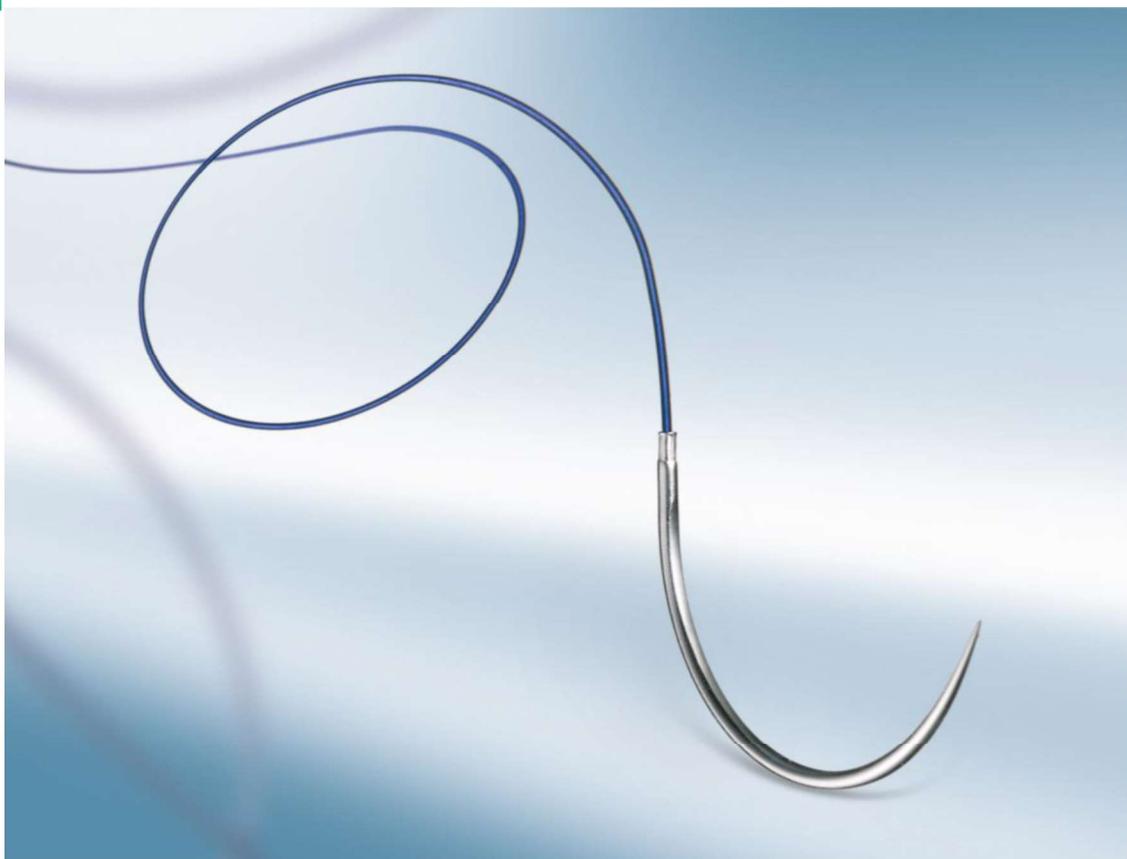


MONOPLUS[®]

TECHNICAL FILE



1 DESCRIPTION

MonoPlus® is a violet long-term absorbable synthetic monofilament suture made of polydioxanone.

2 INDICATIONS

MonoPlus® is indicated in cases where an extended soft tissue wound support of more than 4weeks is desirable. MonoPlus® presents clinical evidence in general surgery. The patient population to be used MonoPlus® is adult who do not meet any contraindication, there is not enough evidence in paediatric patients, pregnant or breastfeeding women. Intended user are healthcare professionals that are qualified and familiar with surgical techniques.

3 CONTRA INDICATIONS

MonoPlus® suture material is contraindicated for tissues that require a permanent wound support, for suturing applying high tension to the tissue or for suturing synthetic implants that require a permanent fixation like in cardio-vascular surgery (vascular grafts or cardiac valves). MonoPlus® suture shall not be used for patients with known intolerances or allergies towards any of the components.

4 MATERIAL SPECIFICATIONS

Material: Polydioxanone

Coating: none

Structure: Monofilament

Color: coloured violet with the colouring D&C Violet No. 2 (C. I. 60725)

USP sizes: USP 7/0 (0,5 metric) to USP 2 (5 metric).

Tensile strength retention: In vitro and in vivo degradation studies indicate that approximately 65 % to 90 % of its original knot pull tensile strength are retained after 28 days

Mass absorption: Hydrolysis, complete mass absorption in 180 till 220 days.

Sterilization: Ethylene oxide.

5 STORAGE / HANDLING / SHELF LIFE

Storage: No special storage conditions are required.

Shelf-Life: 5 years.

