Wound Closure Manual

ETHICON

Johnson & Johnson SURGICAL TECHNOLOGIES

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CHAPTER 1

WOUND HEALING AND MANAGEMENT

The Wound

A wound is a break in the integrity of the skin and may be accompanied by disruption of the structure and function of underlying normal tissue. A wound may result from precise disruption of tissue by the surgeon's knife such as an incision to widespread damage of tissue such as a major trauma or burn. A wound may also result from a contusion, laceration, or an abrasion. The continuity of the skin must be restored as soon as possible because it plays a crucial role in maintaining homeostasis. The healing of acute wounds involves a complex, dynamic, well-orchestrated series of events..[1]

Wound healing is a natural and spontaneous phenomenon. When tissue has been disrupted so severely that it cannot heal naturally (without complications or possible disfiguration) dead tissue and foreign bodies must be removed, infection treated, and the tissue 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 is defined as a collection of similar cells and the intercellular substances surrounding them.

There are 4 basic tissues in the body: 1) epithelium; 2) connective tissues, including blood, bone and cartilage; 3) muscle tissue; and 4) nerve tissue. 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 rupture, relating to the nature of the material rather than its thickness.
- **Breaking Strength**—The load required to break a wound regard- less of its dimension, 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.

RECOVERY OF TENSILE STRENGTH

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. As collagen accumulates during the reparative phase, strength increases rapidly, but it is many months before a plateau is reached.[1] Until this time, the wound requires extrinsic support from the method used to bring it together—usually sutures. 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 duration (the degree to which the tissue has hardened in response to pressure or injury).

PATIENT FACTORS THAT AFFECT WOUND HEALING

A complete understanding of the anatomy and physiology of the skin, the phases of the healing process, and the options for wound repair play an integral role in allowing us to recognize what factors will affect the healing process. The factors below examine how they can impact the healing process.[2]

- **Age**—Wounds in older patients may heal more slowly than those in younger patients, mainly because of comorbidities that occur as a person ages. Older patients may have inadequate nutritional intake, altered hormonal responses, poor hydration, and compromised immune, circulatory, and respiratory systems, any of which can increase the risk of skin breakdown and delay wound healing.

• **Body type**—Body type may also affect wound healing. An obese patient, for example, may experience a compromise in wound healing due to poor blood supply to adipose tissue. In addition, some obese patients have protein malnutrition, which further impedes the healing. Conversely, when a patient is emaciated, the lack of oxygen and nutritional stores may interfere with wound healing.

• **Chronic diseases**—Coronary artery disease, peripheral vascular disease, cancer, and diabetes mellitus are a few of the chronic diseases that can compromise wound healing. Patients with chronic diseases should be followed closely through their course of care to provide the best plan.

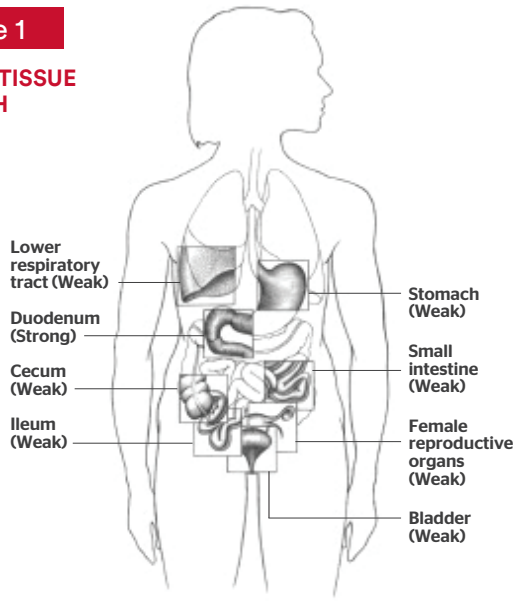
• **Immunosuppression and radiation therapy**—Suppression of the immune system by disease, medication, or age can delay wound healing. Radiation therapy can cause ulceration or change in the skin, either immediately after a treatment or after all treatment has ended.

* **Nutritional status**—Ongoing nutritional assessment is necessary because the visual appearance of the patient or the wound is not a reliable indicator of whether the patient is receiving the proper amount of nutrients. Albumin and prealbumin levels, total lymphocyte count, and transferrin levels are markers for malnutrition and must be assessed and monitored regularly, as protein is needed for cell growth.

• **Laboratory values**—Nutritional markers are not the only laboratory values that must be considered when evaluating healing. Measuring the hemoglobin level helps assess the oxygen-carrying capacity of the blood; however, it may also be necessary to assess hepatic, renal, and thyroid functions to determine the patient's healing capacity.

Figure 1

RELATIVE TISSUE STRENGTH



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. Organisms found within a patient's own body most commonly cause postoperative infection, but microorganisms carried by medical personnel also pose a threat. Whatever the source, the presence of 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.

• **The Length and Direction of the Incision**— A properly planned incision is sufficiently long to afford sufficient 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 incising 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 pre- serve 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 predisposition to microbial colonization.

• **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 diffused oozing on large denuded surfaces may interfere with the surgeon's view of underlying structures.

Achieving complete hemostasis before wound closure also will 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 Tissue—** 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 Material—** 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 Material—** 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.

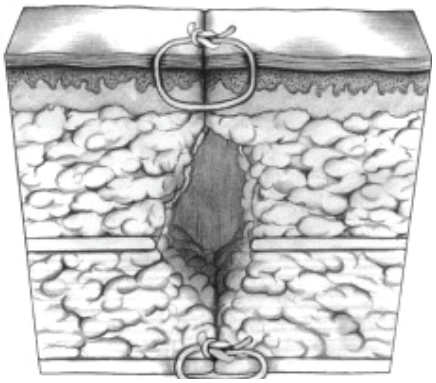
• **Cellular Response to Closure Materials—** Whenever foreign materials such as sutures are implanted in tissue, the tissue reacts. This reaction will range from minimal to moderate, depending upon the type of material implanted. The reaction will be more marked if complicated by infection, allergy, 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—** Dead space in a wound results from separation of portions of the wound beneath the skin edges that have not been closely approximated, or from air or fluid 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 elect to insert a drain or apply a pressure dressing to help eliminate dead space in the wound postoperatively.

Figure 2

DEAD SPACE IN A WOUND



- **Closing 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.

- **Postoperative Distration Forces—** 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.

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—** 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.[3]

Classification of Wounds

The Centers for Disease Control and Prevention (CDC), divides surgical wounds into 4 classes: clean wounds, clean-contaminated wounds, contaminated wounds, and dirty or infected wounds.[4] A discussion of each follows.

Seventy-five percent of all wounds (which are usually elective surgical incisions) fall into the *clean wounds* category—an uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tracts are not entered. These elective incisions are made under aseptic 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 usually are not 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 sutures or other forms of tissue apposition are no longer needed.

Clean-contaminated wounds are operative wounds in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled conditions and without unusual contamination. Specifically, operations involving the biliary tract, appendix, vagina, and oropharynx are included in this category provided no evidence of infection or major break in technique is encountered. Appendectomies, cholecystectomies, and hysterectomies fall into this category, as well as normally clean wounds which become contaminated by entry into a viscus resulting in minimal spillage of contents.

Contaminated wounds include open, traumatic wounds or 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 six 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 neglected 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.

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 the closure. Time Frames are generalized for well-perfused healthy soft tissues, but may vary.

HEALING BY PRIMARY INTENTION

Healing of acute wounds across primary intention occurs as a carefully regulated, systemic cascade of overlapping processes that require the coordinated completion of a variety of cellular activities. These activities occur in a cascade that correlates with the appearance of different cell types in the wound during various stages of the healing process.[1]

Inflammatory (preparative)— 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. These are the responses which prepare the site of injury for repair. The process lasts 3 to 7 days. Any factor which interferes with the progress, may interrupt or delay healing. 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.

Proliferative—After the debridement process is well along, fibroblasts begin to form a collagen matrix in the wound known as granulation tissue. Collagen, a protein substance, is the chief constituent of connective tissue. Collagen fiber formation determines the tensile strength and pliability of the healing wound. As it fills with new blood vessels, the granulation becomes bright, beefy, red tissue. The thick capillary bed which fills the matrix, supplies the nutrients and oxygen necessary for the wound to heal. This phase occurs from day 3 onward.

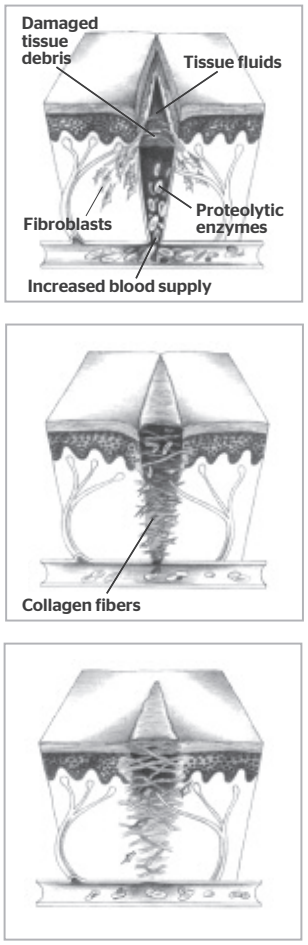
In time, sufficient collagen is laid down across the wound so that it can withstand normal stress. The length of this phase varies with the type of tissue involved and the stresses or tension placed upon the wound during this period.

Wound contraction also occurs during this phase. Wound contraction is a process that pulls the wound edges together for the purpose of closing the wound. In essence, it reduces the open area, and if successful, will result in a smaller wound with less need for repair by scar formation.

Surgical wounds that are closed by primary intention have minimal contraction response. Skin grafting is used to reduce avoided contraction in undesirable locations.

Remodeling—For up to a year after injury, the extracellular matrix is remodeled, helping the wound to regain strength and attain its final cosmetic appearance. As the scar matures, fibronectin and hyaluronan are broken down, and collagen bundles increase in diameter, corresponding with increasing tensile strength of the wound. However, these collagen fibers never regain the original strength of unwounded skin, and a maximum of 80% strength of unwounded skin can be achieved.[1]

Figure 3 **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 occurs in a wound with extensive soft tissue loss, such as in major traumas or severe burns.[1]

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 primary intention healing. Excessive granulation tissue may build up and require treatment if it protrudes above the surface of the wound, preventing epithelialization.

DELAYED PRIMARY CLOSURE

This is considered by many surgeons to be a safe method of management of contaminated, as well as dirty and infected traumatic wounds with extensive tissue loss and a high risk of infection.

The surgeon usually treats these injuries by debridement of nonviable tissues and leaves the wound open, inserting gauze packing which is changed twice a day. Patient sedation or a return to the operating room with general anesthesia generally is only required in the case of large, complex wounds. Wound approximation using adhesive strips, previously placed but untied sutures, staples after achieving local anesthesia can occur within 3 to 5 days if the wound demonstrates no evidence of infection and the appearance of red granulation tissue. Should this not occur, the wound is allowed to heal by secondary intention. When closure is undertaken, skin edges and underlying tissue must be accurately and securely approximated.

Suture as a Risk Factor For Surgical Site Infection (SSI)

Humans consist of 10^{13} cells, and bacteria living in/on humans add 10^{14} more cells, a 10:1 ratio (Avg. 4 lbs per person from bacteria). Most live in the gut and nasopharynx, while significant numbers live on/in epidermal layer of skin.

Estimates place surgical site infection as high as 5% for all surgical procedures. Suture material is prone to allowing development of bacterial biofilm and these biofilms serve as contributing factors in many infectious situations.[5]

Once bacteria have developed a protective biofilm the bacteria become more resistant to antibiotics. With a protective biofilm intact, bacteria can persist as a nidus for infection.[5]

While there is heightened concern around increased risk of SSI with other implanted biomedical devices, suture implants have not always shared this same awareness. The surface structure of suture material makes it susceptible for bacterial adherence. A study by Varma et al., Elek and Cohen, and Raju et al. established suture material is a foreign body and is a nidus for infection when contaminated even at low rates.[6]

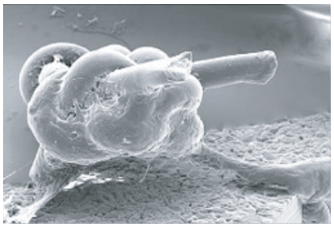
SUTURE CAN BE A SITE FOR INFECTION

Generally, large numbers of bacteria are required for infection to occur. In a typical patient, the infective dose is *2-8 million* microorganisms per gram of tissue. However, sutures—like all implanted material—can substantially lower the infective threshold. Studies have shown that the presence of a suture can decrease the dose of bacteria on the suture necessary to cause an SSI to just *100-300 microorganisms* per gram of tissue.[7]

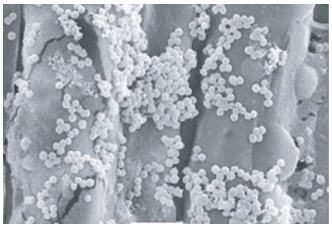
Typical bacterial concentration required for SSI to develop: 2,000,000 - 8,000,000 per gram of tissue[7]

Staphylococci concentration required on suture for SSI to develop: 100 - 300 per gram of tissue[7]

SSI can arise from underlying bacterial biofilms, which can invest implanted foreign bodies and associated soft tissue surfaces.[8]



Colonization of suture knot



Colonization of braided suture

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CHAPTER 2

THE SUTURE

What is a Suture?

The word "suture" describes any strand of material used to ligate (tie) bold vessels or approximate tissues. Sutures are used to close wounds. Sutures and ligatures were used by both the Egyptians and Syrians as far back as 2,000 B.C. Through the centuries, a wide variety of materials -silk, cotton, linen, 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.

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 used 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.
- 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 string, 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 principals that promote wound healing.

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 surgeon's choice of materials:

- His or her area of specialization.
- Wound closure experience during clinical training.
- Professional experience in the operation 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, Coated VICRYL™ Plus Antibacterial (polyglactin 910) Suture and MONOCRYL™ (poliglecaprone 25) Suture for all tissue layers, except possibly skin. Most orthopedic surgeons use Coated VICRYL Suture, Coated VICRYL Plus Antibacterial Suture, PDS™ II (polydioxanone) Suture, and ETHIBOND EXCEL™ Polyester Suture. Many plastic surgeons prefer ETHILON™ Nylon Suture, VICRYL™ (polyglactin 910) Knitted Mesh, or MONOCRYL Suture. Many neursurgeons prefer Coated VICRYL Suture or NUROLON™ 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. As 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.

Suture Characteristics

The choice of suture materials generally depends on whether the wound closure occurs in one or more layers. In selection the most appropriate sutures, the surgeon takes into account the amount of tension on the wound, the number of layers of closure, depth of suture placement, anticipated amount of edema, and anticipated timing of suture removal.

Optimal suture qualities include:

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 0s in the suture size increases, the diameter of the strand decreases. For example, United States Pharmacopeia (USP) 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.

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 that may cause infection.

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.

Table 1

METRIC MEASURES AND USP SUTURE DIAMETER EQUIVALENTS

USP Size	11-0	10-0	9-0	8-0	7-0	6-0	5-0	4-0	3-0	2-0	0	1	2	3	4	5	6
Natural Collagen	--	0.2	0.3	0.5	0.7	1.0	1.5	2.0	3.0	3.5	4.0	5.0	6.0	7.0	8.0	--	--
Synthetic Absorbables	--	0.2	0.3	0.4	0.5	0.7	1.0	1.5	2.0	3.0	3.5	4.0	5.0	6.0	6.0	7.0	--
Nonabsorbable Materials	0.1	0.2	0.3	0.4	0.5	0.7	1.0	1.5	2.0	3.0	3.5	4.0	5.0	6.0	6.0	7.0	8.0

The metric gauging system of suture materials indicates the actual diameter of materials. It has been adopted and approved by both the European and the United States Pharmacopeia. The metric number represents the diameter of the suture in tenths of a millimeter.

