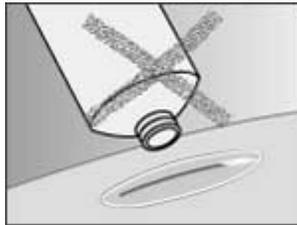
4. When using DERMABOND adhesive on the face, it is important to prevent the product from trickling into the eyes; failure to do so may seal the eyes shut. Prior to application, apply petroleum jelly around the eye to block the adhesive from entering the eye. Protect and hold the eye closed with a dry gauze pad and position the patient with a slight horizontal tilt so that any run-off travels away from the eye.



5. Gradually build up three or four thin layers of adhesive. Ensure the adhesive is evenly distributed over the wound. Maintain approximation of the wound edges until the adhesive sets and forms a flexible film. This should occur about 1 minute after applying the last layer.



6. Do not apply ointments or medications on top of DERMABOND adhesive



Tapes

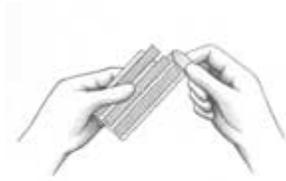
Skin Closure Tapes

PROXI-STRIP skin closures are long, narrow, sterile strips of tape with an adhesive backing. They are used for approximating the edges of lacerations and for closing skin following many operative procedures. Skin closure tapes are an effective alternative to sutures or staples when tensile strength and resistance to infection are not critical factors. Skin closure tapes can also be used to complement suture or staple closures. Clinical evidence indicates that wounds closed with skin closure tapes may develop tensile strength faster than sutured wounds. Stress is applied uniformly to the collagen fibers, aiding in rapid fiber orientation and increased tensile strength. "The superior resistance to infection of taped wounds as compared to sutured wounds indicates that tape closure of contaminated wounds is a significant clinical tool."⁵ "Adhesive strips relieve the patient of the much feared, but seldom painful, suture removal, but they have two disadvantages: they do not bring deeper tissues together and they do not control bleeding from wound edges."⁶

Skin closure tapes may be applied to the skin over a subcuticular closure in lieu of skin sutures or used as a primary closure in conjunction with sutures in an alternating pattern. Skin closure tapes may also be used as a replacement for sutures or staples which are removed on the first to fourth postoperative day. Effective skin closure tapes provide good porosity in terms of air inflow to the wound and water vapor transmission escaping from the wound during the healing process.

PROXI-STRIP skin closures have a high degree of porosity to allow the wound to breathe, but have sufficient adhesive strength to negate the use of adjunct applications, such as tincture of benzoin .

Skin Closure Tapes



1. Using sterile technique, remove card from sleeve and tear off tab.



2. Peel off tapes as needed in diagonal direction.



3. Apply tapes at 1/8-inch intervals as needed to complete wound apposition. Make sure the skin surface is dry before applying each tape.



4. When healing is judged to be adequate, remove each tape by peeling off each half from the outside toward the wound margin. Then, gently lift the tape away from the wound surface.

Polyester Fiber Strip

MERSILENE polyester fiber strip is comprised of a double thickness of MERSILENE polyester fiber that is 5mm wide. The strips are available with and without needles and may be used instead of large-sized suture for ligation, repair, and/or support in selected operative procedures.

Incompetence of the cervix is a condition characterized by the habitual premature, spontaneous abortion of the fetus. A ligature is placed around the cervix in a collarlike fashion, drawn tight, and either sutured together or tied closed. A MERSILENE strip is then woven carefully with a swage blunt needle in and out of the mucosa. When placed properly, the flatness of the ligature will not cut or damage the wall of the cervix. MERSILENE strip attached to a heavy reverse cutting needle provides a wide band of strong material for orthopaedic procedures such as rotator cuff repair and support. The blunt needles used for the incompetent cervix ligation may also be used for this purpose.

Umbilical Tape

Umbilical tape is a white woven cotton ligature, 1/8 or 1/4 inch (0.32 or 0.64cm) wide, that is strong enough to tie off the umbilical cord of the newborn infant. While this was its original use, umbilical tape is also used in pediatric and cardiovascular procedures to suspend small structures and vessels.

Umbilical tape easily absorbs blood when used in an area of gross bleeding. The 1/8-inch (0.32cm) tape is available with a radiopaque thread woven into the length of the fabric to facilitate x-ray identification.

Surgical Mesh

Surgical Mesh

Surgical mesh may be used for repairing abdominal wall hernias and other fascial or tissue deficiencies that require a reinforcing or bridging material to obtain the desired surgical result. Primary closure of large abdominal wall defects under tension usually predisposes to wound necrosis and infection. Insertion of surgical mesh to bridge the defect will maintain position of the viscera within the abdominal cavity until the wound has developed sufficient granulation tissue to avert evisceration. Smaller pieces of surgical mesh may be used for inguinal or other fascial defects.

Surgical mesh is made of either nonabsorbable material (polyester fiber, polypropylene) or absorbable material (polyglactin 910). Regardless of which material is selected, certain characteristics are crucial:

1. The mesh must be pliable to conform to anatomy.
2. The mesh must be inert to avoid greater inflammatory response.
3. The mesh should be porous to encourage drainage of exudate and ingrowth of fibroblasts.
4. The mesh should be sufficiently resilient to maintain its integrity and offer some potential for permanence.⁷

Polyester fiber mesh and polypropylene mesh are knitted by a process which interlinks each fiber junction to provide elasticity in both directions. This permits the mesh to be cut without unraveling, and allows adaptation to various stresses encountered in the body. The fiber junctions are not subject to the same work fatigue exhibited by more rigid metallic meshes. When used in infants and children, it should be kept in mind that mesh products will not stretch significantly as the patient grows.

Nonabsorbable surgical mesh is used to span and reinforce traumatic or surgical wounds to provide extended support both during and following wound healing. It is not subject to degradation or weakening by tissue enzymes. A slight, transient inflammatory reaction may be elicited, followed by the deposition of a thin fibrous layer of tissue. This layer can grow through the interstices of the mesh, thus incorporating the mesh into the adjacent tissue. Nonabsorbable mesh remains soft and pliable, so normal wound healing is not impaired. Mesh placed in contaminated wounds should be used with the understanding that it could lead to fistula formation and/or extrusion, and that subsequent infection may require removal of the material. Resterilization of nonabsorbable mesh is not recommended. However, unused sheets of mesh which have been removed from the package may be reprocessed not more than one time by a conventional steam autoclaving process. PROLENE polypropylene mesh may be resterilized no more than one time at 250° for 20 minutes without compromising the principle of the mesh. If the mesh becomes stained with blood or soiled, it should not be reprocessed or reused.

Absorbable surgical mesh is intended for use as a buttress to provide temporary support during the healing process, and should not be used where extended wound support is required. It may act as a scaffold for ingrowth of connective tissue. Absorbable mesh should not be resterilized.

Surgical mesh should be secured with sutures or staples placed 1/4 to 1/2 inch (6.5 to 12.5mm) apart at a distance of approximately 1/4 inch (6.5mm) from the edge of the mesh. Nonabsorbable mesh can be secured with either nonabsorbable or absorbable sutures, preferably the same material as the mesh, or staples. Absorbable mesh can be secured with either absorbable or nonabsorbable sutures, or staples.

Some surgeons prefer to suture into position an uncut section of mesh that is considerably larger than the defect, then trim away the excess. Suturing would begin on one side of the mesh. The opposite sides are then sutured to ensure proper closure under correct tension. When the margin sutures have been placed, the extra mesh can be trimmed so that approximately 1/4 inch (6.5mm) of mesh extends beyond the suture line.

Polyester Fiber Mesh

MERSILENE polyester fiber mesh is a nonabsorbable mesh made of woven multifilament strands of polyethylene terephthalate, the same material as MERSILENE suture. The approximate 0.010-inch (0.25mm) mesh thickness provides excellent strength, durability, and surgical adaptability, plus maximal porosity for necessary tissue ingrowth. MERSILENE polyester fiber mesh is packaged sterile, in undyed (white) 21/2 x 41/2-inch (6 x 11cm) and 12 x 12-inch (30 x 30cm) sheets which can be cut to the desired shape.

Polypropylene Mesh

PROLENE polypropylene mesh is a nonabsorbable mesh made of knitted filaments of extruded polypropylene, the same material as PROLENE suture. The approximate 0.7mm mesh thickness has a high burst strength and tensile strength. It is packaged as sterile, undyed (clear) sheets in seven sizes which can be cut to the desired shape. Sizes available are 1 x 4 inch (2.5 x 10cm), 1.8 x 4 inch (4.6 x 10.2cm), 2.5 x 4.5 inch (6 x 11cm), 2.4 x 5.4 inch (6.1 x 13.7cm), 3 x 6 inch (7.6 x 15cm), 6 x 6 inch (15 x 15cm), and 12 x 12 inch (30 x 30cm).

Made of undyed PROLENE mesh, the ETHICON PROLENE Hernia System was developed for the repair of abdominal wall defects including indirect and direct inguinal hernia defects. This complete, one-piece system is a sterile, preshaped, three-dimensional device constructed of an onlay patch connected by a mesh cylinder to a circular underlay patch. The PROLENE Hernia System, which requires minimal or no sutures for placement, permits posterior repair with the added security of the onlay patch to reduce the likelihood of defect recurrence. When mesh is used in infants or children with future growth potential, however, the surgeon should be aware that this product will not stretch significantly as the patient grows.

The PROLENE Hernia System is available sterile, undyed in three sizes--medium, large, and extended. It is for single use only and may not be resterilized.

Polyglactin 910 Mesh

VICRYL (polyglactin 910) mesh is an absorbable mesh made of a copolymer of glycolide and lactide identical in composition to VICRYL suture. Significant wound support is provided for at least 14 days postoperatively. Approximately 40 percent of tensile strength is retained after 21 days. Absorption is minimal until approximately 42 days and essentially complete between 60 and 90 days. VICRYL mesh is available in knitted and woven 6 x 6-inch (15 x 15cm) and 12 x 12-inch (30 x 30cm) sheets which can be cut to the desired shape. The knitted and woven styles each have their own indications for use. The safety and efficacy of VICRYL mesh in neural and cardiovascular tissue has not been established. VICRYL mesh cannot be resterilized.

Tendon Repair Kits

The ETHICON tendon repair kit has been designed to meet the suture needs of the Bunnell pull-out suture method of tendon repair. The foldout inner packet, which was designed to prevent kinks in the wire, contains:

- One 14-inch-long (35cm) surgical stainless steel suture double armed with straight cutting needles.
- One 8-inch (20cm) surgical steel suture loop attached to a curved TAPERCUT needle.
- One polypropylene button (also available separately, three to a pack).

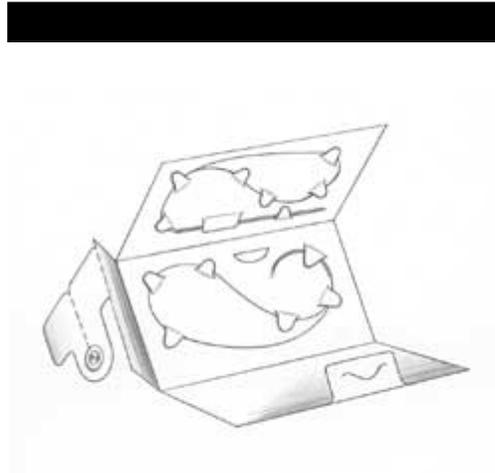


FIG.4

**Ethicon Tendon Repair
Kit**

Temporary Cardiac Pacing Wire

Cardiovascular surgeons generally implant two to four temporary pacing wires to the surfaces of the heart which may be used to pace (stimulate) or monitor the electrical conduction system of the heart. This is done in anticipation of controlling temporary cardiac arrhythmias or low cardiac output syndromes which cannot be adequately controlled by medication. These conditions may be experienced by patients during the first 2 weeks postoperatively. ETHICON temporary cardiac pacing wires are available in 0 and 2-0 gauge multifilament stainless steel suture, 24 inches (60cm) long, with a curved needle swaged on one end and a straight Keith needle swaged on the other end. The suture is coated with a layer of blue polyethylene, leaving a 2 1/2-inch (6cm) section of uncoated wire at the distal end of the suture adjacent to the curved needle. Care should be taken to avoid disrupting the coating or damaging the conductive wire with instruments or when tying knots.

The uninsulated end is sutured to the myocardium using the curved needle. The Keith needle is then passed through the chest wall and the pacing wire firmly attached to the skin. The Keith needle is snapped at the scored point, eliminating the need for any special tools to cut the needle. After breaking, the Keith needle is ready for attachment to an external pacing unit or monitor.

The temporary cardiac pacing wire is meant for *temporary* cardiac pacing or monitoring. It is available in different needle codes to accommodate pediatric and adult patients and satisfy individual surgeon preference. The wires are generally removed on the tenth to fourteenth day postoperatively. Use of the temporary cardiac pacing wire is contraindicated when permanent cardiac pacing or monitoring is required.

Because it can be difficult to distinguish pace wires in the atrial myocardium from those in the ventricle after the chest is closed, a multistrand packet is available that contains two different colored wires to permit differentiation by location.

FIG.4

**Ethicon
Tendon
Repair
Kit**



1. Attach distal end of temporary cardiac pacing wire to myocardium as indicated by surgical requirement and surgeon preference

2. Keith needle is snapped off at score after being passed through the chest wall.

3. Proximal end of wire is ready to connect to temporary unit for pacing or monitoring.

In The Next Section

Wound closure products must be continuously improved to meet the ever-growing demands of modern surgery. The research and development of safer, stronger, more efficacious wound closure materials is addressed in the next section.

References

Johnson P, Fromm D: Effects of bone wax on bacterial clearance, *Surgery* 89(2):206-209, 1981

Barrer S et al: Ideal laparotomy closure: Comparison of retention sutures with new retention bridging devices, *Am Surg* 42:582, 1976

Singer AJ, et al: Prospective, Randomized, Controlled Trial of Tissue Adhesive (2-Octylcyanoacrylate) vs Standard Wound Closure Technique for Laceration Repair, *Acad Emer Med* 5(2):94-99, February 1998

Toriumi DM, et al: Use of Octyl-2-Cyanoacrylate for Skin Closure in Facial Plastic Surgery, *Plas & Recon Surg* 102(6):2209-2219, November 1998

Hunt TK, Dunphy JE (ed): *Fundamentals of Wound Management*, New York: Appleton-Century-Crofts, 1979, p. 438

Myers MB: Sutures and wound healing, *Am J Nurs* 71(9):1726, September 1971

Stone HH et al: Management of acute full-thickness losses of the abdominal wall, *Ann Surg* 193(5):616, May 1981

Research and Development

An Ongoing Process of Change and Improvement

Operative procedures undergo constant change and improvement. Surgical products must therefore be improved continuously to keep pace with the strides being made by surgeons. At ETHICON, INC., the search is unending to develop innovative wound closure products that promote wound healing, and help both the surgeon and mankind. Unceasing efforts are made to provide nurses with the most convenient packaging and presentation of wound closure products for easy handling. Every improvement is for the ultimate benefit of the patient.

Since the development of nylon fibers in the 1940s, scientists have created new polymers to obtain materials with properties not available from natural sources. These new polymers include:

- Polyethylene terephthalate.
- Polypropylene.
- The copolymers of glycolide and lactide.
- The copolymers of caprolactone and glycolide.
- Polydioxanone.

These revolutionary developments have led to beneficial new suture and wound closure materials including MERSILENE polyester fiber suture, PROLENE polypropylene suture, VICRYL (polyglactin 910) suture, PDS II (polydioxanone) suture, and MONOCRYL (poliglecaprone 25) suture.

All new suture and wound closure materials must undergo extensive testing before approval of a marketing application by the FDA (Food and Drug Administration). The two-phase testing process (Preclinical and Clinical Assessments), while time-consuming and expensive, assures that the products are of the highest quality, and meet the strictest standards for safety and efficacy.

Preclinical Assessment

After a potential new suture or wound closure product has passed the manufacturer's own internal Concept and Feasibility Stages, it reaches the Preclinical Screening Phase. At this point, preclinical research test data are accumulated and analyzed. After thorough evaluation, those products which meet or exceed strict international biocompatibility guidelines can proceed to the next testing phase.^{1, 2, 3}

A dedicated group of pathologists, toxicologists, surgeons, veterinarians, and scientists of other disciplines, has been established by ETHICON for the purpose of testing the safety and efficacy of new sutures and other wound closure products. It is an ETHICON policy to use experimental animals to the minimum extent necessary to assess product safety and efficacy. Although *in vitro* systems have contributed to reducing animal use, they cannot obviate the need for animal research. Testing in animals is required to understand the complex interactions between the body's organ systems and materials that comprise surgical devices. Therefore, the use of experimental animals remains an essential element in the conduct of biomedical research and development. The following preclinical testing may be conducted by ETHICON, INC. for new materials that are to be implanted in the body.

Preclinical evaluation of the device is dependent upon exposure assumptions. These include duration of exposure as well as the type of tissue in contact with the medical device. The types of testing considered when evaluating an implantable device may include *in vitro* cytotoxicity; mutagenicity; allergenicity and immunogenicity; pyrogenicity; intracutaneous or mucosal irritation; acute, subacute, and chronic systemic toxicities; carcinogenicity studies; reproductive toxicology; metabolism of absorbable materials; breaking strength retention; tissue reaction and absorption; and surgical efficacy studies. Many of these tests are conducted concurrently.

- **CYTOTOXICITY**--Materials are evaluated *in vitro* for cytotoxic potential using mammalian cells. Materials that elicit a cytotoxic reaction are eliminated or modified prior to development. The results are a good initial indication of suitability of the material to be used for a medical device.
- **MUTAGENICITY**--Extracts of materials from the finished device are evaluated for mutagenic potential. Routine evaluation includes an *in vitro* bacterial cell model, an *in vitro* mammalian cell model, and an *in vivo* mammalian system. The results are evaluated to ensure lack of genotoxicity following subchronic or chronic usage in humans.
- **ALLERGENICITY AND IMMUNOLOGY**--Sutures are implanted and postimplantation humoral antibody responses are measured. Additionally, a series of assays are conducted to evaluate cell-mediated immunity. Any evidence of sensitization or allergenicity is noted.
- **PYROGENICITY**--The suture material is extracted and injected at a high dose level using standard U.S.P. method. The extract is also tested via an *in vitro* test. Pyrogenicity or nonpyrogenicity is determined and device endotoxin levels are strictly controlled.
- **INTRACUTANEOUS OR MUCOSAL IRRITATION**--The irritation potential of the new material is investigated by extraction in nonpolar and solvents. The extracts are injected intracutaneously or applied to the mucous membranes of animals to assess irritation potential. Materials with minimal or no irritation response progress into the next stage of development.
- **ACUTE SYSTEMIC TOXICITY**--Sutures and the suture components are implanted in animals at dose rates exceeding 100 times the estimated human use level. Evaluations include death, clinical observations, body weight changes, and gross observations at necropsy.
- **SUBCHRONIC SYSTEMIC TOXICITY**--The new materials are implanted in animals for up to 30 days. Evaluations include clinical observations; body weight,

clinicopathologic, and organ weight changes; gross observations at necropsy; and subsequent histopathologic observations. Systemic toxicity as well as local tissue reaction at the site of implantation are evaluated.