Packaging: DDP (Direct Dispense Packaging) and RCP® (RacePack)

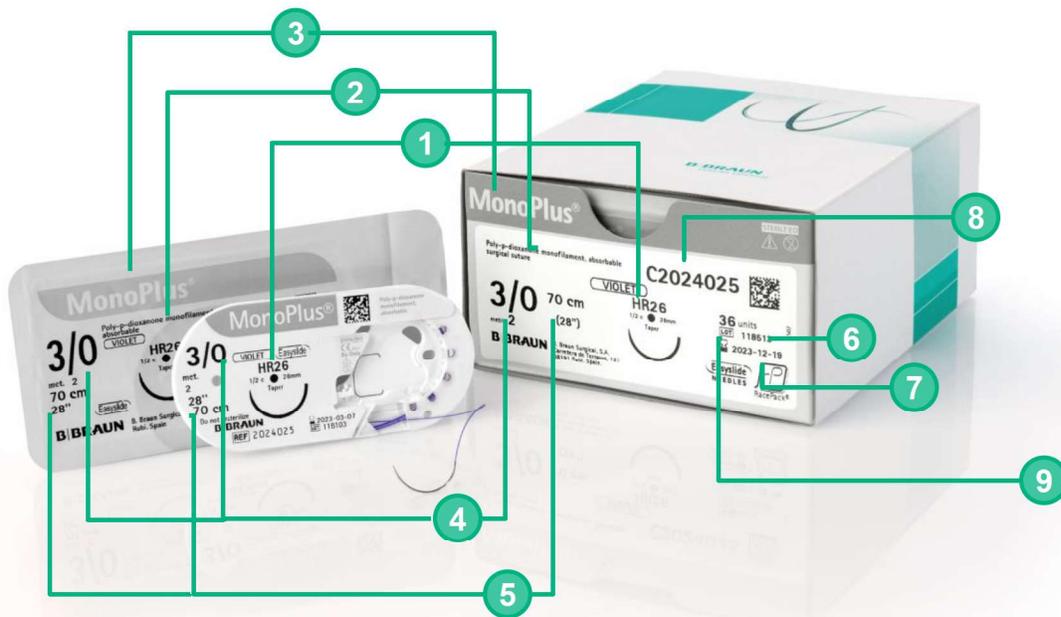
6 CERTIFICATIONS

MonoPlus is a class III medical device, CE Certified according to Regulation (EU) 2017/745.

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



8 UNIT SYMBOLS included from CE MDR

UDI

(1) This QR code includes UDI information (Unique Device Identification)

MD

(2) Medical Device

PDO

(3) Raw material Polydioxanone



(4) Dyed / monofilament / absorbable



(5) Single sterile barrier system with protective packaging inside



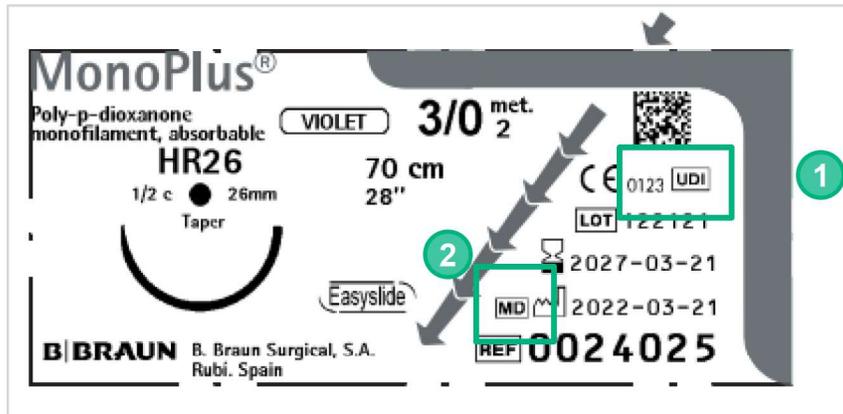
(6) Do not use if package is damaged and consult instructions for use



(7) Do not resterilize



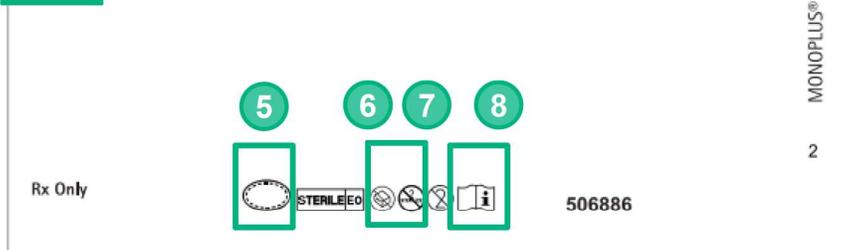
(8) Consult instructions of use or consult electronic IFU



3

PDO 产品名称:带针可吸收外科缝线 型号:参见 REF 其他内容详见说明书
 ④ Моноплюс (MonoPlus). Материал шовный хирургический стерильный
 ⑤ рассасывающийся. ПДС, монофилament, длительный срок рассасывания.
 Рег.уд.№ ФСЗ 2010/06563 от 05.09.2016 г.

4



9

BOX SYMBOLS included from CE MDR



(1) MD symbol (Medical Device)



(2) Instruction of Use



(3) Needles contain Cobalt