ABSORBABLE VS. NONABSORBABLE SUTURES

Sutures are classified according to their degradation properties. Sutures that undergo degradation and absorption in tissues are considered *absorbable* sutures. Sutures that generally maintain their tensile strength and are resistant to absorption are *nonabsorbable* sutures.

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. 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 that 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.

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. In addition, if the sutures become wet or moist prior to use, the absorption process may begin prematurely. Similarly, patients with impaired healing are often not ideal candidates for this type of suture. 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.

Table 2

ABSORBABLE SUTURES: BASIC RAW MATERIALS

SUTURE	RAW MATERIAL
Surgical Gut Plain • Chromic • Fast-Absorbing	Submucosa of sheep intestine or serosa of beef intestine
Polyglactin 910 Uncoated (VICRYLSuture) Coated (Coated VICRYL Suture, Coated VICRYL Plus Antibacterial Suture, Coated VICRYL *RAPIDE* Suture)	Copolymer of glycolide and lactide with polyglactin 370 and calcium stearate, if coated
Polyglycolic Acid	Homopolymer of glycolide
Poliglecaprone 25 (MONOCRYL Suture)	Copolymer of glycolide and epsilon-caprolactone
Polyglyconate	Copolymer of glycolide and trimethylene carbonate
Polydioxanone (PDS II Suture)	Polyester of poly (p-dioxanone)

Nonabsorbable sutures are those which are not digested by body enzymes or hydrolyzed in body tissue. They are made from a variety of nonbiodegradable materials and are ultimately encapsulated or walled off by the body's fibroblasts. Nonabsorbable sutures ordinarily remain where they are buried within the tissues. When used for skin closure, they must be removed postoperatively. Nonabsorbable sutures 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 (ie, 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, typically conforming to the USP limitations for each size. Nonabsorbable sutures have been classified by the USP 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.

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.

Table 3

NON-ABSORBABLE SUTURES: RAW MATERIALS

SUTURE	RAW MATERIAL
Surgical Silk	Raw silk spun by silkworm
Stainless Steel Wire	Specially formulated iron-chromium-nickel-molybdenum alloy
Nylon (ETHILON Suture, NUROLON Suture)	Polyamide polymer
Polyester Fiber Uncoated (MERSILENE® Polyester Fiber Suture) Coated (ETHIBOND EXCEL Suture)	Polymer of polyethylene terephthalate (may be coated)
Polypropylene (PROLENE Suture)	Polymer of propylene
Poly(hexaflouropropylene-VDF) PRONOVA® Poly (Hexaflouropropylene-VDF Suture)	Polymer blend of poly (vinylidene fluoride) and poly (vinylidene fluoride-cohexafluoropropylene)

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. Non-collagenous 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 USP specifications, the serosa layer of beef intestine or processed ribbons of the submucosa layer of sheep intestine are 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 (0.0175 mm) 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 tend 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 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 typically complete within 70 days. The surgeon may choose plain gut for use in tissues that 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 USP 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 TRU 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 offer the strength needed for a wide range of applications, from abdominal and chest wound closure to ophthalmic and plastic surgery.

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 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 that 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 post implantation, 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 post implantation. All of the original tensile strength of undyed MONOCRYL Suture is lost by 21 days post implantation. Absorption is essentially complete at 91 to 119 days.

MONOCRYL™ PLUS ANTIBACTERIAL (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 that 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 Plus Antibacterial Suture contains IRGACARE MP®†, one of the purest forms of the broad-spectrum antibacterial agent triclosan.

MONOCRYL Plus Antibacterial suture has been shown to inhibit colonization of the suture by Staphylococcus epidermidis, Methicillin Resistant S. aureus, Klebsiella and Methicillin Resistant S. epidermidis, Escherichia coli are microorganisms known to contribute to pneumoniae surgical site infections.[1] Clinical trials found comparable wound healing to MONOCRYL without triclosan.[2]

MONOCRYL Plus Antibacterial Suture performs and handles the same as MONOCRYL Suture. MONOCRYL Plus Antibacterial Suture has the same dependable construction as MONOCRYL Suture.

MONOCRYL Plus Antibacterial Suture is available dyed (violet) and undyed (natural). Dyed MONOCRYL Suture retains 60% to 70% of its original strength at 7 days post implantation, 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 post implantation. All of the original tensile strength of undyed MONOCRYL Plus Antibacterial Suture is lost by 21 days post implantation. Absorption is essentially complete at 91 to 119 days.

† A trademark of BASF SE

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 ease of handling, smooth tie down, and unsurpassed knot security.

The coating is a combination of equal parts of copolymer 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, non-flaking lubricant.

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 sizes 6-0 and larger. At 4 weeks, 40% of tensile strength is retained for sizes 7-0 and smaller. At 4 weeks, 25% of the original strength is retained for sizes 6-0 and larger. All the original tensile strength is lost by 5 weeks post- implantation. Absorption of Coated VICRYL Suture is essentially complete between 56 and 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™ PLUS ANTIBACTERIAL (POLYGLACTIN 910) SUTURE

This synthetic, absorbable, sterile, surgical suture is a copolymer made from 90% glycolide and 10% L-lactide. Coated VICRYL Plus Antibacterial Suture is coated with a mixture com- posed of equal parts of copolymer of glycolide and lactide (polyglactin 370) and calcium stearate. Coated VICRYL Plus Antibacterial Suture contains IRGACARE MP®†, one of the purest forms of the broad-spectrum antibacterial agent triclosan.

Coated VICRYL™ Plus Antibacterial Suture has been shown to inhibit colonization of the suture microorganisms known to contribute to surgical site infections.[3] *In vivo* studies demonstrate that Coated VICRYL Plus Antibacterial Suture has no adverse effect on normal wound healing.[2]

Coated VICRYL Plus Antibacterial Suture performs and handles the same as Coated VICRYL Suture. Coated VICRYL Plus Antibacterial Suture has the same dependable construction as Coated VICRYL Suture. *In vivo* testing by surgeons demonstrates the same excellence in performance and handling.[2]

The suture is available undyed (natural) or dyed. Coated VICRYL Plus Antibacterial Suture is indicated for use in general soft tissue approximation and/or ligation requiring medium support, except for ophthalmic, cardiovascular, and neurological tissues. Frequent uses include general closure, bowel, orthopedic, and plastic surgery.

Coated VICRYL Plus Antibacterial Suture retains approximately 75% of the original tensile strength at 2 weeks post implantation. At 3 weeks, approximately 50% of the original strength is retained. At 4 weeks, approximately 25% of the original strength is retained. All of the original tensile strength is lost by 5 weeks post implantation. Absorption of Coated VICRYL Plus Antibacterial Suture is essentially complete between 56 and 70 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. This material is well suited for many types of soft tissue approximation, including pediatric cardiovascular, orthopedic, gynecologic, ophthalmic, plastic, digestive, and colonic surgeries.

Like other synthetic absorbable sutures, PDS II Sutures are absorbed *in vivo* through hydrolysis. For sizes 3-0 and larger approximately 80% of tensile strength remains 2 weeks post implantation, 70% at 4 weeks, and 60% at 6 weeks. For sizes 4-0 and smaller approximately 60% of tensile strength remains 2 weeks post implantation, 40% at 4 weeks, and 35% at 6 weeks.

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Absorption is minimal until about the 90th day postoperatively and essentially complete within 182 – 238 days. 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.

PDS™ PLUS Antibacterial (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. This material is well suited for many types of soft tissue approximation, including pediatric cardiovascular, orthopedic, gynecologic, ophthalmic, plastic, digestive, and colonic surgeries.

PDS Plus Antibacterial Suture contains IRGACARE MP®†, one of the purest forms of the broad-spectrum antibacterial agent triclosan.

Irgacare MP (triclosan) in PDS Plus Antibacterial suture has been shown to inhibit colonization of the suture by Staphylococcus aureus, Staphylococcus epidermidis, Methicillin Resistant S. aureus, Methicillin Resistant S. epidermidis, Escherichia coli, and Klebsiella pneumoniae which are microorganisms known to contribute to surgicalsite infections.[4] Clinical trials found comparable wound healing to PDS without triclosan.[2]

PDS Antibacterial Suture performs and handles the same as PDS II Suture. PDS Plus Antibacterial Suture has the same dependable construction as PDS II Suture. In vivo testing by surgeons demonstrates the same excellence in performance and handling.

Like other synthetic absorbable sutures, PDS Plus Antibacterial Sutures are absorbed in vivo through hydrolysis. For sizes 3-0 and larger approximately 80% of tensile strength remains 2 weeks postimplantation, 70% at 4 weeks, and 60% at 6 weeks. For sizes 4-0 and smaller approximately 60% of tensile strength remains 2 weeks postimplantation, 40% at 4 weeks, and 35% at 6 weeks.

Absorption is minimal until about the 90th day postoperatively and essentially complete within 182 – 238 days. The safety and effectiveness of PDS Plus Antibacterial sutures in microsurgery, neural tissue, and adult cardiovascular tissue have not been established. PDS II sutures are available undyed or dyed violet to enhance visibility.

STRATAFIX™ SYMMETRIC PDS™ PLUS KNOTLESS TISSUE CONTROL DEVICE
STRATAFIX Symmetric PDS Plus Knotless Tissue Control Device is an antibacterial (polydioxanone) monofilament, synthetic absorbable device. The device contains IRGACARE®† MP (triclosan), a broad spectrum antibacterial agent. STRATAFIX Symmetric PDS Plus Antibacterial is available dyed violet.

STRATAFIX Symmetric PDS Plus Device consists of an absorbable thread with unidirectional anchors, equipped with a surgical needle at one end and a fixation tab at the other. The anchors and fixation tab design allows for tissue approximation without the need to tie surgical knots.

Like other synthetic absorbable sutures, STRATAFIX Symmetric PDS Plus Device is absorbed in vivo through hydrolysis. Approximately 75% of tensile strength remains 2 weeks postimplantation, 65% at 4 weeks, and 55% at 6 weeks. Absorption is essentially complete at 210 days post implantation.

STRATAFIX™ SPIRAL PDS™ PLUS KNOTLESS TISSUE CONTROL DEVICE ANTIBACTERIAL
The STRATAFIX Spiral PDS Plus Device is an antibacterial monofilament, synthetic absorbable device consisting of dyed (violet) polydioxanone. The device contains IRGACARE®† MP (triclosan), a broad spectrum antibacterial agent.

The STRATAFIX Spiral PDS Plus Device, Variable Loop Design consists of barbed suture material, armed with a surgical needle on one end and a fixation loop at the opposite end. The STRATAFIX Spiral PDS Plus Device barbs are oriented in one direction to allow tissue approximation without the need to tie knots.

Like other synthetic absorbable sutures, STRATAFIX Symmetric PDS Plus Device is absorbed in vivo through hydrolysis. For sizes 3-0 and larger approximately 80% of its original strength remains 2 weeks post implantation, 80% at 4 weeks, and 40-70% at 6 weeks. For sizes 4-0 and smaller approximately 67% of its original strength remains 2 weeks post implantation, 50% at 4 weeks, and 37% at 6 weeks. Absorption is essentially complete at 210 days post implantation.

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STRATAFIX™ SPIRAL MONOCRYL™ PLUS KNOTLESS TISSUE CONTROL DEVICE ANTIBACTERIAL

The STRATAFIX Spiral MONOCRYL Plus Device is an antibacterial monofilament, synthetic absorbable device. The device contains IRGACARE MP (triclosan), a broad spectrum antibacterial agent.

The STRATAFIX Spiral MONOCRYL Plus Device, Variable Loop Design consists of barbed suture material, armed with a surgical needle on one end and a fixation loop at the opposite end. The STRATAFIX Spiral MONOCRYL Plus Device barbs are oriented in one direction to allow tissue approximation without the need to tie knots.

Like other synthetic absorbable sutures, STRATAFIX Spiral MONOCRYL Plus Device is absorbed in vivo through hydrolysis. Approximately 62% of its original strength remains 7 days post implantation, 27% at 14 days. Absorption is essentially complete at 91 days post implantation.

STRATAFIX™ SPIRAL PGA-PCL KNOTLESS TISSUE CONTROL DEVICE

STRATAFIX Spiral PGA-PCL Knotless Tissue Control Device consist of barbed suture material armed with a surgical needle on each end. Barbs allow for tissue approximation without the need for surgical knots. This suture is provided undyed.

STRATAFIX Spiral PGA-PCL Device is indicated for use in soft tissue approximation where the use of absorbable suture is appropriate.

Like other synthetic absorbable sutures, STRATAFIX Spiral PGA-PCL Device is absorbed in vivo through hydrolysis. Approximately 62% of its original strength remains 7 days post implantation, 27% at 14 days. Absorption is essentially complete between 90 – 120 days post implantation.

STRATAFIX™ SPIRAL PDO KNOTLESS TISSUE CONTROL DEVICE

STRATAFIX Spiral PDO Knotless Tissue Control Device consist of barbed suture material armed with a surgical needle on each end. Barbs allow for tissue approximation without the need for surgical knots. This suture is provided dyed violet.

Like other synthetic absorbable sutures, STRATAFIX Spiral PDO Device is absorbed in vivo through hydrolysis. For sizes 3-0 and larger approximately 80% of its original strength remains 2 weeks post implantation, 80% at 4 weeks, and 40-70% at 6 weeks. For sizes 4-0 and smaller approximately 67% of its original strength remains 2 weeks post implantation, 50% at 4 weeks, and 37% at 6 weeks. Absorption is essentially complete at 210 days post implantation.

NONABSORBABLE SUTURES

SURGICAL SILK

For many surgeons, *surgical silk* represents the standard handling 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 moth 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 that 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™ Silk Sutures.

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

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 orthopedic 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 dehiscence.

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 USP 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

SURGICAL STAINLESS STEEL: WIRE GAUGE EQUIVALENTS

DIAMETER	USP	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
.0360	6	19
.0400	7	18

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. The medical grade polyamide 6-6 is used for sizes 7-0 and finer. While both grades permit good handling, monofilament nylon sutures tend 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 nylon than braided nylon 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
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. 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 polybutilate, a biologically inert, nonabsorbable compound which adheres itself to the braided polyester fiber strand. Polybutilate 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 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.

