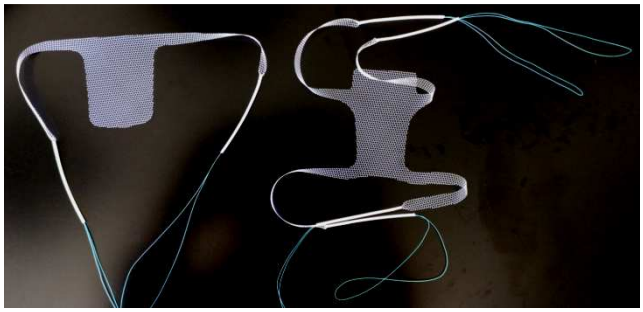
TECHNICAL DATASHEET PROLAFIX-V IMPLANTS



Description

PROLAFIX-V implants are IIb[2] class biocompatible[1] devices specially manufactured for prolapse cure.

PROLAFIX-V implants are indicated in rectocele and cystocele treatment and are inserted through a single vaginal incision.

PROLAFIX-V implants are sterilized under EO process. These implants are available 5 years after sterilization, are sold sealed under double Tyvek pouches and packaged in filmed cardboard boxes.

(1) According to ISO 10993 – 1
(2) According to European Directive 93/42/CEE (2007/47/CE)

Advantages

⊕ Excellent shape memory properties.

⊕ Great flexibility permitting easy deployment in treatment area and providing good comfort for the patient.

⊕ Great mechanical resistance.

Materials

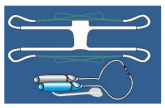
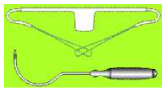
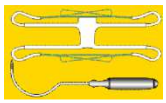
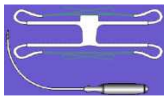
PROLAFIX-V implants are made of the following materials:

- Knitted polypropylene Light Weight (PPT LW)

	Knitted Polypropylene Light Weight
Composition	100% Isotactic Polypropylene Knitted Mono filament double strand Ø 0.15 mm
Process	Ladderproof
Basis Weight	60g/m²
Thickness	0,6 mm
Pore Size	2,3 mm²
	Knitted polypropylene Light Weight
Burst Resistance *ISO 13938 – 1*	>500kPa
Strength at break *ISO 13934 – 1*	>160N (Warp Direction) >210N (Fill Direction)
Elongation at break *ISO 13934 – 1*	>100% (Warp Direction) >70% (Fill Direction)
Porosity *NF S 94-801 : 2007*	60%
Oiling rate *NF S 94 – 167 – 5*	<1,2%
Rejection	-
Surfactant residue rate *NF EN 1644 - 1*	No residue

PROLAFIX-V IMPLANTS

Single Use Kit References

		Light Weight polypropylene (PPT LW)
	**UG-3S** (*PROLAFIX-V4 + Spiral needles right and left + introducer*)	512034
	**UG-1PS** (*PROLAFIX-V2 + Small Curve Needle*)	512062
	**UG-1PS** (*PROLAFIX-V4 + Small Curve Needle*)	512064
	**UG-1S** (*PROLAFIX-V2 + Large Curve needle*)	512092
	**UG-1S** (*PROLAFIX-V4 + Large Curve needle*)	512094

Implants References

	**PROLAFIX-V2**	512002
	**PROLAFIX-V4**	512004

Non Sterile re-usable associated Instruments References

	**UG-1P** (*Small Curve Needle*)	952600
	**UG-1** (*Large Curve Needle*)	952900

Clinical data / Bibliography

- [035] The lightweight and large porous mesh concept for hernia repair – Review ISSN 1743-440, Futures Drugs Ltd. 2005
- [038] Randomized clinical trial comparing lightweight composite mesh with polyester or polypropylene mesh for incisional hernia repair – J. Conze, A.N. Kingsnorth, JB. FLAMENT, R. SIMMERMARCHE, G. ARLT, C. LANGER, E. SCHIPPERS, M. HARTLEY and V. SCHUMPELICK – British Journal of surgery 2005;92:1488-1493
- [072] Tolérance des prothèses herniaires. Caractéristiques de principaux matériaux utilisés - E. ESTOUR – La Journal de Cardio-chirurgie- N°53, Mars2005
- [107] The argument for Lightweight polypropylene Mesh in hernia Repair - W. S. COBB, K.W. KERCHER, B. TODD HENIFORD – Surgical innovation, vol 12, no 1 (march), 2005: pp63-69

Signs used in the label and in the Instructions For Use

Refer to IFU D144

For Single use only

Do not use if damaged packaging

Do not sterilize again

STERILE EO — **Device sterilized under EO process (Implants)**

STERILE R — **Device sterilized under Gamma Rays process (Single Use instruments)**

Available 5 years after sterilization

NON STERILE — **Device non sterile (Re-Usable instruments)**

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