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INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY®

EDITORIALS

ORIGINAL ARTICLES

Continued inside.

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INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY

CONTENTS

Continued from cover

ORIGINAL ARTICLES

CONCISE COMMUNICATIONS

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SHEA: 19 Mantua Rd., Mt. Royal, NJ 08061; telephone, 856-423-0087; fax, 856-423-3420; e-mail address, sheahq@talley.com.

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INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY™

EDITORIAL OFFICE
SLACK Incorporated
6900 Grove Road
Thorofare, NJ 08086
(856) 848-1000; (856) 848-6091 (FAX)
E-mail: iche@slackinc.com

SLACK Incorporated
6900 Grove Road
Thorofare, New Jersey 08086
(856) 848-1000

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Comprehensive Approach to Preventing Surgical-Site Infections

Prepared by ETHICON

Incidence and healthcare impact

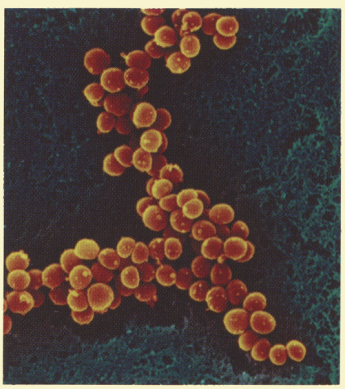
Surgical-site infections have been estimated by the National Nosocomial Infection Survey of the Centers for Disease Control and Prevention to occur following 2.6% of the more than 27 million surgical procedures performed annually in the United States. Other studies, citing specific surgical procedures, have reported that the annual incidence can range from 4% to 11%.[1] Anatomically, the highest infection rates are found in procedures involving the small bowel, heart, liver, pancreas, and head and neck, as well as following cesarean sections and limb amputations.[2] The conservative 2.6% incidence rate predicts that potentially more than 700,000 patients annually will suffer surgical infections. Without effective preventive measures, this figure should rise in proportion to an expected increase in the number of surgical procedures.[1]

Surgical-site infections impose a significant burden on patients and their families. The mortality rate among patients with surgical-site infections can be more than twice the rate for comparable surgical patients without infections.[1] Wound-related complications can include tissue destruction, wound dehiscence, incisional and deep hernias, septic thrombophlebitis, recurrent pain, and disfiguring and disabling scars. Systemic complications include toxemia, bacteremia, shock, disseminated infection, and failure of vital organs.[3] Caring for patients with these infections requires considerable resources. The median length of stay for a patient with a surgical-site infection can increase 4 to 22 days over that of an uninfected patient, and the median cost increase can range from $2,700 to $11,000. The cost can be as high as $82,000 per patient.[1] Actual expenditures depend on the type of operation, extent of infection, and methods of cost analysis.

Because the physical and economic burdens of surgical-site infections are great, preventive strategies have been recommended by the Centers for Disease Control and Prevention and by leading surgeons.[4-6] These strategies recognize that most surgical-site infections can be attributed to multiple risk factors rather than to surgical care alone.[5] In general, the preventive regimens call for procedures and devices that reduce the opportunity for microbial growth.

Microbiology and risk factors

Surgical-site infection begins when the wound is inoculated with bacteria, which may be resistant to antibiotics, either inward from the skin or outward from the organ being operated on; hence, the common procedures of skin preparation and antibiotic prophylaxis. The microbiology of the wound depends on the type of operation being performed, but the majority of infections are caused by gram-positive cocci including *Staphylococcus aureus,* coagulase-negative Staphylococci, and *Enterococcus* spp (19%, 14%, and 12% of isolates, respectively).[5] Although the incidence and distribution of pathogens isolated from hospital-acquired infections has changed little over the past decade, more of these pathogens now show antimicrobial drug resistance.[6] National Nosocomial Infection Survey data have documented a 31% increase in the incidence of vancomycin-resistant *Enterococcus,* a 29% increase in methicillin-resistant *S aureus,* and a 1% increase in the incidence of methicillin-resistant coagulase-negative staphylococci. The proportion of *S aureus* isolates resistant to methicillin, oxacillin, or nafcillin (MRSA) is higher than 55%, and the proportion of coagulase-negative *Staphylococci* resistant to these agents is greater than 87%.[2] In some European hospitals, rampant MRSA forced the closure of wards until decontamination procedures could take effect.[7]



