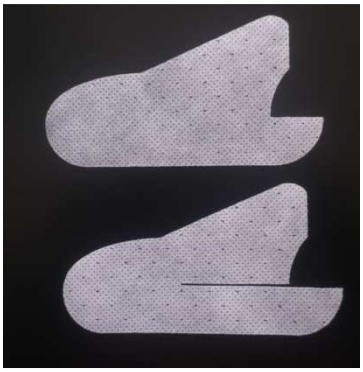
TECHNICAL FILE LG IMPLANTS



Description

LG implants are IIb[2] class biocompatible[1] devices. These implants are specially manufactured for tissue reinforcement during inguinal hernia repair.
LG implants are indicated for groin hernia treatment and are used under open Lichtenstein procedure.

These implants are sterilized under Gamma rays or EO process, and are available 5 years after sterilization. LG implants are sold in Tyvek pouches, and packaged in filmed cardboard boxes.

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

Advantages

⊕ Optimal mechanical resistance

⊕ Optimal flexibility for an easy placement in the hernia location.

⊕ Optimal flexibility providing better comfort for the patient.

Materials

LT implants can be manufactured in :

- Knitted Polyester (PET)
- Non woven polypropylene (PPNT)

	Knitted polyester (PET)	**Non woven polypropylene (PPNT)**
Composition	100% Polyethylene Terephtalate Knitted Multi filament Ø 76dTex 22	100% Polypropylene
Process	Ladderproof	Extrusion and calendering process
Basis weight	100 g/m²	50g/m² 70g/m² 90g/m²
Thickness	0.6 mm	0.30 mm 0.40 mm 0.50 mm
Pore Size	1.9 mm²	Ø 1mm
	Knitted polyester (PET)	**Non woven polypropylene (PPNT)**
Burst resistance *ISO 13938 – 1*	>500 kPa	-
Maximal strength *ISO 13934 – 1 (PET, PPT) EDANA 20-2-89 (PPNT)*	>200N (Warp direction) >400N (Fill direction)	>95N (Production direction) >70N (Transverse direction)
Elongation at break *ISO 13934 – 1 (PET, PPT) EDANA 20-2-89 (PPNT)*	>40% (Warp direction) >50% (Fill direction)	>45% (Production direction) >80% (Transverse direction)
Porosity *NF S 94-801 : 2007*	60%	-
Oiling rate *NF S 94 – 167 – 5*	<1,2%	<1,2%
Degradation		
Surfactant residue rate *NF EN 1644 - 1*	0%	0%

References

		PET	PP NT 50	PP NT 70	PP NT 90
	6*12 cm ♀	-	451125	471125	491125
	6*12 cm ♂	416126	451126	471126	491126

Clinical Datas / 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
- Octobre 2014 – Suivi Clinique MICROVAL sur 30 cas, implant 416515

Signs used in the labels and in the Instructions For Use

Refer to IFU D133

Do not use if damaged packaging

For Single use only

Do not sterilize again

Device sterilized under EO process (PPNT Implants)

Device sterilized under Gamma rays process (PET Implant)

Available 5 years after sterilization

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