INSTRUCTION FOR USE-ABSORBABLE COATED & BRAIDED POLYGLYCOLIC ACID SURGICAL SUTURE

PETCRYL®
STERILE ABSORBABLE COATED & BRAIDED POLYGLYCOLIC ACID SURGICAL SUTURE U.S.P

DESCRIPTION

Petcryl® suture is a synthetic coated, braided absorbable sterile surgical suture composed of homo polymer of glycolide (100%). Petcryl® is dyed violet with CI solvent Violet No. 13 (Color Index No. 60725) and coated with unique combination of polycaprolactone and calcium stearate. PETCRYL® sutures are available in range of gauge sizes and lengths, non needled or attached to stainless steel needles of varying types, sizes and shapes. The needles are attached permanently to the suture. Entire details of the product range are available in the catalogue. Petcryl® complies with the requirements of the United States Pharmacopoeia (U.S.P) for "Absorbable surgical suture" Entire detail of the product range is contained in the catalogue.

INDICATION:

Petcryl® sutures are indicated for use in general, soft tissue including use in ophthalmic. But not for use in cardio vascular & neurological tissues.

SELECTION CRITERIA

Petcryl® sutures should be selected and implanted depending on the patient's condition, surgical experience, surgical technique and wound size.

PERFORMANCE

Petcryl® suture leads to ingrowth of fibrous connective tissue due to minimal initial inflammatory tissue reaction. Progressive loss of tensile strength occurs as the suture gets absorbed by means of hydrolysis, where the polymer degrades to glycolic acid which is subsequently absorbed and metabolized in the body. Absorption begins with loss of tensile strength followed by loss of mass. All of the original tensile strength is lost between four and five weeks post implantation. Petcryl® suture elicits a minimal tissue reaction and in growth of fibrous connective tissue. Absorption of bio absorbable suture occurs by hydrolysis: beginning with loss of tensile strength with loss of mass. Absorption pattern for suture when tested on rats:-

- Approx 96.1 % of the tensile strength at 7 days,
- Approx 83.3 % of tensile strength at 14 days,
- Approx 53.8 % tensile strength after 21 days and
- Approx 19.95 % tensile strength after 28 days.

ADVERSE REACTIONS

Adverse reaction, associated with the use of the device include transitory local irritation at the wound site, transitory inflammatory foreign body response, erythema and induration during the absorption process of subcuticular sutures. Like all foreign bodies, **Petcryl®** suture may enhance an existing infection.

CONTRAINDICATIONS

Petcryl® suture, being absorbable, should not be used where extended approximation of tissues under stress is required. If there is any localized inflammation, itching or any sort of allergy of a particular patient then the usage of this product should be stopped and medical advice should be taken immediately. The use of this suture is contraindicated in patients with known sensitivities or allergies to polyglycolic acid, calcium stearate and polycaprolactone.

WARNINGS

a. Surgeons should be familiar with surgical procedures and techniques involving absorbable sutures before employing **Petcryl®** suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

b. In surgery of the urinary or biliary tract, care should be taken to avoid prolonged contact of this or any other suture with salt solution, to prevent calculus formation.

c. This suture many be inappropriate in patients suffering from conditions which may delay wound healing e.g., patient that are elder, malnourished or depilated. As this is an absorbable suture, the use of supplemental non-absorbable suture should be considered by the surgeon in the close of the abdomen, chest, joints or other sites subjects to expansion or requiring additional support.

d. For single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/ or lead to device failure which, in turn, may result in patient injury or illness.

e. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.

f. Contamination of the device may lead to injury, illness of the patient.

PRECAUTIONS

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

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

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

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

e. Subcuticular sutures should be placed as deeply as possible to minimize the erythema and induration, normally associated with the absorption process.

f. When handling this or any other suture, 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.

INSTRUCTION FOR USE-ABSORBABLE COATED & BRAIDED POLYGLYCOLIC ACID SURGICAL SUTURE

g. Care should be taken to avoid damage while 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.

h. Grasping in the point area could impair the penetration performance and cause fracture of the needle.

i. Grasping at the butt or attachment end could cause bending or breakage.

j. Reshaping the needles may cause them to loose strength and make less resistant to bending and breaking.

k. Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury. Discard the needles after use.

STERILITY

Petcryl® 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 condition 10°C-35°C, away from moisture and direct heat. Do not use after expiry date.

DISPOSAL

Discard used sutures and needles contaminated with blood in the container meant infectious waste. Unused expired pouches should be incinerated.

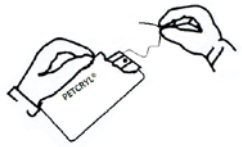
INSTRUCTIONS FOR USE

A. TECHNIQUE FOR OPENING THE OVER WRAP:

1. The scrub nurse should hold the sterile pack in left hand with the color coded top facing her. The notch will be located at the top right.

2. Then with the help of sterilized gloved hand or sterilized forceps pull the paper folder till the needle is visible. For non-needled suture, pull out the entire paper folder from the pack, open the folder and retrieve the suture.

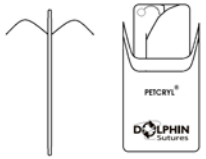
3. Again with the help of sterilized gloved hand or sterilized forceps grasp the needle which is visible. Pull the needle to remove the suture from the folder.



B. TECHNIQUE FOR OPENING THE PEEL OPEN POUCHES CONTAINING PETCRYL®

1. Hold the pack in an upright manner and see the peel logo.

2. Hold the protruded portions of the aluminum foils and peel open to see the needle fixed on the paper folder.



3. With the help of sterilized forceps pull the needle to remove the suture from the folder.

Futura Surgicare Pvt Ltd
86/C2, 3rd Main, 2nd Stage, Yeshwanthpur Industrial Suburb, Bangalore, Karnataka, India, Pin – 560 022
Mfg Lic No: KTK/28/273/1995
E-mail: sales@dolphinsutures.com
Web Site: www.dolphinsutures.com

EC REP
Obelis s.a
Bd. Général Wahis 53
1030 Brussels, BELGIUM
Tel: + (32) 2. 732.59.54
Fax: +(32) 2.732.60.03
E-Mail : mail@obelis.net

SYMBOLS USED ON THE LABELS:

2	Do not reuse	LOT	Batch number
	Date of manufacture		CE Mark with Notified Body
	Date of expiry	®	Registered
STERILE EO	Sterilized by ethylene oxide	EC REP	EU REPRESENTATIVE
	Temperature limitation	2 STERILIZE	Do not resterilize

INSTRUCTION FOR USE-ABSORBABLE COATED & BRAIDED POLYGLYCOLIC ACID SURGICAL SUTURE

	Do not use if package is damaged		Consult instructions for use
	Avoid direct sunlight		Avoid Moisture