- **CHRONIC SYSTEMIC TOXICITY**--Materials are implanted at dosage levels that are far above the estimated human use based upon body weight. The same endpoints are measured throughout the duration of the study (12 to 24 months). The studies conclude with gross observations at necropsy and histopathological examination of tissues. Particular attention is given to the local tissue reaction at the site of implantation.
- **CARCINOGENICITY STUDIES**--Materials with favorable results in *in vitro* and *in vivo* mutagenicity evaluations do not typically undergo chronic carcinogenicity studies in animals. If questionable results are obtained during mutagenicity screening evaluation, carcinogenicity studies in rodents may be conducted. These studies involve large numbers of rodents for a study duration of 18 to 24 months with the main endpoints being identification and characterization of tumors.
- **REPRODUCTIVE TOXICOLOGY (ABSORBABLE MATERIALS ONLY)**--Sutures are implanted at many times the estimated human dosage. Rodents are bred following surgical implantation of the device. Gestational suture absorption and systemic levels of degradation products are greatest during the time of fetal organogenesis. Just prior to parturition, animals are euthanatized and malformations are assessed.
- **METABOLISM: DEGRADATION AND EXCRETION OF CARBON-14 LABELED SUTURE (ABSORBABLE MATERIALS ONLY)**--Samples of absorbable suture material are prepared by elaborate, sophisticated synthesis in which the carbon atoms are replaced by radioactive carbon-14. These radiolabeled sutures are then implanted. The excretion profile is determined by evaluating the carbon-14 activity in urine, feces, and exhaled carbon dioxide for the entire degradation period. Subjects are euthanatized at predetermined intervals, and the carbon-14 activity recovered from the implant sites provides a direct estimation of the amount absorbed. In addition, the radioisotope activity from the body organs is determined.

This analysis is designed to evaluate:

1. Whether the suture is completely absorbed.
 2. Whether the metabolic products of the degradation of the absorbable suture are readily excreted.
 3. The route of excretion of the metabolic products.
 4. The distribution of degradation products to various organs.
- **BREAKING STRENGTH RETENTION**--Various sizes of sutures are implanted subcutaneously. Following *in vivo* residence for periods of 1, 2, 3, 4, 6, and 8 weeks, the suture strands are recovered and tested on an Instron Universal Testing Unit. The average breaking strength is calculated as the percentage of the original unimplanted strength.
 - **BREAKING STRENGTH RETENTION (INFECTED WOUND)**--A study similar to the one described above is performed using sutures that have been purposely contaminated. Infection at the site of implantation and its effect on breaking strength retention is determined.
 - **TISSUE REACTION AND ABSORPTION**--Over 3,400 implant sites are evaluated at various postimplantation periods. Tissue reaction is assessed by histopathologic examination. Absorption, if any, is determined by measuring histologic cross- sections of

suture at the implantation site. Tissue response and suture absorption rate may also be studied in ocular tissue.

- **SURGICAL EFFICACY STUDIES**--The surgical efficacy of suture materials is evaluated in numerous animal studies which demonstrate functional performance in a wide range of surgical procedures.

Clinical Assessment

This phase involves human research, and includes similar requirements for the accumulation and thorough analysis of data. Potential new products that successfully complete this phase may receive marketing application approval by the FDA. It is then up to the manufacturer to bring the new product to market. When changes are made to an existing suture product, such as the addition of a coating or dye, rigorous testing is conducted to confirm that the product remains safe and effective.

Results

Results from the extensive preclinical and clinical studies are evaluated by ETHICON, INC. and reviewed by independent experts. Marketing approval for every material is based upon proof that the product is safe and effective for its intended clinical use. Such careful and exhaustive testing is necessary to be absolutely certain that every new product is safe and effective in adequately maintaining wound support. ETHICON researchers are continuing to extensively evaluate, in the same manner, the new wound closure products of the future.⁴

References

International Standard ISO-10993. Biological Evaluation of Medical Devices. Part 1: Evaluation and Testing. General Program Memorandum #G95-1, Department of Health and Human Services, Office of Device Evaluation, May 1995.

Guideline for Basic Biological Tests of Medical Materials and Devices. Japan Ministry of Health and Welfare, 1995.

Levy AJ: Testing new suture materials, Point of View, 19(2):15, April 1982

Product Terms and Trademarks

Product Terms and Trademarks: ABS - DEC

ABSORBABLE SUTURE

Sutures which are broken down and eventually absorbed by either hydrolysis (synthetic absorbable sutures) or digestion by lysosomal enzymes elicited by white blood cells (surgical gut and collagen).

APPROXIMATE

Bring together sides or edges.

ATRALOC SURGICAL NEEDLES

ETHICON Trademark for eyeless needles permanently attached (swaged) to suture strands.

BONE WAX

Sterile mixture of beeswax and isopropyl palmitate used to achieve local hemostasis of bone by acting as a mechanical barrier.

B & S GAUGE

Brown and Sharpe gauge commonly used in hospitals to identify wire diameter. ETHICON stainless steel suture products are labeled with both B & S gauge and U.S.P. size.

BURIED SUTURE

Any stitch made and tied so that it remains completely under the surface.

CALCIFIED CORONARY NEEDLE (CC)

A TAPERCUT surgical needle with a $\frac{1}{16}$ " cutting tip and slim taper ratio for significant ease of penetration when suturing tough valve cuffs or atherosclerotic vessels.

CARDIOVASCULAR SUTURES

Swaged sutures designed to meet the specific needs of heart and blood vessel surgery.

CATGUT

Outmoded term for surgical gut.

CHROMIC SURGICAL GUT

Gut suture which has been treated by chromium salts to resist digestion by lysosomal enzymes.

CHROMICIZING ETHICON

process for producing chromic gut. Each ribbon of surgical gut is bathed in a chromium salt solution before spinning into strands to provide uniform controlled absorption.

COATED VICRYL (POLYGLACTIN 910) SUTURE ETHICON

Trademark for synthetic absorbable suture extruded from a copolymer of glycolide and lactide and coated with a mixture of polyglactin 370 and calcium stearate.

COATED VICRYL RAPIDE (POLYGLACTIN 910) SUTURE ETHICON

trademark for braided, rapidly absorbing synthetic suture extruded from a copolymer of glycolide and lactide and coated with a mixture of polyglactin 370 and calcium stearate.

COBALT 60

Source of irradiation used by ETHICON, INC., to sterilize some suture materials. Also used in hospitals to treat some cancer patients.

COMPOUND CURVED NEEDLE

Needle that incorporates two curvatures in one needle: a tight curve at the tip, and a more gradual curve through the body. Used for precise positioning of sutures for corneal/scleral closure and for skin suturing.

CONTAMINATE

To cause a sterile object or surface to become unsterile.

CONTINUOUS SUTURE TECHNIQUE

Single suture strand passed back and forth between the two edges of the wound to close a tissue layer; tied only at each end of the suture line.

CONTROL RELEASE NEEDLE ETHICON

Trademark for swaging method which permits fast and controlled separation of the needle from the suture material.

CONVENTIONAL CUTTING NEEDLE

Needle with triangular point and cutting edge along inner curvature of needle body.

CORNEAL BEADED

RETRACTION SUTURE

Swaged suture strand with a small bead of epoxy used to elevate cornea for placement of intraocular lens.

CS ULTIMA OPHTHALMIC NEEDLE (CS) ETHICON

Trademark for needle with reduced side edge angles providing excellent penetration necessary for ophthalmic surgery. Design facilitates knot rotation during surgery. Trademark for needle with reduced side edge angles providing excellent penetration necessary for ophthalmic surgery. Design facilitates knot rotation during surgery.

CUTICULAR SUTURES

Sutures designed for skin closure.

DEAD SPACE

Pockets left in a tissue layer when tissues are not in close approximation.

DECONTAMINATION

Process used to destroy microorganisms known or thought to be present on a surface or object.

Product Terms and Trademarks: DEH - HEM

DEHISCENCE

Total or partial separation of wound edges.

DERMABOND TOPICAL SKIN ADHESIVE (2-OCTYL CYANOACRYLATE) ETHICON

trademark for sterile, liquid topical skin adhesive for approximation of wound edges of trauma-induced lacerations or surgical incisions.

DISPENSER BOXES

Gravity-fed vertical or horizontal boxes that readily dispense wound closure products. Labels on boxes include product information.

DOUBLE-ARMED SUTURE

Suture strand with a needle swaged at each end

EASY ACCESS PACKAGING

ETHICON trademark for patented delivery system that presents the needle in position for immediate arming in the needleholder as soon as the primary packet is opened. trademark for patented delivery system that presents the needle in position for immediate arming in the needleholder as soon as the primary packet is opened.

ELECTROSURGERY Controlled use of high frequency electric current for surgical cutting and coagulation. Controlled use of high frequency electric current for surgical cutting and coagulation.

E-PACK PROCEDURE KIT

ETHICON

trademark for single overwrapped organizer tray containing multiple **ETHICON** suture products. Each E-PACK kit may be customized with choice of sutures for specific procedures or surgeon preferences.

ETHALLOY NEEDLE ALLOY ETHICON

trademark for exclusive patented stainless steel alloy that is 40 percent stronger than needles made of 300 Series stainless steel. trademark for exclusive patented stainless steel alloy that is 40 percent stronger than needles made of 300 Series stainless steel.

Provides improved tissue penetration, smoother needle-to-suture transition, and better flow through tissue.

ETHIBOND EXCEL POLYESTER SUTURE ETHICON

trademark for braided polyester suture coated with polybutylate coating.

ETHICON WOUND CLOSURE PRODUCTS

The brand name for products manufactured by **ETHICON, INC.**

The name was first used in 1926 by Johnson & Johnson.

ETHIGUARD BLUNT POINT

NEEDLE ETHICON trademark for specially designed needle which has a rounded tip.

ETHILON NYLON SUTURE ETHICON

trademark for sutures made of monofilament nylon.

ETHI-PACK PRE-CUT SUTURE ETHICON

trademark for pre-cut strands of nonabsorbable sutures without needles, sterile and nonsterile.

ETHYLENE OXIDE GAS

Chemical agent used to sterilize some suture materials.

EVISGERATION

Protrusion of bowel through separated edges of abdominal wound closure.

EXPIRATION DATE

Date on a suture product representing the time through which satisfactory stability studies have been carried out. As such studies are continued, the expiration date may be extended.

EXTRUSION OF KNOTS, KNOT EXTRUSION, OR "SPITTING"

Attempt by the human body to rid itself of nonabsorbable sutures or absorbable sutures which are not completely absorbed ("foreign bodies"). Suture knots encapsulated by cells may work their way to the skin surface months or even years after surgery.

FASCIA

Areolar tissue layers under the skin (superficial fascia) or fibrous tissue between muscles and forming the sheaths of muscles or investing other structures such as nerves or blood vessels (deep fascia).

FDA

Abbreviation for federal Food and Drug Administration.

GASTROINTESTINAL SUTURES

Sutures designed for use in anastomosis of bowel and stomach surgery.

GAUGE

Term used to express diameter of suture strand.

GENERAL CLOSURE SUTURES

Sutures used in closing fascia, particularly in the abdominal wall. Also for hernia repair and other fascial defects. Sutures used in closing fascia, particularly in the abdominal wall. Also for hernia repair and other fascial defects.

GENTLE BEND* PACKAGE

ETHICON

trademark for packaging designed to deliver monofilament **PROLENE*** polypropylene suture to the surgical field in a straight usable form.

HEMO-SEAL NEEDLE SUTURE ETHICON

trademark for a needle/suture combination manufactured using a swaging method that provides a smoother needle-to-suture transition. Beneficial in reducing leakage from the suture line, especially in cardiovascular procedures.

Product Terms and Trademarks: HEM - MON

HEMOSTASIS

The arrest of bleeding.

HYDROLYSIS

Chemical process whereby a compound or polymer reacts with water to cause an alteration or breakdown of the molecular structure. Synthetic absorbable sutures are degraded in vivo by this mechanism.

INFECTION

Invasion of body tissue by a pathogen

INSTANT COLLAGEN

ABSORBABLE HEMOSTAT ETHICON

trademark for a sterile absorbable sponge-like pad of purified, lyophilized bovine dermal collagen. Used as an adjunct for the control of bleeding in an operative site.

INSTANT MCH

MICROFIBRILLAR COLLAGEN HEMOSTAT ETHICON

trademark for a sterile absorbable hemostatic agent in a microfibrillar form obtained from bovine deep flexor tendon (achilles tendon). Used as an adjunct for the control of bleeding in an operative site.

INTERRUPTED SUTURE TECHNIQUE |

Single stitches separately placed, tied, and cut. Single stitches separately placed, tied, and cut.

KEITH NEEDLE (KS)

Straight needle with cutting edges, used primarily for abdominal skin closure. Named for a Scottish surgeon, Dr. Thomas Keith, who made the needle popular.

KINK

Undesirable deformation of a strand, such as a sharp bend in wire.

LABYRINTH PACKAGE ETHICON

trademark for unique package that dispenses straight, kinkfree, pre-cut nonabsorbable sutures. trademark for unique package that dispenses straight, kinkfree, pre-cut nonabsorbable sutures.

LIGAPAK DISPENSING REEL ETHICON

trademark for dislike plastic reel that contains and dispenses suture for ligation.

LIGAPAK LIGATURE ETHICON trademark for a length of suture material wound on a reel, primarily used for ligating

LIGATING REEL

Tube, plastic disc, or other device from which continuous ligating material is unwound as blood vessels are tied.

LIGATURE

Strand of material used to tie off a blood vessel

LOOPED SUTURE

Single strand of suture material with both ends swaged onto a single needle.

MERSILENE POLYESTER FIBER MESH ETHICON

trademark for machine-knitted fabric which is used in hernia repair and other fascial deficiencies that require addition of a reinforcing or bridging material.

MERSILENE POLYESTER FIBER STRIP/TAPE ETHICON

trademark for a flat band 5mm wide. Useful as a cerclage ligature in patients with an incompetent cervix. Also used for bladder support or repair and support of the rotator cuff in the shoulder.

MERSILENE POLYESTER FIBER SUTURE ETHICON

Trademark for uncoated braided nonabsorbable suture material made of polyester polymer.

MICRO-POINT SPATULA NEEDLE ETHICON

trademark for side-cutting ophthalmic needles which are thin and flat in profile and specially honed for exceptional sharpness.

MICRO-POINT SURGICAL NEEDLE ETHICON

trademark for ophthalmic needles which are honed and polished to an extremely fine finish and sharpness.

MICROSURGERY SUTURES

Sutures for surgeries in which an operating microscope may be used to visualize the very small structures involved, e.g., blood vessels and nerves

MIL

Unit of linear measurement, equivalent to 0.001 inch. Frequently used to express wire diameter of surgical needles.

MODULAR SUTURE STORAGE RACK

Plastic modules of expandable interlocking units that provide neat, convenient storage of ETHICON suture dispenser boxes.

MONOCRYL

(POLIGLECAPRONE 25)

SUTURE

ETHICON trademark for monofilament synthetic absorbable suture prepared from a copolymer of glycolide and ε-caprolactone.

Product Terms and Trademarks: MON-POW

PRECISION COSMETIC NEEDLE (PC)

Conventional cutting needles specially polished and carefully honed for aesthetic plastic surgery.

PRECISION POINT NEEDLE

Reverse-cutting needles specially polished and carefully honed for plastic surgery.

PRE-CUT SUTURES

Strands of suture material packaged pre-cut into various lengths.

PRIMARY PACKET

Suture packet which contains the sterile suture.

PRIMARY WOUND CLOSURE

The approximation of wound edges to facilitate rapid healing.

PRODUCT CODE

Numbers or combination of letters and numbers which identify a specific product.

PROLENE POLYPROPYLENE

HERNIA SYSTEM ETHICON

trademark for a sterile, pre-shaped, three-dimensional device constructed of an onlay patch connected by a mesh cylinder to a circular underlay patch. Used for the repair of indirect and direct inguinal hernia defects.

PROLENE POLYPROPYLENE MESH

ETHICON trademark for mesh made of polypropylene which is knitted by a process which interlinks each fiber juncture. Used for the repair of abdominal wall defects and tissue deficiencies.

PROLENE POLYPROPYLENE SUTURE

ETHICON trademark for synthetic nonabsorbable suture material made of monofilament polypropylene.

PROLENE POLYPROPYLENE MESH ETHICON

trademark for mesh made of polypropylene which is knitted by a process which interlinks each fiber juncture. Used for the repair of abdominal wall defects and tissue deficiencies.

PROLENE POLYPROPYLENE SUTURE ETHICON

trademark for synthetic nonabsorbable suture material made of monofilament polypropylene.

PRONOVA

POLY(HEXAFLUOROPROPYLENE-VDF) SUTURE ETHICON

trademark for synthetic nonabsorbable suture material made of a polymer blend of poly(vinylidene fluoride) and poly(vinylidene fluoride-cohexafluoropropylene).

PROXI-STRIP SKIN CLOSURES ETHICON

trademark for adhesive strips used for skin closure.

RELAY SUTURE DELIVERY SYSTEM

ETHICON trademark for the packaging of single strand and multi-strand sutures. Provides delivery of one suture at a time, one-step arming, individual needle parks, and straight, tangle-free sutures ready for use.

RETENTION SUTURE BOLSTERS

Surgical tubing used to sheath retention sutures to prevent cutting the skin. Also known as "Booties."

RETENTION SUTURE BRIDGE

Clear plastic device designed with a capstan to permit postoperative wound management by adjusting the tension of retention sutures, preventing suture crosshatching on the skin.

REVERSE CUTTING NEEDLE

Needles produced by ETHICON, INC., which have triangular shape throughout their entire length and cutting edge along the outside needle curvature to prevent tissue cutout.

RIBBED NEEDLE

Needles with longitudinal grooves on the inner and outer flattened curvatures. Ribs engage the needleholder jaw and help to minimize movement of the needle in the needleholder.

SABRELOC SPATULA NEEDLE ETHICON

trademark for ophthalmic needles. Side-cutting spatula-shaped edges separate the ultrathin layers of scleral or corneal tissue without cutting through.

SAFETY ORGANIZER TRAY ETHICON

design for a suture tray which delivers multi-strand products. Offers single strand delivery, and a singulated needle park which permits one-step arming and tangle-free straight suture strands.

SECONDARY CLOSURE

Retention sutures placed approximately 2 inches from wound edges to reinforce primary closure and protect it from stress.

SIDE-FLATTENED NEEDLES

Configuration of stainless steel alloy needles designed to increase strength and reduce bending when penetrating vascular prostheses or calcified tissues.

SINGLE STRAND DELIVERY

Terminology used to describe the delivery of one straight suture at a time from the RELAY suture delivery system.

STERILE

Free of living microorganisms (bacteria and their spores, viruses, etc.).

Product Terms and Trademarks: PRE-STE

PRECISION COSMETIC NEEDLE (PC)

Conventional cutting needles specially polished and carefully honed for aesthetic plastic surgery.

PRECISION POINT NEEDLE

Reverse-cutting needles specially polished and carefully honed for plastic surgery.

PRE-CUT SUTURES

Strands of suture material packaged pre-cut into various lengths.

PRIMARY PACKET

Suture packet which contains the sterile suture.

PRIMARY WOUND CLOSURE

The approximation of wound edges to facilitate rapid healing.

PRODUCT CODE

Numbers or combination of letters and numbers which identify a specific product.

PROLENE POLYPROPYLENE

HERNIA SYSTEM ETHICON

trademark for a sterile, pre-shaped, three-dimensional device constructed of an onlay patch connected by a mesh cylinder to a circular underlay patch. Used for the repair of indirect and direct inguinal hernia defects.

PROLENE POLYPROPYLENE MESH

ETHICON trademark for mesh made of polypropylene which is knitted by a process which interlinks each fiber juncture. Used for the repair of abdominal wall defects and tissue deficiencies.

PROLENE POLYPROPYLENE SUTURE

ETHICON trademark for synthetic nonabsorbable suture material made of monofilament polypropylene.

PROLENE POLYPROPYLENE MESH ETHICON

trademark for mesh made of polypropylene which is knitted by a process which interlinks each fiber juncture. Used for the repair of abdominal wall defects and tissue deficiencies.