The development of surgical-site infections is affected by risk factors that should be mitigated or corrected. Preoperative patient factors include chronic inflammation, obesity, diabetes, malnutrition, smoking, peripheral vascular disease, infection, skin carriage of *Staphylococci*, and skin disease such as psoriasis. Environmental factors comprise ineffective disinfection or sterilization, insufficient skin antisepsis, and inadequate ventilation. Treatment factors can involve drains, hypothermia, inadequate antibiotic prophylaxis, prolonged preoperative hospitalization, and prolonged operative time. In the postoperative period infection can be potentiated by blood transfusion, hyperglycemia, and poor nutrition.[5]

Preventive measures

The Centers for Disease Control and Prevention advocates preventive measures for surgical-site infections that address pre-, intra-, and postoperative procedures for patients, surgeons, and other healthcare professionals.[4] This "total system" approach to all aspects of the surgical procedure should reduce the likelihood of microbial contamination and infection. In addition to the regimen of meticulous care practiced by all surgeons, ETHICON believes that a conscientious decision to include devices that have antimicrobial properties or that provide a microbial barrier may further reduce the risk of surgical-site infections. For example, SURGICEL* Absorbable Hemostat, the only hemostat with proven bactericidal (*in vitro*) properties, may help control the risk of infection when

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a hemostatic agent is required. Also, VICRYL* *PLUS* Antibacterial (polyglactin 910) Suture has been shown to inhibit the colonization of *S aureus, Staphylococcus epidermis,* and their methicillin-resistant strains on the suture *in vitro.*[8] In addition, DERMABOND* Topical Skin Adhesive has been shown to be an effective barrier against the penetration of common infection-causing bacteria. In an *in vitro* model, DERMABOND Adhesive provided a barrier to microbial penetration for 72 hours, with 99% efficacy for the following bacterial species: *S epidermis, Escherichia*

an *in vitro* model, DERMABOND Adhesive provided a barrier to microbial penetration for 72 hours, with 99% efficacy for the following bacterial species: *S epidermis, Escherichia*

SURGICEL Hemostat has been used successfully for rapid intraoperative hemostasis during millions of surgica procedures. Its advantages include excellent biocompatibility, rapid absorption, and its derivation from plant-based materials. Positive clinical experiences in the hands of thousands of surgeons have proven SURGICEL Hemostat to be safe, effective, and reliable.

SURGICEL Hemostat is now available in three forms to meet the different needs of all specialties. SURGICEL*

SURGICEL Hemostat is now available in three forms to meet the different needs of all specialties. SURGICEL*
NU-KNIT Absorbable Hemostat is dense and thick for heavy

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SURGICEL*, SURGICEL* FIBRILLAR, and SURGICEL NU-KNIT*

Absorbable Hemostats (oxidized regenerated cellulose)

FOR SURGICAL USE

lobe that SURGICEL Hemostat, when left in the patient after closure, migrated from the site of application into foramina in bone around the spinal cord resulting in paralysis and, in another case, the left orbit of the eye, causing blindness. While these reports cannot be confirmed, special care must be taken by physicians, ***regardless of the type of surgical procedure***, to consider the advisability of removing SURGICEL Hemostat after hemostasis is achieved.

Although SURGICEL Hemostat is bactericidal against a wide range of pathogenic

DERMABOND*

Topical Skin Adhesive
(2-Octyl Cyanoacrylate)

INDICATIONS
DERMABOND Topical Skin Adhesive is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. DERMABOND adhesive may be used in conjunction with, but not in place of, deep dermal stitches.

CONTRAINDICATIONS
- Do not use on any wound with evidence of active infection, gangrene, or wounds of decubitus etiology.
- Do not use on mucosal surfaces or across mucocutaneous junctions (e.g., oral cavity, lips), or on skin which may be regularly exposed to body fluids or with dense natural hair, (e.g., scalp).
- Do not use on patients with a known hypersensitivity to cyanoacrylate or formaldehyde.

