



MID TERM ABSORPTION SURGICAL SUTURE

Technical data sheet

Trade name: Suture PGA

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

Manufacturer: Ergon Sutramed S.p.A.

Head office: Via Giuseppe Gregoraci, 12 – 00173 Roma

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

Classification: Multifilament of surgical suture synthetic, sterile and braided according to European Pharmacopea requirements

Composition and molecule : PGA (polyglycolic acid) $-(O-CH_2-CO)_n$

Coating: Polycaprolactone and calcium stearate : $[O-(CH_2)_5-CO]_n + [CH_3-(CH_2)_{16}-CO-O]_2Ca$

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-needed 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.

Assufil can be also manufactured with a button (made of the same material of the suture) used to anchor the thread . Further details are described in the catalogue .

“Latex and phtalati “ 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 by hydrolysis which degrades polyglycolic acid to allow the absorption and the subsequent metabolization in the body; in vivo and in vitro studies proved that Dar-vin absorption is complete within 60-90 days from implantation (average of 75 days) :

POST IMPLANTATION	APPROX.TENSILE STRENGTH RESIDUAL
1 week	~90%
2 weeks	~75%
3 weeks	~50%
4 weeks	~30%

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: Dar-vin 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: Ethylene Oxide (EO)

Shelf life : 5 years

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

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

MECHANICAL CHARACTERISTICS													
AVERAGE STRENGTH													
ERGON SUTRAMED						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	0,056	0,055	0,080	0,078								
0,3	9/0	0,069	0,068	0,092	0,091					0,045	0,045	0,023	0,023
0,4	8/0	0,106	0,104	0,160	0,157	0,051	0,050	0,026	0,025	0,071	0,070	0,036	0,035
0,5	7/0	0,189	0,185	0,287	0,281	0,082	0,080	0,041	0,040	0,143	0,140	0,071	0,070
0,7	6/0	0,311	0,305	0,522	0,511	0,173	0,17	0,082	0,080	0,255	0,25	0,133	0,130
1	5/0	0,770	0,755	1,103	1,081	0,235	0,230	0,112	0,110	0,694	0,680	0,347	0,340
1,5	4/0	1,000	0,980	1,610	1,578	0,459	0,450	0,235	0,230	0,969	0,950	0,49	0,48
2	3/0	1,190	1,166	2,40	2,35	0,694	0,68	0,347	0,340	1,81	1,77	0,908	0,890
3	2/0	2,230	2,185	3,650	3,577	1,12	1,10	0,459	0,450	2,73	2,68	1,35	1,34
3,5	0	2,850	2,793	4,910	4,812	1,53	1,50	0,459	0,450	3,98	3,89	1,89	1,85
4	1	3,620	3,548	6,40	6,27	1,84	1,80	0,612	0,600	5,18	5,08	2,59	2,54
5	2	4,10	4,02	10,860	10,642	1,84	1,80	0,714	0,700	6,48	6,35	3,24	3,18
6	3&4	4,60	4,51	11,270	11,045								