PROLENE POLYPROPYLENE SUTURE ETHICON

trademark for synthetic nonabsorbable suture material made of monofilament polypropylene.

PRONOVA

POLY(HEXAFLUOROPROPYLENE-VDF) SUTURE ETHICON

trademark for synthetic nonabsorbable suture material made of a polymer blend of poly(vinylidene fluoride) and poly(vinylidene fluoride-cohexafluoropropylene).

PROXI-STRIP SKIN CLOSURES ETHICON

trademark for adhesive strips used for skin closure.

RELAY SUTURE DELIVERY SYSTEM

ETHICON trademark for the packaging of single strand and multi-strand sutures. Provides delivery of one suture at a time, one-step arming, individual needle parks, and straight, tangle-free sutures ready for use.

RETENTION SUTURE BOLSTERS

Surgical tubing used to sheath retention sutures to prevent cutting the skin. Also known as "Booties."

RETENTION SUTURE BRIDGE

Clear plastic device designed with a capstan to permit postoperative wound management by adjusting the tension of retention sutures, preventing suture crosshatching on the skin.

REVERSE CUTTING NEEDLE

Needles produced by ETHICON, INC., which have triangular shape throughout their entire length and cutting edge along the outside needle curvature to prevent tissue cutout.

RIBBED NEEDLE

Needles with longitudinal grooves on the inner and outer flattened curvatures. Ribs engage the needleholder jaw and help to minimize movement of the needle in the needleholder.

SABRELOC SPATULA NEEDLE ETHICON

trademark for ophthalmic needles. Side-cutting spatula-shaped edges separate the ultrathin layers of scleral or corneal tissue without cutting through.

SAFETY ORGANIZER TRAY ETHICON

design for a suture tray which delivers multi-strand products. Offers single strand delivery, and a singulated needle park which permits one-step arming and tangle-free straight suture strands.

SECONDARY CLOSURE

Retention sutures placed approximately 2 inches from wound edges to reinforce primary closure and protect it from stress.

SIDE-FLATTENED NEEDLES

Configuration of stainless steel alloy needles designed to increase strength and reduce bending when penetrating vascular prostheses or calcified tissues.

SINGLE STRAND DELIVERY

Terminology used to describe the delivery of one straight suture at a time from the RELAY suture delivery system.

STERILE

Free of living microorganisms (bacteria and their spores, viruses, etc.).

Product Terms and Trademarks: STE-TUB

STERILE TECHNIQUE

Collectively, all the efforts made and procedures followed to exclude microorganisms from the operative wound and field.

STERILIZATION

Process by which all living microorganisms on an object are destroyed.

SUPER-SMOOTH FINISH

An exclusive process that provides a finish on most ETHICON needles, enabling the needles to penetrate and pass through the toughest tissue with minimal resistance.

SURGICAL GUT

Absorbable suture made from serosal layer of beef intestine or submucosal layer of sheep intestine.

SURGICAL STAINLESS STEEL SUTURE

Nonabsorbable suture made of 316L steel alloy.

SURGICEL/SURGICEL NU-KNIT/SURGICEL/ FIBRILLAR ABSORBABLE HEMOSTAT (OXIDIZED REGENERATED CELLULOSE) ETHICON

trademark for a sterile absorbable knitted fabric prepared by the controlled oxidation of cellulose. Used as an adjunct for the control of bleeding in an operative site.

SUTUPAK PRE-CUT STERILE SUTURES ETHICON

trademark for packet containing multiple pre-cut lengths of suture material without needles, sterile and ready for immediate use.

SUTURE

Material used to approximate (sew) tissues or tie off (ligate) blood vessels.

SUTURE BOOK

Sterile towel folded by the scrub person and used to contain multiple sutures.

SWAGED SUTURE

Strand of material with eyeless needle attached by the manufacturer.

TAPERCUT SURGICAL NEEDLE ETHICON

trademark for a needle which has a $\frac{1}{16}$ triangular tip with three cutting edges. Remainder of needle has a gradually tapered body.

TAPER POINT NEEDLE (TP)

Needle with a body that gradually tapers to a sharp point, making the smallest possible hole in tissue.

TEMPORARY CARDIAC PACING WIRE

Multifilament stainless steel suture coated with polyethylene, with curved needle swaged to the distal end and a scored straight needle to the other. Used in temporary cardiac pacing or monitoring.

TENDON REPAIR KIT An ETHICON

product which includes a pull-out wire set and a polypropylene button in a single packet. Components are appropriate for use in the Bunnell technique of tendon repair.

TENSILE STRENGTH

Amount of tension or pull, expressed in pounds, which a suture strand will withstand before it breaks.

TIES (LIGATURES)

Strands of suture used to tie off the ends of severed blood vessels: free or freehand--single strands used as individual ties; continuous--

long strands unwound from a reel or other device as blood vessels are tied; suture ligature--strand on a needle used to transfix (suture) a large blood vessel to ensure security against knot slippage; stick tie--a suture ligature or a single strand handed to surgeon for ligating with a hemostat clamped on one suture end; transfixion suture--suture ligature.

THROMBOGEN TOPICAL THROMBIN, U.S.P. (BOVINE ORIGIN)

ETHICON trademark for a sterile protein powder produced through a conversion reaction in which prothrombin of bovine origin is activated by tissue thromboplastin in the presence of calcium chloride.

Used as an adjunct for the control of bleeding in an operative site.

TRANSVERSE GROUND NEEDLES (TG)

Spatulated ophthalmic needles specially honed to a long, sharp, slim tip.

TRU-GAUGING ETHICON

process which ensures uniform diameter and uniformly higher tensile strength of surgical gut.

TRU-PERMANIZING ETHICON process of treating silk for noncapillarity.

TUBING FLUID

Solution inside packets of surgical gut and collagen. Purpose is to maintain material (and needle, if attached) in optimum condition for immediate use upon withdrawal from the packet.

Product Terms and Trademarks: UMB-WOU

UMBILICAL TAPE

Woven cotton tape, classified as a ligature, used as a gentle means of retracting vessels in cardiovascular and pediatric surgery and for tying off the umbilicus of the newborn.

UROLOGICAL SUTURES

Sutures designed to meet the needs of surgery performed by urologists. Features 5/8 circle needles which turn out of tissue quickly.

VICRYL (POLYGLACTIN 910) MESH

ETHICON trademark for mesh prepared from a copolymer of glycolide and lactide. An absorbable material used as a buttress to provide temporary support during healing.

VICRYL (POLYGLACTIN 910) PERIODONTAL MESH

ETHICON trademark for mesh prepared from a copolymer of glycolide and lactide. An absorbable material used in periodontal surgery for guided tissue regeneration.

VISI-BLACK SURGICAL NEEDLES

ETHICON trademark for surgical needles with a black surface finish to enhance visibility in the operative site.

WOUND DISRUPTION

Separation of wound edges.

References

- Abidin MR et al: Metallurgically bonded needle holder jaws, *Am Surg* 56(10):643-647, October 1990
- American College of Surgeons, Altemeier WA, et al (eds): *Manual on Control of Infection in Surgical Patients*, Philadelphia: Lippincott, 1976
- Amshel AL: The use of Vicryl (polyglactin 910) sutures in colonic and rectal surgery, *Dis Col & Rect* 20(7):635-638, October 1977
- Artandi C: Industrial sterilization, *Point of View* 16(2):14-15, April 1979
- Barrer S et al: Ideal laparotomy closure: Comparison of retention sutures with new retention bridging devices, *Am Surg* 42:582, 1976
- Blaydes JE, Berry J: Comparative evaluation of coated and uncoated polyglactin 910 in cataract and muscle surgery, *Ophth Surg* 11(11):790-793, November 1980
- Chu CC, Williams DF: Effects of physical configuration and chemical structure of suture material on bacterial adhesion, *Am J Surg* 147:197-204, February 1984
- Chusak RB, Dibbell DG: Clinical experience with polydioxanone monofilament absorbable sutures in plastic surgery, *Plas & Recon Surg* 72(2):217-220, August 1983
- Craig PH, et al: A biologic comparison of polyglactin 910 and polyglycolic acid synthetic absorbable sutures, *Surg Gyn & Obs* 14(1):1-10, July 1975
- Cruse P, Foorde R: The epidemiology of wound infection, *Surg Clin NA* 60(1): 27-40, 1980
- Davis JH: *Clinical Surgery*, CV Mosby Co., 1987
- Dineen P: The effect of suture material in the development of vascular infection. *Vasc Surg* 11(1):29-32, January/February 1977
- Durdey P, Bucknall TE: Assessment of sutures for use in colonic surgery: An experimental study, *J Royal Society of Med* 77:472-477, June 1984
- Edlich RF et al: Scientific basis for selecting surgical needles and needle holders for wound closure, *Clin Plastic Surg* 17(3):583-601, July 1990
- Gottrup F: *Acta Chir Scand* 149:57, 1983
- Herrman JB: Tensile strength and knot security of surgical suture materials, *Am Surg* 37:211, April 1971
- Houdart R et al: Polydioxanone in digestive surgery, *Am J Surg* 152:268-271, September 1986
- Hunt TK, Dunphy JE (ed): *Fundamentals of Wound Management*, New York: Appleton-Century-Crofts, 1979, p. 438
- Hunter P: 10-0 Vicryl suture offers alternative to no stitch, *Ocular Surg News* 9(16): August 15, 1991
- Johnson P, Fromm D: Effects of bone wax on bacterial clearance, *Surgery* 89(2):206-209, 1981
- Kenady DE: Management of abdominal wounds. *Surg Clin NA* 64(4):803-806, 1984
- Kohn ML: Sterile transfer--to flip or not to flip, *Point of View* 16(2):16, April 1979
- Kronenthal RL: Intraocular degradation of nonabsorbable sutures, *Amer Intra-Ocular Implant Soc J* 3:222-228, July/October 1977
- Levy AJ: Testing new suture materials, *Point of View*, 19(2):15, April 1982
- Lo Piccolo M (ed): Mersilene suture results found comparable to nylon, *Ophthalmology Times*:18, August 15, 1988
- McCullum CN, Kester RC: A sliding suture technique for inaccessible arterial anastomoses, *Surg Gynecol Obstet* 153(6):907, 1981
- Murray DH, Blaisdell FW: Use of synthetic absorbable sutures for abdominal and chest wound closure, *Arch Surg* 113:477-480, April 1978
- Myers MB: Sutures and wound healing, *Am J Nurs* 71(9):1726, September 1971
- Nealon TF: *Fundamental Skills in Surgery*, 3d ed, Philadelphia: Saunders, 1979, p. 47
- Pfeffer WH: How to choose sutures for microsurgery, *Contemporary OB/GYN*:1-5, November 1983
- Quinn J, et al: A randomized trial comparing octylcyanoacrylate tissue adhesive and sutures in the management of lacerations, *J Am Med Assn* 277(19):1527-1530, May 21, 1997
- Singer AJ, et al: Prospective, Randomized, Controlled Trial of Tissue Adhesive (2-Octylcyanoacrylate) vs Standard Wound Closure Technique for Laceration Repair, *Acad Emer Med* 5(2):94-99, February 1998
- Stone HH et al: Management of acute full-thickness losses of the abdominal wall, *Ann Surg* 193(5):616, May 1981
- Taylor EJ et al (ed): *Dorland's Medical Dictionary*, Philadelphia: Saunders, 1988
- Tera H, Aberg C: Tissue holding power to a single suture in different parts of the alimentary tract, *Acta Chir Scand* 142:343-348, 1976
- Thacker JG et al: Surgical needle sharpness, *Am J Surg* 157:334-339, March 1989
- Toriumi DM, et al: Use of Octyl-2-Cyanoacrylate for Skin Closure in Facial Plastic Surgery, *Plas & Recon Surg* 102(6):2209-2219, November 1998
- Towler MA et al: Laser-drilled cardiovascular surgical needles, *J Appl Biomaterials* 2:183-186, 1991

Trier WC: Considerations in the choice of surgical needles, *Surg Gynecol Obstet* 149:84, 1979

Troutman RC, McGregor W: New compound curved needle TG6-C Plus, *Ophthalmology, Instrument and Book Suppl* 92(8):84-86, 1985

Vallors B, et al: Absorbable or Nonabsorbable Suture Materials for Closure of the Dura Mater?, *Neurosurgery* 9(4):407-413, 1981

VanWinkle Jr W: Epithelization and wound contraction, In *Symposium on Basic Science in Plastic Surgery* (Krizek TJ, Hoopes JE, eds). Mosby, St. Louis 1976, p. 87

VanWinkle Jr W: The healing of skin and visceral wounds and the effect of suture materials, In *Symposium on Basic Science in Plastic Surgery* (Krizek TJ, Hoopes JE, eds). Mosby, St. Louis 1976, p. 135

VanWinkle Jr W, Hastings JC: Considerations in the choice of suture material for various tissues, *Surg Gyn & Obs* 135:113-126, July 1972

Product Information

Surgical Gut Suture

ABSORBABLE SURGICAL SUTURES, U.S.P.

DESCRIPTION

Surgical gut suture is an absorbable, sterile surgical suture composed of purified connective tissue (mostly collagen) derived from either the serosal layer of beef (bovine) or the submucosal fibrous layer of sheep (ovine) intestines. Surgical gut sutures are available in plain or chromic. Chromic gut is processed to provide greater resistance to absorption. Surgical gut is packaged in tubing fluid. Blue dyed chromic gut suture is also available. Surgical gut suture meets all requirements established by the United States Pharmacopeia (U.S.P.) for absorbable surgical sutures.

INDICATIONS

Surgical gut suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological tissues.

ACTIONS

When surgical gut suture is placed in tissue, a moderate tissue inflammation occurs which is characteristic of foreign body response to a substance. This is followed by a loss of tensile strength and a loss of suture mass, as the proteolytic enzymatic digestive process dissolves the surgical gut. This process continues until the suture is completely absorbed. Many variable factors may affect the rate of absorption. Some of the major factors which can affect tensile strength loss and absorption rates are:

1. Type of suture - plain gut generally absorbs more rapidly than chromic gut.
2. Infection - surgical gut is absorbed more rapidly in infected tissue than in non-infected tissue.
3. Tissue sites - surgical gut will absorb more rapidly in tissue where increased levels of proteolytic enzymes are present, as in the secretions exhibited in the stomach, cervix and vagina.

CONTRAINDICATIONS

This suture, being absorbable, should not be used where extended approximation of tissue is required. The use of this suture is contraindicated in patients with known sensitivities or allergies to collagen or chromium, as gut is a collagen based material, and chromic gut is treated with chromic salt solutions.

WARNINGS

Users should be familiar with surgical procedures and techniques involving gut suture before using surgical gut suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used. Physicians should consider the in vivo performance when selecting a suture. The use of this suture may be inappropriate in elderly, malnourished, or debilitated patients, or in patients suffering from conditions which may delay wound healing. As this is an absorbable material, the use of supplemental nonabsorbable sutures

should be considered by the surgeon in the closure of sites which may undergo expansion, stretching or distention or which may require additional support. As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. As an absorbable suture, surgical gut may act transiently as a foreign body. Acceptable surgical practice should be followed for the management of contaminated or infected wounds. Do not resterilize. Discard open packages and unused sutures. Certain patients may be hypersensitive to collagen or chromium and might exhibit an immunological reaction resulting in inflammation, tissue granulation or fibrosis, wound suppuration and bleeding, as well as sinus formation.

PRECAUTIONS

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders. Surgical gut sutures require the accepted surgical technique of flat and square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon. Under some circumstances, notably orthopaedic procedures, immobilization of joints by external support may be employed at the discretion of the surgeon. The surgeon should avoid unnecessary tension when running down knots, to reduce the occurrence of surface fraying and weakening of the strand. Avoid prolonged exposure to elevated temperatures. To avoid damaging needle points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, variable rates of absorption over time (depending on such factors as the type of suture used, the presence of infection and the tissue site), failure to provide adequate wound support in closure of sites where expansion, stretching or distension occur, etc., unless additional support is supplied through the use of nonabsorbable suture material, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from cancer, anemia, obesity, diabetes, infection or other conditions which may delay wound healing, allergic response in patients with known sensitivities to collagen or chromium which may result in an immunological reaction resulting in inflammation, tissue granulation or fibrosis, wound suppuration and bleeding, as well as sinus formation, infection, moderate tissue inflammatory response characteristic of foreign body response, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

HOW SUPPLIED

Surgical gut sutures are available in U.S.P. sizes 7-0 through 3 (metric sizes 0.7-7.0) in a variety of lengths with and without permanently attached needles and on LIGAPAK dispensing reels. Surgical gut sutures are also available in U.S.P. sizes 0 through 1 (metric sizes 4.0-5.0) attached to CONTROL RELEASE removable needles. The suture is supplied sterile in one, two and three dozen boxes.

Fast Absorbing Surgical Gut (Plain)

ABSORBABLE SURGICAL SUTURES, U.S.P.

DESCRIPTION

Fast absorbing surgical gut suture is a strand of collagenous material prepared from the submucosal layers of the small intestine of healthy sheep, or from the serosal layers of the small intestine of healthy cattle. Fast absorbing surgical gut sutures are sterile and elicit only a slight to minimal tissue reaction during absorption. Fast absorbing surgical gut sutures differ from U.S.P. minimum strength requirements by less than 30%.

INDICATIONS

Fast absorbing surgical gut sutures are intended for dermal (skin) suturing only. They should be utilized only for external knot tying procedures.

ACTIONS

The results of implantation studies of fast absorbing surgical gut sutures in the skin of animals indicate that nearly all of its original strength is lost within approximately seven (7) days of implantation. When surgical gut suture is placed in tissue, a moderate tissue inflammation occurs which is characteristic of foreign body response to a substance. This is followed by a loss of tensile strength and a loss of suture mass, as the proteolytic enzymatic digestive process dissolves the surgical gut. This process continues until the suture is completely absorbed. Many variable factors may affect the rate of absorption. Some of the major factors which can affect tensile strength loss and absorption rates are:

1. Type of suture - plain gut generally absorbs more rapidly than chromic gut.
2. Infection - surgical gut is absorbed more rapidly in infected tissue than in non-infected tissue.
3. Tissue sites - surgical gut will absorb more rapidly in tissue where increased levels of proteolytic enzymes are present, as in the secretions exhibited in the stomach, cervix and vagina.

Data obtained from implantation studies in rats show that the absorption of these sutures is essentially complete by the twenty-first (21st) to forty-second (42nd) post implantation day.

CONTRAINDICATIONS

This suture, being absorbable, should not be used where extended approximation of tissue is required. These sutures have been designed to absorb at a rapid rate and must be used on dermal tissue only. These sutures should never be used on internal tissue. The use of this suture is contraindicated in patients with known sensitivities or allergies to collagen, as gut is a collagen based material.

WARNINGS

Users should be familiar with surgical procedures and techniques involving gut suture before using fast absorbing surgical gut suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used. Physicians should consider the in vivo performance when selecting a suture for use in patients. The use of this suture may be inappropriate in elderly, malnourished, or debilitated patients, or in patients suffering from conditions which may delay wound healing. As this is an absorbable material, the use of

supplemental nonabsorbable sutures should be considered by the surgeon in the closure of sites which may undergo expansion, stretching or distention or which may require additional support.

As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. As an absorbable suture, fast absorbing surgical gut may act transiently as a foreign body. Acceptable surgical practice should be followed for the management of contaminated or infected wounds. Do not resterilize. Discard open packages and unused sutures. Store at room temperature. Certain patients may be hypersensitive to collagen and might exhibit an immunological reaction resulting in inflammation, tissue granulation or fibrosis, wound suppuration and bleeding, as well as sinus formation.

