INSTRUCTION FOR USE-NON ABSORBABLE MONOFILAMENT PTFE SURGICAL SUTURE

POLYTETRA FLUORO ETHYLENE (PTFE)
STERILE NON-ABSORBABLE MONOFILAMENT PTFE SURGICAL SUTURE

DESCRIPTION

Polytetra Fluoro Ethylene (PTFE) suture is a non-absorbable, monofilament suture manufactured from 100% high density poly tetra fluoro ethylene (PTFE) polymer, extruded in such a fashion as to produce a structure with a minimal pore size and volume while maintaining integrity and tensile strength. The structure is undyed with no additives.

Available in a broad range of suture sizes and lengths, is either non-needled or attached to standard stainless steel needles of varying types and sizes.

INTENDED USE

It is indicated for use in all types of soft tissue approximation and/ or ligation, including dental and general surgeries. The device is not indicated for the use in ophthalmic surgery and peripheral neural tissue.

SELECTION CRITERIA

The suture should be selected and implanted depending on patient's condition, surgical experience, surgical technique, and wound size. Normally the skin sutures are removed within 30 days depending on wound condition. The decision of physician is final in removing the skin sutures.

PERFORMANCE

Polytetra Fluoro Ethylene (PTFE) suture elicits a minimal initial inflammatory reaction in tissues which is followed by gradual encapsulation of the suture by fibrous connective tissue. PTFE suture is not absorbed or subject to weakening by tissue enzymes and does not degrade in the presence of infection.

ADVERSE REACTIONS

Adverse reactions associated with the use of Polytetra Fluoro Ethylene (PTFE) include transitory local irritation at the wound site or transitory inflammatory foreign body response. Like all foreign bodies Polytetra Fluoro Ethylene (PTFE) may potentate an existing infection.

CONTRAINDICATIONS

The use of this suture is contraindicated in patients with known sensitivities or allergies to poly tetra fluoro ethylene.

WARNINGS

a. The safety and effectiveness of this suture in ophthalmic, microsurgical and peripheral neural application has not been established.

b. Tissue invasion of Polytetra Fluoro Ethylene (PTFE) suture can result in attachment of the suture to the tissue it penetrates in long term use. Such attachment may make removal of the suture difficult.

c. Surgeons should consider the in-vivo performance and should be familiar with surgical procedure and techniques involving non-absorbable sutures before employing Polytetra Fluoro Ethylene (PTFE) suture for wound closure, as a risk of wound dehiscence may vary with the site of application and the suture material used.

a. 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.

b. For single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization maycompromise the structural integrity of the deviceand/ or lead to device failure which, in turn, mayresult in patient injury or illness.

c. 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.

d. Contamination of the device may lead to injury or illness of the patient.

e. Do no use for invasive procedures related to central nervous system and central circulatory system.

PRECAUTIONS

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

b. In handling this suture material, care should be taken to avoid damaging the surface of the material with surgical instruments as this could lead to fracture of the material in use.

c. Avoid crushing or crimping damage due to surgical instruments such as forceps or needle holders.

d. Adequate knot security requires the standard surgical technique of flat and square ties with additional throws as indicated by surgical circumstances and the experience of the surgeon.

e. The use of addition throws is particularly appropriate when knotting Mono filament PTFE sutures.

f. While tying knots with the PTFE suture, tension should be applied by pulling each strand of the suture in opposite direction with equal force. This tension shall not be applied by pulling the needle itself, but is applied by grasping the suture with the fingers or surgical instruments with blunt surface so that the suture is not damaged in the process. As the knot is tensioned, the air inside the suture is forced out creating a secure knot.

g. Care shall be taken to avoid using a jerking motion, which could break the suture or cause separation of the suture from the needle. Uneven tensioning of a well formed square knot can result in a formation of

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unsecure knot. When Polytetra Fluoro Ethylene (PTFE) suture is properly tensioned and formed standard knotting technique will produce a secure knot.

h. Care should be taken to avoid damage while handling surgical needles, Grasp the needle in an area of one third (1/3) to one half (1/2) of the distance from the attachment end to the sharp point.

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

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

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

l. Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury.

m. Discard the used needles appropriately.

STERILITY

Polytetra Fluoro Ethylene (PTFE) 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 10ºC-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.

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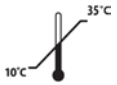
CE 2460

SYMBOLS USED ON THE LABELS

	Do not reuse	LOT	Batch number

	Date of manufacture	CE 2460	CE Mark with Notified Body Number
	Date of expiry	®	Registered
STERILE EO	Sterilized by ethylene oxide	EC REP	EU REPRESENTATIVE
	Temperature limitation		Do not resterilize
	Do not use if package is damaged		Consult instructions for use
	Avoid direct sunlight		Avoid Moisture

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