WARNINGS
- DERMABOND adhesive is a fast setting adhesive capable of adhering to most body tissue and many other materials, such as latex gloves and stainless steel. Inadvertent contact with any body tissue, and any surfaces or equipment that are not disposable or that cannot be readily cleaned with a solvent such as acetone should be avoided.
- Polymerization of DERMABOND adhesive may be accelerated by water or fluids containing alcohol: DERMABOND adhesive should not be applied to wet wounds.
- DERMABOND adhesive should not be applied to the eye. If contact with the eye occurs, flush the eye copiously with saline or water. If residual adhesive remains, apply topical ophthalmic ointment to help loosen the bond and contact an ophthalmologist.
- When closing facial wounds near the eye with DERMABOND adhesive, position the patient so that any run-off of adhesive is away from the eye. The eye should be closed and protected with gauze. Prophylactic placement of petroleum jelly around the eye, to act as a mechanical barrier or dam, can be effective in preventing inadvertent flow of adhesive into the eye. DERMABOND adhesive will not adhere to skin pre-coated with petroleum jelly. Therefore, avoid using petroleum jelly on any skin area where DERMABOND adhesive is intended to adhere. Use of DERMABOND adhesive near the eye has inadvertently caused some patient's eyelids to be sealed shut. In some of these cases, general anesthesia and surgical removal has been required to open the eyelid.
- DERMABOND adhesive should not be used below the skin because the polymerized material is not absorbed by tissue and can elicit a foreign body reaction.
- DERMABOND adhesive should not be used in high skin tension areas or across areas of increased skin tension, such as knuckles, elbows, or knees, unless the joint will be immobilized during the skin healing period.
- DERMABOND adhesive treated wounds should be monitored for signs of infection. Wounds with signs of infection, such as erythema, edema, warmth, pain and pus, should be evaluated and treated according to standard practice for infection.
- DERMABOND adhesive should not be used on wound sites that will be subjected to repeated or prolonged moisture or friction.
- DERMABOND adhesive should only be used after wounds have been cleaned and debrided in accordance with standard surgical practice. Local anesthetic should be used when necessary to assure adequate cleansing and debridement.
- Excessive pressure of the applicator tip against wound edges or surrounding skin can force the wound edges apart and allow adhesive into the wound. Adhesive within the wound could delay wound healing and/or result in adverse cosmetic outcome. Therefore, DERMABOND adhesive should be applied with a very light brushing motion of the applicator tip over easily approximated wound edges.
- DERMABOND adhesive polymerizes through an exothermic reaction in which a small amount of heat is released. With the proper technique of applying DERMABOND adhesive in multiple thin layers (at least three) onto a dry wound and allowing time for polymerization between applications, heat is released slowly and the sensation of heat or pain experienced by the patient is minimized. However, if DERMABOND adhesive is applied so that large droplets of liquid are allowed to remain unspread, the patient may experience a sensation of heat or discomfort.
- DERMABOND adhesive is packaged for single patient use. Discard remaining opened material after each wound closure procedure.
- Do not resterilize DERMABOND adhesive.
- Do not place DERMABOND adhesive in a procedure pack/tray that is to be sterilized prior to use. Exposure of DERMABOND adhesive, after its final manufacture, to excessive heat (as in autoclaves or ethylene oxide sterilization) or radiation (such as gamma or electron beam), is known to increase its viscosity and may render the product unusable.

PRECAUTIONS
- Do not apply liquid or ointment medications or other substances to the wound after closure with DERMABOND adhesive, as these substances can weaken the polymerized film and allow for wound dehiscence. DERMABOND adhesive permeability by topical medications has not been studied.
- DERMABOND adhesive permeability by fluids is not known and has not been studied.
- DERMABOND adhesive is a free flowing liquid slightly more viscous than water. To prevent inadvertent flow of liquid DERMABOND adhesive to unintended areas: (1) the wound should be held in a horizontal position, with DERMABOND adhesive applied from above, and (2) DERMABOND adhesive should be applied in multiple (at least 3), thin layers rather than in a few large droplets.
- Hold applicator away from yourself and the patient and break ampule close to its center one time only. Do not crush the contents of the applicator tube repeatedly as further manipulation of the applicator may cause glass shard penetration of the outer tube.
- DERMABOND adhesive should be used immediately after crushing the glass ampule as the liquid adhesive will not flow freely from the applicator tip after a few minutes.
- If unintended bonding of intact skin occurs, peel, but do not pull the skin apart. Petroleum jelly or acetone may help loosen the bond. Other agents such as water, saline, Betadine® Antibiotics, HIBICLENS† (chlorhexidene gluconate), or soap, are not expected to immediately loosen the bond.
- Safety and effectiveness of DERMABOND adhesive on wounds of patients with peripheral vascular disease, insulin dependent diabetes mellitus, blood clotting disorders, personal or family history of keloid formation or hypertrophy, or burst stellate lacerations, have not been studied.
- Safety and effectiveness of DERMABOND adhesive on the following wounds have not been studied: animal or human bites, puncture or stab wounds.

