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ETHIBOND™ EXCEL

AR	خييط	FR	FIL DE SUTURE	RU	ШОВНЫЙ МАТЕРИАЛ
CS	ŠÍČÍ MATERIÁL	HU	VARRÓANYAG	SK	NIŤ
DA	SUTUR	IT	SUTURA	SV	SUTUR
DE	NAHTMATERIAL	KO	봉합사	TR	SÜTÜR
EL	PAMMA	NL	HECHTMATERIAAL	ZH-CN	缝线
EN	SUTURE	NO	SUTUR	ZH-TW	缝合線
ES	SUTURA	PL	NICI		
FI	POLYESTERILANKA	PT	FIO DE SUTURA		

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Instructions for use

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ETHIBOND™ EXCEL POLYBUTYLATE COATED POLYESTER STERILE SYNTHETIC NON-ABSORBABLE SUTURE

DESCRIPTION

ETHIBOND™ EXCEL Suture is a coated, braided, non-absorbable sterile surgical suture composed of poly (ethylene terephthalate). The empirical molecular formula of the polymer is $(C_{10}H_8O_4)_n$. The suture is coated with polybutylate, which acts as a lubricant to mechanically improve the ease of passage through tissue and the overall handling qualities of the suture. ETHIBOND™ EXCEL is available undyed (white) and dyed green with D & C Green No. 6, Colour Index No. 61565.

ETHIBOND™ EXCEL is available in a range of gauge sizes and lengths non-needed or attached to stainless steel needles of various types and sizes. The needles may be attached permanently or as CONTROL RELEASE™, which enables the needles to be pulled off instead of being cut off.

The material may also be supplied in presentations containing the following:

1. Multi-strand sutures with PTFE (polytetrafluoroethylene) pledgets for use as a pad between the suture and the tissue surface to increase the load bearing area.
2. A range of components in a variety of materials to allow use as supporting or retention sutures.

Full details of the product range are contained in the catalogue.

ETHIBOND™ EXCEL complies with the requirements of the European Pharmacopoeia for Sterile Poly (ethylene terephthalate) Suture and the United States Pharmacopoeia for Non-Absorbable Surgical Sutures.

INDICATIONS

ETHIBOND™ EXCEL Sutures are intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

APPLICATION

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

PERFORMANCE

ETHIBOND™ EXCEL Suture elicits a minimal initial inflammatory reaction in tissue followed by a gradual encapsulation of the suture by fibrous connective tissue. Implantation studies in animals show no meaningful decline in polyester suture strength over time.

CONTRAINDICATIONS

None known.

WARNINGS/PRECAUTIONS/INTERACTIONS

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

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.

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

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.

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

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 reactions associated with the use of this device include minimal, initial inflammatory tissue reaction and transient local irritation at the wound site. Like all foreign bodies, ETHIBOND™ EXCEL may potentiate an existing infection.

STERILITY

ETHIBOND™ EXCEL Sutures are sterilized by irradiation or ethylene oxide as indicated on the package. 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

 Sterilized using ethylene oxide or irradiation



(CE-mark and Identification number of Notified Body. The product meets the essential requirements of Medical Device Directive 93/42/EEC.



Batch number



See instructions for use

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