

General Instructions for opening and handling of all types of Ethicon packages are mentioned below: Depending on the type of package, choose the appropriate instructions.

I Recommended technique for opening and handling Peelable Foil Pack



- 1) Hold pack in your hand. Grasp the upper foil flap in your right hand and lower foil flap in your left hand. Roll thumbs outward separating the flaps and exposing sterile zipper tray/paper folder.



- 2) Project the sterile zipper tray on the sterile table only after peeling apart the peelable foil completely. For paper folder follow step III, 1



- 3) Hold the zipper tray in the gloved left hand securely without bending it as shown in the figure. Do not place the thumb on the paper lid but keep it on the upper edge of the zipper tray. Do not remove the paper lid prior to removing the needled suture.



- 4) Arm the needle with an appropriate needle holder using the no-touch technique.



- 5) Remove the needled suture with a smooth and moderate pull in a direction parallel to the zipper tray. If resistance is observed while removing, then relax the suture and pull again. Please do not pull against the swaged end of the suture.

II Recommended technique for opening and handling Overwrap :



- 1) Hold pack in left hand, grasp foil flap between thumb and index-finger of right hand, thus exposing plastic flap.



- 2) Grasp transparent plastic flap with thumb and index-finger of left hand, gripping pack between knuckles.



- 3) Roll thumbs outward separating the flaps and exposing sterile primary foil pack/paper folder/zipper tray/Mesh. Keep constant pressure between knuckles for best control. For zipper tray follow step I, 3.

4. The sterile primary foil pack / paper folder / Mesh is now exposed for delivery to sterile field or to the scrub nurse by one of the following methods :



- a) The scrub nurse removes the sterile primary foil pack / paper folder / Mesh with sterile forceps or with a gloved hand;

OR



- b) From a suitable distance the circulating nurse "flips" sterile primary foil pack / paper folder/ Mesh on to the sterile field (e.g. on a sterile trolley);

OR



- c) The circulating nurse folds back both the flaps of the Overwrap now holding it with one hand-then removes the sterile primary foil pack / paper folder/ Mesh with sterile forceps and delivers it to the scrub nurse.

III Recommended technique for opening and handling Primary Foil Pack / Folder



1. The scrub nurse should now hold the sterile Primary Foil Pack / Folder with the colour coded top facing her. The notch will be located at the top right. The sterile primary foil pack / folder to be held with the left hand close to the notch.



2. With the right hand, tear the right hand end of the sterile primary foil pack / folder at the notch down towards you.



3. Withdraw the exposed suture now. In case unprinted folder is inside, open the same to access suture.

4. Easy Access "EA" Packs may be opened by tearing at the notch as indicated by the arrow. Grp the exposed needle with the needle holder & pull out the suture.

HANDLING DIRECTIONS

FOR

VICRYL* Plus

ETHICON

MANUFACTURED IN INDIA BY

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Instructions for use

VICRYL* Plus

ANTIBACTERIAL, WITH TRICLOSAN
ABSORBABLE SURGICAL SUTURE U.S.P. (SYNTHETIC)
STERILISED SURGICAL NEEDLED SUTURE
(MONOFILAMENT/BRAIDED COATED POLYGLACTIN 910
VIOLET/UNDYED)

DESCRIPTION

VICRYL* Plus Antibacterial Suture is a synthetic absorbable sterile surgical suture composed of a copolymer made from 90% glycolide and 10% L-lactide.

Braided VICRYL* Plus Antibacterial Sutures are coated with a mixture composed of equal parts of copolymer of glycolide and lactide (Polyglactin 370) and calcium stearate. The suture coating contains Triclosan (Irgacare**MP), a broad spectrum antibacterial agent at no more than 472ug/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). VICRYL* Plus Antibacterial Sutures meet all the requirements established by the United States Pharmacopoeia (U.S.P.) for Synthetic Absorbable 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	0.020
4-0	0.020
3-0	0.020
2-0	0.021
0	0.040
1	0.021

INDICATIONS

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

ACTIONS

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 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 loss of mass. Implantation studies in rats indicate that VICRYL* Plus Antibacterial Suture retains approximately 75% of the original 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 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, 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. VICRYL* Plus Antibacterial Suture should not be used in patients with known allergic reaction to Triclosan (Irgacare**MP).

WARNINGS

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing 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 site which may undergo expansion, stretching or distension, 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 urinary or biliary tracts, may result in calculus formation. As an absorbable suture, 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 tissue with poor blood supply as suture extrusion and delayed absorption may occur.

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders. 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 resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle stick. Discard used needles in 'Sharps' containers.

ADVERSE REACTIONS

Adverse reaction 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 occurs, 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 Triclosan

(Irgacare**MP). Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmissions of blood borne pathogens.

HOW SUPPLIED

VICRYL* Plus Antibacterial Sutures are available sterile, as braided dyed (violet) and Undyed (natural) strands in various sizes, in a variety of lengths, with needles. VICRYL* Plus Antibacterial Sutures are available in box containing 12 packs.

STERILITY

VICRYL* Plus Antibacterial sutures are sterilized by ethylene oxide. Do not re-sterilize! Do not use if package is opened or damaged! Discard opened unused sutures!

STORAGE

Recommended storage conditions: Below 25° C, away from moisture and direct heat. Do not use after expiry date!

SYMBOLS USED ON LABELLING.

 = Do not reuse

 = Use by -Year & Month

 = Method of Sterilization - Ethylene oxide.

 = Batch Number

 = See Instructions for use

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