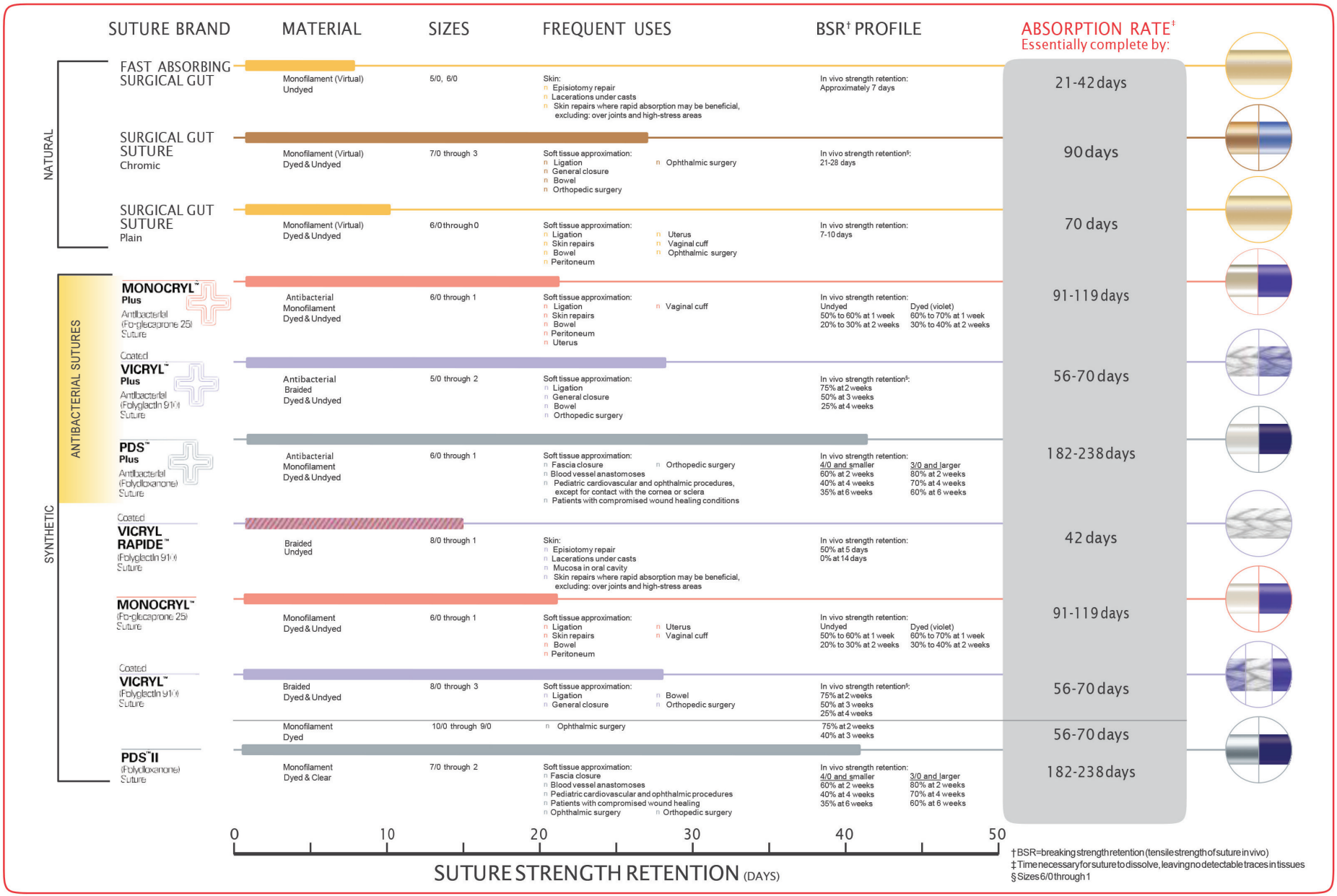
PROLENE™ POLYPROPYLENE SUTURE
Widely used in general, cardiovascular, plastic, and orthopedic surgery, PROLENE Sutures do not adhere to tissue and are therefore efficacious. PROLENE Sutures are relatively biologically inert, offering proven strength, reliability, and versatility. PROLENE Sutures are recommended for use where minimal suture reaction is desired. They are available clear or dyed blue.

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 cause minimal tissue reaction and hold knots better than most other synthetic monofilament materials.

PRONOVA™ POLY (HEXAFLUOROPROPYLENE-VDF) SUTURE
This monofilament nonabsorbable suture is a polymer blend of poly (vinylidene fluoride) and poly (vinylidene fluoride-cohexafluoro- propylene). 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 Sutures as a pull-out suture.

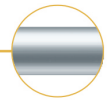
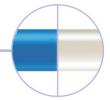
This material is well suited for many types of soft tissue approximation and ligation, including use in cardiovascular, ophthalmic, and neurological procedures.

Absorbable Sutures: The Strength You Need for the Choices You Make



† BSR=breaking strength retention (tensile strength of suture in vivo)
‡ Time necessary for suture to dissolve, leaving no detectable traces in tissues
§ Sizes 6/0 through 1

Nonabsorbable Sutures: The Strength You Need for the Choices You Make

	SUTURE BRAND	MATERIAL	SIZES	FREQUENT USES	BSR† PROFILE	
NATURAL	PERMA-HAND® Silk Suture	Braided Black	5, 2 through 7/0	General soft tissue approximation and/or ligation: n Cardiovascular n Ophthalmic n Neurological	Gradual loss of all tensile strength over time	
NATURAL	SURGICAL STAINLESS STEEL Suture	Monofilament Silver Metallic	7 through 5/0	Soft tissue approximation: n Abdominal n Sternal Closure n Orthopedic procedures including cerclage and tendon repair	Indefinite	
SYNTHETIC	NUROLON™ Nylon Suture	Braided Black	1 through 6/0	General soft tissue approximation and/or ligation: n Neurological n Cardiovascular n Ophthalmic	Gradual loss of tensile strength over time	
SYNTHETIC	ETHILON™ Nylon Suture	Monofilament Black/Green/ Undyed (Clear)	2 through 11/0	General soft tissue approximation and/or ligation: n Cardiovascular n Ophthalmic n Neurological n Skin Closure	Gradual loss of tensile strength over time	
SYNTHETIC	MERSILENE™ Polyester Fiber Suture	Braided Green / Undyed (white) Monofilament Green	1 through 6/0 10/0 through 11/0	General soft tissue approximation and/or ligation: n Cardiovascular n Ophthalmic n Neurological	Indefinite	
SYNTHETIC	ETHIBOND EXCEL™ Polyester Suture	Braided Green / Undyed (white)	5, 2 through 7/0	General soft tissue approximation and/or ligation: n Cardiovascular n Ophthalmic n Neurological	Indefinite	
SYNTHETIC	PROLENE™ Polypropylene Suture	Monofilament Blue / Clear	2 through 10/0	General soft tissue approximation and/or ligation: n Cardiovascular n Ophthalmic n Neurological	Indefinite	
SYNTHETIC	PRONOVA™ Poly (Hexafluoropropylene-VDF) Suture	Monofilament Blue	2/0 through 8/0	General soft tissue approximation and/or ligation: n Cardiovascular n Ophthalmic n Neurological	Indefinite	

† BSR=breaking strength retention (tensile strength of suture in vivo)

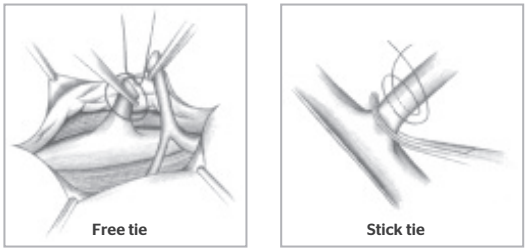
Common Suturing Techniques

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 2 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 or other similar type of surgical clamp 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 square and 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.

Figure 1 LIGATURES



THE PRIMARY SUTURE LINE

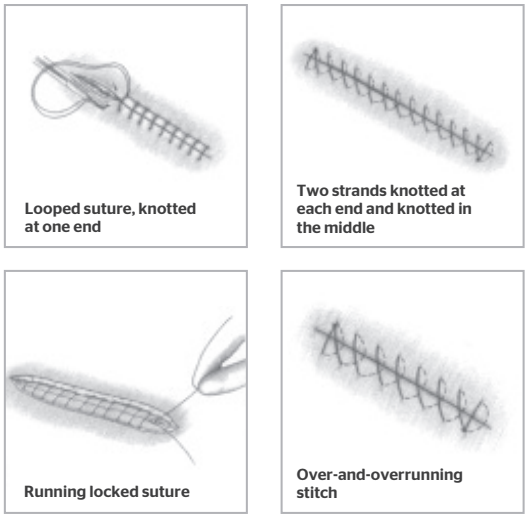
The *primary suture* line is the line of sutures that holds the wound edges in approximation during healing by first intention. It may consist of a continuous strand of material or a series of interrupted suture strands. Other types of primary sutures, such as deep sutures, buried sutures, purse-string 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. Excessive tension 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 1 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.

Figure 2 CONTINUOUS SUTURING TECHNIQUES



LOOP 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 of 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.

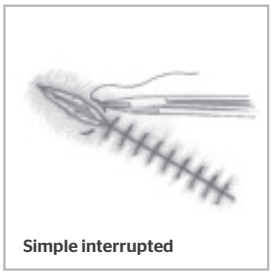
INTERRUPTED SUTURES

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.

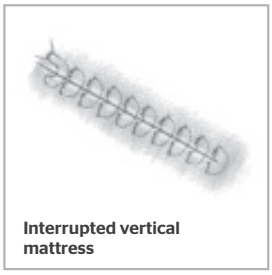
Interrupted sutures may be used if a wound is infected, because microorganisms may be less likely to travel along a series of interrupted stitches.

Figure 3

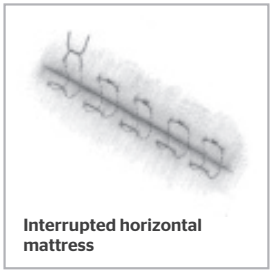
INTERRUPTED SUTURING TECHNIQUES



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.

Figure 4

DEEP SUTURES

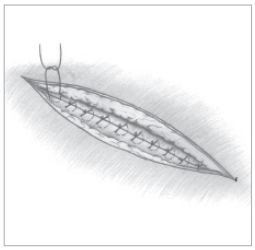
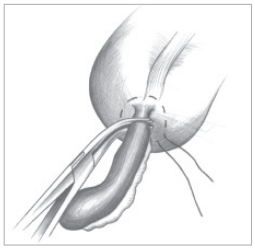


Figure 5

PURSE-STRING SUTURES



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).

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.

Figure 6

SUBCUTANEOUS SUTURES

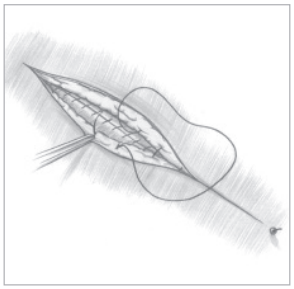
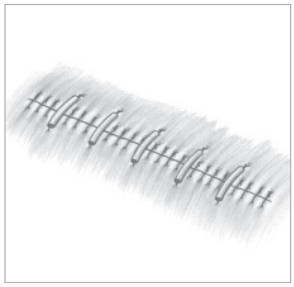


Figure 7

RETENTION SUTURE BOLSTER



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 (ie, 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 approximately three quarters of 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.

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.

Knot Tying

Of the more than 1,400 different types of knots described in *THE ENCYCLOPEDIA OF KNOTS*, only a few are used in modern surgery. It is of paramount importance that each knot placed for approximation of tissues or ligation of vessels be tied with precision and each must hold with proper tension.

KNOT SECURITY

The construction of ETHICON™ Sutures has been carefully designed to produce the optimum combination of strength, uniformity, and hand for each material. The term *hand* is the most subtle of all suture quality aspects. It relates to the feel of the suture in the surgeon's hands, 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 in which the suture will stretch slightly during knot tying and then recover. The stretching characteristics provide the signal that alerts the surgeon to the precise moment when the suture knot is snug.

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, however, all the synthetic materials require a specific knotting technique. With multifilament sutures, the nature of the material and the braided or twisted construction provide a high coefficient of friction and the knots remain as they are laid down. In monofilament sutures, on the other hand, the coefficient of friction is relatively low, resulting in a greater tendency for the knot to loosen after it has been tied. In addition, monofilament synthetic polymeric materials possess the property of memory. *Memory* is the tendency not to lie flat, but to return to a given shape set by the material's extrusion process or the suture's packaging. The RELAY* Suture Delivery System delivers sutures with minimal package memory due to its unique package design.

Suture knots must be properly placed to be secure. Speed in knot tying frequently results in less than perfect placement of the strands. In addition to variables inherent in the suture materials, considerable variation can be found between knots tied by different surgeons and even between knots tied by the same individual on different occasions.

The general principles of knot tying that apply to all suture materials are:

1. The completed knot must be firm, and so tied that slipping is virtually impossible. The simplest knot for the material is the most desirable.

2. The knot must be as small as possible to prevent an excessive amount of tissue reaction when absorbable sutures are used, or to minimize foreign body reaction to nonabsorbable sutures. Ends should be cut as short as possible.

3. In tying any knot, friction between strands ("sawing") must be avoided as this can weaken the integrity of the suture.

4. Care should be taken to avoid damage to the suture material when handling. Avoid the crushing or crimping application of surgical instruments, such as needle holder and forceps, to the strand except when grasping the free end of the suture during an instrument tie.

5. Excessive tension applied by the surgeon will cause breaking of the suture and may cut tissue. Practice in avoiding excessive tension leads to successful use of finer gauge materials.

6. Sutures used for approximation should not be tied too tightly, because this may contribute to tissue strangulation.

7. After the first loop is tied, it is necessary to maintain traction on one end of the strand to avoid loosening of the throw if being tied under any tension.

8. Final tension on final throw should be as nearly horizontal as possible.

9. The surgeon should not hesitate to change stance or position in relation to the patient in order to place a knot securely and flat.

10. Extra ties do not add to the strength of a properly tied and squared knot. They only contribute to its bulk. With some synthetic materials, knot security requires the standard surgical technique to flat and square ties with additional throws if indicated by surgical circumstance and the experience of the surgeon.

Table 5 COMMONLY USED TYPES OF STITCHES

CONTINUOUS SUTURE	INTERRUPTED SUTURES
To appose skin and other tissue	
Over-and-over Subcuticular	Over-and-over Vertical mattress Horizontal mattress
To invert tissue	
Lembert Cushing Connell	Lembert Halstead Purse-string
To evert tissue	
Horizontal mattress	Horizontal mattress

KNOT TYING TECHNIQUES MOST OFTEN USED

An important part of good suturing technique is correct method in knot tying. A seesaw motion, or the sawing of one strand down over another until the knot is formed, may materially weaken sutures to the point that they may break when the second throw is made, or even worse, in the postoperative period when the suture is further weakened by increased tension or motion. If the 2 ends of the suture are pulled in opposite directions with uniform rate and tension, the knot may be tied more securely.

Some procedures involve tying knots with the fingers, using 1 or 2 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.

The following are the most frequently used knot tying techniques with accompanying illustrations of finished knots.

SQUARE KNOT

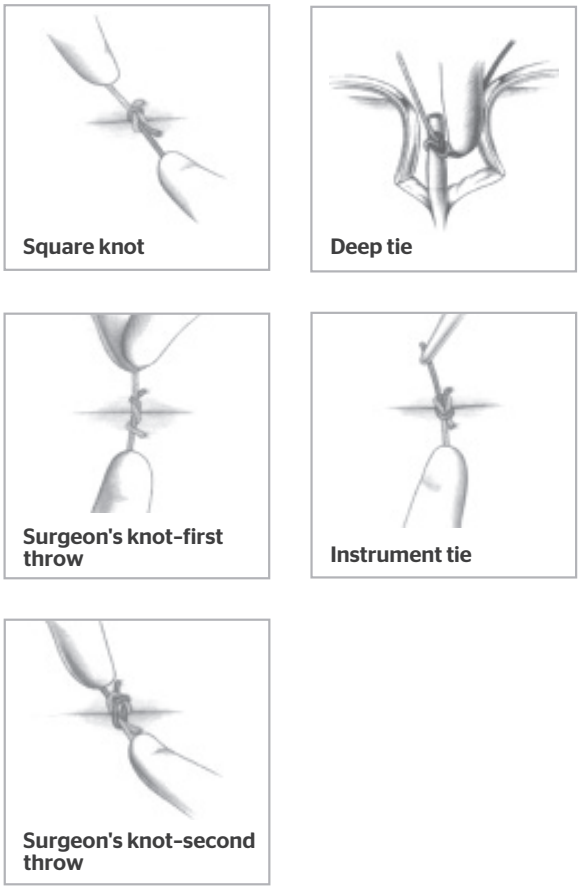
The 2-hand square knot is the easiest and most reliable for tying most suture materials. It may be used to tie surgical gut, virgin silk, surgical cotton, and surgical stainless steel. Standard technique of flat and square ties with additional throws if indicated by the surgical circumstance and the experience of the operator should be used to tie MONOCRYL Suture, MONOCRYL Plus Suture, VICRYL Suture, Coated VICRYL Suture, Coated VICRYL Plus Suture, Coated VICRYL RAPIDE Suture, PDS II Suture, ETHILON Nylon Suture, ETHIBOND EXCEL Suture, PERMA-HAND Silk Suture, PRONOVA poly (hexafluoropropylene-VDF) Suture, and PROLENE Suture. Wherever possible, the square knot is tied using the 2-hand technique. On some occasions it will be necessary to use 1 hand, either the left or the right, to tie a square knot.