PRECAUTIONS

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders. Surgical gut sutures require the accepted surgical technique of flat and square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon. Under some circumstances, notably orthopaedic procedures, immobilization of joints by external support may be employed at the discretion of the surgeon. The surgeon should avoid unnecessary tension when running down knots, to reduce the occurrence of surface fraying and weakening of the strand. Avoid prolonged exposure to elevated temperatures. To avoid damaging needle points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, variable rates of absorption over time (depending on such factors as the type of suture used, the presence of infection and the tissue site), failure to provide adequate wound support in closure of sites where expansion, stretching or distension occur, etc., unless additional support is supplied through the use of nonabsorbable suture material, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from cancer, anemia, obesity, diabetes, infection or other conditions which may delay wound healing, allergic response in patients with known sensitivities to collagen which may result in an immunological reaction resulting in inflammation, tissue granulation or fibrosis, wound suppuration and bleeding, as well as sinus formation, infection, moderate tissue inflammatory response characteristic of foreign body response, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

HOW SUPPLIED

Fast absorbing surgical gut sutures are available in sizes 5-0 (metric size 1.5) and 6-0 (metric size 1.0) with needles attached in one, two and three dozen boxes.

Coated VICRYL RAPIDE (Polyglactin 910) Braided Coated Synthetic Absorbable Suture, Undyed

NON-U.S.P.

DESCRIPTION

Coated VICRYL RAPIDE (polyglactin 910) suture is a synthetic absorbable sterile surgical suture composed of a copolymer made from 90% glycolide and 10% L-lactide. The empirical formula of the copolymer is $(C_2H_2O_2)_m(C_3H_4O_2)_n$. The characteristic of rapid loss of strength is achieved by use of a polymer material with a lower molecular weight than Coated VICRYL (polyglactin 910) suture. Coated VICRYL RAPIDE sutures are obtained by coating the braided suture material with a mixture of equal parts of copolymer of glycolide and lactide (polyglactin 370) and calcium stearate. Polyglactin 910 copolymer and polyglactin 370 with calcium stearate have been found to be nonantigenic, nonpyrogenic and elicit only a mild tissue reaction during absorption. Coated VICRYL RAPIDE sutures are only available undyed. Although this suture is a synthetic absorbable suture, its performance characteristics are intended to model the performance of collagen (surgical gut) suture. The knot tensile strength of Coated VICRYL RAPIDE suture meets U.S.P. knot tensile strength requirements for collagen sutures, however, Coated VICRYL RAPIDE suture strength is up to 26% less than knot tensile strength requirements for synthetic absorbable sutures.

MAXIMUM SUTURE OVERSIZE IN DIAMETER (MM) FROM U.S.P

U.S.P SUTURE SIZE DISIGNATION	MAXIMUM OVERSIZE (MM)
5-0	.016
4-0	.017
3-0	.018
2-0	.010
0	.022

INDICATIONS

Coated VICRYL RAPIDE synthetic absorbable suture is indicated only for use in superficial soft tissue approximation of the skin and mucosa, where only short term wound support (7-10 days) is required. Coated VICRYL RAPIDE suture is not intended for use in ligation, ophthalmic, cardiovascular or neurological procedures.

ACTIONS

Coated VICRYL RAPIDE suture, when used in closure of skin and mucous membranes, typically begins to fall off 7-10 days post-operatively and can be wiped off subsequently with sterile gauze. Natural mechanical abrasion of the sutures while in situ may also accelerate this disappearance rate. Rapid loss of tensile strength may preclude the need for stitch removal. Coated VICRYL RAPIDE elicits a minimal to moderate acute inflammatory reaction in tissue. Progressive loss of tensile strength and eventual absorption of Coated VICRYL RAPIDE occurs by means of hydrolysis, where the copolymer degrades to glycolic and lactic acids which are subsequently absorbed and metabolized in the body. Absorption begins as a loss of tensile strength followed by a loss of mass. Subcutaneous tissue implantation studies of Coated

VICRYL RAPIDE sutures in rats show that 5 days post-implantation approximately 50% of the original tensile strength remains. All of the original tensile strength is lost by approximately 10 to 14 days post-implantation. Intramuscular implantation studies in rats show that the absorption of these sutures occurs thereafter and is essentially complete by 42 days.

CONTRAINDICATIONS

Due to the rapid loss of tensile strength, this suture should not be used where extended approximation of tissues under stress is required or where wound support beyond 7 days is required.

WARNINGS

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing Coated VICRYL RAPIDE suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used. Physicians should consider the *in vivo* performance when selecting a suture. The use of this suture may be inappropriate in elderly, malnourished, or debilitated patients, or in patients suffering from conditions which may delay wound healing. Do not resterilize. Discard opened packages and unused sutures. As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. As an absorbable suture, Coated VICRYL RAPIDE suture may act transiently as a foreign body. Acceptable surgical practice should be followed for the management of contaminated or infected wounds. As this is an absorbable suture material, the use of supplemental nonabsorbable sutures should be considered by the surgeon in the closure of the sites which may undergo expansion, stretching or distention, or which may require additional support.

PRECAUTIONS

Skin sutures which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated. Under some circumstances, notably orthopaedic procedures, immobilization of joints by external support may be employed at the discretion of the surgeon. Consideration should be taken in the use of absorbable sutures in tissues with poor blood supply as suture extrusion and delayed absorption may occur. In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders. Coated VICRYL RAPIDE suture, which is treated with coating to enhance handling characteristics, requires the accepted surgical technique of flat and square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon. Avoid prolonged exposure to elevated temperatures. To avoid damaging needle points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, failure to provide adequate wound support in closure of the sites where expansion, stretching, or distention occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing, infection, minimal acute inflammatory tissue reaction, localized irritation when skin sutures are left in place for greater than 7 days, suture extrusion and delayed absorption in tissue with poor blood supply, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as

urine and bile occurs, and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

HOW SUPPLIED

Coated VICRYL RAPIDE sutures are available sterile, undyed and attached to stainless steel needles of varying types and sizes. Coated VICRYL RAPIDE sutures are available in various lengths in sizes 5-0 to 1 (1.0 to 4.0 metric) in one and three dozen boxes.

Coated VICRYL (Polyglactin 910) Suture

.S.P., EXCEPT FOR DIAMETER DESCRIPTION Coated VICRYL* (polyglactin 910) suture is a synthetic absorbable sterile surgical suture composed of a copolymer made from 90% glycolide and 10% L-lactide. Coated VICRYL suture is prepared by coating VICRYL suture material with a mixture composed of equal parts of copolymer of glycolide and lactide (polyglactin 370) with calcium stearate have been found to be nonantigenic, nonpyrogenic and elicits only a mild tissue reaction during absorption. The sutures are available dyed and undyed (natural). Coated VICRYL sutures are U.S.P. except for diameters in the following sizes:

MAXIMUM SUTURE OVERSIZE IN DIAMETER (MM) FROM U.S.P

U.S.P SUTURE SIZE DISIGNATION	MAXIMUM OVERSIZE (MM)
6-0	.008
5-0	.016
4-0	.017
3-0	.018
2-0	.010
0	.022

INDICATIONS

Coated VICRYL suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular or neurological tissues.

ACTIONS

Coated VICRYL suture elicits a minimal acute inflammatory reaction in tissue and ingrowth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of Coated VICRYL suture occurs by means of hydrolysis, where the copolymer degrades to glycolic and lactic acids which are subsequently absorbed and metabolized in the body. Absorption begins as a loss of tensile strength followed by a loss of mass. Implantation studies in rats indicate that Coated VICRYL suture retains approximately 75% of the original tensile strength at two weeks post implantation. At three weeks, approximately 50% of the original strength is retained for sizes 6-0 and larger and approximately 40% of its original strength is retained for sizes 7-0 and smaller. All of the original tensile strength is lost between four and five weeks post implantation. Absorption of Coated VICRYL suture is essentially complete between 56 and 70 days.

Days Implantation	Approximate % Original Strength Remaining
14 Days	75%
21 Days (6-0 and larger)	50%
21 Days (7-0 and Smaller)	40%

CONTRAINDICATIONS

This suture, being absorbable, should not be used where extended approximation of tissue under stress is required.

WARNINGS

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing Coated VICRYL suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used. Physicians should consider the in vivo performance (under ACTIONS section) when selecting a suture.

The use of this suture may be inappropriate in elderly, malnourished, or debilitated patients, or in patients suffering from conditions which may delay wound healing. As this is an absorbable suture material, the use of supplemental nonabsorbable sutures should be considered by the surgeon in the closure of the sites which may undergo expansion, stretching or distention, or which may require additional support.

Do not resterilize. Discard opened packages and unused sutures.

As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. Coated VICRYL suture may act transiently as a foreign body. Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

PRECAUTIONS

Skin sutures which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated.

Under some circumstances, notably orthopaedic procedures, immobilization of joints by external support may be employed at the discretion of the surgeon.

Consideration should be taken in the use of absorbable sutures in tissue with poor blood supply as suture extrusion and delayed absorption may occur.

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders. Coated VICRYL sutures, which are treated to enhance handling characteristics, require the accepted surgical technique of flat and square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon.

Avoid prolonged exposure to elevated temperatures.

To avoid damaging needle points and swage areas, grasp the needle in an area one-third ($\frac{1}{3}$) to one-half ($\frac{1}{2}$) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, failure to provide adequate wound support in closure of the sites where expansion, stretching, or distention occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing, infection, minimal

acute inflammatory tissue reaction, localized irritation when skin sutures are left in place for greater than 7 days, suture extrusion and delayed absorption in tissue with poor blood supply, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

HOW SUPPLIED

Coated VICRYL sutures are available sterile, as braided dyed (violet) and undyed (natural) strands in sizes 8-0 through 3 (metric sizes 0.4-

MONOCRYL Violet Monofilament (Poliglecaprone 25) Suture

SYNTHETIC ABSORBABLE SUTURE, U.S.P., EXCEPT FOR DIAMETER

DESCRIPTION

MONOCRYL (poliglecaprone 25) suture is a monofilament synthetic absorbable surgical suture prepared from a copolymer of glycolide and epsilon-caprolactone. Poliglecaprone 25 copolymer has been found to be nonantigenic, nonpyrogenic and elicits only a slight tissue reaction during absorption.

MONOCRYL sutures are U.S.P. except for diameters in the following sizes:

MAXIMUM SUTURE OVERSIZE IN DIAMETER (MM) FROM U.S.P.

U.S.P. SUTURE SIZE DESIGNATION	MAXIMUM OVERSIZE (MM)
6-0	0.049
5-0	0.033
4-0	0.045
3-0	0.067
2-0	0.055
0	0.088
1	0.066
2	0.099

INDICATIONS

MONOCRYL sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

ACTIONS

MONOCRYL suture is a monofilament which elicits a minimal acute inflammatory reaction in tissues and ingrowth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of MONOCRYL sutures occurs by means of hydrolysis. Absorption begins as a loss of tensile strength followed by a loss of mass. Implantation studies in rats indicate that MONOCRYL suture retains approximately 60 to 70% of its original tensile strength 7 days post implantation, and approximately 30 to 40% of its original tensile strength at 14 days post implantation. Essentially all of the original tensile strength is lost by 28 days post implantation. Absorption of MONOCRYL absorbable synthetic suture is essentially complete between 91 and 119 days.

DAYS IMPLANTATION	APPROXIMATE % ORIGINAL STRENGTH REMAINING
--------------------------	--

7 DAYS
14 DAYS

60 TO 70%
30 TO 40%

CONTRAINDICATIONS

This suture, being absorbable, should not be used where extended approximation of tissue under stress is required.

WARNINGS

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing MONOCRYL suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used. Physicians should consider the in vivo performance (under ACTIONS section) when selecting a suture for use in patients. The use of this suture may be inappropriate in elderly, malnourished, or debilitated patients, or in patients suffering from conditions which may delay wound healing.

Do not resterilize. Discard open packages and unused sutures. As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. As an absorbable suture, MONOCRYL suture may act transiently as a foreign body. Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

As this is an absorbable suture material, the use of supplemental nonabsorbable sutures should be considered by the surgeon in the closure of the sites which may undergo expansion, stretching or distention, or which may require additional support.

PRECAUTIONS

Skin sutures which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated. Subcuticular sutures should be placed as deeply as possible to minimize the erythema and induration normally associated with absorption.

Under some circumstances, notably orthopaedic procedures, immobilization of joints by external support may be employed at the discretion of the surgeon.

Consideration should be taken in the use of absorbable sutures in tissue with poor blood supply as suture extrusion and delayed absorption may occur.

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

MONOCRYL suture knots must be properly placed to be secure. Adequate knot security requires the accepted surgical technique of flat and square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilaments.

Avoid prolonged exposure to elevated temperatures.

To avoid damaging needle points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause

them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

ADVERSE REACTIONS

Adverse effects associated with the use of synthetic absorbable sutures include wound dehiscence, failure to provide adequate wound support in closure of the sites where expansion, stretching, or distension occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing, infection, minimal acute inflammatory tissue reaction, localized irritation when skin sutures are left in place for greater than 7 days, suture extrusion and delayed absorption in tissue with poor blood supply, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

HOW SUPPLIED

MONOCRYL sutures are available as sterile, monofilament, dyed (violet) strands in sizes 6-0 through 2 (metric sizes 0.7-5), in a variety of lengths, with or without needles. MONOCRYL sutures are also available in sizes 3-0 through 1 (metric sizes 2-4) attached to CONTROL RELEASE removable needles.

MONOCRYL sutures are available in one and three dozen boxes.

MONOCRYL (Poliglecaprone 25) Suture

SYNTHETIC ABSORBABLE SUTURE, U.S.P., EXCEPT FOR DIAMETER

DESCRIPTION

MONOCRYL (poliglecaprone 25) suture is a monofilament synthetic absorbable surgical suture prepared from a copolymer of glycolide and epsilon-caprolactone. Poliglecaprone 25 copolymer has been found to be nonantigenic, nonpyrogenic and elicits only a slight tissue reaction during absorption.

MONOCRYL sutures are U.S.P. except for diameters in the following sizes:

MAXIMUM SUTURE OVERSIZE IN DIAMETER (MM) FROM U.S.P.

U.S.P. SUTURE SIZE DESIGNATION	MAXIMUM OVERSIZE (MM)
6-0	0.049
5-0	0.033
4-0	0.045
3-0	0.067
2-0	0.055
0	0.088
1	0.066
2	0.099

INDICATIONS

MONOCRYL sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

ACTIONS

MONOCRYL suture is a monofilament which elicits a minimal acute inflammatory reaction in tissues and ingrowth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of MONOCRYL sutures occurs by means of hydrolysis. Absorption begins as a loss of tensile strength followed by a loss of mass. Implantation studies in rats indicate that MONOCRYL suture retains approximately 50 to 60% of its original tensile strength 7 days post implantation, and approximately 20 to 30% of its original tensile strength at 14 days post implantation. Essentially all of the original tensile strength is lost by 21 days post implantation. The absolute strength remaining 14 days post implantation meets or exceeds that historically observed with plain or chromic surgical gut sutures. Absorption of MONOCRYL absorbable synthetic suture is essentially complete between 91 and 119 days.

DAYS IMPLANTATION

**APPROXIMATE % ORIGINAL
STRENGTH REMAINING**

7 DAYS
14 DAYS

50 TO 60%
20 TO 30%

CONTRAINDICATIONS

This suture, being absorbable, should not be used where extended approximation of tissue under stress is required, such as in fascia.

WARNINGS

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing MONOCRYL suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used. Physicians should consider the in vivo performance (under ACTIONS section) when selecting a suture for use in patients.

The use of this suture may be inappropriate in elderly, malnourished, or debilitated patients, or in patients suffering from conditions which may delay wound healing.

Do not resterilize. Discard opened packages and unused sutures.

As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. As an absorbable suture, MONOCRYL suture may act transiently as a foreign body. Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

As this is an absorbable suture material, the use of supplemental nonabsorbable sutures should be considered by the surgeon in the closure of the sites which may undergo expansion, stretching or distention, or which may require additional support.

PRECAUTIONS

Skin sutures which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated. Subcuticular sutures should be placed as deeply as possible to minimize the erythema and induration normally associated with absorption.

Under some circumstances, notably orthopaedic procedures, immobilization of joints by external support may be employed at the discretion of the surgeon.

Consideration should be taken in the use of absorbable sutures in tissue with poor blood supply as suture extrusion and delayed absorption may occur.

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

MONOCRYL suture knots must be properly placed to be secure. Adequate knot security requires the accepted surgical technique of flat and square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilaments.

Avoid prolonged exposure to elevated temperatures.

To avoid damaging needle points and swage areas, grasp the needle in an area one-third ($\frac{1}{3}$) to one-half ($\frac{1}{2}$) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

ADVERSE REACTIONS

Adverse effects associated with the use of synthetic absorbable sutures include wound dehiscence, failure to provide adequate wound support in closure of the sites where expansion, stretching, or distension occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing, infection, minimal acute inflammatory tissue reaction, localized irritation when skin sutures are left in place for greater than 7 days, suture extrusion and delayed absorption in tissue with poor blood supply, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

HOW SUPPLIED

MONOCRYL sutures are available as sterile, monofilament, undyed (natural) strands in sizes 6-0 through 2 (metric sizes 0.7-5), in a variety of lengths, with or without needles. MONOCRYL sutures are also available in sizes 3-0 through 1 (metric sizes 2-4) attached to CONTROL RELEASE removable needles.

MONOCRYL sutures are available in one and three dozen boxes.

PDS II (Polydioxanone) Suture Dyed and Clear Monofilament

SYNTHETIC ABSORBABLE SUTURES, U.S.P., EXCEPT FOR DIAMETER

DESCRIPTION

PDS II (polydioxanone) monofilament synthetic absorbable suture is prepared from the polyester, poly (p-dioxanone). The empirical molecular formula of the polymer is $(C_4H_6O_3)_x$.

Polydioxanone polymer has been found to be nonantigenic, nonpyrogenic and elicits only a slight tissue reaction during absorption.

PDS II sutures are U.S.P., except for diameter.

MAXIMUM SUTURE OVERSIZE IN DIAMETER (MM) FROM U.S.P.

U.S.P. SUTURE SIZE DESIGNATION	MAXIMUM OVERSIZE (MM)
9-0	.005
8-0	.008
7-0	.020
6-0	.015
5-0	.029
4-0	.029
3-0	.056
2-0	.029
0	.071
1	.047
2	.023

ACTIONS

Two important characteristics describe the in vivo performance of absorbable sutures: first, tensile strength retention, and second, the absorption rate (loss of mass). PDS II synthetic absorbable suture has been formulated to minimize the variability of these characteristics and to provide wound support through an extended healing period.

The results of implantation studies of PDS II monofilament suture in animals indicate that approximately 70% of its original strength remains two weeks after implantation. At four weeks post-implantation, approximately 50% of its original strength is retained, and at six weeks, approximately 25% of the original strength is retained.

Data obtained from implantation studies in rats show that the absorption of these sutures is minimal until about the 90th post-implantation day. Absorption is essentially complete within six months.

INDICATIONS

PDS II monofilament synthetic absorbable sutures are indicated for use in all types of soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery. PDS II suture is not indicated in adult cardiovascular tissue, microsurgery and neural tissue. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable.

CONTRAINDICATIONS

These sutures, being absorbable, are not to be used where prolonged (beyond six weeks) approximation of tissues under stress is required and are not to be used in conjunction with prosthetic devices, i.e., heart valves or synthetic grafts.

WARNINGS

The safety and effectiveness of PDS II (polydioxanone) sutures have not been established in neural tissue, adult cardiovascular tissue or for use in microsurgery.

