

FILBLOC 90

MONOFILAMENT OF ABSORBABLE SURGICAL SUTURE , BARBED AND SYNTHETIC [Poly(glicolide-co-ε-caprolactone)]

Technical data sheet

Tarde name: FilBloc 90

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 according to European Pharmacopea requirements .

Composition and molecule : PGCL Copolymer of glicolide (75%) and epsilon caprolactone (25%) $[(\text{CHO})-\text{CO}-\text{O}]_x-[\text{C}_5\text{H}_{10}-\text{CO}-\text{O}]_y$ (x:y=7.5:2.5)

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 1,5 EP to 5 ; from 4/0 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 90 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 tissues

Tensile strength and residual absorption: The progressive loss of the suture tensile strength occurs in consequence of PGCL hydrolysis which allows the absorption and the subsequent metabolization in the body. In vivo and in vitro studies , have proved that Filbloc 90 absorption is complete within 90-120 days from the implantation :

POST IMPLANTATION	APPROX. RESIDUAL TENSILE STRENGTH
1 week	~50%
2 weeks	~20%

Indications: FilBloc 90 surgical suture is intended for use in all surgical procedures

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