



SILK

NON-ABSORBABLE SURGICAL SUTURE

Technical data sheet

Trade Name : Silk Suture

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 : Sterile, braided ,non-absorbable surgical suture of natural origin according to European Pharmacopea requirements .

Composition and molecule : Fibroin, a protein deriving from species BOMBIX MORI silkworm larvas , composed of a linear macromolecule consisting of n. 10 different amino acids containing –CO- and –NH- groups

Coating : Silicone or beeswax for black silk . Virgin silk (dyed blue) is non-coated .

Colour : - Black silk (Logwood Black C.I. 75290);
- Blue silk (C.I. 52015) for virgin silk

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 or attached to stainless steel needles (AISI 300 and AISI 400 series) of different sizes and shapes .
Further details are described in the catalogue .

Latex free device

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

Specifity: A loss of tensile strength has been noted after one year, as a consequence of degradation 'in vivo'

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: Silk surgical suture is intended for use in the replacement of heart valves, in cardiac surgery and in all surgical procedures, at the user's discretion .

Sterility: Gamma Rays (R)

Shelf Life: 5 years

Packaging: Sterile double pack – box of 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

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	0,058	0,056	0,098	0,096								
0,3	9/0	0,199	0,195	0,154	0,150					0,036	0,035	0,006	0,006
0,4	8/0	0,301	0,295	0,223	0,219	0,051	0,05	0,026	0,025	0,061	0,060	0,015	0,015
0,5	7/0	0,385	0,377	0,351	0,344	0,082	0,08	0,041	0,040	0,102	0,10	0,036	0,035
0,7	6/0	0,462	0,453	0,446	0,437	0,173	0,17	0,082	0,080	0,153	0,15	0,061	0,060
1	5/0	1,21	1,19	0,928	0,909	0,235	0,23	0,112	0,11	0,306	0,30	0,102	0,10
1,5	4/0	1,64	1,61	1,02	0,999	0,459	0,45	0,235	0,23	0,510	0,50	0,153	0,15
2	3/0	1,82	1,78	2,06	2,02	0,694	0,68	0,347	0,34	0,918	0,90	0,306	0,30
3	2/0	2,38	2,34	3,65	3,58	1,12	1,10	0,459	0,45	1,531	1,50	0,918	0,90
3,5	0	2,83	2,77	4,91	4,81	1,53	1,50	0,459	0,45	2,245	2,20	1,326	1,30
4	1	3,69	3,62	5,66	5,55	1,84	1,80	0,612	0,60	2,755	2,70	1,531	1,50
5	2	7,63	7,48	10,86	10,64	1,84	1,80	0,714	0,70	3,571	3,50	2,245	2,20
6	3&4	7,51	7,36	11,27	11,04	2,55	2,50	1,275	1,25	5,102	5,00	2,755	2,70