DROP IMPLANT TECHNICAL DATASHEET

Description

The DROP implant is a biocompatible device[(1)] class IIb[(2)] preformed specifically designed for tissues reinforcement in the treatment of inguinal hernias. DROP Implant is indicated in cases of groin hernias and is used under laparoscopic surgery.

The implant is valid for 5 years after sterilization, and is sold under double Tyvek pouches, packaged in a cardboard box filmed, and sterilized by ethylene oxide.

(1) According to ISO 10993-1
(2) According to European Directive 93/42 / EEC (2007/47 / EC)

Benefits

⊕ Anatomic shape for optimal conformability in the implanted area

⊕ Reinforced non woven polypropylene borders for good maintain after implantation.

⊕ Central part in lightweight knitted polypropylene for good visualization and good flexibility.

Material

❖ DROP Implant is available in combination of knitted lightweight polypropylene and non-woven polypropylene.

	Knitted Polypropylene Lightweight Mesh (PPT LW)	**Non Woven polypropylene (PPNT)**
Composition	100% isotactic Polypropylene Double-stranded knitted monofilament Ø 0,15 mm	100% Polypropylene
Process	Ladder-proof knitting	Non woven by extrusion and calendering
Surface Mass	60g/m²	70 g/m² (PPNT70)
Thickness	0,6 mm	0.40 mm
Pore size	2,3 mm²	Ø 1mm
Resistance to splintering *ISO 13938 – 1*	>500kPa	-
Maximum breaking strength *ISO 13934 – 1 (PET, PPT)* *EDANA 20-2-89 (PPNT)*	>160N (weft direction) >210N (warp direction)	>95N (machine direction) >70N (cross-machine direction)
Elongation at break *ISO 13934 – 1 (PET, PPT)* *EDANA 20-2-89 (PPNT)*	>100% (weft direction) >70% (warp direction)	>45% (machine direction) >80% (cross-machine direction)
Porosity *NF S 94-801 :2007*	60%	-
Rate of oiling *NF S 94 – 167 – 5*	<1,2%	<1,2%
Release	-	-
Surfactant residue level *NF EN 1644 - 1*	Complete Absence	Complete Absence

DROP IMPLANT

References

		PPT LW + PPNT 70
	**14*10 cm**	412104

Clinical data / Bibliographic references

- [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 des pincipaux 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
- Octobre 2014 – Suivi Clinique MICROVAL sur 30 cas, implant 416515

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

Please consult the instructions for use D133

Do NOT use if the packaging is damaged

STERILE EO

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

Single use

Do NOT re-sterilize

5 years after sterilization

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