ETHICON, LLC
475 C Street
Los Frailes Industrial Park
Suite 401 Guaynabo, Puerto Rico 00969
USA
1-877-ETHICON
+1-513-337-6928

EC REP Johnson & Johnson Medical Ltd
Simpson Parkway
Kirkton Campus
Livingston
EH54 7AT
United Kingdom

ETHILON™

ar	خيط جراحي	fr	SUTURE	pt	FIO DE SUTURA
cs	ŠICÍ MATERIÁL	hu	SUTURE (VARRÓANYAG)	ru	ШОВНЫЙ МАТЕРИАЛ
da	SUTUR	it	SUTURA	sk	NIŤ
de	NAHTMATERIAL	ko	봉합사	sv	SUTUR
el	PAMMA	nl	HECHTDRAAD	tr	SÜTÜR
en	SUTURE	no	SUTUR	zh-cn	缝线
es	SUTURA	pl	NIĆ CHIRURGICZNA	zh-tw	縫合線
fi	OMMELAINE				

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Instructions for use

ETHILON™

POLYAMIDE 6 OR POLYAMIDE 6,6
STERILE SYNTHETIC NON-ABSORBABLE SURGICAL SUTURE, USP / Ph. Eur.

DESCRIPTION

ETHILON™ Suture is a sterile, monofilament, synthetic, non-absorbable, surgical suture composed of polyamide 6 $[NH\text{-}CO\text{-}(CH_2)_5]_n$ or polyamide 6,6 $[NH\text{-}(CH_2)_6\text{-}NH\text{-}CO\text{-}(CH_2)_4\text{-}CO]_n$.

ETHILON™ Suture is available undyed and dyed black with Hematine HCK (Color Index 75290) to enhance visibility in the surgical field.

ETHILON™ Suture is available in a range of gauge sizes and lengths, non-needled or attached to needles of various types and sizes, and in presentations as described in the HOW SUPPLIED section.

ETHILON™ Suture complies with the requirements of the European Pharmacopoeia (Ph. Eur.) for Sterile Polyamide 6 or Polyamide 6,6 Suture and United States Pharmacopeia (USP) for Non-Absorbable Surgical Sutures. The European Pharmacopoeia recognizes units of measure Metric and Ph. Eur. sizes as equivalent which is reflected on the labeling.

INDICATIONS

ETHILON™ Suture is indicated for use in general soft tissue approximation and/or ligation, including cardiovascular, ophthalmic and neurosurgical procedures.

APPLICATION

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

PERFORMANCE / ACTIONS

ETHILON™ Suture elicits an initial, minimal inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. While polyamide is not absorbed, progressive hydrolysis of the polyamide ***in vivo*** may result in gradual loss of tensile strength over time.

CONTRAINDICATIONS

Due to the gradual loss of tensile strength which may occur over prolonged periods ***in vivo***, ETHILON™ Suture should not be used where permanent retention of tensile strength is required.

WARNINGS

Users should be familiar with surgical procedures and techniques involving non-absorbable sutures before employing ETHILON™ Suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used.

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

Do not resterilize/reuse. Reuse of this device (or portions of this device) may create a risk of product degradation, which may result in device failure and/or cross-contamination, which may lead to infection or transmission of blood-borne pathogens to patients and users. Like all foreign bodies, this product may potentiate infection.

PRECAUTIONS

In handling this or any other suture material, care should be taken to avoid damage. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

As with any suture material, adequate knot security requires the standard surgical technique of flat, square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilament sutures.

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 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. 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 blood-borne pathogens. Discard used needles in "sharps" containers.

ADVERSE REACTIONS

Adverse reactions associated with the use of this device include wound dehiscence, gradual loss of tensile strength over time, calculi formation in urinary or biliary tracts when prolonged contact with salt solutions such as urine or bile occurs, minimal inflammatory tissue reaction, and transient local irritation at the wound site.

STERILITY

ETHILON™ Suture is sterilized by irradiation. Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused sutures.

STORAGE

No special storage conditions required. Do not use after expiry date.

HOW SUPPLIED

Please note that not all sizes are available in all markets. Please contact your local sales representative for size availability.

ETHILON™ Suture is available as sterile monofilament strands in USP sizes 11-0 through 2 (metric sizes 0.1 – 5.0) in a variety of lengths, with and without permanently attached needles.

The sutures are also available in presentations containing the following:

1. Lead Seal and Surgical Bolster in which the lead seal is used to maintain the position of the bolster relevant to the suture knot to maintain proper tension.
2. Retention tubing (elastomer tubing), which is used to spread the load of the suture at the surface of the skin.

ETHILON™ Suture is available in one, two or three dozen units per box.