Under certain circumstances, notably orthopaedic procedures, immobilization by external support may be employed at the discretion of the surgeon.

Do not resterilize.

PRECAUTIONS

The PDS II suture knots must be properly placed to be secure. As with other synthetic sutures, knot security requires the standard surgical technique of flat and square ties with additional throws if indicated by surgical circumstance and the experience of the operator.

As with any suture, care should be taken to avoid damage when handling. Avoid the crushing or crimping application of surgical instruments, such as needle holders and forceps, to the strand except when grasping the free end of the suture during an instrument tie.

Conjunctival and vaginal mucosal sutures remaining in place for extended periods may be associated with localized irritation and should be removed as indicated.

Subcuticular sutures should be placed as deeply as possible in order to minimize the erythema and induration normally associated with absorption.

Acceptable surgical practice should be followed with respect to drainage and closure of infected wounds.

ADVERSE REACTIONS

Due to prolonged suture absorption, some irritation and bleeding has been observed in the conjunctiva and mild irritation has been observed in the vaginal mucosa.

DOSAGE AND ADMINISTRATION

Use as required per surgical procedure.

HOW SUPPLIED

PDS II sutures are available as sterile, monofilament dyed (violet) strands in sizes 9-0 thru 2 (metric sizes 0.3-5), and sterile, monofilament dyed (blue) strands in sizes 9-0 thru 7-0 (metric sizes 0.3-0.5) in a variety of lengths, with a variety of needles.

PDS II monofilament dyed (violet) sutures, sizes 4-0 thru 1 (metric sizes 1.5-4) are also available attached to CONTROL RELEASE removable needles.

PDS II Clear suture strands are available in sizes 7-0 thru 1 (metric size 0.5-4) in a variety of lengths with permanently attached needles.

CAUTION: Federal Law restricts this device to sale, distribution and use by or on the order of a physician or a veterinarian.

PANACRYL Suture

SYNTHETIC ABSORBABLE SUTURE, U.S.P.,
EXCEPT FOR DIAMETER

DESCRIPTION

PANACRYL suture is a synthetic, braided, undyed, absorbable, sterile surgical suture composed of a copolymer of 95% lactide and 5% glycolide. The suture is coated with a copolymer composed of 90% caprolactone and 10% glycolide. The copolymers in this product have been shown to be nonantigenic, nonpyrogenic and to elicit mild tissue reaction during absorption.

PANACRYL sutures are U.S.P. except for diameters in the following sizes:

MAXIMUM SUTURE OVERSIZE IN DIAMETER (MM) FROM U.S.P.

U.S.P. SUTURE SIZE DESIGNATION	MAXIMUM OVERSIZE (MM)
3-0	0.067
2-0	0.055
0	0.088
1	0.066
2	0.099

INDICATIONS

PANACRYL suture is indicated for use in general soft tissue approximation and/or ligation, and orthopaedic uses including tendon and ligament repairs and reattachment to bone but not for use in ophthalmic, cardiovascular or neurological tissue. PANACRYL suture is particularly useful where extended wound support (up to 6 months) is desirable.

ACTIONS

PANACRYL suture elicits a minimal inflammatory reaction in tissue and allows ingrowth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of PANACRYL suture occurs by means of hydrolysis, where the copolymer degrades to glycolic and lactic acids which are subsequently absorbed and metabolized in the body. Absorption begins as a loss of tensile strength followed by a loss of mass.

Implantation studies in rats indicate that PANACRYL suture retains approximately 80% of its original strength at 3 months and 60% of its original strength at 6 months post implantation. PANACRYL suture is essentially absorbed in 1.5 years or longer.

DAYS IMPLANTATION	APPROXIMATE % ORIGINAL STRENGTH REMAINING
3 months	80%

CONTRAINDICATIONS

PANACRYL suture, being absorbable, should not be used where extended approximation of tissue beyond 6 months is required.

WARNINGS

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing PANACRYL suture for wound closure, as a risk of wound dehiscence may vary with the site of application and the suture material used. Physicians should consider the in vivo performance (under ACTIONS Section) when selecting the suture. Use of this suture may be inappropriate in patients suffering conditions which could delay wound healing beyond 6 months.

Do not resterilize. Discard opened packages and unused sutures.

As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. As an absorbable suture, PANACRYL suture may act transiently as a foreign body.

Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

PRECAUTIONS

Under some circumstances, notably orthopaedic procedures, immobilization of joints by external support may be employed at the discretion of the surgeon.

Consideration should be taken in the use of absorbable sutures in tissues with poor blood supply as suture extrusion and delayed absorption may occur.

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

PANACRYL sutures, which are treated to enhance handling characteristics, require the accepted surgical technique of flat and square ties with additional throws as warranted by surgical circumstances and the experience of the surgeon.

To avoid damaging needle points and swage areas, grasp the needles in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

Avoid prolonged exposure to elevated temperatures.

ADVERSE REACTIONS

Adverse effects associated with the use of PANACRYL suture include wound dehiscence, infection, minimal acute inflammatory tissue reaction, localized irritation when skin sutures are left in place for greater than seven days, suture extrusion and delayed absorption in tissue with poor blood supply, calculi formation in urinary or biliary tracts when prolonged contact with salt solutions such as urine and bile occurs and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

HOW SUPPLIED

PANACRYL sutures are available as sterile, braided, undyed (white) strands in sizes 3-0 through 2 in a variety of lengths with and without needles. PANACRYL sutures are also available attached to CONTROL RELEASE removable needles.

PANACRYL sutures are available in one, two, or three dozen boxes.

PERMA-HAND Silk Suture

NONABSORBABLE SURGICAL SUTURE, U.S.P.

DESCRIPTION

PERMA-HAND silk suture is a nonabsorbable, sterile, surgical suture composed of an organic protein called fibroin. This protein is derived from the domesticated species Bombyx mori (B. More) of the family Bombycidae. PERMA-HAND sutures are processed to remove the natural waxes and gums. PERMA-HAND suture is dyed black and coated with a special wax mixture. PERMA-HAND suture is also available in its natural color. PERMA-HAND Virgin silk suture is available in which the sericin gum is not removed and serves to hold the filaments together.

PERMA-HAND suture meets requirements established by the United States Pharmacopoeia (U.S.P.) for nonabsorbable surgical suture.

INDICATIONS

PERMA-HAND suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

ACTIONS

PERMA-HAND suture elicits an acute inflammatory reaction in tissue, which is followed by a gradual encapsulation of the suture by fibrous connective tissue. While silk sutures are not absorbed, progressive degradation of the proteinaceous silk fiber in vivo may result in gradual loss of all of the suture's tensile strength over time.

CONTRAINDICATIONS

The use of this suture is contraindicated in patients with known sensitivities or allergies to silk.

Due to the gradual loss of tensile strength which may occur over prolonged periods in vivo, silk should not be used where permanent retention of tensile strength is required.

WARNINGS

Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing PERMA-HAND suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used.

As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. Acceptable surgical practice should be followed for the management of infected or contaminated wounds.

Do not resterilize. Discard opened packages and unused sutures.

PRECAUTIONS

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

As with any suture material, adequate knot security requires the accepted surgical technique of flat and square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon.

To avoid damaging needle points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, gradual loss of all tensile strength over time, allergic response in patients that are known to be sensitive to silk, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infection, acute inflammatory tissue reaction, and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

HOW SUPPLIED

PERMA-HAND sutures are available in U.S.P. sizes 9-0 through 5 (metric sizes 0.3-7.0) in a variety of lengths with and without permanently attached needles and on LIGAPAK dispensing reels.

PERMA-HAND sutures are also available in U.S.P. sizes 4-0 through 1 (metric sizes 1.5-4.0) attached to CONTROL RELEASE removable needles.

PERMA-HAND sutures are available in one, two, and three dozen boxes.

Surgical Stainless Steel Suture

NONABSORBABLE SURGICAL SUTURES, U.S.P.

DESCRIPTION

Surgical stainless steel suture is a nonabsorbable, sterile surgical suture composed of 316L stainless steel. Surgical stainless steel suture is available as a monofilament and multifilament suture.

Surgical stainless steel suture meets all requirements established by the United States Pharmacopoeia (U.S.P.) for nonabsorbable, surgical sutures. Surgical stainless steel suture is also labeled with the B&S gauge classifications.

INDICATIONS

Surgical stainless steel suture is indicated for use in abdominal wound closure, hernia repair, sternal closure and orthopaedic procedures including cerclage and tendon repair.

ACTIONS

Surgical stainless steel suture elicits a minimal acute inflammatory reaction in tissue and is not absorbed.

CONTRAINDICATIONS

The use of this suture is contraindicated in patients with known sensitivities or allergies to 316L stainless steel, or constituent metals such as chromium and nickel.

WARNINGS

Users should be familiar with surgical procedures and techniques involving nonabsorbable, stainless steel sutures before employing for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used.

Acceptable surgical practice must be followed for the management of contaminated or infected wounds.

PRECAUTIONS

In handling this or any other suture material, care should be taken to avoid damage from handling, such as kinking or excessive twisting.

To avoid damaging needle points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, gradual loss of all tensile strength over time, allergic response in patients with known sensitivities to 316L stainless steel, or constituent metals such as chromium and nickel, infection, minimal acute

inflammatory tissue reaction, pain, edema and local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

HOW SUPPLIED

Surgical stainless steel sutures are available in sizes 7 through 10-0 (metric sizes 9.0-0.2) in a variety of lengths with and without permanently attached needles in one, two and three dozen boxes.

ETHILON Nylon Suture

NONABSORBABLE SURGICAL SUTURES, U.S.P.

DESCRIPTION

ETHILON nylon suture is a nonabsorbable, sterile surgical monofilament suture composed of the long-chain aliphatic polymers Nylon 6 and Nylon 6,6. ETHILON sutures are dyed black or green to enhance visibility in tissue. The suture is also available undyed (clear).

ETHILON suture meets all requirements established by the United States Pharmacopoeia (U.S.P.) for nonabsorbable surgical suture.

INDICATIONS

ETHILON suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

ACTIONS

ETHILON suture elicits a minimal acute inflammatory reaction in tissue, which is followed by gradual encapsulation of the suture by fibrous connective tissue. While nylon is not absorbed, progressive hydrolysis of the nylon in vivo may result in gradual loss over time of tensile strength.

CONTRAINDICATIONS

Due to the gradual loss of tensile strength which may occur over prolonged periods in vivo, nylon suture should not be used where permanent retention of tensile strength is required.

WARNINGS

Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing ETHILON suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

Do not resterilize. Discard open packages and unused sutures.

PRECAUTIONS

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

As with any suture material, adequate knot security requires the accepted surgical technique of flat and square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilaments.

To avoid damaging needle points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, gradual loss of tensile strength over time, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infection, minimal acute inflammatory tissue reaction, and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

HOW SUPPLIED

ETHILON sutures are available as sterile monofilament strands in U.S.P. sizes 11-0 through 2 (metric size 0.1-5.0) in a variety of lengths, with and without permanently attached needles. ETHILON sutures are available in one, two and three dozen boxes.

NUROLON Nylon Suture

NONABSORBABLE SURGICAL SUTURE, U.S.P.

DESCRIPTION

NUROLON nylon suture is a nonabsorbable sterile surgical braided suture composed of the long-chain aliphatic polymers Nylon 6 or Nylon 6,6. NUROLON sutures are dyed black to enhance visibility in tissue. The suture is also available undyed (clear).

NUROLON suture meets all requirements established by the United States Pharmacopoeia (U.S.P.) for nonabsorbable surgical suture.

INDICATIONS

NUROLON suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

ACTIONS

NUROLON suture elicits a minimal acute inflammatory reaction in tissue, which is followed by a gradual encapsulation of the suture by fibrous connective tissue. While nylon is not absorbed, progressive hydrolysis of the nylon in vivo may result in gradual loss of tensile strength over time.

CONTRAINDICATIONS

Due to the gradual loss of tensile strength which may occur over prolonged periods in vivo, nylon suture should not be used where permanent retention of tensile strength is required.

WARNINGS

Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing NUROLON suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. Acceptable surgical practice should be followed for the management of infected or contaminated wounds.

Do not resterilize. Discard opened packages and unused sutures.

PRECAUTIONS

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

As with any suture material, adequate knot security requires the accepted surgical technique of flat and square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon.

To avoid damaging needle points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, gradual loss of tensile strength over time, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infection, minimal acute inflammatory tissue reaction, and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

HOW SUPPLIED

NUROLON sutures are available in U.S.P. sizes 6-0 through 1 (metric sizes 0.7-4.0) in a variety of lengths with and without permanently attached needles.

NUROLON sutures are available in U.S.P. sizes 4-0 through 1 (metric sizes 1.5-4.0) attached to CONTROL RELEASE removable needles.

NUROLON sutures are available in one, two and three dozen boxes.

MERSILENE Polyester Fiber Suture

NONABSORBABLE SURGICAL SUTURE, U.S.P.

EXCEPT FOR SIZE 6-0 DIAMETER

DESCRIPTION

MERSILENE polyester suture is a nonabsorbable, braided, sterile, surgical suture composed of Poly (ethylene terephthalate). It is prepared from fibers of high molecular weight, long-chain, linear polyesters having recurrent aromatic rings as an integral component. MERSILENE sutures are braided for optimal handling properties, and for good visibility in the surgical field, are dyed green.

Size 6-0 MERSILENE sutures are U.S.P., except for diameter.

MAXIMUM SUTURE OVERSIZE IN DIAMETER (MM) FROM U.S.P.

**U.S.P. SUTURE SIZE
DESIGNATION**

MAXIMUM OVERSIZE (MM)

6-0

0.024

INDICATIONS

MERSILENE suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

ACTIONS

MERSILENE suture elicits a minimal acute inflammatory reaction in tissue, followed by a gradual encapsulation of the suture by fibrous connective tissue. Implantation studies in animals show no meaningful decline in polyester suture strength over time. The polyester fiber suture material is pharmacologically inactive.

CONTRAINDICATIONS

None known.

WARNINGS

Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing MERSILENE suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used.

Do not resterilize. Discard opened packages and unused sutures.

As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. Acceptable surgical practice should be followed for the management of infected or contaminated wounds.

PRECAUTIONS

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders. The use of additional throws is particularly appropriate when knotting monofilament sutures.

As with any suture material, adequate knot security requires the accepted surgical technique of flat and square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon.

To avoid damaging needle points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infection, minimal acute inflammatory tissue reaction and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

HOW SUPPLIED

MERSILENE sutures are available as sterile, braided, green and undyed (white) strands in sizes 6-0 through 5 (metric sizes 0.7-7) in a variety of lengths, with and without permanently attached needles.

MERSILENE sutures are also available in green monofilament in U.S.P. sizes 10-0 and 11-0 (metric sizes 0.2-0.1).

MERSILENE sutures, green, braided in U.S.P. size 0 (metric size 3.5)

are also available attached to CONTROL RELEASE removable needles.

MERSILENE sutures are available in one, two and three dozen boxes.

ETHIBOND Excel Polyester Suture

NONABSORBABLE SURGICAL SUTURE, U.S.P. EXCEPT FOR SIZE 6-0 DIAMETER

DESCRIPTION

ETHIBOND *EXCEL* polyester suture is a nonabsorbable, braided, sterile, surgical suture composed of Poly (ethylene terephthalate). It is prepared from fibers of high molecular weight, long-chain, linear polyesters having recurrent aromatic rings as an integral component. ETHIBOND *EXCEL* suture is uniformly coated with polybutylate or poly {1xy-1, 4 butanediylxy (1, 6-dioxo-1, 6 hexanediyl)}. The highly adherent coating is a relatively nonreactive nonabsorbable compound which acts as a lubricant to mechanically improve the physical properties of the uncoated suture by improving handling qualities as contrasted to the braided, uncoated fiber.

ETHIBOND *EXCEL* sutures are braided for optimal handling properties, and for good visibility in the surgical field, are dyed green.

Size 6-0 ETHIBOND *EXCEL* sutures are U.S.P., except for diameter.

MAXIMUM SUTURE OVERSIZE IN DIAMETER (MM) FROM U.S.P.

U.S.P. SUTURE SIZE DESIGNATION	MAXIMUM OVERSIZE (MM)
---	------------------------------

6-0	.0024
-----	-------

INDICATIONS

ETHIBOND *EXCEL* suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

ACTIONS

ETHIBOND *EXCEL* suture elicits a minimal acute inflammatory reaction in tissue, followed by a gradual encapsulation of the suture by fibrous connective tissue. Implantation studies in animals show no meaningful decline in polyester suture strength over time. Both polyester fiber suture material and the polybutylate coating are pharmacologically inactive.

CONTRAINDICATIONS

None known.

WARNINGS

Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing ETHIBOND *EXCEL* suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used.

Do not resterilize. Discard opened packages and unused sutures.

As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. Acceptable surgical practice should be followed for the management of infected or contaminated wounds.

PRECAUTIONS

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

As with any suture material, adequate knot security requires the accepted surgical technique of flat and square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon.

To avoid damaging needle points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infection, minimal acute inflammatory tissue reaction and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

HOW SUPPLIED

ETHIBOND *EXCEL* sutures are available as sterile, braided, green and undyed (white) strands in sizes 7-0 through 5 (metric sizes 0.5-7) in a variety of lengths, with and without permanently attached needles.

ETHIBOND *EXCEL* sutures, green, braided, in sizes 4-0 through 1 (metric sizes 1.5-4) are also available attached to CONTROL RELEASE* removable needles.

ETHIBOND *EXCEL* sutures, green and undyed, are also available attached to TFE polymer pledgets measuring 1/8" x 1/8" x 1/16" (3.0mm x 3.0mm x 1.5mm), 1/4" x 1/8" x 1/16" (7.0mm x 3.0mm x 1.5mm).

ETHIBOND *EXCEL* sutures are available in one, two and three dozen boxes.

PROLENE Polypropylene Suture

NONABSORBABLE SURGICAL SUTURE, U.S.P.

Except for size 7-0 diameter and HEMO-SEAL Needle Suture Attachment

DESCRIPTION

PROLENE polypropylene suture (clear or pigmented) is a nonabsorbable sterile surgical suture composed of an isotactic crystalline stereoisomer of polypropylene, a synthetic linear polyolefin. The suture is pigmented blue to enhance visibility.

Size 7-0 PROLENE sutures are U.S.P., except for diameter.

MAXIMUM SUTURE OVERSIZE IN DIAMETER (MM) FROM U.S.P.

**U.S.P. SUTURE SIZE
DESIGNATION**

MAXIMUM OVERSIZE (MM)

7-0

.007

PROLENE suture, available as HEMO-SEAL needle suture, is a needle suture combination in which the diameter of the needle swage area has been reduced to facilitate attachment of finer wire diameter needles. The diameter of the suture strand and the needle wire have been more closely aligned to reduce the degree of needle hole bleeding. HEMO-SEAL needle suture differs from U.S.P. in needle attachment requirements only.

INDICATIONS

PROLENE suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

ACTIONS

PROLENE suture elicits a minimal acute inflammatory reaction in tissue, which is followed by a gradual encapsulation of the suture by fibrous connective tissue. PROLENE suture is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes. As a monofilament, PROLENE suture, U.S.P. resists involvement in infection and has been successfully employed in contaminated and infected wounds to eliminate or minimize later sinus formation and suture extrusion. The lack of adherence to tissues has facilitated the use of PROLENE suture as a pull-out suture.

CONTRAINDICATIONS

None known.

WARNINGS

Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing PROLENE suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used.

Do not resterilize. Discard opened packages and unused sutures.

As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. Acceptable surgical practice must be followed for the management of infected or contaminated wounds.

PRECAUTIONS

In handling this suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

Adequate knot security requires the accepted surgical technique of flat, square ties of single suture strands. The use of additional throws is particularly appropriate when knotting polypropylene sutures.

