

MONOFIL FAST

SHORT TERM ABSORPTION SURGICAL SUTURE

Technical data sheet

Trade name : Monofil Fast

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

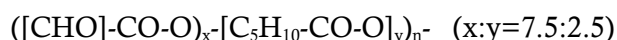
Manufacturer: Assut Europe S.p.A.

Head office: Via Giuseppe Gregoraci, 12 – 00173 Roma

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

Classification Monofilament of surgical suture, ,synthetic, sterile, short term absorption according to European Pharmacopea requirements .

Composition and molecule: PGCL Copolymer of glycolid (75%) and epsilon caprolactone (25%)



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 0,2 EP to 6 ; from 10/0 USP to 3&4 USP) and lengths, non-needled threads or attached to stainless steel needles (AISI 300 and AISI 400 series) of different sizes and shapes . Needles maybe permanently attached or 'Easy detaching' ,to enable the needle to be pulled instead of being cut off.

Further details are described in the catalogue .

“Latex free” device

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

Tensile strength and absorption : The progressive loss of the suture tensile strength occurs in consequence of the PGCL hydrolysis which allows the absorption and the subsequent metabolization in the body; 'in vivo'and 'in vitro' studies have proved that Monofil Fast absorption is complete within 50-60 days from implantation :

POST IMPLANTATION	APPROX. TENSILE RESIDUAL STRENGTH
5 days	~48-55%
10 days	~25%
20 days	~2%

Knotting properties: Greater knot security requires standard surgical technique of flat or square knots , to be applied with additional throws as maybe indicated by the surgical circumstances and surgeon's experience

Indications: Monofil Fast surgical suture is intended for use in all surgical procedures

Precautions: It is recommended that surgeon evaluate the possible use of non-absorbable sutures for the closure of tissues which may undergo distension or stretching or requiring an additional support. This kind of suture maybe inappropriate in elderly, malnourished or weakened patients or in patients suffering from conditions which may delay wound healing process .

Sterility: Gamma Rays (R)

Shelf life : 5 years

Packaging : Sterile double pack – box of 12/24/36/48 units

Warnings: Disposable
Do not use it 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

Special: After technical tests and according to Company, it is possible to produce combinations of non standard-codes

MECHANICAL CHARACTERISTICS													
AVARAGE STRENGTH													
ASSUT EUROPE						PHARMACOPEA							
GAUGE		Needle-thread capacity		Thread with standard knot		Needle-thread capacity		Minimum allowed		Thread with standard knot		Minimum allowed	
EP	USP	Kg	daN	Kg	daN	Kg	daN	Kg	daN	Kg	daN	Kg	daN
0,2	10/0	0,058	0,056	0,098	0,096								
0,3	9/0	0,199	0,195	0,154	0,150								
0,4	8/0	0,301	0,295	0,223	0,219	0,051	0,050	0,026	0,025	0,071	0,070	0,036	0,035
0,5	7/0	0,385	0,377	0,351	0,344	0,082	0,080	0,041	0,040	0,143	0,140	0,070	0,069
0,7	6/0	0,462	0,453	0,446	0,437	0,173	0,169	0,082	0,080	0,255	0,025	0,132	0,129
1	5/0	1,21	1,19	0,928	0,909	0,235	0,230	0,112	0,110	0,694	0,680	0,490	0,480
1,5	4/0	1,64	1,61	1,02	0,999	0,459	0,450	0,235	0,230	0,969	0,950	0,694	0,680
2	3/0	1,82	1,78	2,06	2,02	0,693	0,679	0,347	0,340	1,80	1,76	0,908	0,890
3	2/0	2,38	2,34	3,65	3,58	1,12	1,10	0,459	0,450	2,73	2,68	1,36	1,33
3,5	0	2,83	2,77	4,91	4,81	1,53	1,50	0,459	0,450	3,97	3,89	1,88	1,84
4	1	3,69	3,62	5,66	5,55	1,84	1,80	0,612	0,600	5,18	5,08	2,59	2,54
5	2	7,63	7,48	10,86	10,64	1,84	1,80	0,714	0,700	6,47	6,34	3,24	3,18
6	3&4	7,51	7,36	11,27	11,04								