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.

SURGEON'S OR FRICTION KNOT

The surgeon's or friction knot is recommended for tying VICRYL Suture, Coated VICRYL Plus Suture, ETHIBOND EXCEL Suture, ETHILON Nylon Suture, MERSILENE Suture, NUROLON Suture, PRONOVA poly (hexa-fluoropropylene-VDF) Suture, and PROLENE Suture. The surgeon's knot also may be performed using a 1-hand technique.

Figure 8 FINISHED SUTURE TIES



DEEP TIE

Tying deep in a body cavity can be difficult. The square knot must be firmly snugged down as in all situations. However, the operator must avoid upward tension that may tear or avulse the tissue.

LIGATION USING A HEMOSTATIC CLAMP

Frequently it is necessary to ligate a blood vessel or tissue grasped in a hemostatic clamp to achieve hemostasis in the operative field.

INSTRUMENT TIE

The instrument tie is useful when one or both ends of the suture material are short. For best results, exercise caution when using a needle holder with any monofilament suture, as repeated bending may cause these sutures to break.

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 needle holder, 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 THE SECURED 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 inch (6 mm) from the knot. Other materials are cut closer to the knot, approximately 1/8 inch (3 mm), 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 external wound has healed so that it no longer needs the support of nonabsorbable 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. 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.

- **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.

Suture Selection Procedure

PRINCIPLES OF SUTURE SELECTION

The surgeon has a choice of suture materials from which to select for use in body tissues. Adequate strength of the suture material will prevent suture breakage. Secure knots will prevent knot slippage. But the surgeon must understand the nature of the suture material, the biologic forces in the healing wound, and the interaction of the suture and the tissues. The following principles should guide the surgeon in suture selection.

1. When a wound has reached maximal strength, sutures are no longer needed. Therefore:

- **a.** Tissues that ordinarily heal slowly such as skin, fascia, and tendons should usually be closed with nonabsorbable sutures. An absorbable suture with extended (up to 6 months) wound support may also be used.
- **b.** Tissues that heal rapidly such as stomach, colon, and bladder may be closed with absorbable sutures.

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

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

- **a.** Use the smallest inert monofilament suture materials such as nylon or polypropylene.
- **b.** Avoid skin sutures and close subcuticularly whenever possible.
- **c.** Under certain circumstances, to secure close apposition of skin edges, a topical skin adhesive or skin closure tape may be used.

4. Foreign bodies in the presence of fluids containing high concentrations of crystalloids may act as a nidus for precipitation and stone formation. Therefore:

- **a.** In the urinary and biliary tracts, use rapidly absorbed sutures.

5. Regarding suture size:

- **a.** Use the finest size suture commensurate with the natural strength of the tissue.
- **b.** If the postoperative course of the patient may produce sudden strains on the suture line, reinforce it with retention sutures. Remove them as soon as the patient's condition is stabilized.

SURGERY WITHIN THE ABDOMINAL WALL CAVITY

Entering the abdomen, the surgeon will need to seal or tie off subcutaneous blood vessels immediately after the incision is made, using either an electrosurgical unit designed for this purpose or free ties (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 performing a procedure involving 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 inch (6 mm) 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.

Many surgeons prefer to use a double-layer closure, placing a second layer of interrupted sutures through the serosa for insurance. Absorbable VICRYL and VICRYL Plus 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. 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.

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 that 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 typically heals very rapidly, reaching maximal strength in approximately 14 days.

Figure 9

ANASTOMOTIC CLOSURE TECHNIQUE

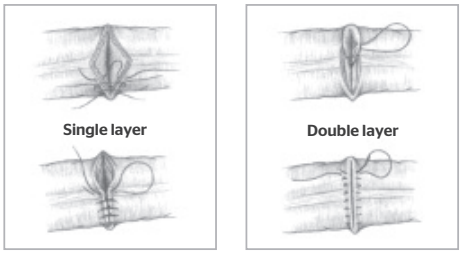
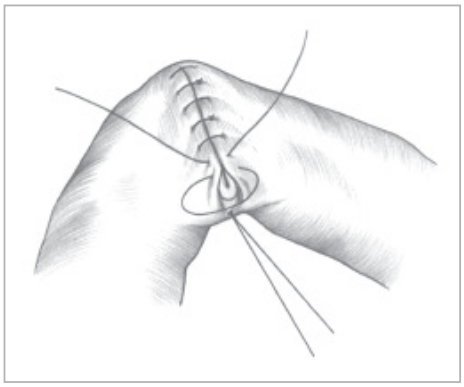


Figure 10

INVERTED CLOSURE TECHNIQUE



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 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.

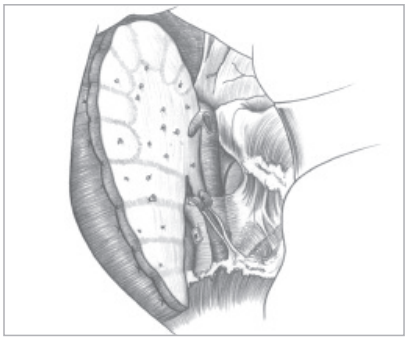
Because these organs are composed chiefly of cells with little connective tissue for support, attempts must be made to coapt the outer fibrous capsule of the torn tissue. In the absence of hemorrhage, little tension is placed on the suture line and only small size sutures need to be used. If the tissue 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 within 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 Coated VICRYL Sutures or silk. Raw surfaces can be closed or repaired using VICRYL Woven Mesh.

Figure 11

LIVER RESECTION



CLOSING THE ABDOMEN

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

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 intraabdominal 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.

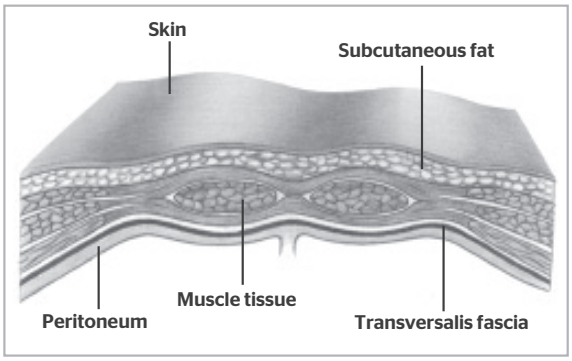
Fascia regains approximately 40% of its original strength in 2 months. It may take up to a year or longer to regain maximum strength. Full original strength is never regained.

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 postoperative 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, may also provide adequate support. PDS II Sutures are especially well suited for use in younger, healthy patients.

Many surgeons prefer the use of interrupted simple or figure-of-eight sutures to close fascia, while others employ running suture or a combination of these techniques. 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 materia*l like PDS II Sutures or inert *nonabsorbable sutures* like stainless steel or PROLENE Sutures may be used.

Figure 12 THE ABDOMINAL WALL



MUSCLE

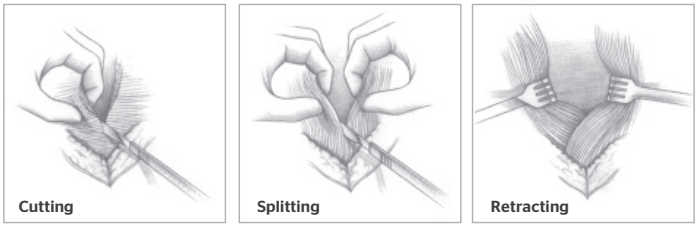
Muscle does not tolerate suturing well. However, there are several options in this area.

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.

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™ Woven Mesh 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.

Figure 13 SURGICAL OPTIONS IN MUSCLE



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 Woven Mesh 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.

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 close 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 can maintain 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 Chapter 3: The Surgical Needle)*

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.

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.

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 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.

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.

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 2 sutures at 12 and 6 o'clock positions, or 4 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 1 or 2 nonabsorbable sutures. This prevents the drain from slipping into or out of the wound.

SUTURE NEEDS IN OTHER BODY TISSUES/ NEUROSURGERY

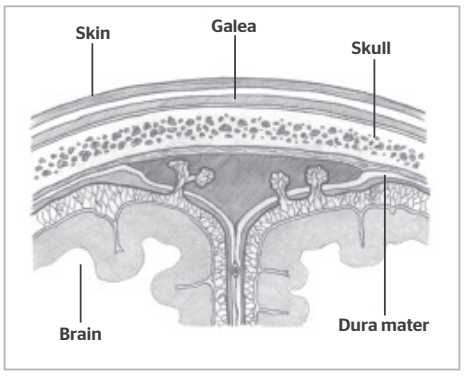
Surgeons have traditionally used an interrupted technique to close the galea and dura mater.

The tissue of the galea, like 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.

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 because it ties easily, offers greater strength than surgical silk, and causes less tissue reaction. PROLENE Sutures has also been accepted by surgeons who prefer a continuous closure technique, who must repair potentially infected wounds, or who must repair dural tears.

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.

Figure 14 LAYERS OF SUTURES SURROUNDING A DRAIN



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

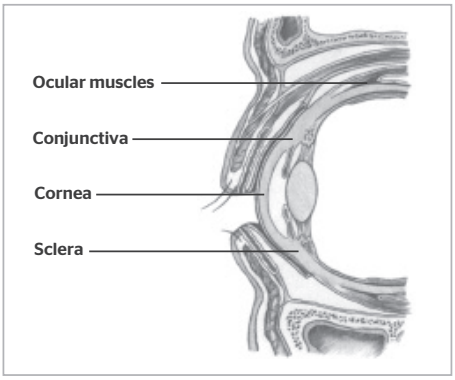
The eye presents special healing challenges. The ocular muscles, the conjunctiva, and the sclera have good blood supplies; but the cornea is an avascular structure. While epithelialization of the cornea occurs rapidly in the absence of infection, full thickness cornea wounds heal slowly. Therefore, in 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.

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, Coated VICRYL Sutures have proven useful in muscle and cataract surgery.

The ophthalmologist has many fine size suture materials to choose from for keratoplasty, cataract, and vitreous retinal microsurgical procedures. In addition to Coated 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.

Figure 15

THE EYE



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 gut 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.

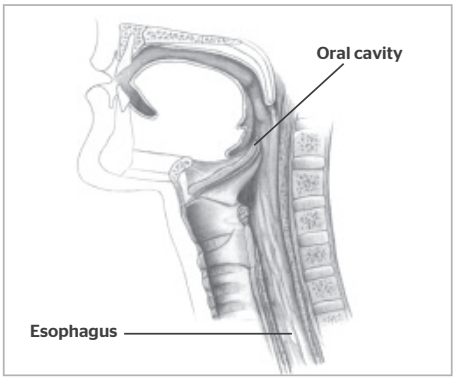
The oral cavity and pharynx generally heal quickly if not infected. Fine size sutures are adequate in this area as the wound is under little tension. *Absorbable sutures* may be preferred. Patients, especially children, usually find them more comfortable. However, the surgeon may prefer a monofilament *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™ (polyglactin 910) 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.

Figure 16

THE UPPER ALIMENTARY CANAL



RESPIRATORY TRACT SURGERY

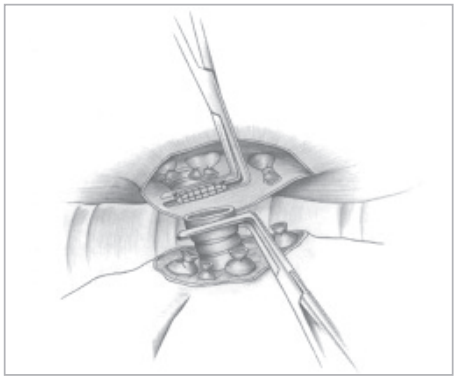
Relatively few studies have been done on healing in the respiratory tract. Bronchial stump closure following lobectomy or pneumonectomy presents a particular challenge. Infection, long stumps, poor approximation of the transected bronchus, and incomplete closure (ie, air leaks) may lead to bronchopleural 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.

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.

Figure 17

BRONCHIAL STUMP CLOSURE

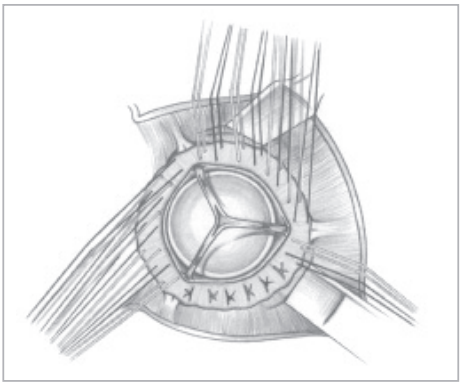


CARDIOVASCULAR SURGERY

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 typically used on the sternum unless it is fragile, in which case absorbable sutures can be used.

Figure 18

SEATING A HEART VALVE WITH ETHIBOND EXCEL SUTURE



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. 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 two 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 that 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.

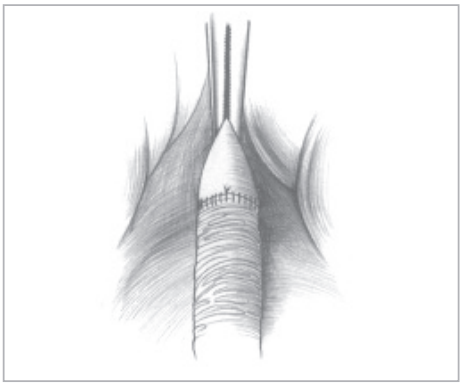
Either a continuous or interrupted technique may be used for vessel to graft anastomoses.

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.

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.

Figure 19

CONTINUOUS STRAND SUTURING IN VASCULAR SURGERY



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.

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. Coated VICRYL Suture is an excellent choice to prevent bacterial colonization.

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 Coated 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 Coated 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 peritendonous 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.

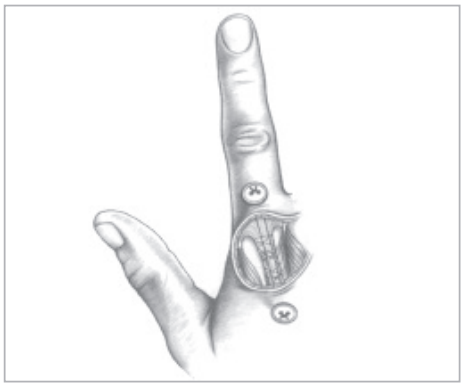
The suture material the surgeon chooses must be inert and strong. Because tendon ends can separate due to muscle pull, sutures with a great degree of elasticity should be avoided. Surgical steel is widely used because of its durability and lack of elasticity. *Synthetic nonabsorbable materials* including polyester fibers, polypropylene, and nylon may be used. In 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.