Clinical Study Outcomes	*No Subcuticular Sutures*		*With Subcuticular Sutures*	
	DERMABOND N (%)	Control N (%)	DERMABOND N (%)	Control N (%)
Accounting				
N. patients enrolled	240	243	167	168
N. patients treated	239	242	167	166
Patients completed	228 (95%)	215 (88%)	164 (98%)	162 (96%)
Adverse Reactions				
*Suspected Infection**	8 (3.6%)	2 (0.9%)	6 (3.6%)	2 (1.2%)
Wound type				
# Lacerations	8	2	1	0
# Incisions	0	0	5	2
Dehiscence with Need for Retreatment	6 (2.5%)	5 (2.1%)	3 (1.8%)	0
Acute Inflammation				
Erythema	26 (11.5%)	74 (33.0%)	52 (31.3%)	75 (45.1%)
Edema	22 (9.7%)	28 (12.5%)	62 (37.3%)	71 (42.8%)
Pain	14 (6.1%)	13 (5.8%)	56 (33.7%)	57 (34.3%)
Warmth	3 (1.3%)	6 (2.6%)	3 (1.8%)	4 (2.4%)

- Safety and effectiveness on wounds that have been treated with DERMABOND adhesive and then exposed for prolonged periods to direct sunlight or tanning lamps have not been studied.
- Safety and effectiveness of DERMABOND adhesive on wounds in vermilion surfaces has not been studied.

ADVERSE REACTIONS
- Adverse reactions encountered during clinical study:

*In the clinical study, presence of infection was to be identified by observation of redness more than 3–5 mm from the repaired wound, swelling, purulent discharge, pain, increased skin temperature, fever, or other systemic signs of infection. (See clinical study). Confirmatory culture was not routinely obtained. Among cases of suspected infection for DERMABOND adhesive, 7/14 (50%) were in patients less than 12 years old with traumatic lacerations; overall, 8 of the 14 (approximately 60%) DERMABOND adhesive wounds with suspected infections were associated with sub-optimal cosmetic outcome.

- Reactions may occur in patients who are hypersensitive to cyanoacrylate or formaldehyde. See CONTRAINDICATIONS.
- The polymerization of DERMABOND adhesive on the skin releases small amounts of heat which may cause a sensation of heat or discomfort in some patients.
- Adverse reactions may be experienced following DERMABOND adhesive contact with the eye.

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†Registered Trademark of Zeneca Pharmaceuticals

High Viscosity

DERMABOND*

Topical Skin Adhesive
(2-Octyl Cyanoacrylate)

INDICATIONS
High viscosity DERMABOND Topical Skin Adhesive is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. High viscosity DERMABOND adhesive may be used in conjunction with, but not in place of, deep dermal stitches.

CONTRAINDICATIONS
- Do not use on any wound with evidence of active infection, gangrene, or wounds of decubitus etiology.
- Do not use on mucosal surfaces or across mucocutaneous junctions (e.g., oral cavity, lips), or on skin which may be regularly exposed to body fluids or with dense natural hair, (e.g., scalp).
- Do not use on patients with a known hypersensitivity to cyanoacrylate or formaldehyde.