To avoid damaging needle points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infection, minimal acute inflammatory tissue reaction, and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

HOW SUPPLIED

PROLENE sutures, pigmented, are available as sterile strands in U.S.P. sizes 10-0 through 8-0 (metric sizes 0.2-0.4) and 6-0 through 2 (metric sizes 0.7-5.0).

PROLENE sutures, clear, are available as sterile strands in U.S.P. sizes 6-0 through 2 (metric sizes 0.7-5.0). Size 7-0 (metric size 0.5) PROLENE sutures, pigmented and clear are U.S.P. except for diameter. All PROLENE sutures are available in a variety of lengths, with permanently attached needles.

PROLENE sutures, pigmented and clear are also available as sterile strands in U.S.P. sizes 0 through 2 (metric sizes 3.5-5.0) attached to CONTROL RELEASE removable needles.

PROLENE sutures, pigmented and clear are also available as sterile strands in U.S.P. sizes 0 through 5-0, attached to TFE pledgets measuring 1/4" x 1/8" x 1/16" (7.0mm x 3.0mm x 1.5mm).

PROLENE sutures, pigmented and clear are also available in sterile strands as HEMO-SEAL needle sutures in the following sizes:

**PROLENE
SUTURE U.S.P.**

**HEMO-SEAL
NEEDLE**

**HEMO-SEAL NEEDLE SUTURE
LIMITS ON NEEDLE**

SIZE	SUTURE	ATTACHMENT
	AVG. (KGF)	INDIVIDUAL (KGF) MIN.
5-0	HS-7 0.17	0.08
4-0	HS-6 0.23	0.11
3-0	HS-5 0.45	0.23

USP LIMITS ON NEEDLE ATTACHMENT

U.S.P. SIZE	AVG. (KGF) MIN.	INDIVIDIAL (KGF) MIN.
5-0	0.23	0.11
4-0	0.45	0.23
3-0	0.68	0.34

PROLENE sutures are available in one, two and three dozen boxes.

PRONOVA Poly (Hexafluoropropylene-VDF) Suture

NONABSORBABLE SURGICAL SUTURE, U.S.P.
EXCEPT FOR SIZE 7-0 DIAMETER

DESCRIPTION

PRONOVA suture (clear or pigmented) is a nonabsorbable, sterile surgical suture made from a polymer blend of poly(vinylidene fluoride) and poly(vinylidene fluoride-cohexafluoropropylene). The suture is pigmented blue to enhance visibility.

Size 7-0 PRONOVA sutures are U.S.P., except for diameter.

MAXIMUM SUTURE OVERSIZE IN DIAMETER (MM) FROM U.S.P.

U.S.P. SUTURE SIZE DESIGNATION	MAXIMUM OVERSIZE (MM)
---	------------------------------

7-0	.007
-----	------

INDICATIONS

PRONOVA suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

ACTIONS

PRONOVA suture elicits a minimal to mild inflammatory reaction in tissue, which is followed by a gradual encapsulation of the suture by fibrous connective tissue. PRONOVA suture is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes. As a monofilament, PRONOVA suture, U.S.P. resists involvement in infection and has been successfully employed in contaminated and infected wounds to eliminate or minimize later sinus formation and suture extrusion. Furthermore, the lack of adherence to tissues has facilitated the use of PRONOVA suture as a pull-out suture.

CONTRAINDICATIONS

None known.

WARNINGS

Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing PRONOVA suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used.

Do not resterilize. Discard opened packages and unused sutures.

As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. Acceptable surgical practice must be followed for the management of infected or contaminated wounds.

PRECAUTIONS

In handling this suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

Adequate knot security requires the accepted surgical technique of flat, square ties of single suture strands. The use of additional throws is particularly appropriate when knotting monofilament sutures.

To avoid damaging needle points and swage areas, grasp the needle in an area one-third ($\frac{1}{3}$) to one-half ($\frac{1}{2}$) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in OsharpsO containers.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infection, minimal to mild inflammatory tissue reaction, and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

HOW SUPPLIED

PRONOVA sutures, pigmented, are available as sterile strands in U.S.P. sizes 10-0 through 8-0 (metric sizes 0.2-0.4) and 6-0 through 2 (metric sizes 0.7-5.0).

PRONOVA sutures, clear, are available as sterile strands in U.S.P. sizes 6-0 through 2 (metric sizes 0.7-5.0). Size 7-0 (metric size 0.5) PRONOVA sutures, pigmented and clear are U.S.P. except for diameter. All PRONOVA sutures are available in a variety of lengths, with permanently attached needles.

PRONOVA sutures, pigmented and clear are also available as sterile strands in U.S.P. sizes 0 through 2 (metric sizes 3.5-5.0) attached to CONTROL RELEASE* removable needles.

PRONOVA sutures are available in one, two, and three dozen boxes.

PROLENE Polypropylene Hernia System

NONABSORBABLE SYNTHETIC SURGICAL MESH

DESCRIPTION

The PROLENE polypropylene Hernia System is a sterile, pre-shaped, three-dimensional device constructed of an onlay patch connected by a mesh cylinder to a circular underlay patch. The material is undyed PROLENE polypropylene mesh constructed of knitted nonabsorbable polypropylene filaments.

ACTIONS/PERFORMANCE

The PROLENE Hernia System is a nonabsorbable mesh used to reinforce or bridge inguinal hernia deficiencies to provide extended support during and following wound healing. Animal studies show that implantation of PROLENE mesh elicits a minimum to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is neither absorbed nor is it subject to degradation or weakening by the action of tissue enzymes.

INDICATIONS

This product is indicated for the repair of indirect and direct inguinal hernia defects.

WARNINGS

The PROLENE Hernia System is provided by ETHICON, INC. as a sterile product. This device is for single use only. Do not resterilize. Discard opened packages and unused product. When this device is used in infants or children with future growth potential, the surgeon should be aware that this product will not stretch significantly as the patient grows. The PROLENE Hernia System should only be used in contaminated wounds with the understanding that subsequent infection may require removal of the device.

PRECAUTIONS

Sutures or clips, if necessary, should be placed such that a minimum of 6.5mm (1/4") of mesh should extend beyond the suture line.

ADVERSE REACTIONS

Potential adverse reactions are those typically associated with surgically implantable materials which include infection potentiation, inflammation, adhesion formation, fistula formation and extrusion.

STERILITY

The PROLENE Hernia System is sterilized by Ethylene Oxide. Do not resterilize. Do not use if package is opened or damaged. Discard open, unused product.

STORAGE

Recommended storage conditions: below 25°C, 77°F, away from moisture and direct heat. Do not use after expire date.

HOW SUPPLIED

The PROLENE Hernia System is available sterile, undyed in two sizes-medium and large.

CAUTION

Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

PROLENE Polypropylene Mesh

NONABSORBABLE SYNTHETIC SURGICAL MESH

DESCRIPTION

PROLENE polypropylene mesh is constructed of knitted filaments of extruded polypropylene identical in composition to that used in PROLENE Polypropylene Suture, Nonabsorbable Surgical Sutures, U.S.P. (ETHICON, INC.). The mesh is approximately 0.027 inches thick. This material, when used as a suture, has been reported to be nonreactive and to retain its strength indefinitely in clinical use.

PROLENE mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The fiber junctions are not subject to the same work fatigue exhibited by more rigid metallic meshes. This bi-directional elastic property allows adaptation to various stresses encountered in the body.

ACTIONS

PROLENE mesh is a nonabsorbable mesh used to span and reinforce traumatic or surgical wounds to provide extended support during and following wound healing. Animal studies show that implantation of PROLENE mesh elicits a minimum to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed nor is it subject to degradation or weakening by the action of tissue enzymes.

INDICATIONS

This mesh may be used for the repair of hernia and other fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

CONTRAINDICATIONS

When this mesh is used in infants or children with future growth potential, the surgeon should be aware that this product will not stretch significantly as the patient grows. PROLENE mesh in contaminated wounds should be used with the understanding that subsequent infection may require removal of the material.

WARNINGS

PROLENE mesh is provided by ETHICON, INC. as a sterile product. Resterilization of the device is NOT recommended. However, testing has demonstrated that reprocessing of unused PROLENE mesh which has been removed from the package will not be adversely affected when exposed not more than one time to conventional steam autoclave conditions at 250°F (121°C) for 20 minutes. Reprocessing under any other condition or by any other means is neither recommended nor endorsed by ETHICON, INC. PROLENE mesh should not be flash autoclaved.

If this product should become stained with blood or soiled, it should not be resterilized for reuse. When reprocessed as outlined above, it is the responsibility of the end-user to assure sterility of

the product via a validated sterilization process as ETHICON, INC. has no control over environmental conditions the product may encounter prior to, during, or after reprocessing.

PRECAUTIONS

A minimum of 6.5mm (1/4") of mesh should extend beyond the suture line.

ADVERSE REACTIONS

Potential adverse reactions are those typically associated with surgically implantable materials which include infection potentiation, inflammation, adhesion formation, fistula formation and extrusion.

INSTRUCTIONS FOR USE

It is recommended that nonabsorbable sutures be placed 6.5mm to 12.5 mm (1/4" to 1/2") apart at a distance approximately 6.5mm (1/4") from edge of the mesh. Some surgeons prefer to suture an uncut section of mesh that is considerably larger than the defect into position over the wound. The opposite sides are then sutured to assure proper closure under correct tension. When the margin sutures have all been placed the extra mesh is trimmed away.

HOW SUPPLIED

PROLENE mesh is available in single packets as sterile, undyed (clear) sheets in seven sizes. The sizes available are 2.5cm x 10cm (1" x 4"), 4.6cm x 10.2cm (1.8" x 4"), 6cm x 11cm (2.5" x 4.5"), 6.1cm x 13.7cm (2.4" x 5.4"), 7.6cm x 15cm (3" x 6"), 15cm x 15cm (6" x 6") and 30cm x 30cm (12" x 12"). Each sheet is approximately 0.7mm (0.027") thick.

VICRYL (Polyglactin 910) Knitted Mesh

DESCRIPTION

VICRYL (polyglactin 910) knitted mesh is prepared from a synthetic absorbable copolymer of glycolide and lactide, derived respectively from glycolic and lactic acids. This knitted mesh is prepared from uncoated, undyed fiber identical in composition to that used in VICRYL (polyglactin 910) synthetic absorbable suture, which has been found to be inert, nonantigenic, nonpyrogenic and to elicit only a mild tissue reaction during absorption.

VICRYL knitted mesh is intended for use as a buttress to provide temporary support during the healing process.

ACTIONS

Two important characteristics describe the in vivo function and behavior of VICRYL knitted mesh: reinforced wound strength and the rate of absorption (loss of mass).

The dehiscence force of healing abdominal wounds in rats closed with size 4-0 absorbable sutures was compared with corresponding wounds closed with size 4-0 absorbable sutures and reinforced with VICRYL knitted mesh. In this animal model, the strength of the incision, when supported by the mesh, was significantly greater than the sutured incisional wound. Explanted VICRYL knitted mesh, which, before implantation had an initial average burst strength of 63 lbs., was found to have 80% of its original burst strength remaining after fourteen days in vivo.

Subcutaneous implantation studies in rats indicate that the absorption of VICRYL mesh material is minimal until about six weeks post implantation and essentially complete between 60 and 90 days.

INDICATIONS

VICRYL knitted mesh may be used wherever temporary wound or organ support is required, particularly in instances in which compliant and stretchable support material is desired and containment of wound transudate is not required. VICRYL knitted mesh may be cut to the shape or size desired for each specific application.

CONTRAINDICATIONS

Because VICRYL knitted mesh is absorbable, it should not be used where extended wound or organ support is required.

WARNINGS

DO NOT RESTERILIZE.

The safety and effectiveness of VICRYL knitted mesh in neural and in cardiovascular tissue has not been established.

PRECAUTIONS

None.

ADVERSE REACTIONS

No significant clinical adverse reactions to the mesh have been reported.

DIRECTIONS FOR USE

It is recommended that absorbable or nonabsorbable sutures be placed $\frac{1}{4}$ to $\frac{1}{2}$ inch (6 to 12mm) apart at a distance approximately $\frac{1}{4}$ inch (6mm) from the edge of the mesh. Some surgeons prefer to suture a mesh larger than the defect into position over the defect. The edges are then sutured to assure proper closure under correct tension. When all margin sutures have been placed, the excess mesh is trimmed away, leaving at least $\frac{1}{4}$ inch of mesh extending beyond the suture line.

HOW SUPPLIED

VICRYL knitted mesh is available in single packets as a sterile, undyed fabric mesh in single sheet sizes of approximately 6 x 6 inches and 12 x 12 inches (15 x 15 centimeters and 30 x 30 centimeters).

VICRYL (Polyglactin 910) Woven Mesh

DESCRIPTION

VICRYL (polyglactin 910) woven mesh is prepared from a synthetic absorbable copolymer of glycolide and lactide, derived respectively from glycolic and lactic acids. This tightly woven mesh is prepared from uncoated, undyed fiber identical in composition to that used in VICRYL (polyglactin 910) synthetic absorbable suture, which has been found to be inert, nonantigenic, nonpyrogenic and to elicit only a mild tissue reaction during absorption.

VICRYL woven mesh is intended for use as a buttress to provide temporary support during the healing process.

ACTIONS

Two important characteristics describe the in vivo function and behavior of VICRYL woven mesh: reinforced wound strength and the rate of absorption (loss of mass).

The dehiscence force of healing abdominal wounds in rats closed with size 4-0 absorbable sutures was compared with corresponding wounds closed with size 4-0 absorbable sutures and reinforced with VICRYL woven mesh. In this animal model, the strength of the incision, when supported by the mesh, was significantly greater than the sutured incisional wound. Explanted VICRYL woven mesh, which, before implantation had an initial average burst strength of approximately 121 lbs., was found to have approximately 23% of its original burst strength remaining after fourteen days in vivo.

Subcutaneous implantation studies in rats indicate that the absorption of VICRYL mesh material is minimal until about six weeks post implantation and essentially complete between 60 and 90 days.

INDICATIONS

VICRYL woven mesh may be used wherever temporary wound or organ support is required. The woven mesh structure is less porous than VICRYL knitted mesh. It is indicated in instances in which containment of wound transudate is desirable. VICRYL woven mesh may be cut to the shape or size desired for each specific application.

CONTRAINDICATIONS

Because VICRYL woven mesh is absorbable, it should not be used where extended wound or organ support is required.

WARNINGS

DO NOT RESTERILIZE.

The safety and effectiveness of VICRYL woven mesh in neural tissue and in cardiovascular tissue has not been established.

PRECAUTIONS

None.

ADVERSE REACTIONS

None known.

DIRECTIONS FOR USE

It is recommended that absorbable or nonabsorbable sutures be placed $\frac{1}{4}$ to $\frac{1}{2}$ inch (6 to 12mm) apart at a distance approximately $\frac{1}{4}$ inch (6mm) from the edge of the mesh. Some surgeons prefer to suture a mesh larger than the defect into position over the defect. The edges are then sutured to assure proper closure under correct tension. When all margin sutures have been placed, the excess mesh is trimmed away, leaving at least $\frac{1}{4}$ inch of mesh extending beyond the suture line.

HOW SUPPLIED

VICRYL woven mesh is available in single packets as a sterile, undyed fabric mesh in single sheet sizes of approximately 6 x 6 inches and 12 x 12 inches (15 x 15 centimeters and 30 x 30 centimeters).

MERSILENE Polyester Fiber Mesh

NONABSORBABLE SYNTHETIC
SURGICAL MESH, STERILE

DESCRIPTION

MERSILENE Polyester Fiber Mesh is constructed from polyethylene terephthalate, the same material used to make MERSILENE Polyester Fiber Suture, Nonabsorbable Surgical Suture, U.S.P. (ETHICON, INC.). MERSILENE Polyester Fiber Mesh affords the excellent strength, durability and surgical adaptability, along with maximal porosity for necessary tissue ingrowth. The mesh is approximately 0.010 inches thick and is a highly flexible and compliant material.

MERSILENE mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The fiber junctions are not subject to the same work fatigue exhibited by more rigid metallic meshes. This bi-directional elastic property allows adaption to various stresses encountered in the body.

ACTIONS

MERSILENE mesh is a nonabsorbable mesh used to span and reinforce traumatic or surgical wounds to provide extended support during and following wound healing. Animal studies show that implantation of MERSILENE mesh elicits a minimum to slight inflammatory reactions, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed nor is it subject to degradation or weakening by the action of tissue enzymes.

INDICATIONS

This mesh may be used for the repair of hernia and other fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

CONTRAINDICATIONS

When this mesh is used in infants or children with future growth potential, the surgeon should be aware that this product will not stretch significantly as the patient grows.

MERSILENE polyester fiber mesh in contaminated wounds should be used with the understanding that subsequent infection may require removal of the material.

WARNINGS

MERSILENE mesh is provided by ETHICON, INC. as a sterile product. Unused MERSILENE mesh which has been removed from the package may be resterilized not more than one time by a conventional steam autoclaving process at conditions of 250°F (121°C) for 20 minutes. MERSILENE mesh may also be flash autoclaved not more than one time at conditions of 270°F (132°C) for 10 minutes. Resterilization under any other conditions or by any other means is neither recommended nor endorsed by ETHICON, INC.

If this product should become stained with blood or soiled, it should not be resterilized for reuse.

PRECAUTIONS

A minimum of 6.5mm (1/4 inch) of mesh should extend beyond the suture line.

ADVERSE REACTIONS

No significant adverse clinical reactions to MERSILENE mesh have been reported. The use of nonabsorbable MERSILENE mesh in a wound that is contaminated or infected could lead to fistula formation and/or extrusion of the mesh.

INDICATIONS FOR USE

It is recommended that nonabsorbable sutures be placed 6.5 to 12.5mm (1/4 to 1/2 inch) apart at a distance approximately 6.5mm (1/4 inch) from edge of the mesh. Some surgeons prefer to suture an uncut section of mesh that is considerably larger than the defect into position over the wound. The opposite sides are then sutured to assure proper closure under correct tension. When the margin sutures have all been placed, the extra mesh is trimmed away.

HOW SUPPLIED

MERSILENE mesh is available in single packets as sterile, undyed (white) sheets in two sizes. The sizes available are 6 x 11cm (2.5 x 4.5 inches) and 30 x 30cm (12 x 12 inches). Each sheet is 0.25mm (0.010 inch) thick.

DERMABOND Topical Skin Adhesive page 1 of 3

2 - OCTYL CYANOACRYLATE)

DESCRIPTION

DERMABOND Topical Skin Adhesive is a sterile, liquid topical skin adhesive containing a monomeric (2-octyl cyanoacrylate) formulation and the colorant D & C Violet #2. It is provided in a single use applicator packaged in a blister pouch. The applicator is comprised of a crushable glass ampule contained within a plastic vial with attached applicator tip. As applied to the skin, the liquid adhesive is slightly more viscous than water and polymerizes within minutes. See DIRECTIONS FOR USE.

INDICATIONS

DERMABOND adhesive is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. DERMABOND adhesive may be used in conjunction with, but not in place of, subcuticular sutures.

CONTRAINDICATIONS

- DERMABOND adhesive is contraindicated for use on any wounds with evidence of active infection, gangrene, or wounds from decubitus etiology.
- DERMABOND adhesive is contraindicated for use on mucosal surfaces or across mucocutaneous junctions (e.g., oral cavity, lips), or on skin which may be regularly exposed to body fluids or with dense natural hair, (e.g., scalp).
- DERMABOND adhesive is contraindicated for use on patients with a known hypersensitivity to cyanoacrylate or formaldehyde.