NUROLON Sutures, PROLENE Sutures, PRONOVA Sutures and ETHIBOND EXCEL 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.

Figure 20

THE BUNNELL TECHNIQUE



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 sides of the sternum will result, causing postoperative pain and possibly dehiscence. Painful nonunion is another possible complication.

The surgeon may use a bone anchor to hold one end of a suture in place when needed (eg. 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.

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.

In general, contaminated wounds should not be closed but should be left open to heal by secondary intention because of the risk of infection. 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 anticipation of 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 a skin strip (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.

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2. Ford HR, Jones P, Gaines B, et. al., Intraoperative Handling and Wound Healing: Controlled Clinical Trial Comparing Coated VICRYL® Plus Antibacterial Suture (Coated Polyglactin 910 Suture with Triclosan) with Coated VICRYL® Suture (Coated Polyglactin 910 Suture), Surgical Infections, Volume 6, Number 3, 2005
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CHAPTER 3

THE SURGICAL NEEDLE

Necessary for the placement of sutures in tissue, surgical needles must be designed to carry suture material through tissue with minimal trauma. The must be sharp enough to penetrate tissue with minimal resistance. They should be ridged enough to resist bending, yet flexible enough to bend before breaking. The must be sterile and corrosion resistant to prevent introduction of microorganisms or foreign bodies int the wound.

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 or other similar quality metals.
- 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.

Variations in needle geometries are just as important as variations in suture sizes. Needle dimensions must be compatible with the suture sizes, allowing the two to work in tandem.

Elements of Needle Design

Needle design involves analyzing a surgical procedure and density of the tissue involved in great detail. ETHICON™, engineers work continuously to improve upon their needle offering, sometimes making subtle alterations resulting in a positive impact upon the procedure itself. The anatomy of the ideal surgical needle has three factors that make up the ideal needle: *Coating, Geometry (Point and Body), and Alloy*

- **Advanced Needle Coating —** continued advances in coatings help to maintain needle sharpness pass after pass and consistency from needle to needle
- **PRIME Needle Geometry in Cutting Needles —** require less penetration force to minimize tissue trauma
- **ETHALLOY™ and EVERPOINT™ Needle Alloys —** provide superior strength, stiffness, and ductility (bending without breaking)

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 Alloy (Patent No. 5,000,912) was developed for unsurpassed strength in precision needles used in cardiovascular, ophthalmic, plastic, and micro- surgical procedures. It is produced economically without sacrificing ductility or corrosion resistance.

EVERPOINT Alloy is shaped from an ultra-high-strength, tungsten-rhenium alloy and finished with a unique multilayer silicone coating. Without compromising ductility, the tungsten-rhenium alloy makes EVERPOINT Needles up to 38% stronger and 121% more bend resistant than the stainless-steel alloys found in conventional suture needles. A unique multilayer silicone coating helps give EVERPOINT Needles outstanding penetration and allows them to maintain point durability over multiple passes – even through unanticipated calcium deposits.

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. 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. 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. 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 a patented silicone formulation that improves penetration performance over multiple passes. According to laboratory tests, this coating serves several important functions:

- Reduces the force needed to make initial penetration through tissue
- Significantly improves the consistency of the needle penetration (pass to pass, needle to needle)
- Maintains sharpness for better penetration and control over multiple passes while delivering ongoing strength, sharpness, and control

Needle performance is also influenced by the stability of the needle in the grasp of a needle- holder. Most curved needles are flattened in the grasping area to enhance control. 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 cross-locking action in the for added needle control. This reduces undesirable rocking, twisting, and turning in the needle holder.

Figure 1 **TAPER RATIO**

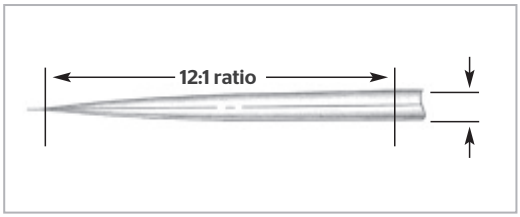
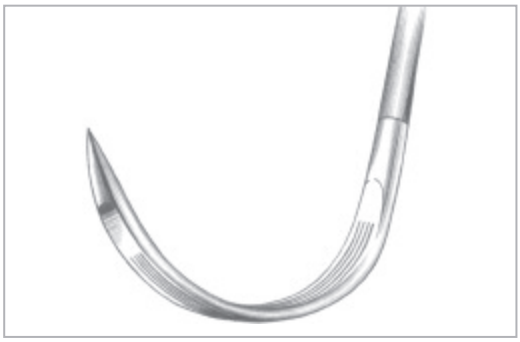


Figure 2 **ETHICON™ RIBBED NEEDLE**



PRINCIPLES OF CHOOSING A SURGICAL NEEDLE

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

Figure 3 NEEDLE COMPONENTS

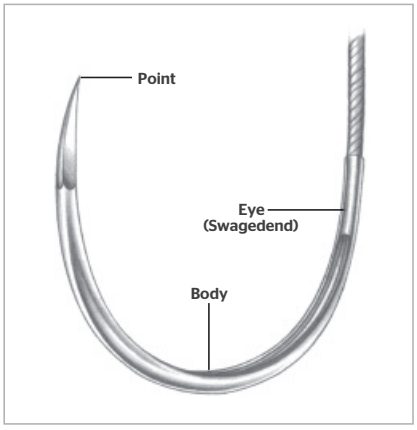
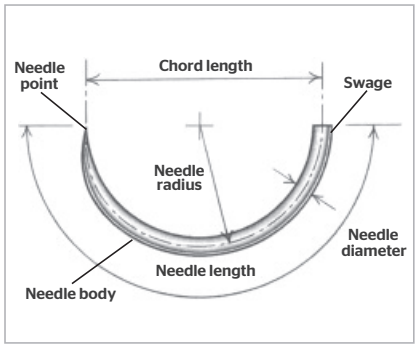


Figure 4 ANATOMY OF A NEEDLE



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™ Surgical 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, even during a single operative procedure.

4. 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.

THE ANATOMY OF A NEEDLE

Regardless of its intended use, every surgical needle has 3 basic components:

- **The eye or swage**
- **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. The chord length determines the length or size of bite taken.

- **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. The radius determines the depth of the bite taken.

- **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 2 extremes. The diameter of a needle may increase or decrease relative to the size suture it is swage to.

THE NEEDLE EYE

The eye falls into 1 of 3 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.

Figure 5

THE NEEDLE EYE

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 or swaging 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.

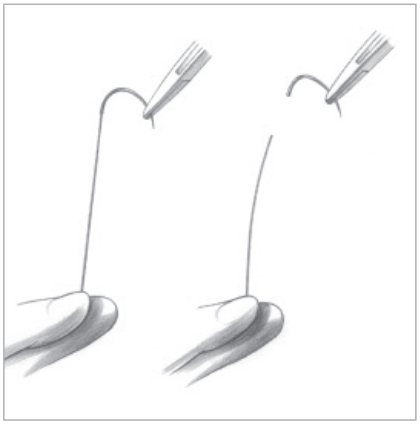
Small diameter ETHICON™, taper point needles commonly used in cardiovascular surgery were compared in laboratory tests—some with "split" channels and some with laser-drilled holes. The needles with laser-drilled holes produced less drag force as they passed through a membrane that simulated vascular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

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 that 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 when the needle is inverted will release the needle from the suture.

This needle/suture configuration was created originally for abdominal closure and hysterectomies, but is now used in a wide variety of procedures.

Figure 6

CONTROL RELEASE NEEDLE SUTURE



Holding the needle securely in the needle holder, 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 that is grasped by the needle holder 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 trans-chamber 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.

Figure 7 **NEEDLE SHAPES AND TYPICAL APPLICATIONS**

SHAPE	APPLICATION
Straight	gastrointestinal tract, nasal cavity, qnerve, oral cavity, pharynx, skin, tendon, vessels
Half-curved	skin (rarely used) laparoscopy
1/4 Circle	eye (primary application) microsurgery
3/8 Circle	aponeurosis, biliary tract, cardiovascular system, dura, eye, gastrointestinal tract, muscle, myocardium, nerve, perichon-drium, periosteum, pleura, skin, tendon, urogenital tract, vessels
1/2 Circle	biliary tract, cardiovascular system, eye, fascia, gastrointestinal tract, muscle, nasal cavity, oral cavity, pelvis, peritoneum, pharynx, pleura, respiratory tract, skin, tendon, subcutaneous fat, urogenital tract
5/8 Circle	anal (hemorrhoidectomy), nasal cavity, pelvis,urogenital tract (primary application)
Compound Curved	eye (anterior segment) laparoscopy

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 some pronation and supination of the wrist. But even the point 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. This design requires less pronation and supination of the wrist.

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 point 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 comeal-scleral junction minimizes the possibility of astigmatism following anterior segment surgery.

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.

Types of Needles

CUTTING NEEDLES

Cutting needles have at least 2 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.

Figure 8 **NEEDLE POINTS AND BODY SHAPES AND TYPICAL APPLICATIONS**

SHAPE	APPLICATION
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)
CS ULTIMA* OphthalmicNeedle 	eye (primary application)
Taper 	aponeurosis, biliary tract, dura, fascia, gastrointestinal tract, laparoscopy, muscle, myocardium, nerve, peritoneum, pleura, subcutaneous fat, urogenital tract, vessels, valve
TAPERCUT* SurgicalNeedle 	bronchus, calcified tissue, fascia, laparoscopy, ligament, nasal cavity, oral cavity, ovary, perichondrium, periosteum, pharynx, sternum, tendon, trachea, uterus, valve, vessels (sclerotic)
Blunt 	blunt dissection (friable tissue), cervix (ligating incompetent cervix), fascia, intestine, kidney, liver, spleen

CONVENTIONAL CUTTING NEEDLES

In addition to the 2 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 surface 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 needle holder. Flattened sides reduce bending that might occur due to the fine wire diameter.

The point 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 inch (6 mm) from the body and terminate in a triangular-shaped tip. This particular sternotomy needle maximizes cutting efficiency and control in the needle holder. TAPERCUT Needles may also be used for this procedure.

Figure 9 **THE PC PRIME NEEDLE**

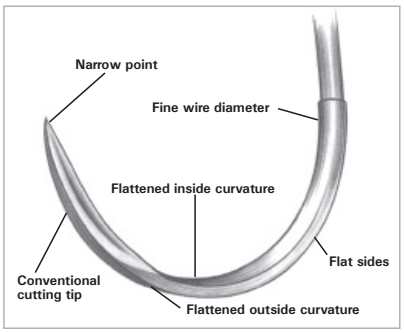
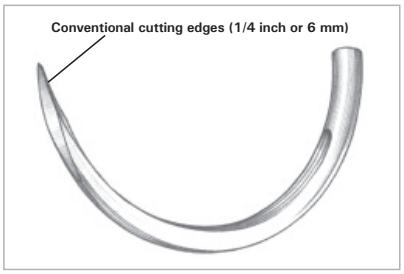


Figure 10 **STERNOTOMY NEEDLE**



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.

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.

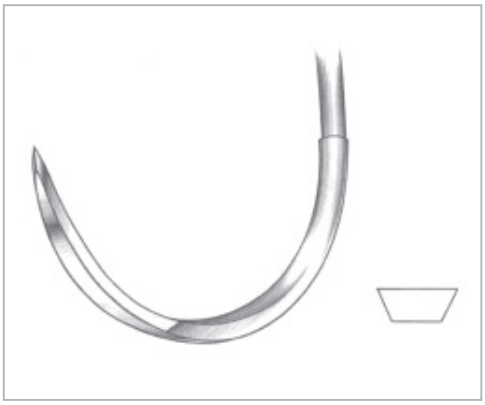
The OS (Orthopedic Surgery) needles are curved, heavy bodied, reverse-cutting needles. The orthopedic surgeon may use the OS needle for extremely tough tissue, such as cartilage, where force is required for penetration.

Figure 11

REVERSE CUTTING NEEDLE

Figure 12

SPATULA NEEDLE CROSS-SECTION



SIDE CUTTING NEEDLES

Also referred to as spatula needles, they feature a unique design that 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 comeal 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.

The SABRELOC® Spatula Needle has 2 cutting edges and a trapezoidal-shaped body.

The SABRELOC Needle with the cobra-shaped tip has 4 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 that results in a sharper needle. The surgeon encounters low penetration resistance with the TG PLUS Needle and gets excellent tactile feedback.

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 that 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 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 issue.

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.

TABLE 1 ETHICON™ NEEDLE CODES & OTHER MEANINGS

CODE	MEANING
BB	Blue Baby
BIF	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
FS	For Skin
FSL	For Skin Large
FSLX	For Skin Extra Large
G	Greishaber
GS	Greishaber Spatula
J	Conjunctive
KS	Keith Straight
LH	Large Half
LR	Larger Retention
LS	Large Sternotomy
M	Muscle
MF	Modified Fergusan

CODE	MEANING
MH	Medium Half (circle)
MO	Mayo
MOB	Mayo Blunt
OPS	Ocular Plastic Surgery
OS	Orthopedic 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 Module
ST	Straight Taper
STB	Straight Blunt
STC	Straight Cutting
STP	Straight Taper Point
TE	Three-Eighths
TF	Tetralogy of Fallot
TG	Transverse Ground
TGW	Transverse Ground Wide
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)

BLUNT POINT NEEDLES

Blunt point (BP) needles literally dissect friable tissue rather than cutting or piercing 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 that 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

relative safety of the blunt point with the security of a ribbed and flattened design, and the convenience of a swaged needle. The ETHIGUARD Blunt Point Needle allows for soft tissue penetration by piercing with minimum force, decreasing the incidence of needlestick injury.

Needleholders

The surgeon uses the needle holder 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.

Needle holder 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 needle if too much pressure is applied. Most, but not all, needle holders have a ratchet lock near to thumb and finger rings.

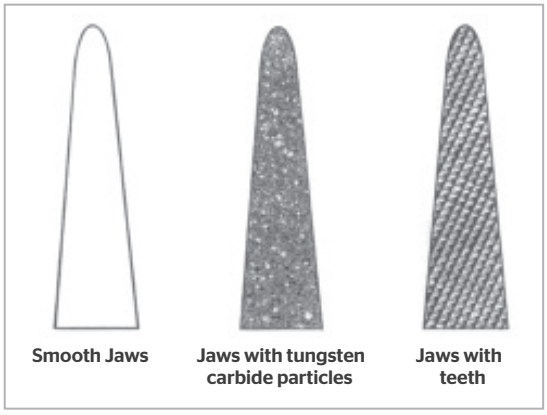
Surgical needles are designed for optimum needle holder stability. Because this tool actually drives the needle through tissue, its performance will have an impact upon the entire suturing procedure. The surgeon has maximum control only when the needle sits well in the holder without wobbling as it is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

When selecting a needle holder, 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 needle holder should be.

- It should be an appropriate size for the procedure. If the surgeon is working deep inside the body cavity, a longer needle holder is in order.

Figure 13



Needleholder Use

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

1. Grasp the needle with the tip of the needle holder 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 needle-holder may deform, damage, or bend it irreversibly.

3. Always check alignment of the needle holder jaw to make certain the needle does not rock, twist, or turn.

4. Handle the needle and needle holder as a unit.

5. Pass the needle holder 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 needle holder— 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 needle holder. Needles are less likely to be lost if they are passed one-for-one (one returned for each one received).

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.

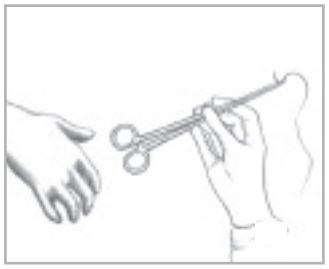
6. Do not damage taper points or cutting edges when using the needleholder to pull the needle through tissue. Grasp as far back on the body as possible.

