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.

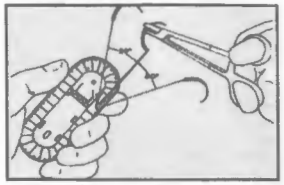
I Recommended technique for opening and handling Peelable Foil Pack

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 1, 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. Grip the exposed needle with the needle holder & pull out the suture.

HANDLING DIRECTIONS

FOR

VICRYL*

ETHICON

MANUFACTURED IN INDIA BY

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V06
*TM

Instructions for use

VICRYL*

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

DESCRIPTION

VICRYL* suture is a synthetic absorbable sterile surgical suture composed of a copolymer made from 90% glycolide and 10% L-lactide. The empirical formula of the copolymer is $(C_2H_2O_2)_m(C_3H_4O_2)_n$.

Braided VICRYL* sutures are coated with a mixture composed of equal parts of copolymer of glycolide and lactide (Polyglactin 370) and calcium stearate. Polyglactin 910 copolymer and Polyglactin 370 with calcium stearate have been found to be nonantigenic, nonpyrogenic and elicit only slight tissue reaction during absorption.

VICRYL* sutures are dyed by adding D and C#2 (Colour Index number: 60725) during polymerisation. Sutures are also available in the undyed form.

VICRYL* is available in a range of gauge sizes and lengths, non-needled or attached to stainless steel needles of varying types and sizes. The needles may be attached permanently or as CR-needles (control release), enabling the needles to be pulled off instead of being cut off. Full details are contained in the catalogue.

VICRYL* complies with the requirements of the United States Pharmacopoeia for "Absorbable Surgical Suture" and the European Pharmacopoeia for "Sterile Synthetic Absorbable Braided Sutures" (except for an occasional slight oversize in some gauges). Maximum Suture oversize in diameter (mm) from U.S.P.

U.S.P. SUTURE SIZE DESIGNATION	MAXIMUM OVERSIZE (mm)
9-0	0.005
8-0	0.008
6-0	0.010
5-0	0.020
4-0	0.020
3-0	0.020
2-0	0.021
0	0.040
1	0.021

INDICATIONS

VICRYL* sutures are intended for use in general soft tissue approximation and/or ligation, including use in ophthalmic surgery, peripheral nerve anastomosis and microsurgery for vessels less than 2 mm diameter. The safety and effectiveness of VICRYL* sutures in cardiovascular tissue have not been established.

APPLICATION

Sutures should be selected and implanted depending on patient condition, surgical experience, surgical technique and wound size.

PERFORMANCE

VICRYL* suture elicits a minimal initial inflammatory reaction in tissues and ingrowth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of VICRYL* sutures 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. All of the original tensile strength is lost between four and five weeks post implantation. Absorption of VICRYL* suture is essentially complete between 56 and 70 days.

Days Implantation	Approximate % original Strength Remaining
14 days (6-0 and larger)	75%
21 days (6-0 and larger)	50%
21 days (7-0 and smaller)	40%
28 days (6-0 and larger)	25%

CONTRA-INDICATIONS

These sutures, being absorbable, should not be used where extended approximation of tissues under stress is required.

WARNINGS / PRECAUTIONS / INTERACTIONS

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing VICRYL* suture material for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used. Surgeons should consider the in-vivo performance (under 'PERFORMANCE' section) when selecting a suture. 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, VICRYL* may act transiently as a foreign body.

Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

As this is an absorbable suture material, the use of supplemental non-absorbable sutures should be considered by the surgeon in the closure of the sites which may undergo expansion, stretching or distension or which may require additional support.

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

Under some circumstances, notably orthopaedic procedures, immobilisation 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. Subcuticular sutures should be placed as deeply as possible to minimize the erythema and induration normally associated with the absorption process. This suture may be inappropriate in elderly, malnourished or debilitated patients, or in patients suffering from conditions which may delay wound healing.

When 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.

Care should be taken to avoid damage when handling surgical needles. Grasp the needle in an area one third (1/3) to one half (1/2) of the distance from the attachment end to the point. Grasping in the point area could impair the penetration performance and cause fracture of the needle. Grasping at the butt or attachment end could cause bending or breakage. 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 injury. Discard used needles in 'Sharps' containers.

ADVERSE REACTIONS

Adverse reaction associated with the use of the device include: allergic response in certain patients, transient local irritation at the wound site, transient inflammatory foreign body response erythema and induration during the absorption process of subcuticular sutures.

STERILITY

VICRYL* 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 until Year & Month

STERILE EO = Sterile unless the package is damaged or opened. Method of Sterilization - Ethylene oxide.

LOT = Batch Number

= See Instructions for use