WARNINGS

- DERMABOND adhesive is a fast setting adhesive capable of adhering to most body tissue and many other materials, such as latex gloves and stainless steel. Inadvertent contact with any body tissue, and any surfaces or equipment that are not disposable or that cannot be readily cleaned with a solvent such as acetone should be avoided.
- Polymerization of DERMABOND adhesive may be accelerated by water or fluids containing alcohol: DERMABOND adhesive should not be applied to wet wounds.
- DERMABOND adhesive should not be applied to the eye. If contact with the eye occurs, flush the eye copiously with saline or water. If residual adhesive remains, apply topical ophthalmic ointment to help loosen the bond and contact an ophthalmologist.
- DERMABOND adhesive should not be used below the skin because the polymerized material is not absorbed by tissue and can elicit a foreign body reaction.
- DERMABOND adhesive should not be used in high skin tension areas or across areas of increased skin tension, such as knuckles, elbows, or knees, unless the joint will be immobilized during the skin healing period.

- DERMABOND adhesive treated wounds should be monitored for signs of infection. Wounds with signs of infection, such as erythema, edema, warmth, pain and pus, should be evaluated and treated according to standard practice for infection.
- DERMABOND adhesive should not be used on wound sites that will be subjected to repeated or prolonged moisture or friction.
- DERMABOND adhesive should only be used after wounds have been cleaned and debrided in accordance with standard surgical practice. Local anesthetic should be used when necessary to assure adequate cleansing and debridement.
- Excessive pressure of the applicator tip against the wound edges or surrounding skin can force the wound edges apart and allow adhesive into the wound. Adhesive within the wound could delay wound healing and/or result in adverse cosmetic outcome. Therefore, DERMABOND adhesive should be applied with a very light brushing motion of the applicator tip over easily approximated wound edges.
- DERMABOND adhesive polymerizes through an exothermic reaction in which a small amount of heat is released. With the proper technique of applying DERMABOND adhesive in multiple thin layers (at least three) onto a dry wound and allowing time for polymerization between applications, heat is released slowly and the sensation of heat or pain experienced by the patient is minimized. However, if DERMABOND adhesive is applied so that large droplets of liquid are allowed to remain unspread, the patient may experience a sensation of heat or discomfort.
- DERMABOND adhesive is packaged for single patient use. Discard remaining opened material after each wound closure procedure.
- Do not resterilize DERMABOND adhesive.
- Do not place DERMABOND adhesive in a procedure pack/tray that is to be sterilized prior to use. Exposure of DERMABOND adhesive, after its final manufacture, to excessive heat (as in autoclaves of ethylene oxide sterilization) or radiation (such as gamma or electron beam), is known to increase its viscosity and may render the product unusable.

PRECAUTIONS

- Do not apply liquid or ointment medications or other substances to the wound after closure with DERMABOND adhesive, as these substances can weaken the polymerized film and allow for wound dehiscence. DERMABOND adhesive permeability by topical medications has not been studied.
- DERMABOND adhesive permeability by fluids is not known and has not been studied.
- DERMABOND adhesive is a free flowing liquid slightly more viscous than water. To prevent inadvertent flow of liquid DERMABOND adhesive to unintended areas: (1) the wound should be held in a horizontal position, with DERMABOND adhesive applied from above, and (2) DERMABOND adhesive should be applied in multiple (at least 3), thin layers rather than in a few large droplets.
- DERMABOND adhesive should be used immediately after crushing the glass ampule as the liquid adhesive will not flow freely from the applicator tip after a few minutes.

- If unintended bonding of intact skin occurs, peel, but do not pull the skin apart. Petroleum jelly or acetone may help loosen the bond. Other agents such as water, saline, betadine, Hibiclens, or soap, are not expected to immediately loosen the bond.
- Safety and effectiveness of DERMABOND adhesive on wounds of patients with peripheral vascular disease, insulin dependent diabetes mellitus, blood clotting disorders, personal or family history of keloid formation or hypertrophy, burst stellate lacerations, have not been studied.
- Safety and effectiveness of DERMABOND adhesive on the following wounds have not been studied: animal or human bites, puncture or stab wounds.
- Safety and effectiveness on wounds that have been treated with DERMABOND adhesive and then exposed for prolonged periods to direct sunlight or tanning lamps have not been studied.
- Safety and effectiveness of DERMABOND adhesive on wounds in vermilion surfaces has not been studied.

DERMABOND Topical Skin Adhesive page 2 of 3

ADVERSE REACTIONS

- Adverse reactions encountered during clinical study:

Clinical Study Outcomes	No Subcuticular Sutures		With Subcuticular Sutures	
	DERMABOND	Control	DERMABOND	CONTROL
	N(%)	N(%)	N(%)	N(%)
Accounting				
N, patients enrolled	240	243	167	168
N, patients treated	239	242	167	166
Patients completed	228 (95%)	215 (88%)	164 (98%)	162 (96%)
Adverse Reactions				
Suspected infection*	8 (3.6%)	2 (0.9%)	6 (3.6%)	2 (1.2%)
Wound type #Lacerations	8	2	1	0
#Incisions	0	0	5	2
Dehiscence with Need for Retreatment	6 (2.5%)	5 (2.1%)	3 (1.8%)	0
Acute Inflammation				
Erythema				

DERMABOND Topical Skin Adhesive page 3 of 3

Follow-up was at 5-10 days and at 3 months. All wounds were assessed by visual inspection at 5-10 days after wound closure. The types of wounds treated in the study were 46.1% lacerations and 53.9% incisions. The incisions were comprised of 47.8% excisions of skin lesions, 27.3% minimally invasive surgery punctures, and 24.8% general surgery incisions.

For wounds closed without subcuticular stitches, mean wound length was 1.5cm, mean wound width was 2.5mm, and mean wound depth was 5.8mm. For wounds closed with subcuticular stitches, mean wound length was 3.2cm, mean wound width was 5.3mm, and mean wound depth was 3.8mm.

If the primary method of closure was insufficient for closure, an additional securing device was placed. The time to perform treatment included the time required later to remove the closure device when applicable.

The Modified Hollander Cosmesis Scale (MHCS), a validated scale, was used to evaluate cosmesis at three months: step-off borders, edge inversion, contour irregularities, excess inflammation, wound margin separation, and overall appearance.

DIRECTIONS FOR USE

1. The application of DERMABOND adhesive requires thorough wound cleansing. Follow standard surgical practice for wound preparation before application of DERMABOND adhesive (i.e., anesthetize, irrigate, debride, obtain hemostasis and close deep layers).
2. Pat the wound dry with dry, sterile gauze to assure direct tissue contact for adherence of DERMABOND adhesive to the skin. Moisture accelerates the polymerization of DERMABOND adhesive and may affect wound closure results.
3. To prevent inadvertent flow of liquid DERMABOND adhesive to unintended areas of the body, the wound should be held in a horizontal position and DERMABOND adhesive should be applied from above the wound.
4. DERMABOND adhesive should be used immediately after crushing the glass ampule, since the liquid adhesive will flow freely from the tip for only a few minutes. Remove the applicator from the blister pouch. Hold the applicator with the thumb and a finger and away from the patient to prevent any unintentional placement of the liquid DERMABOND adhesive into the wound or on the patient. While holding the applicator, and with applicator tip pointed upward, apply pressure at the midpoint of the ampule to crush the inner glass ampule. Invert and gently squeeze the applicator just sufficiently to express the liquid DERMABOND adhesive to moisten the applicator tip.
5. Approximate wound edges with gloved fingers or sterile forceps. Slowly apply the liquid DERMABOND adhesive in multiple (at least 3) thin layers to the surface of the approximated wound edges using a gentle brushing motion. Wait approximately 30 seconds between applications or layers. Maintain manual approximation of the wound edges for approximately 60 seconds after the final layer.

NOTE: DERMABOND adhesive polymerizes through an exothermic reaction. If the liquid DERMABOND adhesive is applied so that large droplets are allowed to remain without being evenly spread, the patient may experience a sensation of heat or discomfort. The sensation may be higher on sensitive tissues. This can be minimized by applying DERMABOND adhesive in multiple thin layers (at least 3).

NOTE: Excessive pressure of the applicator tip against the wound edges or surrounding skin can result in forcing the wound edges apart and allowing DERMABOND adhesive into the wound. DERMABOND adhesive within the wound could delay wound healing and/or result in adverse cosmetic outcome.

NOTE: Full apposition strength is expected to be achieved about 2.5 minutes after the final layer is applied, although the top adhesive layer may remain tacky for up to approximately 5 minutes. Full polymerization is expected when the top DERMABOND adhesive layer is no longer sticky.

6. Do not apply liquid or ointment medications onto wounds closed with DERMABOND adhesive because these substances can weaken the polymerized film, leading to wound dehiscence.

7. Protective dry dressings, such as gauze, may be applied only after DERMABOND adhesive film is completely solid/polymerized: not tacky to the touch (approximately five minutes after application). Allow the top layer to fully polymerize before applying a bandage.

If a dressing, bandage, adhesive backing or tape is applied before complete polymerization, the dressing can adhere to the film. When the dressing is removed, the film can be disrupted from the skin and wound dehiscence can occur.

8. Patients should be instructed to not pick at the polymerized film of DERMABOND adhesive. Picking at the film can disrupt its adhesion to the skin and cause dehiscence of the wound. Picking at the film can be discouraged by an overlying dressing.

9. Apply a dry protective dressing for children or other patients who may not be able to follow instructions for proper wound care.

10. Patients treated with DERMABOND adhesive should be provided the printed instruction sheet entitled How to Care For Your Wound After It's Treated With DERMABOND Topical Skin Adhesive. This instruction sheet should be reviewed with each patient or guardian to assure understanding of the proper care for the treatment site.

11. Patients should be instructed that until the polymerized film of DERMABOND adhesive has sloughed naturally (usually in 5-10 days), there should be only transient wetting of the treatment site. Patients may shower and bathe the site gently. The site should not be scrubbed, soaked, or exposed to prolonged wetness until after the film has sloughed naturally and the wound has healed closed. Patients should be instructed not to go swimming during this period.

12. If removal of DERMABOND adhesive is necessary for any reason, carefully apply petroleum jelly or acetone to the DERMABOND film to help loosen the bond. Peel off the film, do not pull the skin apart.

HOW SUPPLIED

DERMABOND adhesive is supplied sterile, in a pre-filled, single-use applicator. The applicator is comprised of a crushable glass ampule contained within a plastic vial with attached applicator

tip. The applicator contains 0.5 ml of liquid adhesive. The applicator is packaged in a blister pouch to maintain the device sterile until opened or damaged.

DERMABOND adhesive is available in boxes of 12 applicators.

STORAGE

Recommended storage conditions: below 30°C, 86°F, away from moisture and direct heat. Do not use after expiry date.

STERILITY

DERMABOND adhesive is originally sterilized by dry heat and ethylene oxide gas. Do not resterilize. Do not use if package is opened or damaged. Discard any unused material following completion of medical procedure.

STERILE SINGLE USE ONLY

REPORTING

Physicians should use the following toll free number 1-800-255-2500 (valid in U.S.A. only), when reporting adverse reactions or potentially threatening complications involving DERMABOND adhesive.

CAUTION

Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

Manufactured for ETHICON, INC. by Closure Medical Corp.

SURGICEL, SURGICEL Fibrillar, and SURGICEL Nu-Knit Absorbable Hemostats

page 1 of 2

(OXIDIZED REGENERATED CELLULOSE)
FOR SURGICAL USE

BRIEF SUMMARY

See package insert for complete prescribing information and endoscopic application.

DESCRIPTION

SURGICEL absorbable hemostat is a sterile absorbable knitted fabric prepared by the controlled oxidation of regenerated cellulose. The fabric is white with a pale yellow cast and has a faint, caramel-like aroma. It is strong and can be sutured or cut without fraying. It is stable and should be stored at controlled room temperature. A slight discoloration may occur with age, but this does not affect performance.

The fibrillar form of the product allows the surgeon to grasp with forceps any amount of SURGICEL fibrillar hemostat needed to achieve hemostasis at a particular bleeding site. The fibrillar form may be more convenient than the knitted form for hard to reach or irregularly shaped bleeding sites. Although it is easy to pull the desired amount of SURGICEL fibrillar hemostat from the entire supply, the group of selected fibers continue to cohere to one another and application to the bleeding site is easily controlled. Unwanted dispersal over the operative site does not occur.

INDICATIONS

SURGICEL hemostat (oxidized regenerated cellulose) is used adjunctively in surgical procedures to assist in the control of capillary, venous, and small arterial hemorrhage when ligation or other conventional methods of control are impractical or ineffective. SURGICEL, SURGICEL fibrillar, and SURGICEL NU-KNIT hemostats can be cut to size for use in endoscopic procedures.

CONTRAINDICATIONS

Although packing or wadding sometimes is medically necessary, SURGICEL hemostat should not be used in this manner, unless it is to be removed after hemostasis is achieved (See WARNINGS and PRECAUTIONS).

SURGICEL hemostat should not be used for implantation in bone defects, such as fractures, since there is a possibility of interference with callus formation and a theoretical chance of cyst formation.

When SURGICEL hemostat is used to help achieve hemostasis in, around, or in proximity to foramina in bone, areas of bony confine, the spinal cord, or the optic nerve and chiasm, it must always be removed after hemostasis is achieved since it will swell and could exert unwanted pressure.

SURGICEL hemostat should not be used to control hemorrhage from large arteries.

SURGICEL hemostat should not be used on non-hemorrhagic serous oozing surfaces, since body fluids other than whole blood, such as serum, do not react with SURGICEL hemostat to produce satisfactory hemostatic effect.

SURGICEL hemostat is an absorbable hemostat, and should not be used as an adhesion prevention product.

WARNINGS

SURGICEL hemostat is supplied sterile and as the material is not compatible with autoclaving or ethylene oxide sterilization, SURGICEL hemostat should not be resterilized.

SURGICEL hemostat is not intended as a substitute for careful surgery and the proper use of sutures and ligatures.

Closing SURGICEL hemostat in a contaminated wound without drainage may lead to complications and should be avoided.

The hemostatic effect of SURGICEL hemostat is greater when it is applied dry; therefore it should not be moistened with water or saline.

SURGICEL hemostat should not be impregnated with anti-infective agents or with any other materials such as buffering or hemostatic substances. Its hemostatic effect is not enhanced by the addition of thrombin, the activity of which is destroyed by the low pH of the product.

Although SURGICEL hemostat may be left in situ when necessary, it is advisable to remove it once hemostasis is achieved. It must always be removed from the site of application when used in, around, or in proximity to foramina in bone, areas of bony confine, the spinal cord, and/or the optic nerve and chiasm regardless of the type of surgical procedure because SURGICEL hemostat, by swelling, may exert pressure resulting in paralysis and/or nerve damage. Dislodgement of SURGICEL hemostat could possible occur by means such as repacking, further intraoperative manipulation, lavage, exaggerated respiration, etc. There have been reports that in procedures such as lobectomy, laminectomy and repair of frontal skull fracture and lacerated lobe that SURGICEL hemostat, when left in the patient after closure, migrated from the site of application into foramina in bone around the spinal cord resulting in paralysis and, in another case, the left orbit of the eye, causing blindness. While these reports cannot be confirmed, special care must be taken by physicians, *regardless of the type of surgical procedure*, to consider the advisability of removing SURGICEL hemostat after hemostasis is achieved.

Although SURGICEL hemostat is bactericidal against a wide range of pathogenic microorganisms, it is not intended as a substitute for systemically administered therapeutic or prophylactic antimicrobial agents to control or prevent postoperative infections.

PRECAUTIONS

Use only as much SURGICEL hemostat as is necessary for hemostasis, holding it firmly in place until bleeding stops. Remove any excess before surgical closure in order to facilitate absorption and minimize the possibility of foreign body reaction.

In urological procedures, minimal amounts of SURGICEL hemostat should be used and care must be exercised to prevent plugging of the urethra, ureter, or a catheter by dislodged portions of the product.

Since absorption of SURGICEL hemostat could be prevented in chemically cauterized areas, its use should not be preceded by application of silver nitrate or any other escharotic chemicals.

SURGICEL, SURGICEL Fibrillar, and SURGICEL Nu-Knit Absorbable Hemostats page 2 of 2

If SURGICEL hemostat is used temporarily to line the cavity of large open wounds, it should be placed so as not to overlap the skin edges. It should also be removed from open wounds by forceps or by irrigation with sterile water or saline solution after bleeding has stopped.

Precautions should be taken in otorhinolaryngologic surgery to assure that none of the material is aspirated by the patient. (Examples: controlling hemorrhage after tonsillectomy and controlling epistaxis.)

Care should be taken not to SURGICEL hemostat too tightly when it is used as a wrap during vascular surgery (see ADVERSE REACTIONS).

Endoscopic procedures should be performed only by persons having adequate training and familiarity with endoscopic techniques. Consult medical literature relative to techniques, complications and hazards prior to performance of any endoscopic procedure.

A thorough understanding of the principles and techniques involved in laparoscopic laser and electrosurgical procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Refer to appropriate electrosurgical system users manual for use indications and instructions to ensure that all safety precautions are followed.

When endoscopic instruments and accessories from different manufacturers are employed together during a procedure, verify their compatibility prior to initiation of the procedure and ensure that isolation or grounding is not compromised.

ADVERSE REACTIONS

"Encapsulation" of fluid and foreign body reactions have been reported.

There have been reports of stenotic effect when SURGICEL hemostat has been applied as a wrap during vascular surgery. Although it has not been established that the stenosis was directly related to the use of SURGICEL hemostat, it is important to be cautious and avoid applying the material tightly as a wrapping.

Paralysis and nerve damage have been reported when SURGICEL hemostat was used around, in, or in proximity to foramina in bone, areas of bony confine, the spinal cord, and/or the optic nerve and chiasm. While most of these reports have been in connection with laminectomy, reports of paralysis have also been received in connection with other procedures. Blindness has been reported in connection with surgical repair of a lacerated left frontal lobe when SURGICEL hemostat was placed in the anterior cranial fossa (See WARNINGS and PRECAUTIONS).

Possible prolongation of drainage in cholecystectomies and difficulty passing urine per urethra after prostatectomy have been reported. There has been one report of a blocked ureter after kidney resection, in which postoperative catheterization was required.

Occasional reports of "burning" and "stinging" sensations and sneezing when SURGICEL hemostat has been used as packing in epistaxis, are believed due to the low pH of the product.

Burning has been reported when SURGICEL hemostat was applied after nasal polyp removal and after hemorrhoidectomy. Headache, burning, stinging, and sneezing in epistaxis and other rhinological procedures, and stinging when SURGICEL hemostat was applied on surface wounds (varicose ulcerations, dermabrasions, and donor sites) also have been reported.

HOW SUPPLIED

Sterile SURGICEL fibrillar absorbable hemostat is supplied as stable fiber in an envelopes in the following sizes.

Code No. 1961 1 in. x 2 in. (2.5cm x 5.1cm)

Code No. 1962 2 in. x 4 in. (5.1cm x 10.2cm)

Code No. 1963 4 in x 4 in. (10.2cm x 10.2cm).

Sterile SURGICEL absorbable hemostat (oxidized regenerated cellulose) is supplied as knitted fabric strips in envelopes in the following sizes.

Code No. 1951 2 in. x 14 in. (5.1cm x 35.6cm)

Code No. 1952 4 in. x 8 in. (10.2cm x 20.3cm)

Code No. 1953 2 in. x 3 in. (5.1cm x 7.6cm)

Code No. 1955 $1\frac{1}{2}$ in. x 2 in. (1.3cm x 5.1cm).

SURGICEL NU-KNIT absorbable hemostat

Code No. 1940 1 in. x 1 in. (2.5cm x 2.5cm)

Code No. 1941 1 in. x 3.5 in. (2.5cm x 8.9cm)

Code No. 1943 3 in. x 4 in. (7.6cm x 10.2cm)

Code No. 1946 6 in. x 9 in. (15.2cm x 22.9cm).