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 and a second needleholder should be used to locate a needle in a confined body cavity.

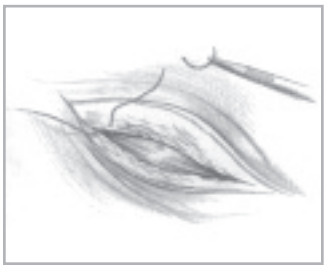
9. If a glove is punctured by a needle, the needle must be discarded immediately and the glove must be changed for the safety of the patient, as well as the surgical team. Appropriate serological testing of the patient should be undertaken for transmissible agents such as hepatitis B and C and HIV.

FIGURE 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 reclamps 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.

Needle Handling Tips

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

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

2. Make sure the needle is free of corrosion.

3. 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.

4. If a needle is defective, discard it.

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

6. Employ the non-transfer technique to avoid inadvertent needlesticks: the surgeon places the needle and needle holder down in a neutral area of the sterile field; the scrub person then picks up the needle holder.

7. 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.

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

9. 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:

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

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

3. 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.

4. Discard used needles in a “sharps” container.

CHAPTER 4

PACKAGING

An Integral Part of the Product

The purpose of a package is to protect it contents and provide convenience to the user. ETHICON™ wound closure packaging is an integral part of each product. 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
- Advances in packaging technology
- Stringent regulatory requirements

To prevent an 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, stapling instruments, adhesive tapes and topical skin adhesives. 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.

GRAVITY-FED DISPENSER and GLOBAL HORIZONTAL BOXES

ETHICON™ utilizes a number of different boxes worldwide for storage of conventional sutures products.

Straight pack boxes contain long straight packages for steel and some PROLENE Polypropylene and PRONOVA Polyvinyline Fluoride Sutures.

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. Dispenser boxes come in large (2 and 3 dozen) box and small (1 dozen) box.

Global Horizontal Boxes are inserted in sleeves and are opened like a drawer to access suture packages from the top. Global Horizontal Boxes come in a large box size (2 and 3 dozen) and small box size (1 dozen). Some bulky packages, such as, LIGAPAK Dispensing Reels, ETHIBOND Suture Valve Packs are packaged in Large Global Horizontal Box (1dozen and 6 each counts respectively).

ETHICON™ is simplifying and streamlining our global suture portfolio to standardize Gravity-fed Dispenser Boxes to the Global Horizontal Box design. These changes began in 2016 and will extend over a multi-year period.

Key Improvements and Differences:

- ✓ 2 primary global horizontal box configurations to simplify inventory management.
- ✓ Sturdy Box Material Design
- ✓ Open-Box Drawer Access for Visual Product Count
- ✓ New Global Boxes are Slightly Smaller Dimensions

Current Box Design:

US Large Vertical | US Small Vertical | Large Horizontal US | Large Horizontal EU

New Global Box Design:

Large Horizontal:
4 4/8 in. X 2 ½ in. X 5 ½ in.
11.75 cm X 6.35 cm X 13.97 cm

Small Horizontal:
2 3/8 in. X 2 ½ in. X 5 ½ in.
6.03 cm X6.35 cm X 13.97 cm

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, bar coding and descriptive symbols. The information required for quick reference and easy selection of suture materials is highlighted in a logical sequence. The 3 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 includes:

1. Product code number

2. Suture length and color

3. Metric diameter equivalent of suture size and length

4. Shape and quantity of needles (single- or double-armed, shown

5. Needle point geometry

6. Other accessories (pledgets, retention tubing, etc)

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 dispenser boxes.

The product code number suffix and/or a statement on the box indicate the quantity of suture packets in the box (product code suffix N= 6 eaches, G = 1 dozen, D = 1 dozen (w/ Safety Organizer Tray packaging), T = 2 dozen, H = 3 dozen).

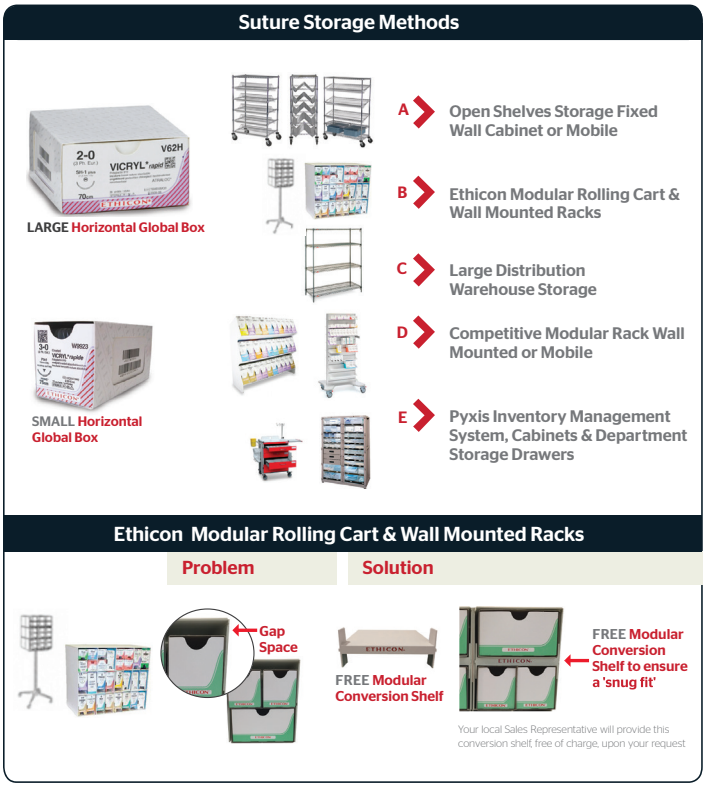
MODULAR STORAGE RACKS

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 gravity fed dispenser box and global horizontal suture drawer boxes. Any number of modules can be fastened together to meet both small and large storage needs.

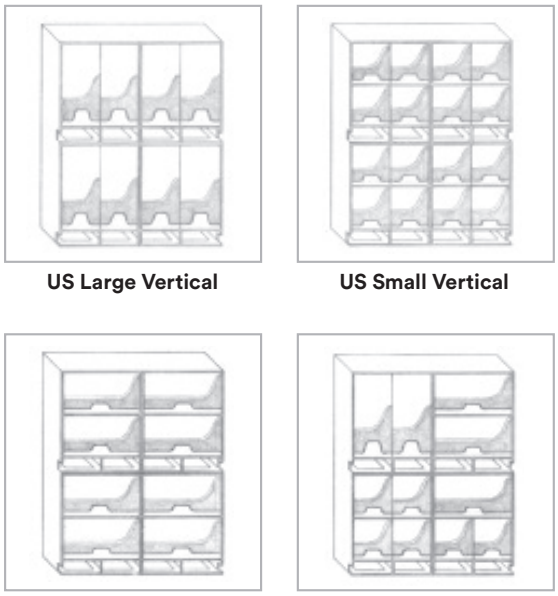
Once assembled, the racks may be used on shelves, mounted on walls, placed on mobile carts, or connected to IV poles. Racks can also be fitted with a rotating base for more convenient access, as well as with a handle for easy carrying.

The conversion from the Gravity-fed Dispenser Box to the Global Horizontal Boxes will require some modifications to the modular storage racks when used in mobile applications. When placed on mobile carts, or connected to IV poles, the Modular Conversion Shelf should be used to hold the Global Horizontal Box snuggly in the modular rack. Failure to use the Modular Conversion Shelf may result in the box falling off the shelf during transit. When racks are used on shelves, or mounted on walls the Modular Conversion Shelf may or may not be used depending on whether the box is required to fit snuggly on the shelf.



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 (ie, general closure, gastrointestinal surgery, plastic surgery).

FIGURE 1 **ETHICON™ MODULAR STORAGE RACKS**



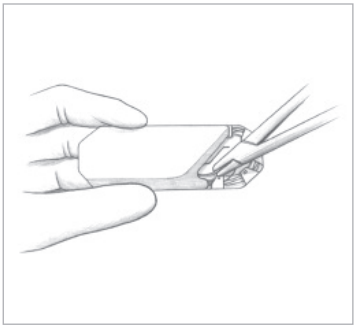
PRIMARY PACKETS

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 that 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 waste 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.

METHOD FOR PREPARING 1-STEP RELAY PACKAGE SUTURES:
Arm the needle directly from the 1-step RELAY tray and deliver the single suture to the surgeon.



Primary packets of suture material may contain sutures in 1 of 5 styles:

1. Standard lengths of non-needled material: 54 inches (135 cm) of absorbable or 60 inches (150 cm) of nonabsorbable suture, which may be cut in half, third, or quarter lengths for ligating or threading.

2. SUTUPAK® Pre-cut Sterile Suture is non-needled 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 1-step RELAY Packaging, 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 1-step RELAY Delivery Packaging. 1-step RELAY Packaging allow the needle to be armed in the needle holder 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 1-step RELAY Packaging by pushing up the flap behind the needle park, thereby elevating the needle so it can be grasped by hand.

4. 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 Sutures, MONOCRYL Sutures, PDS II (polydioxanone) Sutures, ETHIBOND EXCEL Sutures, NUROLON Sutures, MERSILENE Sutures, and PERMA-HAND 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 Sutures, NUROLON 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.

5. 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. 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 (eg, 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.

All suture material is packaged dry, with the exception of surgical gut. 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.

Expiration Date

The expiration date of a product is determined by product stability studies. ETHICON™ 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.

The RELAY 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 stamed 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 a 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, becoming unusable. Instead, they are gas sterilized. Gas sterilization uses ethylene oxide gas. As an environmental measure, ETHICON™, replaced chloro- fluorocarbons (CFCs) with more environmentally friendly compounds 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.

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™ Sutures and spools or cardreels of nonabsorbable materials supplied nonsterile.

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 (electronic or manual) 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*, 3 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. Opening 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 to 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 1-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 (eg, operating room, delivery room, emergency department, or physician's office), the individual who removes the nonsterile overwrap must remember these 3 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 2 methods commonly used for achieving sterile transfer of suture packets: handing-off the sterile inner 1-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 2 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 pressure between the knuckles for control, offer the sterile inner packet or tray to the scrub person, who takes it with a 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. It should also be used for transfer of flexible, lightweight, transparent packets containing microsurgery and ophthalmic products.

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 electrosurgical 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.

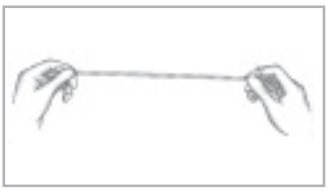
Ligature material which remains toward the end of the procedure may be the same material and size specified by the surgeon for sutures in the subcutaneous layer of wound closure. In this case, the remaining ligating material should be used rather than opening an additional suture packet.

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.

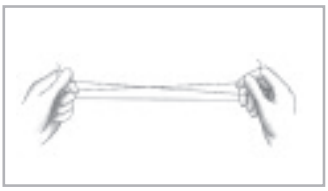
FIGURE 2

PREPARATION OF STANDARD LENGTH LIGATURE STRANDS

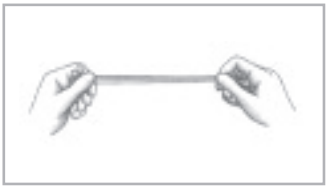
1. Prepare cut lengths of ligature material, coil around fingers of left hand, grasp free ends with right hand, and unwind to full length.



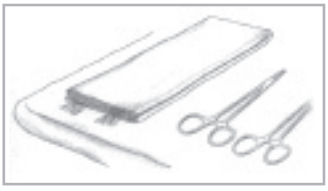
2. Maintain loop in left hand and 2 free ends in right hand. Gently pull the strand to straighten.



3. To make 1/3 lengths: Pass 1 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.

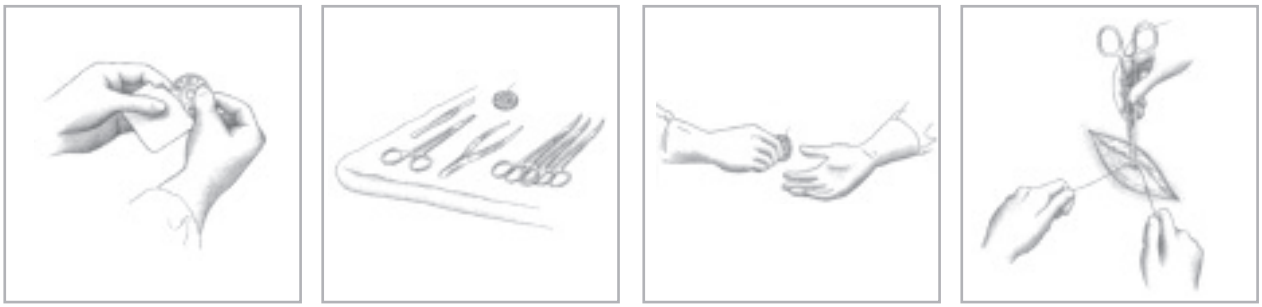


4. To make 1/4 lengths: Pass both free ends from right to left hand. Simultaneously catch a double loop around third finger of right hand. Cut the loops.



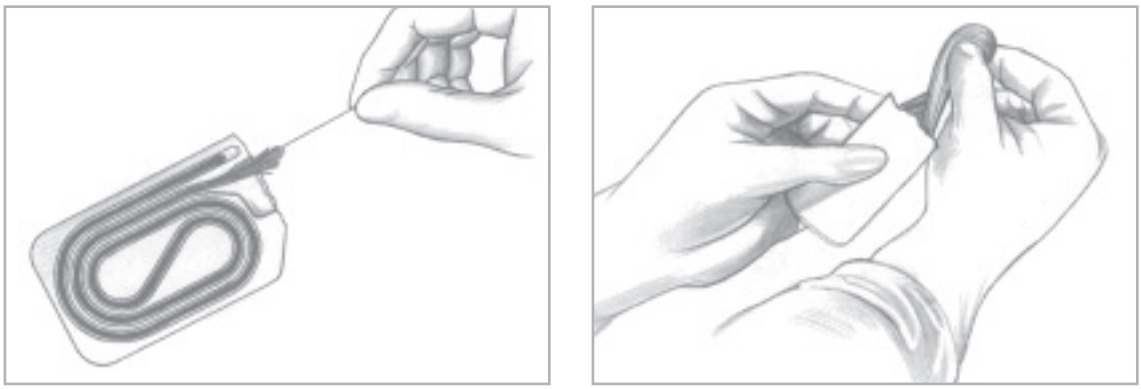
5. Place packets or strands in suture book (folded towel)—or under Mayo tray—with ends extended far enough to permit rapid extraction.

FIGURE 3 PREPARATION OF CONTINUOUS TIES ON A LIGAPAK DISPENSING REEL



1. Open the packet containing the 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.

FIGURE 4 PREPARATION OF PRE-CUT SUTURES FOR TIES OR LIGATURE SUTURES



1. Remove 1 pre-cut length from nonabsorbable suture at a time from the labyrinth packet as it is needed by the surgeon.
2. Extract pre-cut strands of SUTUPAK 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 needle holders 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. 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.

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 Needle 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 1-step RELAY package or

folder containing suture materials from the primary packet being offered from the circulating nurse.

2. Hold the 1-step RELAY package 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 the 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.

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 needle holder forward of the swaged area, approximately one third to one half the distance from the swage to the point.

