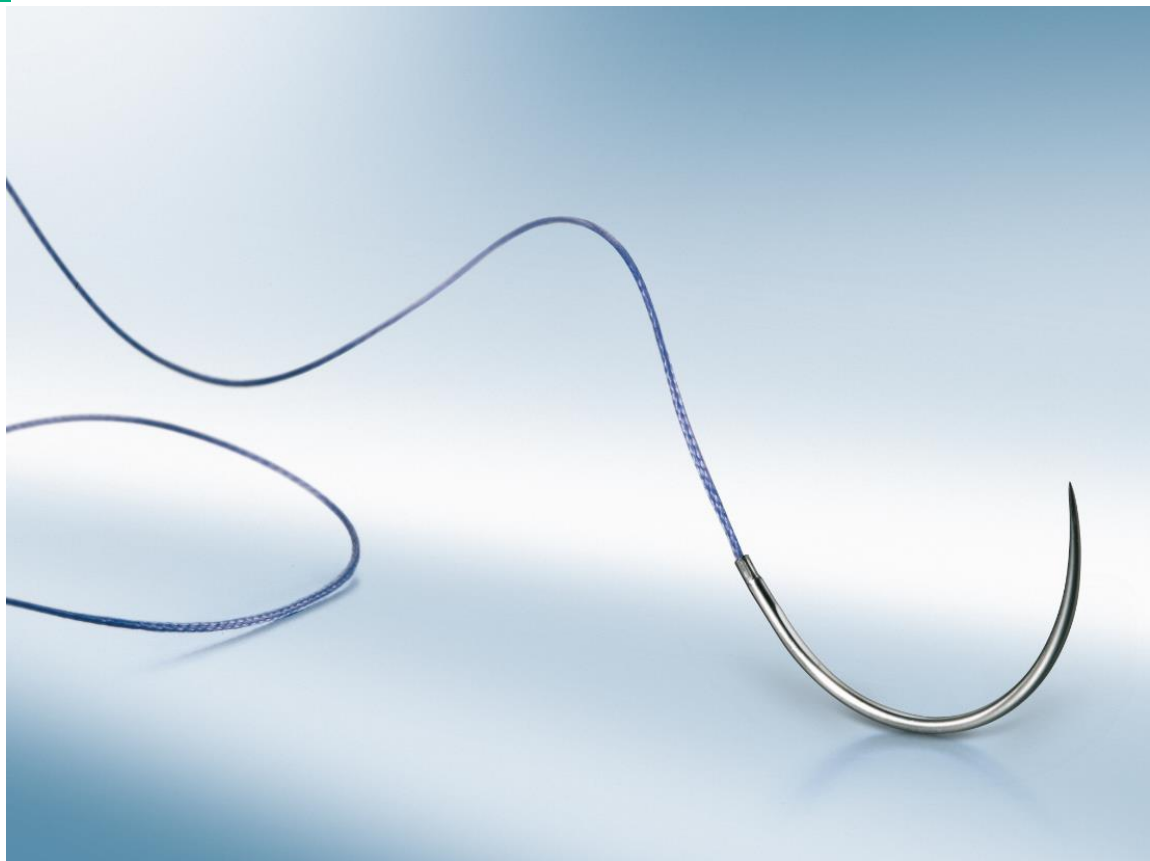


# NOVOSYN<sup>®</sup>

## TECHNICAL FILE



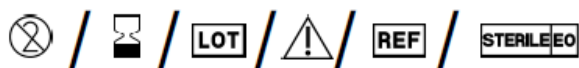
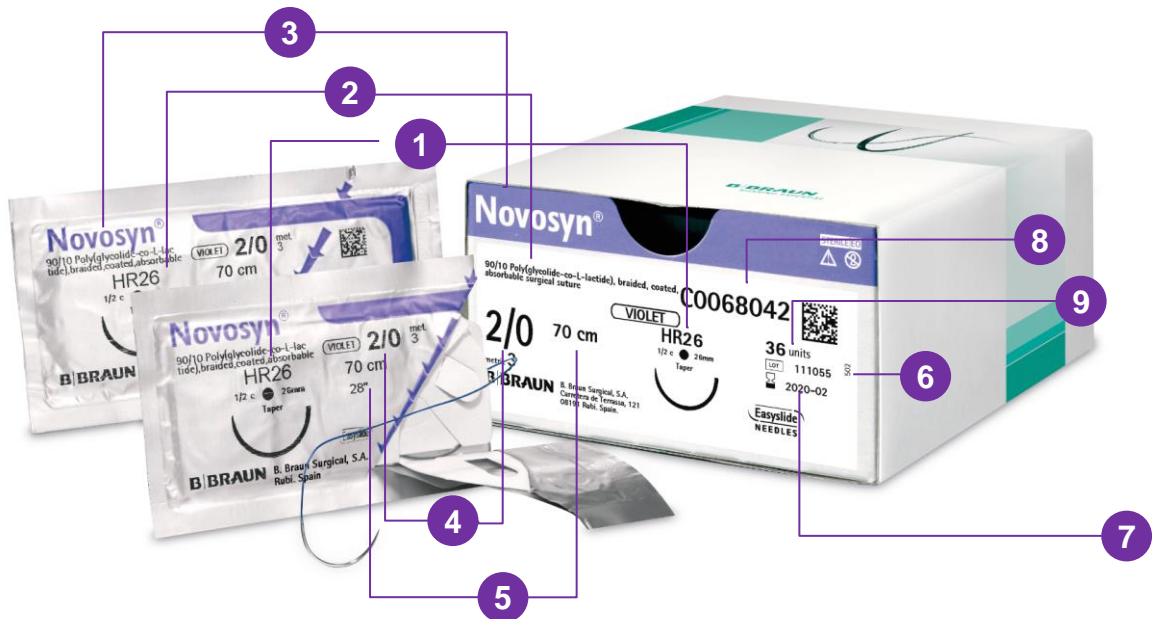
1	DESCRIPTION
	<p>Novosyn® is a sterile, absorbable surgical suture material produced from a copolymer composed of 90% glycolide and 10% L-lactide. Novosyn® is coloured violet with the colouring D&amp;C Violet No. 2 (C. I. 60725) to make it recognizable, but is also available undyed in the natural beige 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.</p>
2	INDICATIONS
	<p>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.</p> <p>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.</p>
3	CONTRA INDICATIONS
	<p>Novosyn® suture materials are contra-indicated for applications where prolonged support of the wound closure by the suture material is required.</p> <p>The use of this suture is contraindicated on patients with known sensitivities or allergies to its components</p>

4	<h2>MATERIAL SPECIFICATIONS</h2>
	<p>Material: copolymer composed of 90% glycolide and 10% L-lactide (PGLA 90/10).</p> <p>Coating: Polyglactin 370 + calcium stearate.</p> <p>Colour: Novosyn® is coloured violet with the colouring D&amp;C Violet No. 2 (C. I. 60725) and also available undyed in the natural beige colour.</p> <p>USP sizes: USP 8/0 (0,4 metric) to USP 2 (5 metric).</p> <p>Tensile strength retention: 50% at 21 days, 75% at 14 days and 25% at 28 days.</p> <p>Mass absorption: Hydrolysis, complete mass absorption in 56 till 70 days.</p> <p>Sterilization: Ethylene oxide.</p>
5	<h2>STORAGE / HANDLING / SHELF LIFE</h2>
	<p>Storage: Novosyn® does not require special storage conditions.</p> <p>Shelf-Life: 5 years.</p> <p>Packaging: DDP (Direct Dispense Packaging), TD for Take-off combinations and RCP (RacePack®)</p>
6	<h2>CERTIFICATIONS</h2>
	<p>Novosyn® suture is CE marked according to Directive 93/42/EEC on Medical Devices (MDD) and it is classified as a class III product.</p>

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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