

FILBLOC

MONOFILAMENT OF ABSORBABLE SURGICAL SUTURE, BARBED AND SYNTHETIC [Poly(p-dioxanone)]

Technical data sheet

Trade name: FilBloc

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

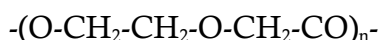
Manufacturer : Assut Europe S.p.A.

Head Office : Via Giuseppe Gregoraci, 12 – 00173 Roma

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

Classification : Monofilament of absorbable surgical suture, **'barbed'**, sterile and synthetic , with or without PDO final block according to European Pharmacopea requirements .

Composition and molecule: PDO Poli(p-dioxanone)



Colour: Violet (D&C Violet n.2 = C.I. 60725) or natural white.

Sizes and standard needles : Sutures are available in a range of gauges sizes (from 2 EP to 5 ; from 3/0 USP to 2 USP) and lengths, non needled or attached to stainless steel needles (AISI 300 and AISI 400 series) of different sizes and shapes . Filbloc can be also manufactured with a button (made of the same material of the suture) used to anchor the thread .

“Latex free” device

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

Tensile strength and absorption : The progressive loss of the suture tensile strength occurs in consequence of PDO hydrolysis which allows the absorption and the subsequent metabolization in the body. In vivo and in vitro studies , have proved that Filbloc absorption is complete within 180-210 days from the implantation :

POST IMPLANTATION

4 weeks

6 weeks

RESIDUAL TENSILE STRENGTH

~70-75%

~ 55-60%

Indications:: Filbloc surgical suture is intended for use in all surgical procedures at the user's discretion

Sterility: Ethylene Oxide (EO)

Shelf Life: 5 years

Packaging: Sterile double pack – box of 3/6/9/12/18/24/36/48 units

Warnings: Disposable
Do not use if the package is opened or damaged
Do not use after the expiry date
Keep in a dry and cool place, away from any direct heat

MECHANICAL CHARACTERISTICS				
AVERAGE STRENGTH				
GAUGE		Needle-thread capacity	Tensile strength	Block-thread capacity
EP	USP	Kg	Kg	Kg
1,5	4/0	1,64	1,45	1,21
2	3/0	1,82	1,97	1,90
3	2/0	2,38	3,41	3,08
3,5	0	2,83	4,71	4,47
4	1	3,69	5,52	5,03
5	2	7,63	10,20	10,09