

PROLAFIX IMPLANTS DATA SHEET



Description

The PROLAFIX slings are biocompatible devices (1) class IIb (2) specially designed for the treatment of genital prolapse accompanied with rectocele and cystocele with or without a uterus.

The PROLAFIX slings are implanted by laparoscopic or laparotomy approach.

These implants are valid 5 years after sterilization, and are sold under Tyvek bag packaged in a filmed cardboard box, and sterilized by gamma radiation or ethylene oxide

(1) According to ISO 10993 – 1

(2) According to European Directive 93/42/CEE (2007/47/EC)

Benefits

⊕ Flexible strips, atraumatic, hydrophilic and promoting colonization and rapid tissue fixation.

⊕ Excellent shape memory for an easy handling

⊕ Excellent mechanical properties, high tear resistance

⊕ Totally inert and non-pyrogenic

Materials

The PROLAFIX slings are available in :

- ❖ Knitted Polyester (PET)
- ❖ Knitted Polypropylene :
 - Standard Mesh (PPT Std)
 - Light Weight Mesh (PPT LW)

	Knitted Polyester (PET)	Knitted Polypropylene	
		Standard Mesh (PPT Std)	Light weight Mesh (PPT LW)
Composition	100% Terephthalate Polyethylene Knitted Multi filament Ø 76dTex 22	100% Isotactic Polypropylene Double-stranded knitted monofilament Ø 0,15 mm	
Process	Ladder proof knitting	Ladder proof knitting	
Masse surfacique	100 g/m ²	90g/m ²	60g/m ²
Epaisseur	0,6 mm	0,6 mm	
Taille des pores	1,9 mm ²	0,7 mm ²	2,3 mm ²
	Knitted Polyester (PET)	Knitted Polypropylene	
		Standard Mesh (PPT Std)	Light weight Mesh (PPT LW)
Resistance to splintering <i>ISO 13938 – 1</i>	>500 kPa	>500kPa	
Maximum breaking strength <i>ISO 13934 – 1</i>	>200N (warp direction) >400N (weft direction)	>180N (warp direction) >320N (weft direction)	>200N (warp direction) >400N (weft direction)
Elongation at break <i>ISO 13934 – 1</i>	>40% (warp direction) >50% (weft direction)	>80% (warp direction) >50% (weft direction)	>40% (warp direction) >50% (weft direction)
Porosity <i>NF S 94-801 : 2007</i>	60%	50%	60%
Rate of oiling <i>NF S 94 – 167 – 5</i>	<1,2%	<1,2%	
Release	-	-	
Surfactant residue level <i>NF EN 1644 - 1</i>	Complete Absence	Complete Absence	

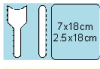

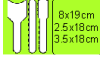


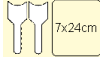
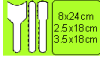
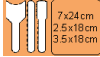

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(En)

Approval: 30/01/2017 [PM] [OC] [AAK] [MR][MDN]

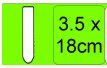

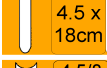
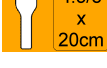
Our technical and medical resources are constantly changing; the information contained in this document is purely indicative and may be subject to change without notice.

References

Kits

	PET	PPT Std	PPT LW
 7x18cm 2.5x18cm	416801	413801	414801
 7x18cm	416802	413802	414802
 8x19cm 2.5x18cm 3.5x18cm	416803	413803	414803
 7x18cm 2.5x18cm 3.5x18cm	416804	413804	414804
 7x24cm 2.5x18cm	416811	-	414811
 7x24cm	416812	-	414812
 6x24cm 2.5x18cm 3.5x18cm	416813	-	414813
 7x24cm 2.5x18cm 3.5x18cm	416814	-	414814
 7x24cm 2.5x24cm	416821	-	414821

Single Implants

	PET	PPT Std	PPT LW
 3.5 x 18cm	416880	-	414880
 3.5/7 x 20cm	416890	-	414890
 4.5 x 18cm	416881	-	414881
 4.5/8 x 20cm	416891	-	414891

Symbols used on labels and/or on the instructions for use



Please consult the instructions for use D134



Single use



Do NOT use if the packaging is damaged



Do NOT re-sterilize

STERILE EO

Device sterilized with ethylene oxide
(Implants PPT Std, PPT LW)

STERILE R

Device sterilized with GAMMA (Implant PET)



5 years after sterilization



MICROVAL

ZA Champ de Berre - 43240 Saint Just Malmont, France
Tel : 33 4 77 35 03 03 Fax : 33 4 77 35 03 19 info@microval.fr