WARNINGS
- High viscosity DERMABOND adhesive is a fast setting adhesive capable of adhering to most body tissue and many other materials, such as latex gloves and stainless steel. Inadvertent contact with any body tissue, and any surfaces or equipment that are not disposable or that cannot be readily cleaned with a solvent such as acetone should be avoided.
- Polymerization of high viscosity DERMABOND adhesive may be accelerated by water or fluids containing alcohol: High viscosity DERMABOND adhesive should not be applied to wet wounds.
- High viscosity DERMABOND adhesive should not be applied to the eye. If contact with the eye occurs, flush the eye copiously with saline or water. If residual adhesive remains, apply topical ophthalmic ointment to help loosen the bond and contact an ophthalmologist.
- When closing facial wounds near the eye with high viscosity DERMABOND adhesive, position the patient so that any run-off of adhesive is away from the eye. The eye should be closed and protected with gauze. Prophylactic placement of petroleum jelly around the eye, to act as a mechanical barrier or dam, can be effective in preventing inadvertent flow of adhesive into the eye. High viscosity DERMABOND adhesive will not adhere to skin pre-coated with petroleum jelly. Therefore, avoid using petroleum jelly on any skin area where high viscosity DERMABOND adhesive is intended to adhere. Use of DERMABOND adhesive near the eye has inadvertently caused some patient's eyelids to be sealed shut. In some of these cases, general anesthesia and surgical removal has been required to open the eyelid.
- High viscosity DERMABOND adhesive should not be used below the skin because the polymerized material is not absorbed by tissue and can elicit a foreign body reaction.
- High viscosity DERMABOND adhesive should not be used in high skin tension areas or across areas of increased skin tension, such as knuckles, elbows, or knees, unless the joint will be immobilized during the skin healing period.
- High viscosity DERMABOND adhesive treated wounds should be monitored for signs of infection. Wounds with signs of infection, such as erythema, edema, warmth, pain and pus, should be evaluated and treated according to standard practice for infection.
- High viscosity DERMABOND adhesive should not be used on wound sites that will be subjected to repeated or prolonged moisture or friction.
- High viscosity DERMABOND adhesive should only be used after wounds have been cleaned, debrided and are otherwise closed in accordance with standard surgical practice. Local anesthetic should be used when necessary to assure adequate cleansing and debridement.
- Excessive pressure of the applicator tip against wound edges or surrounding skin can force the wound edges apart and allow adhesive into the wound. Adhesive within the wound could delay wound healing and/or result in adverse cosmetic outcome. Therefore, high viscosity DERMABOND adhesive should be applied with a very light brushing motion of the applicator tip over easily approximated wound edges.
- High viscosity DERMABOND adhesive polymerizes through an exothermic reaction in which a small amount of heat is released. With the proper technique of applying high viscosity DERMABOND adhesive in multiple thin layers (at least three) onto a dry wound and allowing time for polymerization between applications, heat is released slowly and the sensation of heat or pain experienced by the patient is minimized. However, if high viscosity DERMABOND adhesive is applied so that large droplets of liquid are allowed to remain unspread, the patient may experience a sensation of heat or discomfort.
- High viscosity DERMABOND adhesive is packaged for single patient use. Discard remaining opened material after each wound closure procedure.
- Do not resterilize high viscosity DERMABOND adhesive.
- Do not place high viscosity DERMABOND adhesive in a procedure pack/tray that is to be sterilized prior to use. Exposure of high viscosity DERMABOND adhesive, after its final manufacture, to excessive heat (as in autoclaves or ethylene oxide sterilization) or radiation (such as gamma or electron beam), is known to increase its viscosity and may render the product unusable.

PRECAUTIONS
- High viscosity DERMABOND adhesive has not been evaluated for use on wounds such as surgical incisions, punctures from minimally invasive surgery.
- Do not apply liquid or ointment medications or other substances to the wound after closure with high viscosity DERMABOND adhesive, as these substances can weaken the polymerized film and allow for wound dehiscence. High viscosity DERMABOND adhesive permeability by topical medications has not been studied.
- High viscosity DERMABOND adhesive permeability by fluids is not known and has not been studied.
- High viscosity DERMABOND adhesive, as a liquid, is syrup-like in viscosity. To prevent inadvertent flow of liquid high viscosity DERMABOND adhesive to unintended areas: (1) the wound should be held in a horizontal position, with high viscosity DERMABOND adhesive applied from above, and (2) high viscosity DERMABOND adhesive should be applied in multiple (at least 3), thin layers rather than in a few large droplets.
- Hold applicator away from yourself and the patient and break ampule close to its center one time only. Do not crush the contents of the applicator tube repeatedly as further manipulation of the applicator may cause glass shard penetration of the outer tube.
- High viscosity DERMABOND adhesive should be used immediately after crushing the glass ampule as the liquid adhesive will not flow freely from the applicator tip after a few minutes.
- If unintended bonding of intact skin occurs, peel, but do not pull the skin apart. Petroleum jelly or acetone may help loosen the bond. Other agents such as water, saline, Betadine® Antibiotics, HIBICLENS† (chlorhexidene gluconate), or soap, are not expected to immediately loosen the bond.
- Safety and effectiveness of high viscosity DERMABOND adhesive on wounds of patients with peripheral vascular disease, insulin dependent diabetes mellitus, blood clotting disorders, personal or family history of keloid formation or hypertrophy, or burst stellate lacerations, have not been studied.
- Safety and effectiveness of high viscosity DERMABOND adhesive on the following wounds have not been studied: animal or human bites, puncture or stab wounds.
- Safety and effectiveness on wounds that have been treated with high viscosity DERMABOND adhesive and then exposed for prolonged periods to direct sunlight or tanning lamps have not been studied.
- Safety and effectiveness of high viscosity DERMABOND adhesive on wounds in vermilion surfaces has not been studied.