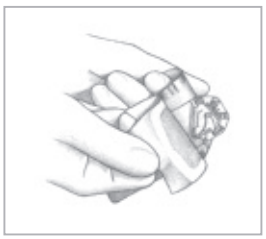
10. Microsurgery sutures and needles are so fine that they may be difficult to see and handle. They are packaged with the needles parked in foam to protect delicate points and edges. The needles may be armed directly from the foam needle park. If the microsurgeon prefers to arm the needle, the removable 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. Cut surgical steel with wire scissors.

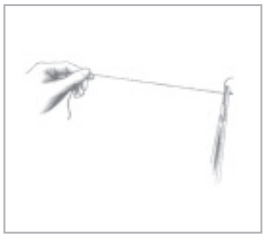
13. When requesting additional suture material from the circulating nurse, estimate usage as accurately as possible to avoid waste.

FIGURE 5



1 With a rolling-outward motion, peel the flaps apart to approximately one third the way down the sealed edges. Keeping pressure beween the knuckles for control, offer the sterile inner RELAY package 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 SURGEON

1. Avoid damage to the suture strand when handling. This is particularly critical when handling fine sizes of monofilament material. Touch strands only with gloved hand or closed blunt instrument. Do not crush or crimp sutures with instruments, such as needle holders or forceps, except when grasping the free end of the suture during an instrument tie.

2. Clamp a rubber shod hemostat onto the suture to anchor the free needle on a double-armed strand until the second needle is used. Never clamp the portion of suture that will be incorporated into the closure or the knot.

3. Use a closed needle holder or nerve hook to distribute tension along a continuous suture line. Be careful not to damage the suture.

4. Use knot tying techniques that are appropriate for the suture material being used.

PRESERVATION OF TENSILE STRENGTH ABSORBABLE SUTURES

1. Protect absorbable sutures from heat and moisture.

- **a.** Store suture packets at room temperature. Avoid prolonged storage in hot areas such as near steam pipes or sterilizers.
- **b.** Do not soak absorbable sutures. Also avoid prolonged placement of sutures in a moist suture book.
- **c.** 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.
- **d.** Synthetic absorbable sutures must be kept dry. Use strands directly from packet when possible. Store sutures in a dry suture book if necessary.

2. Straighten strands with a gently, steady, even pull. Jerking and tugging can weaken sutures.

3. Do not “test” suture strength.

4. Do not resterilize.

PRESERVATION OF TENSILE STRENGTH: NONABSORBABLE SUTURES

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. Handle carefully 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 instrument damage. Do not resterilize.

CHAPTER 5

TOPICAL SKIN ADHESIVES

The most significant advancement in the field of topical skin adhesives has been the development of 2-octyl cyanoacrylate developed with specific ratios of an initiator and additives that provide a strong, flexible closure with antibacterial barrier protection. This formula is marketed as DERMABOND™ Topical Skin Adhesive (TSA) by ETHICON™. This topical skin adhesive forms a transparent and flexible bond. The flexibility of octyl cyanoacrylate (2-OCA) allows it to be applied over nonuniform surfaces. This flexibility also combats the topical shear forces exerted on the adhesive, reducing the risk of premature sloughing and wound dehiscence. Additionally, 2-OCA monomer has demonstrated significantly greater strength and flexibility than butyl-based adhesives.[1]

It utilizes the moisture on the skin's surface to form a strong, flexible bond and can be used in many instances where sutures, staples or skin strips have been traditionally used. DERMABOND Adhesive is ideally suited for wounds on the face, torso, and limbs. It can be used in conjunction with, but not in place of, deep dermal sutures.

Approved by the FDA in 1998, DERMABOND Adhesive has been used extensively by health professionals in the fields of trauma and other surgeries, emergency medicine, and pediatrics. Unlike sutures, the adhesive does not produce suture or "track" marks along the healed incision and a patient can shower right away without fear of compromising the incision.

STRENGTH AND SECURITY

In less than three minutes, DERMABOND Adhesive provides the strength of healed tissue at 7-14 days.[2] Published,
peer-reviewed data demonstrates DERMABOND ADVANCED provides strength to maintain barrier and wound closure integrity during critical wound healing period (48 hours).[1,3]

SEALS OUT BACTERIA

DERMABOND Adhesive studies have shown that following application, DERMABOND acts as a barrier to prevent microbial penetration as long as the adhesive remains.[4] For trauma and postsurgical patients, infections are often the most common, and in some cases, the most serious complications. DERMABOND Adhesive is a flexible, watertight, microbial barrier with 99% protection in vitro for 72 hours against organisms commonly responsible for surgical site infection. It has demonstrated in vitro to inhibit 99%. of bacteria (MRSA, MRSE, and E coli) on direct contact.*

PROMOTES A MOIST, WOUND HEALING ENVIRONMENT

DERMABOND Adhesive allows moisture vapor to pass through the wound while keeping excess water and bacteria out, creating an optimal, moist wound healing environment.[5] Maintaining a moist wound healing around the wound has been shown to speed the rate of epithelialization.[6]

PROVIDES GOOD COSMETIC RESULTS

In a prospective, randomized, controlled, unmasked study of 818 patients, DERMABOND Topical Skin Adhesive provided cosmesis equivalent to that of sutures. At 3 months, it produced optimal cosmesis in 80% of patients, using the Modified Hollander Cosmesis Scale.[2]

ADDITIONAL PHYSICIAN AND PATIENT BENEFITS

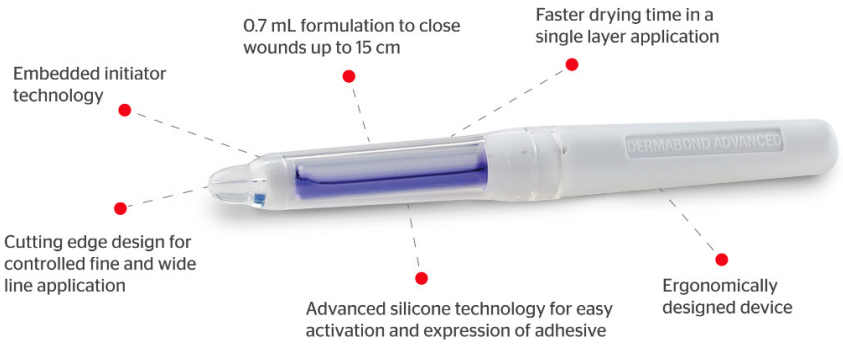
When used in addition to sutures, DERMABOND ADVANCED Adhesive was shown ex vivo to add 75% more strength to wound closure than sutures alone.[7] Additionally, DERMABOND ADVANCED™ is meant to slough off naturally, so there is no additional doctor visit for painful removal.[8]

DERMABOND PRINEO Skin Closure System is a non-invasive alternative to skin sutures and staples.† It combines the strength, flexibility, and microbial barrier protection of DERMABOND ADVANCED™ with the added support and security of self-adhering mesh.^[9-15]

DERMABOND is marketed in three forms, *DERMABOND ADVANCED, DERMABOND MINI, AND DERMABOND PRINEO Skin Closure System*.

* Clinical significance unknown.
† Deep dermal stitches required.
^ As demonstrated in vitro.

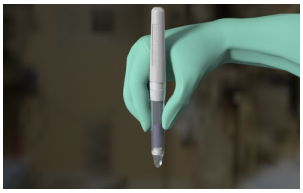
DERMABOND ADVANCED™ Topical Skin Adhesive (2-octyl cyanoacrylate)



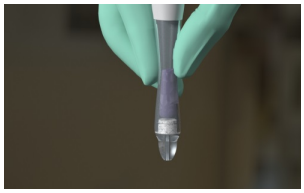
DERMABOND ADVANCED is a sterile, liquid topical adhesive designed to hold closed, easily approximated skin edges of lacerations and surgical incisions.

DERMABOND ADVANCED utilizes a liquid monomer, 2-octyl cyanoacrylate, as its foundation. Upon polymerization, 2-octyl cyanoacrylate monomers product strong and flexible films. DERMABOND ADVANCED contains specially designed chemicals, known as "formulation additives" which provide the polymerized film with additional flexibility as well as increase the affinity of the liquid formulation for the surface of the skin. Located in the tip of the applicator, the initiator is a chemical that ensures the polymerization of the monomer occurs in a controlled and consistent manner, resulting in a polymer film with superior strength and better adherence to the skin surface. (paragraph from In-service presentation DBA-377-11)

APPLICATION INSTRUCTIONS

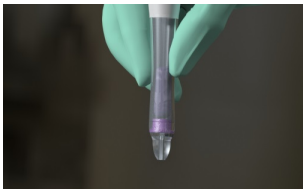


Hold the applicator away from the patient with the tip pointed downward.

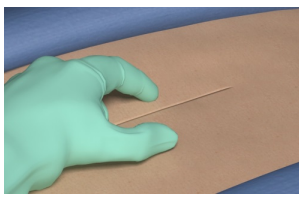


Squeeze the bulb to crush the ampoule inside, and then release pressure.

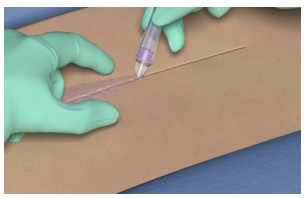
PRECAUTION: Do not continuously crush glass ampoule inside the bulb.



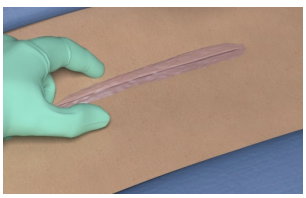
Gently squeeze the bulb again to moisten the internal filter with adhesive.



Approximate the wound edges with gloved fingers or forceps.



Apply DERMABOND ADVANCED Adhesive in a single continuous layer, maintaining steady bulb pressure.



Hold skin edges for about 60 seconds. Full polymerization is expected when the adhesive is no longer sticky.

PRIOR TO APPLICATION

1. Ensure completion of deep dermal approximation to relieve tension on the skin edges. DERMABOND ADVANCED Adhesive was designed to be used in conjunction with subcuticular sutures.

2. Ensure hemostasis is achieved.

3. Make sure the wound is thoroughly cleansed, hemostasis is achieved, and patted dry.

4. Approximate the wound edges with gloved fingers or sterile forceps, as necessary.

5. Hold the applicator away from yourself and the patient with the tip pointing down and crush the glass ampoule at its midpoint. PRECAUTION: Do not crush the contents of the applicator repeatedly as further manipulation of the applicator may cause shard penetration and can result in inadvertent skin punctures, which may result in transmission of bloodborne pathogens.

6. Gently squeeze the applicator sufficiently to moisten the internal filter with the liquid adhesive.

7. Stop squeezing and allow the liquid DERMABOND ADVANCED Adhesive to draw back into the applicator.

Note: Any delays in application from the time of glass ampoule crushing may result in the formulation drying in the pen prior to application.

DURING APPLICATION

8. DERMABOND ADVANCED Topical Skin Adhesive requires only a single layer of application, which allows for up to 15 cm of incision coverage. Applying a second layer is not required or recommended.

9. The width of the adhesive layer can be increased or decreased by adjusting the amount of pressure applied to the bulb during application and reducing or increasing the sped of application. The harder one presses on the pen and the slower they travel down the incision, the wider the coverage will be. One the other hand, when a narrow covering is desired, one should not press as hard on the silicone part of the pen when traveling down the incision.

10. Do not press the applicator tip excessively hard against the wound edges or surrounding skin. This could force the skin apart and allow liquid topical skin adhesive into the wound, delaying wound healing and/or resulting in adverse cosmetic results. This could also result in the tip of the pen “pushing” away the recent application of the adhesive.

11. When applying, minimize the pressure applied to the skin to avoid any clogging of the tip (too much pressure on the skin may restrict the adhesive flow, potentially making the product set prematurely).

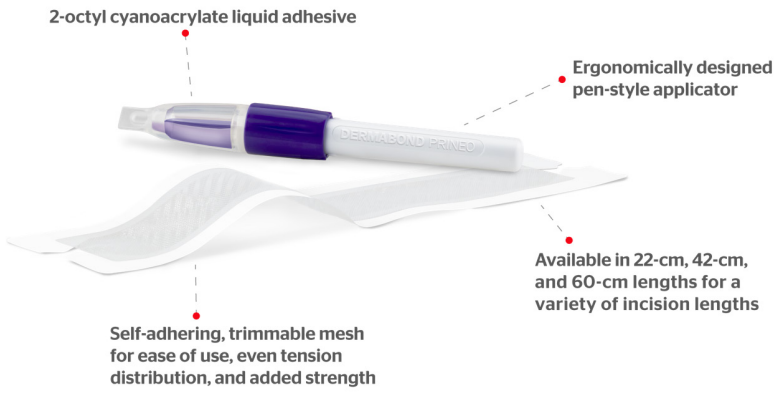
AFTER APPLICATION

12. Do not apply a liquid or ointment medications onto wounds closed with DERMABOND ADVANCE Adhesive because these substances can weaken the polymerized film, leading to the skin edge separation.

13. Protective dry dressings such as gauze or bandages may be applied only after DERMABOND ADVANCED Adhesive film has completely polymerized (not tacky to the touch). This may take a few minutes.

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

DERMABOND™ PRINEO™ Skin Closure System



DERMABOND PRINEO Skin Closure System is an innovative skin closure device that can be used to efficiently and conveniently approximate the skin edges of surgical incision and laceration. DERMAND PRINEO System redistributes tension to the surrounding healthy surface area and requires no piercing of the skin. DERMABOND PRINEO Skin Closure System is a flexible, watertight, microbial barrier with 99% protection in vitro for 72 hours against organisms commonly responsible for surgical site infection.* It has demonstrated in vitro to inhibit 99%.[10]* of bacteria (MRSA, MRSE, and E coli) on direct contact.

DERMABOND PRINEO Skin Closure System is currently the only skin closure system that combines the benefits of a proven topical skin adhesive with the flexible self-adhering mesh.

DERMABOND PRINEO Skin Closure System is available in 22 cm, 42 cm, and 60 cm lengths, each if which is trimmable, self-adhering, and must be used in combination with the supplied liquid adhesive.

Application Instructions

Pre-Application

1. Prior to applying DERMABOND PRINEO System (42 cm), ensure that the wound is clean, dry, and hemostatic. Close deep layers such that there is no tension on the skin edges. The skin edges must be closely approximated prior to application of the mesh, such that significant manual approximation is not required during mesh application.

2. Remove the first mesh patch from the mesh carrier and dispose of the mesh carrier (Figure 1).

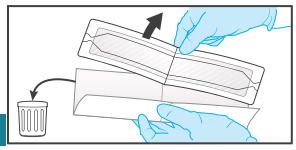


FIGURE 1

Flatten the mesh patch at the crease gently. Remove the center section of the release backing paper from the mesh (Figure 2).

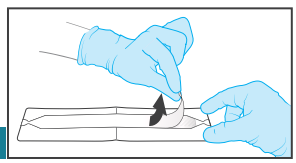


FIGURE 2

Hold the mesh by the corners of the backing paper, ensuring that the adhesive side of the mesh will be adhered to the patient's skin (Figure 3).

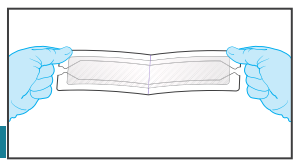


FIGURE 3

*Clinical Significance Unknown

Application

3. Position the mesh so one half is on either side of the incision, ensuring approximately 1 cm of mesh extends from the beginning of the incision (Figure 4).

Press gently to ensure intimate contact of the mesh to the selected side of the incision.