STORAGE

Store at controlled temperature 15?-30?C (59?-86?F).

CAUTION

Federal law restricts this device to sale by or on the order of a physician.

INSTAT Collagen Absorbable Hemostat

DESCRIPTION

INSTAT collagen absorbable hemostat is a purified and lyophilized bovine dermal collagen. The material, prepared as a sponge-like pad, is lightly cross-linked, sterile, non-pyrogenic, and absorbable. Hemostatic activity, which is an inherent property of collagen, is largely dependent on the basic helical structure of this protein. The helical structure of native collagen is preserved during the manufacture of INSTAT hemostat. When collagen comes into contact with blood, platelets aggregate on the collagen and release coagulation factors which, together with plasma factors result in the formation of fibrin, and finally in the formation of a clot.

INDICATIONS

INSTAT hemostat is indicated in surgical procedures (other than in neurosurgical and ophthalmological surgery) for use as an adjunct to hemostasis when control of bleeding by ligature or other conventional methods is ineffective or impractical.

CONTRAINDICATIONS

INSTAT hemostat should not be used in the closure of skin incisions as it may interfere with the healing of skin edges. This interference is due to simple mechanical interposition of dry collagen and not due to any intrinsic interference with wound healing. It has been reported with another absorbable collagen hemostat that, in filling porosities of cancellous bone, collagen may reduce the bonding strength of methylmethacrylate. Therefore, INSTAT hemostat should not be applied on bone surfaces to which prosthetic materials are to be attached with methylmethacrylate adhesives.

WARNINGS

INSTAT hemostat is inactivated by autoclaving. It should not be resterilized. As with any foreign substance, use in contaminated wounds may enhance infection.

INSTAT hemostat should not be used in instances of pumping arterial hemorrhage.

INSTAT hemostat should not be used where blood or other fluids have pooled or in cases where the point of hemorrhage is submerged. INSTAT hemostat will not act as a tampon or plug in a bleeding site nor will it close off an area of blood collection behind a tampon.

Only the amount of INSTAT hemostat necessary to provide hemostasis should be used. The long-term effects of leaving INSTAT hemostat in situ are unknown. Opened, unused INSTAT hemostat should be discarded because it cannot be resterilized.

PRECAUTIONS

As with other hemostatic agents, it is not recommended that INSTAT hemostat be left in an infected or contaminated space, nor is it recommended for use in persons known to be sensitive to materials of bovine origin. When placed into cavities or closed spaces, care should be exercised to avoid overpacking INSTAT hemostat as it may absorb fluid and expand and press against neighboring structures. In urological procedures, INSTAT hemostat should not be left in the renal pelvis or ureters to eliminate the potential foci for calculus formation.

Safety of this product has not been established in children and pregnant women; therefore, INSTAT hemostat should only be used when benefit to risk clearly warrants its use.

INSTAT hemostat is not intended to be used to treat systemic coagulation disorders.

ADVERSE REACTIONS

INSTAT hemostat is a collagen product. Although several types of post-operative complications were observed in INSTAT hemostat treated patients, none were attributed to INSTAT hemostat except one case of fibrotic reaction where INSTAT hemostat involvement could not be ruled out. Adverse reactions reported for other collagen hemostats include hematoma, potentiation of infection, wound dehiscence, inflammation and edema. Other reported adverse reactions that may be related to the use of collagen hemostats include adhesion formation, allergic reaction, foreign body reaction and subgaleal seroma (in a single case). The use of microfibrillar collagen in dental extraction sockets has been reported to increase the incidence of alveolalgia. The possibility that all of the above reactions may occur with INSTAT hemostat cannot be excluded.

ADMINISTRATION

INSTAT hemostat is applied directly to the bleeding surface with pressure. INSTAT hemostat can be cut to size. The amount needed and the period of time necessary to apply pressure will vary with the type and amount of bleeding to be controlled. Hemostasis time depends upon the type of surgery and degree of pretreatment bleeding. It usually occurred between 2 to 5 minutes with INSTAT hemostat.

INSTAT hemostat maintains its integrity in the presence of blood and is not dispersed when wet. It is easily removed from the site following hemostasis. It is most effective when used dry.

INSTAT hemostat may be left in situ whenever necessary. However, the surgeon, at his discretion, should remove any excess of INSTAT hemostat prior to wound closure. Animal implant studies have demonstrated that absorption and tissue reaction to INSTAT hemostat are similar to those observed with another absorbable collagen hemostatic agent. In these studies, on visual examination, most of INSTAT hemostat was found to be absorbed in 8 to 10 weeks after implantation.

CLINICAL STUDIES

The safety, effectiveness and handling characteristics of INSTAT hemostat were evaluated in a variety of surgical procedures. The median time to hemostasis for INSTAT hemostat was 3 minutes. Passive Hemagglutination Assay (PHA) and Enzyme-Linked Immunoabsorbent Assay (ELISA) methods have been used to evaluate the immunologic potential for INSTAT hemostat to produce antibodies in patients. These assays revealed mild elevation of antibody titers in both INSTAT hemostat treated patients and patients treated with a collagen control hemostat, confirming that INSTAT hemostat, like other collagen hemostats, is a weak antigen.

HOW SUPPLIED

INSTAT hemostat is supplied in a sponge-like form in peelable plastic envelopes in the following sizes:

Code No. 1981 1 in. x 2 in. (2.5cm x 5.1cm)

Code No. 1983 3 in. x 4 in. (7.6cm x 10.2cm).

The sterility of the product is guaranteed unless the individual envelope is damaged or opened.

STORAGE

Store at controlled room temperature 59°-86°F (15°-30°C).

CAUTION

Federal law restricts this device to sale, distribution, and use by or on the order of a physician.

INSTAT MCH Microfibrillar Collagen Hemostat

DESCRIPTION

INSTAT MCH Microfibrillar Collagen Hemostat is a dry, white absorbent hemostatic agent in a microfibrillar form. The raw material for INSTAT MCH is obtained from bovine deep flexor tendon (achilles tendon), known to be one of the purest sources of collagen that can be readily processed in commercial amounts. Further purification during processing ensures that INSTAT MCH is a consistent material with uniform behavior.

The microfibrillar form of the product allows the surgeon to grasp with forceps any amount of INSTAT MCH needed to achieve hemostasis at a particular bleeding site. The microfibrillar form may be more convenient than the sponge form for hard to reach or irregularly shaped bleeding sites. Although it is easy to pull the desired amount of INSTAT MCH from the entire supply, the group of selected fibers continue to cohere to one another and application to the bleeding site is easily controlled. Unwanted dispersal over the operative site does not occur.

INDICATIONS

INSTAT MCH is recommended for use in surgical procedures (except in Neurological, Urological, and Ophthalmological surgery) as an adjunct to hemostasis when control of bleeding by ligature or conventional procedures is ineffective or impractical.

INFORMATION FOR USE

In contact with blood, collagen is known to cause aggregation of platelets. Platelets deposit in large numbers on the collagen structure, disintegrate and release coagulation factors that, together with plasma factors, enable the formation of fibrin. The microfibrillar structure of INSTAT MCH provides for the additional strengthening of the clot.

Topical application of INSTAT MCH effectively controls bleeding, usually within 2 to 4 minutes, when applied directly to the bleeding site. INSTAT MCH is designed to be completely absorbable if left in situ after hemostasis. In contact with blood, the fibers expand to become a coherent gelatinous mass that conforms to the shape of the bleeding area. If desired, recovery of this mass is easily accomplished.

Absorption of a collagen hemostatic agent was evaluated after subcutaneous and intrahepatic implantation in rats. In 1 out of 5 animals, complete subcutaneous absorption was observed by day 14; and by day 56, 3 out of 4 had complete absorption. Complete intraperitoneal absorption was not observed by day 56. Tissue reactions elicited by the collagen hemostatic agent during implantation are similar to tissue reactions caused by other hemostatic agents.

The collagen hemostatic agent has been evaluated *in-vitro* for the enhancement of bacterial growth of *Staphylococcus aureus* and *Escherichia coli*. Enhancement of bacterial growth did not occur for either organism.

In vivo studies using guinea pigs showed that incidence of infection (abscess) of incision sites inoculated with *Staphylococcus aureus* was not enhanced by the presence of the collagen material when compared to another collagen hemostatic agent. However, extent of wound infection tended to be greater than control with the collagen material as was the case with another collagen hemostatic agent tested. This tendency is observed with many foreign substances.

The collagen hemostatic agent was evaluated for potential allergenic sensitivity. A guinea pig maximization study showed that the collagen material did not produce irritation or contact sensitization. A chemical assay of the collagen material compared to one other collagen hemostat showed significantly less specific glycoprotein immunoreactive substances in the collagen material. A hemoagglutination study was conducted evaluating the collagen material as the antigen. There was no agglutination observed.

PRECAUTIONS

As with other hemostatic agents, it is not recommended that INSTAT MCH be left in an infected or contaminated space. Safety of this product has not been established in pregnant women; therefore, it should only be used when benefit to risk clearly warrants its use.

Another microfibrillar collagen agent has been reported to cause interference with the healing of skin edges when used in the closure of skin incisions, and to reduce the strength of methyl methacrylate adhesives used to attach prosthetic devices to bone surfaces.

INSTAT MCH is not intended to be used to treat systemic coagulation disorders.

The long term effects of leaving INSTAT MCH *in situ* are unknown.

ADMINISTRATION

Using forceps, the desired amount of INSTAT MCH can be easily selected from the entire supply. The coherent fibers should then be applied directly to the bleeding surface using some pressure. The period of time pressure is needed and the amount of INSTAT MCH necessary to achieve hemostasis will be dependent upon the nature and amount of bleeding to be controlled. It has been shown that hemostasis usually occurs within 2-4 minutes. In contact with blood, INSTAT MCH becomes a coherent gelatinous unit that is completely absorbed if left *in situ*. However, it is suggested that the surgeon simply remove the collagen mass prior to wound closure.

ADVERSE REACTIONS

Adverse reactions reported with another microfibrillar collagen hemostatic agent that were possibly related to its use were adhesion formation, allergic reaction, foreign body reaction, and subgaleal seroma (report of a single case). The use of microfibrillar collagen in dental extraction sockets has been reported to increase the incidence of alveolgia.

HOW SUPPLIED

Sterile INSTAT MCH, an absorbable collagen hemostatic agent in a microfibrillar form, is supplied in the following sizes:

Product Code Size Quantity Per Case

1985 1 gram 12

1984 0.5 gram 12

Do not resterilize this product.

CAUTION

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Thrombin, Topical USP THROMBOGEN (Bovine Origin)

THROMBIN, TOPICAL USP THROMBOGEN (BOVINE ORIGIN)

THROMBOGEN Thrombin must not be injected! Apply on the surface of bleeding tissue as a solution or powder.

DESCRIPTION

(THROMBIN, TOPICAL USP) THROMBOGEN is a protein substance produced through the conversion reaction in which prothrombin of bovine origin is activated by tissue thromboplastin in the presence of calcium chloride. It is supplied as a sterile powder that has been freeze-dried in the final container. Also in this preparation are calcium chloride, sodium chloride, aminoacetic acid (glycine) and benzethonium chloride. Glycine is included to make the dried product friable and more readily soluble, and benzethonium chloride as a preservative at 0.2 mg./vial. This product is prepared under rigid assay control. The unit is defined by the U.S. standard and is approximately equal to the stated unitage. A U.S. unit is defined as the amount required to clot 1 ml of standardized fibrinogen solution in 15 seconds. Approximately 2 U.S. units are required to clot 1 ml of oxalated human plasma in the same period of time.

CLINICAL PHARMACOLOGY

THROMBOGEN Thrombin requires no intermediate physiological agent for its action. It clots the fibrinogen of the blood directly. Failure to clot blood occurs in the rare cases where the primary clotting defect is the absence of fibrinogen itself. The speed with which thrombin clots blood is dependent upon its concentration.

INDICATIONS AND USAGE

THROMBOGEN Thrombin is indicated as an aid in hemostasis wherever oozing blood from capillaries and small venules is accessible.

In various types of surgery, solutions of THROMBOGEN Thrombin may be used in conjunction with Absorbable Gelatin Sponge, USP for hemostasis.

CONTRAINDICATIONS

THROMBOGEN Thrombin is contraindicated in persons known to be sensitive to any of its components and/or to material of bovine origin.

WARNING

Because of its action in the clotting mechanism, THROMBOGEN Thrombin must not be injected or otherwise allowed to enter large blood vessels. Extensive intravascular clotting and even death may result. THROMBOGEN Thrombin is an antigenic substance and has caused sensitivity and allergic reactions when injected into animals.

PRECAUTIONS

General--Consult the Absorbable Gelatin Sponge, USP product labeling for complete information for use prior to utilizing the thrombin-saturated sponge procedure.

Pregnancy--Category C--Animal reproduction studies have not been conducted with Thrombin, Topical USP (Bovine origin). It is also not known whether Thrombin, Topical USP (Bovine

origin) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Thrombin, Topical USP (Bovine origin) should be given to a pregnant woman only if clearly indicated.

Pediatric Use--Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Allergic reactions may be encountered in persons known to be sensitive to bovine materials.

DOSAGE AND ADMINISTRATION

Solutions of THROMBOGEN Thrombin may be prepared in sterile distilled water or isotonic saline. The intended use determines the strength of the solution to prepare. For general use in plastic surgery, dental extractions, skin grafting, neurosurgery, etc. solutions containing approximately 100 units per ml are frequently used. For this, 10 ml of diluent added to the 1,000 unit package is suitable. Where bleeding is profuse, as from abraded surfaces of liver and spleen, concentrations as high as 1,000 to 2,000 units per ml may be required. Intermediate strengths to suit the needs of the case may be prepared by selecting the proper strength package and dissolving the contents in an appropriate volume of diluent. In many situations, it may be advantageous to use THROMBOGEN Thrombin in dry form on oozing surfaces.

Caution: Solutions should be used immediately upon reconstitution. However, the solution may be refrigerated at 2-8° C for up to three hours.

The following techniques are suggested for the topical application of THROMBOGEN Thrombin.

1. The recipient surface should be sponged (not wiped) free of blood **BEFORE THROMBOGEN THROMBIN IS APPLIED.**
2. A spray may be used or the surface may be flooded using a sterile syringe and small gauge needle. The most effective hemostasis results when the THROMBOGEN Thrombin mixes freely with the blood as soon as it reaches the surface.
3. In instances where a concentration of approximately 1,000 units per ml is desired, the contents of the vial of sterile isotonic saline diluent may be easily transferred into the vial of THROMBOGEN Thrombin with a sterile syringe or a sterile transfer needle. If the transfer needle method is utilized, transfer the diluent as follows:
 - (a) Flip plastic cover off of diluent vial.
 - (b) Remove clear plastic cover from the transfer needle by twisting to break the seal. (c) Insert the exposed needle into the diluent.
 - (d) Flip the plastic cover up on the THROMBOGEN Thrombin vial. **DO NOT REMOVE THE COVER AND ALUMINUM SEAL.**
 - (e) Remove the pink plastic cap from the transfer needle exposing the needle.
 - (f) Invert the vial of diluent and insert the exposed needle into the THROMBOGEN Thrombin vial.

(g) Allow the vacuum to draw the complete contents of the diluent vial into the THROMBOGEN Thrombin vial.

IMPORTANT

* Insert needle in diluent first.

* Do not remove the cover and aluminum seal on the THROMBOGEN Thrombin vial

4. In instances where THROMBOGEN Thrombin in dry form is needed, the vial is opened by removing the metal ring by flipping up the metal tab and tearing counterclockwise. The rubber-diaphragm cap may be easily removed and the dried THROMBOGEN Thrombin is then broken up into a powder by means of sterile glass rod or other suitable sterile instrument.

5. Sponging of treated surfaces should be avoided in order that the clot remains securely in place.

THROMBOGEN Thrombin may be used in conjunction with Absorbable Gelatin Sponge, USP as follows:

1. Prepare THROMBOGEN Thrombin solution of the desired strength.

2. Immerse sponge strips of the desired size in the THROMBOGEN Thrombin solution. Knead the sponge strips vigorously with moistened fingers to remove trapped air, thereby facilitating saturation of the sponge.

3. Apply saturated sponge to the bleeding area. Hold in place for 10 to 15 seconds with a pledget of cotton or a small gauze pad.

HOW SUPPLIED

THROMBOGEN Thrombin is supplied as:

NDC 56091-038-01 Package contains one 1,000 unit vial of THROMBIN, TOPICAL USP THROMBOGEN.

NDC 56091-039-05 Package contains one 5,000 unit vial of THROMBIN, TOPICAL USP THROMBOGEN with one 5 ml vial of isotonic saline diluent and a transfer needle.

NDC 56091-040-05 Package contains one 10,000 unit vial of THROMBIN, TOPICAL USP THROMBOGEN with one 10 ml vial of isotonic saline diluent and a transfer needle.

NDC 56091-041-05 Package contains one 20,000 unit vial of THROMBIN, TOPICAL USP THROMBOGEN with one 20 ml vial of isotonic saline diluent and a transfer needle.

STORAGE

Store at normal, controlled room temperature, except 1,000 unit vial of THROMBIN, TOPICAL USP THROMBOGEN must be stored between 2°-8°C (36°-46°F).

POWERSTAR Bipolar Scissors

POWERSTAR BIPOLAR CABLE

INDICATIONS

The POWERSTAR* Bipolar Scissors are non-sterile, reusable devices intended to facilitate cutting and bipolar coagulation of soft tissue in open surgical procedures.

CONTRAINDICATIONS

The POWERSTAR Bipolar Scissors are not indicated for contraceptive coagulation of the fallopian tube, but may be used to achieve hemostasis following transection of the fallopian tube.

WARNING AND CAUTIONS

Do not use this device with a monopolar source output; damage to the instrument and harm to the patient or medical personnel could result.

A thorough understanding of the principles and techniques associated with electrosurgical procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical isolation or grounding is not compromised.

Avoid contact of the bipolar scissors with a monopolar instrument. Damage to the electrosurgical generator may result.

Limit the use of the scissors to only properly trained, qualified medical personnel.

Because of the variability of output voltages and modes from generator to generator, do not use the instrument with generators having bipolar output voltages that exceed 1000 volts peak to peak. Refer to appropriate electrosurgical generator manual for indications and instructions on bipolar output characteristics to ensure that all safety precautions are followed.

The POWERSTAR Bipolar Scissors are only compatible with the POWERSTAR Bipolar Cable. Use of these scissors with other cables will result in damage to the scissors.

To initiate the use of the POWERSTAR Bipolar Scissors, the power setting on the generator should be set to the lowest power setting needed to achieve adequate hemostasis. If adequate hemostasis is not achieved, increase power settings in small increments until adequate hemostasis is achieved.

Never touch the active blades of the scissors while energized. This may result in burns. Use surgical gloves designed by their manufacturers for electrosurgical procedures. The use of other gloves may result in burns or shocks.

Do not touch the blades of the Bipolar Scissors to any staples, clips, or sutures when the scissors are energized. Damage to the Bipolar Scissors and these products may occur.

Do not use the POWERSTAR Bipolar Scissors to cut staples or clips. When not energized, the scissors can be used in a manner appropriate for standard surgical dissecting scissors of like type and size. Cutting of sutures, meshes and similar materials may lead to premature dulling of the scissors blades.

Scissors are not intended to be sharpened or repaired in any way. This may damage the electrodes.

Do not use abrasive cleaning tools or solutions on the device.

CAUTION

Federal law (U.S.) restricts this device to sale by or on the order of a physician.