ADVERSE REACTIONS
Adverse reactions encountered during the clinical study for closure of trauma-induced lacerations using high viscosity DERMABOND adhesive and the clinical study comparing low viscosity DERMABOND adhesive to sutures, staples, and adhesive strips are listed below:

The safety of both high viscosity DERMABOND adhesive and the low viscosity DERMABOND adhesive control was measured in a randomized clinical study of 84 patients, 42 patients receiving high viscosity product and 42 receiving low viscosity product, by 1) the presence or the extent of an inflammatory reaction, 2) the presence of signs of clinical infection, 3) cosmetic outcome at Day 30, 4) assessment of thermal discomfort, and 5) the reported adverse events associated with use of the device. No significant differences between the two treatment groups were observed for any of these safety outcome measures, although 17 patients (44%) randomized to the high viscosity DERMABOND adhesive treatment group experienced a sensation of heat during application of the skin adhesive compared to 10 patients (26%) randomized to the low viscosity DERMABOND adhesive treatment group. Of those 17 patients in the high viscosity group, 5 of the patients noted that sensation of heat was uncomfortable. None of the patients in the low viscosity group observed objectionable sensation of heat.

As indicated under WARNINGS, high viscosity DERMABOND adhesive polymerizes through an exothermic reaction in which heat is released. It is important to use the proper technique of applying high viscosity DERMABOND adhesive in thin layers to minimize the risk that the patient may experience a sensation of heat or discomfort. This is especially important in the application of high viscosity DERMABOND adhesive, because the increased viscosity of the product relative to low viscosity DERMABOND adhesive can create a thicker applied layer resulting in a higher potential for heat to be generated. High viscosity DERMABOND adhesive should always be applied in thin layers so that large amounts of liquid are not allowed to collect,resulting in thermal discomfort for the patient.

Adverse reactions encountered during clinical study comparing low viscosity DERMABOND adhesive to suture, staples, and adhesive strips are listed in the table to the left.

- Reactions may occur in patients who are hypersensitive to cyanoacrylate or formaldehyde. See CONTRAINDICATIONS.
- Adverse reactions may be experienced following high viscosity DERMABOND adhesive contact with the eye.

Manufactured for ETHICON, INC.
by Closure Medical Corp.
*Trademark

®Trademark of Purdue Fredericks
†Registered Trademark of Zeneca Pharmaceuticals

Coated VICRYL Plus Antibacterial (Polyglactin 910) Suture

U.S.P., EXCEPT FOR DIAMETER

DESCRIPTION

Coated VICRYL* Plus Antibacterial (Polyglactin 910) Suture is a synthetic absorbable, sterile, surgical suture composed of a copolymer made from 90% glycolide and 10% L-lactide. Coated VICRYL Plus Antibacterial Suture is coated with a mixture composed of equal parts of a copolymer of glycolide and lactide (Polyglactin 370) and calcium stearate. *The suture contains Irgacare MP** (triclosan), a broad-spectrum antibacterial agent.* at no more than 50ug/m. The copolymers in this product have been found to be nonantigenic, nonpyrogenic and elicit only a mild tissue reaction during absorption. The suture is available undyed (natural) or dyed (D&C Violet No.2).

