



C-BLOCK

Technical data sheet

Trade name: C-Block

EC: 0373 – Class III according to 93/42 EEC amended by 2007/47/EC Directive

Manufacture: Assut Europe S.p.A.

Head office: Via Giuseppe Gregoraci, 12 – 00173 Roma

Manufacturing: Zona Industriale – 67062 Magliano dei Marsi (AQ)

Composition and molecule: ligating clip made of poly(L-lactide-co-D,L-lactide) - (C₆H₈O₄) -

Description: C-Block is a clip designed as an alternative to the surgical knot to be placed at the end of the suture. The clip consists of two parts: body and pin. Once locked these two parts cannot be separated. A specifically designed applicator should be used to apply the clip. The Poly(L-lactide-co-D,L-lactide) does not show a significant degradation in short terms but loses its physical properties about six months post-implantation. The loss of the device tensile strength depends mainly on the suture material used: the manufacturer guarantees that the effective strength is lost in about 30 days post-implantation.

Indications: The device is intended for use as an alternative to the surgical knot to be placed at the end of the suture. It is especially indicated in laparoscopic surgery. C-Block clip should be used only with synthetic braided surgical sutures mid-term absorption USP 4/0 e USP 3/0.

Tissue reaction: It may cause a slight inflammatory reaction in the tissue

“Latex free” device

Sterility: Sterilized by Beta rays

Validity: 3 years from manufacturing date

Packaging: Five aluminium pouches in a box, two clips per pouch with cartridge.

Warnings:

- Disposable, do not resterilize
- Do not use if the package is opened or damaged
- Do not use after expiry date
- Keep in a dry and cool place, away from direct heat.
- The suture and the clip should be placed by minimising the pressure on the device caused by patient's normal activities
- Avoid contact with alcohol and disinfectants

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