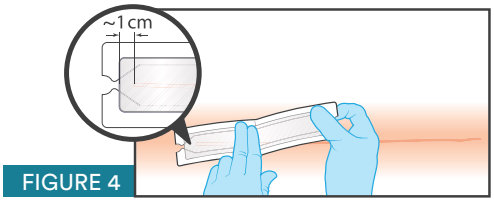


FIGURE 4

4. Gently pull the mesh perpendicularly over the incision while adjusting with fingers or forceps to achieve skin edge approximation and affix the remainder of the mesh to the other side of the incision (Figure 5). If there are areas where the mesh is loose, gently pass a gloved finger or instrument over the affected area to ensure complete adherence of the mesh to the skin.

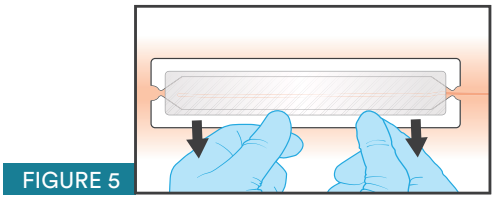


FIGURE 5

Application — Key Steps

5. Remove both paper backings/frames (Figure 6).
DO NOT APPLY LIQUID ADHESIVE UNTIL THE SECOND MESH HAS BEEN DEPLOYED.

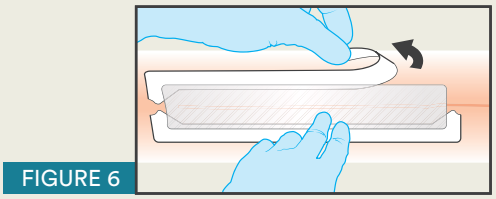


FIGURE 6

6. Repeat Steps 2 and 3 using the second mesh patch. **ENSURE A MINIMUM MESH OVERLAP OF APPROXIMATELY 1 CM - 5 CM BETWEEN THE FIRST AND SECOND MESHES** (Figure 7).

Trim mesh as necessary, ensuring at least 1 cm of the mesh extends beyond the end of the incision (Figure 8).

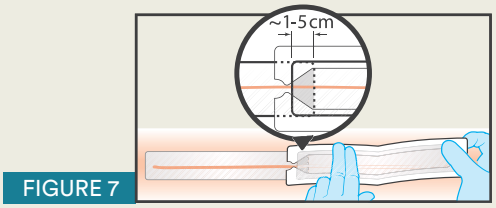


FIGURE 7

7. Ensure that the meshes are in intimate contact with the skin prior to application of the liquid adhesive. If there are areas where the mesh is loose or not adhered to skin, gently pass a gloved finger or instrument over the affected area to ensure complete adherence of the mesh to the skin.

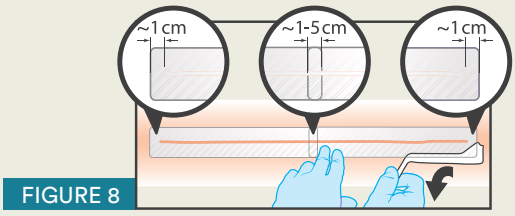


FIGURE 8

8. Apply liquid topical skin adhesive immediately after applying the mesh*:

- Activate the liquid adhesive applicator by twisting the purple dial until a snap is heard (Figure 9)

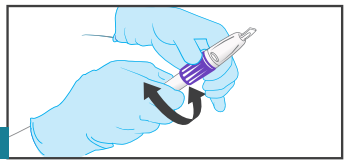


FIGURE 9

- Position the applicator tip straight down and away from the application area. Pinch the tip of the applicator and squeeze the flexible bulb one time. Once the pressure in the bulb is released, it will partly or completely fill with liquid adhesive (Figure 10). This primes the applicator for dispensing the liquid adhesive

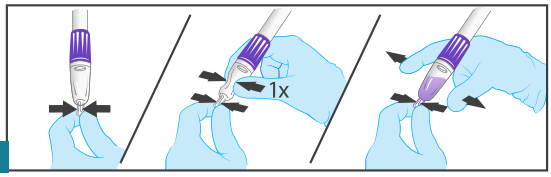


FIGURE 10

- Using short strokes and moving from one end of the meshes to the other, **spread the liquid adhesive smoothly and evenly over the entire length of the meshes and surrounding skin** (Figure 11).
NOTE: DO NOT APPLY A SECOND COAT

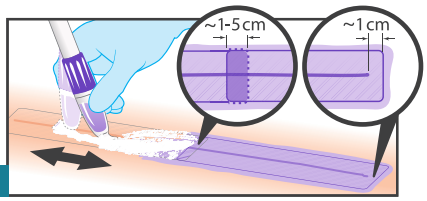


FIGURE 11

* Please always refer to the Instructions for Use / Package Insert that come with the device for the most current and complete instructions.

Post-Application

9. Once applied to the meshes, the liquid adhesive will polymerize within approximately 60 seconds. After 60 seconds, check that polymerization is complete by gently dabbing along the length of the meshes with a gloved finger, checking for tackiness. When no liquid or tackiness is apparent, the polymerization process is complete and the wound is closed and sealed.

10. Finally, inspect the incision for any blood or fluid accumulation under the mesh, including areas where fluid may be seeping through the mesh. If such areas exist, carefully cut any affected segments of the mesh and remove them from the skin. Ensure the skin edges are clean and dry, and reapply new mesh and liquid adhesive according to the directions for use, overlapping the ends of the existing mesh by approximately 1 - 5 cm.

11. A protective, dry wound dressing such as gauze may be applied only after the liquid adhesive has completely polymerized and the DERMABOND PRINEO System is no longer tacky to the touch. If the liquid adhesive is not allowed to fully polymerize prior to application of a dressing, DERMABOND PRINEO System may adhere to the dressing, causing it to become loose or be pulled away from the skin when the dressing is removed and can result in dehiscence (skin edge separation).

Removal Instructions

1. Gently grasp the edge of the DERMABOND PRINEO System at one end of the wound. If the edge of the device is still adhered to the skin, gently pick at the edge until it begins to peel away from the skin.

2. Slowly peel the DERMABOND PRINEO System away from the skin along the line of the wound. Do not pull the mesh straight up from the skin. The DERMABOND PRINEO System should be pulled back along the line of the wound close to the skin. Use the other hand to stabilize the wound as the mesh is peeled off.

3. Once the entire length of the DERMABOND PRINEO System has been removed, discard the device in an appropriate medical waste container.

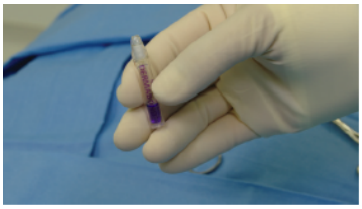
Any residual adhesive and/or dried wound exudate can be cleaned from the skin according to the institutional standard of care for skin cleansing.

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

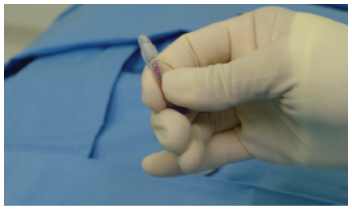
DERMABOND™ Mini Topical Skin Adhesive

DERMABOND Mini utilizes a liquid monomer, 2-octyl cyanoacrylate, as its foundation. Upon polymerization, 2-octyl cyanoacrylate monomers product strong and flexible films. DERMANBOND Mini contains specially designed chemicals, known as “formulation additives”, which provide the polymerized film with additional flexibility as well as increase the affinity of the liquid formulation for the surface of the skin. The DERMABOND Mini Applicator contains 0.36 mL.

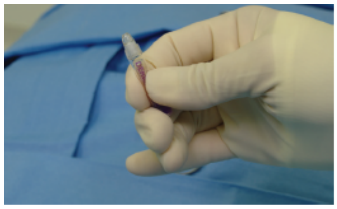
APPLICATION INSTRUCTIONS



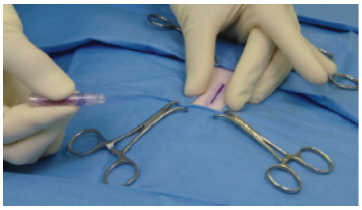
Hold the applicator away from the patient with the tip pointed upward.



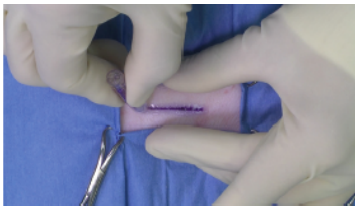
Squeeze the bulb to crush the ampoule inside, and then release pressure.



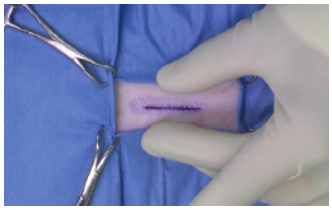
Gently squeeze the bulb again to moisten the internal filter with adhesive.



Approximate the wound edges with gloved fingers or forceps.



Apply DERMABOND Mini in a single continuous layer, maintaining steady bulb pressure.



Hold skin edges and wait approximately 30 seconds. Apply a second coat, full polymerization in about 3 minutes.

Patient Care for a Wound After it's Been Treated with DERMABOND Topical Skin Adhesive

DERMABOND Adhesive (2-octyl cyanoacrylate) is a sterile, liquid skin adhesive that holds wound edges together. The film will usually remain in place for 5 to 10 days, then naturally falls off the patient's skin.

The following will answer some questions and provide instructions for proper care for your patient's wounds while they are healing.

CHECK WOUND APPEARANCE

- Some swelling, redness, and pain are common with all wounds and normally will go away as the wound heals. If swelling, redness, or pain increases or if the wound feels warm to the touch, instruct patients to contact a doctor. They should also contact a doctor if the wound edges reopen or separate.

REPLACE BANDAGES

- If the wound is bandaged, keep the bandage dry.

- Replace dressing daily until the adhesive film has fallen off or if the bandage should become wet, unless otherwise instructed by the physician.

- When changing the dressing, do not place tape directly over the DERMABOND Adhesive film, because removing the tape later may also remove the film.

- Do not apply liquid or ointment medications or any other product to the wound while the DERMABOND Adhesive film is in place. These may loosen the film before the wound is healed.

KEEP WOUND DRY AND PROTECTED

- Apply a clean, dry bandage over the wound if necessary to protect it.

- Patients may occasionally and briefly wet the wound in the shower or bath. Do not soak or scrub the wound, do not swim, and avoid periods of heavy perspiration until the DERMABOND Adhesive has naturally fallen off. After showering or bathing, gently blot the wound dry with a soft towel. If a protective dressing is being used, a fresh, dry bandage should be applied, keeping tape off the DERMABOND Adhesive film.

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* Clinical significance unknown.
† Deep dermal stitches required.
^ As demonstrated in vitro.

CHAPTER 6

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.

UMBILICAL TAPE

Umbilical tape is a white woven cotton ligature, 1/8 or ¼ inch (.32 or .64 cm) 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 during the operation, but is not left in place.

Umbilical tape easily absorbs blood when used in an area of gross bleeding. The 1/8-inch (0.32 cm) tape is available with or without a radiopaque thread woven into the length of the fabric to facilitate x-ray identification.

POLYESTER FIBER STRIP

MERSILENE Polyester Fiber Strip is comprised of a double thickness of MERSILENE Polyester Fiber Mesh that is 5 mm 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 collar-like 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 orthopedic procedures such as rotator cuff repair and support. The blunt needles used for the incompetent cervix ligation may also be used for this purpose.

SURGICAL STAPLES

The staple closure is mainly used for large wounds that are not on the face. Stapling is especially useful for closing scalp wounds. Staples are also used for linear lacerations of the torso and extremities, especially if they are relatively long.

Surgical staples have established a diverse range of applications including the closure of orthopaedic wounds. This method allows surgeons to quickly close wounds without the risk of needle-stick injuries associated with suturing. Reported disadvantages of this modality include higher material cost, poorer cosmesis, and increased pain with removal.[1]

A variety of stapling devices are available for wound closure. With all devices, the staple creates an incomplete rectangle: the legs of the staple extend into the skin, and the cross-limb lies on the skin surface across the wound. Each device may differ in its handling characteristics, visual access, the angle at which the staples enter tissues, the ease of position and the pre-cocking mechanism. Optimal visibility as the staple is placed in the skin is important, as is the angle at which the staple enters the skin because insertion of the staple perpendicular to the surface of the skin results in deep penetration that increases the likelihood of tissue strangulation and permanent cross-hatching of the wound.

Before inserting staples, it is important to line up the wound edges with the centerline indicator on the head of the stapler to make sure that the legs of the staple will enter the skin at equal distances on either side of the wound edge. Each edge is typically picked up with a forceps, everted and precisely lined up. The surgeon then places the staples to close the wound while the first assistant advances the forceps, everting the edges of the wound.

Care must be taken to avoid uneven or overlapping wound edges when placing staples.[2]

INDICATIONS AND USAGE

Wound closure with staples is indicated for scalp lacerations that do not require extensive hemostasis and do not involve tears in the underlying frontooccipital aponeurosis (galea). They are also indicated for linear nonfacial lacerations caused by shear forces (eg, sharp objects).

AFTERCARE AND REMOVAL

Skin staples should be removed at the same time that sutures would be removed, based on wound location and tension. For scalp wounds, staples should be removed on day 7 after insertion. For trunk and extremity wounds, staples should be removed between days 7 and 14. Wounds closed with staples may be covered with a topical antibiotic cream or ointment. Patients may bathe or shower the next day, but should avoid prolonged exposure to moisture. When used on the scalp, patients should be very careful about combing or brushing their hair. A specially designed, single-handed, disposable staple remover should be used to remove the staples by a healthcare professional.

PROXIMATE™ Skin Staplers PROXIMATE Skin Staplers place single staples to close surgical incisions. Staples are made of lubricant-coated stainless steel; the staplers are not reloadable. ETHICON™ Endo-Surgery makes 3 different skins staplers to meet surgeons' needs.

PROXIMATE™ PX skin stapler provides many of the same features as the PROXIMATE RH skin stapler but in a fixed-head format.

PROXIMATE™ PLUS MD is a high-value, low-cost skin stapler that permits multi-directional release in an ergonomic design.

PROXIMATE* RH Skin Staplers (Rotating Head Skin Staplers)		PROXIMATE* PX Skin Staplers		PROXIMATE* PLUS MD Skin Staplers (Multi-Directional Skin Staplers)	
FEATURES	BENEFITS	FEATURES	BENEFITS	FEATURES	BENEFITS
Rectangular staples	Minimize staple rotation	Ergonomic pistol grip	Intuitive and comfortable to use	Improved kick-off spring design	Mulit-direc-tion release
Head rotates 360°, cartridge is clear	Improves visibility and access	Positive ratchet mechanism	Easy staple placement	Ergonomic design	Comfortable for smaller hands
Staples are coated with lubricant	Easy staple extraction	Staples are coated with lubricant	Easy staple extraction	Alignment indicator	Improves visibility
Pistol-grip handle	Comfortable to use			Staples are coated with lubricant	Easy staple extraction

RETENTION SUTURE DEVICES

Retention sutures, if not placed carefully without excessive tension, can cut the skin. Bolsters are used to prevent such complications and eliminate pressure. However, care should also be taken in the use of this device. *Retention suture bolsters* are sterile 2 1/2-inch (6 cm) lengths of 3/16-inch (0.48 cm) diameter surgical latex tubing with a 1/32-inch (0.08 cm) wall. The suture is threaded through the bolster and tied. Sutures sheathed in this manner can cause an inflammatory response with reaction both at the site of the suture exit from the skin and along the entire length of the suture itself. Also, the skin may become necrotic beneath the bolsters if the sutures are too tight. This invariably occurs if the sutures are tightly tied at the time of the operation, as subsequent tissue edema ensues.

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For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

Notes

ETHICON

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