Coated VICRYL Plus Antibacterial Sutures meet all the requirements established by the United States Pharmacopoeia (U.S.P.) for Synthetic Absorbable Surgical Suture (except for diameter) in the following sizes:

MAXIMUM SUTURE OVERSIZE IN DIAMETER (mm) FROM U.S.P.	
U.S.P. SUTURE SIZE DESIGNATION	MAXIMUM OVERSIZE (mm)
5-0	.016
4-0	.017
3-0	.018
2-0	.004
0	.022

INDICATIONS

Coated VICRYL Plus Antibacterial Suture is indicated for use in general soft tissue approximation and/or ligation, except for ophthalmic, cardiovascular and neurological tissues.

ACTIONS

Coated VICRYL Plus Antibacterial Suture elicits a minimal acute inflammatory reaction in tissue and ingrowth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of Coated VICRYL Plus Antibacterial Suture occurs by means of hydrolysis, where the copolymer degrades to glycolic and lactic acids, which are subsequently absorbed and metabolized in the body. Absorption begins as a loss of tensile strength followed by a loss of mass. Implantation studies in rats indicate that Coated VICRYL Plus Antibacterial Suture retains approximately 75% of the original tensile strength at two weeks post implantation. At three weeks, approximately 50% of the original strength is retained. At four weeks, approximately 25% of the original strength is retained. All of the original tensile strength is lost by five weeks post implantation. Absorption of Coated VICRYL Plus Antibacterial Suture is essentially complete between 56 and 70 days.

DAYS IMPLANTATION	APPROXIMATE % ORIGINAL STRENGTH REMAINING
14 Days	75%
21 Days	50%
28 Days	25%

Using zone of inhibition studies, Coated VICRYL Plus Antibacterial Suture has been shown to inhibit colonization of the suture by Staphylococcus aureus and Staphylococcus epidermidis. The clinical significance of this finding is unknown.

CONTRAINDICATIONS

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

Coated VICRYL Plus Antibacterial Suture should not be used in patients with known allergic reactions to Irgacare MP (triclosan).

WARNINGS

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing Coated VICRYL Plus Antibacterial Suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used. Physicians should consider the in vivo performance (under ACTIONS section) when selecting a suture. The use of this suture may be inappropriate in elderly, malnourished, or debilitated patients, or in patients suffering from conditions which may delay wound healing. As this is an absorbable suture material, the use of supplemental nonabsorbable sutures should be considered by the surgeon in the closure of the sites which may undergo expansion, stretching or distention, or which may require additional support.

Do not resterilize. Discard opened packages and unused sutures.

As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. As an absorbable suture, *Coated VICRYL Plus Antibacterial Suture may act transiently as a* foreign body. Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

PRECAUTIONS

Skin sutures which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated.

Under some circumstances, notably orthopaedic procedures, immobilization of joints by external support may be employed at the discretion of the surgeon.

Consideration should be taken in the use of absorbable sutures in tissues with poor blood supply as suture extrusion and delayed absorption may occur.

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders. Coated VICRYL Plus Antibacterial Sutures, which are treated to enhance handling characteristics, require the accepted surgical technique of flat and square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon.

Avoid prolonged exposure to elevated temperatures.

To avoid damaging needle points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistent to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" container.

ADVERSE REACTIONS

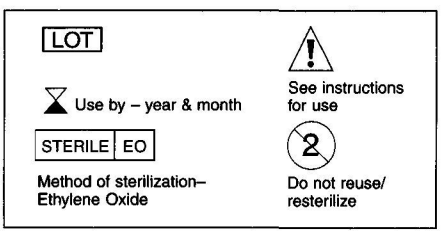
Adverse effects associated with the use of this device include wound dehiscence, failure to provide adequate wound support in closure of the sites where expansion, stretching, or distension occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing, infection, minimal acute inflammatory tissue reaction, localized irritation when skin sutures are left in place for greater than 7 days, suture extrusion and delayed absorption in tissue with poor blood supply, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation at the wound site, as well as allergic reaction to Irgacare MP (triclosan). Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

HOW SUPPLIED

Coated VICRYL Plus Antibacterial Sutures are available sterile, as braided dyed (violet) and undyed (natural) strands in sizes 5-0 through 0 (metric sizes 1 - 3.5) in a variety of lengths, with or without needles, and on LIGAPAK* dispensing reels.

Needles may be attached permanently or as CONTROL RELEASE* removable needles enabling the needles to be pulled off instead of being cut off. Coated VICRYL Plus Antibacterial Sutures are available in one, two and three dozen boxes. Full details are contained in the catalog.

Batch number



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