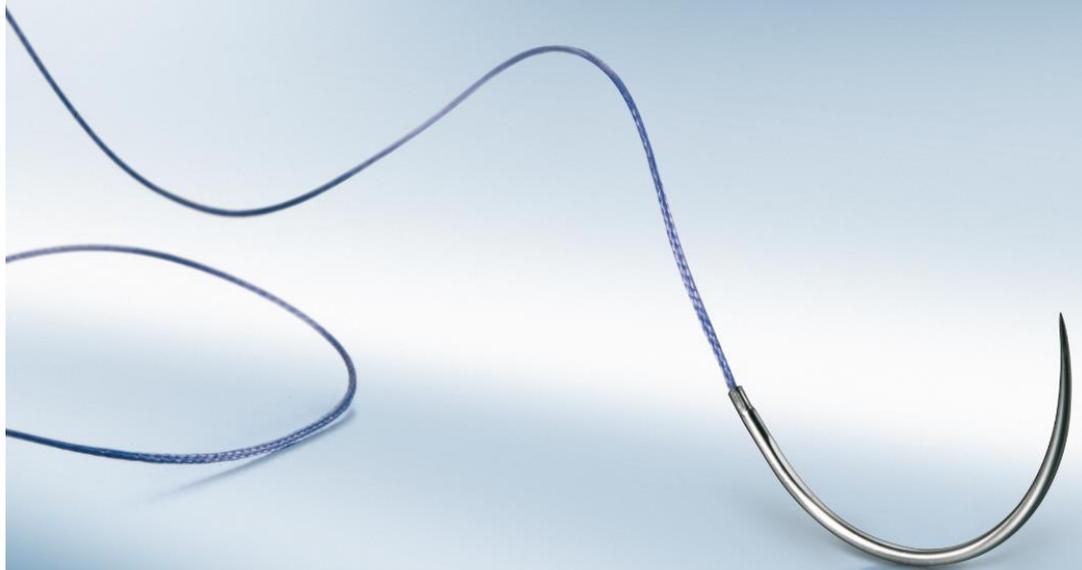


NOVOSYN[®]

TECHNICAL FILE



1 DESCRIPTION

Novosyn[®] is a sterile, absorbable surgical suture material produced from a copolymer composed of 90% glycolide and 10% L-lactide. Novosyn[®] is coloured violet with the colouring D&C Violet No. 2 (C. I. 60725) to make it recognizable, but is also available undyed in the natural beige colour. The braided threads are treated with an absorbable synthetic coating consisting of a mixture of equal parts of a copolymer consisting of glycolide and L-lactide and calcium stearate so that they slide easily without causing a sawing effect.

2 INDICATIONS

Novosyn[®] is indicated for soft tissue approximation and/or ligation in general surgery, when surgical practice requires the use of synthetic, absorbable, braided suture material.

Novosyn[®] sutures are also for use particularly in gynaecology and urology. Novosyn[®] is also indicated for ophthalmology and for microsurgery if an absorbable suture material is preferred.

3 CONTRA INDICATIONS

Novosyn[®] suture materials are contra-indicated for applications where prolonged support of the wound closure by the suture material is required.

The use of this suture is contraindicated on patients with known sensitivities or allergies to its components

4 MATERIAL SPECIFICATIONS

Material: copolymer composed of 90% glycolide and 10% L-lactide (PGLA 90/10).

Coating: Polyglactin 370 + calcium stearate.

Colour: Novosyn® is coloured violet with the colouring D&C Violet No. 2 (C. I. 60725) and also available undyed in the natural beige colour.

USP sizes: USP 8/0 (0,4 metric) to USP 2 (5 metric).

Tensile strength retention: 50% at 21 days, 75% at 14 days and 25% at 28 days.

Mass absorption: Hydrolysis, complete mass absorption in 56 till 70 days.

Sterilization: Ethylene oxide.

5 STORAGE / HANDLING / SHELF LIFE

Storage: Novosyn® does not require special storage conditions.

Shelf-Life: 5 years.

Packaging: DDP (Direct Dispense Packaging), TD for Take-off combinations and RCP (RacePack®)

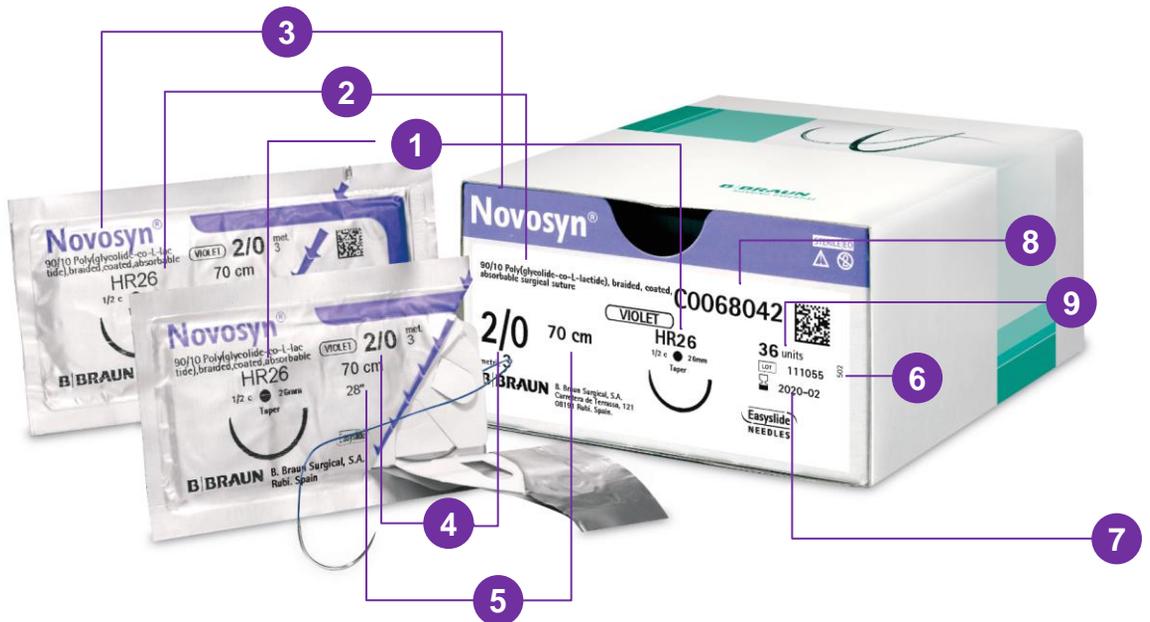
6 CERTIFICATIONS

Novosyn® suture is CE marked according to Directive 93/42/EEC on Medical Devices (MDD) and it is classified as a class III product.

7

LABELS / SYMBOLS

- (1) NEEDLE CODE
- (2) DESCRIPTION OF THE SUTURE
- (3) PRODUCT NAME
- (4) USP AND EP SIZE
- (5) LENGTH OF THE SUTURE
- (6) BATCH CODE
- (7) EXPIRY DATE (YEAR-MONTH-DAY)
- (8) ARTICLE NUMBER
- (9) NUMBER OF UNITS



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