

Description

LT implants are IIB⁽²⁾ class biocompatible⁽¹⁾ devices. These implants are specially manufactured for tissue reinforcement during inguinal hernia repair.

LT implants are indicated for groin hernia treatment and are used under open Lichtenstein procedure.

These implants are sterilized by gamma rays or EO process, and remain available 5 years after sterilization. LT implants are sold in Tyvek pouches, 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 offering better comfort for the patient







Materials

LT implants can be manufactured in :

- ❖ Knitted Polyester (PET)
- ❖ Standard knitted polypropylene (PPT Std) and Light weight knitted polypropylene (PPT LW)
- ❖ Non woven polypropylene (PPNT)




	Knitted polyester (PET)	Knitted polypropylene		Non woven polypropylene (PPNT)
		Standard (PPT Std)	Light weight (PPT LW)	
Composition	100% PolyethyleneTerephthalate Knitted Multi filament Ø 76dTex 22	100% IsotacticPolypropylene Knitted Mono filament double strand Ø 0.15 mm		100% Polypropylene
Process	Ladderproof	Ladderproof		Extrusion and calenderingprocess
Basis weight	100 g/m ²	90g/m ²	60g/m ²	50 g/m ² (PPNT50) 70 g/m ² (PPNT70) 90 g /m ² (PPNT90)
Thickness	0.6 mm	0.6 mm		0.30 mm 0.40 mm 0.50 mm
Pore Size	1.9 mm ²	0.7 mm ²	2.3 mm ²	Ø 1mm
	Knitted polyester (PET)	Knitted polypropylene		Non woven polypropylene (PPNT)
		Standard (PPT Std)	Light weight (PPT LW)	
Burst resistance <i>ISO 13938 – 1</i>	>500 kPa	>500kPa		-
Maximal strength <i>ISO 13934 – 1 (PET, PPT)</i> <i>EDANA 20-2-89 (PPNT)</i>	>200N (Warp direction) >400N (Fill direction)	>180N (Warp direction) >320N (Fill direction)	>160N (Warp direction) >210N (Fill direction)	>95N (Warp direction) >70N (Transverse direction)
Elongation at break <i>ISO 13934 – 1 (PET, PPT)</i> <i>EDANA 20-2-89 (PPNT)</i>	>40% (Warp direction) >50% (Fill direction)	>80% (Warp direction) >50% (Fill direction)	>100% (Warp direction) >70% (Fill direction)	>45% (Warp direction) >80% (Transverse direction)
Porosity <i>NF S 94-801 : 2007</i>	60%	50%	60%	-
Oiling rate <i>NF S 94 – 167 – 5</i>	<1,2%	<1,2%		<1,2%
Rejection	-	-		-
Surfactant residue rate <i>NF EN 1644 - 1</i>	0%	0%		0%

References

		PET	PPT Std	PPT LW	PP NT 50	PP NT 70	PP NT 90
	5.5*10 cm	-	413155	414155	451155	471155	-
	6*11 cm	-	413116 413116/50 ^(*)	414116	451116	471116	491116
	5*9 cm	416095	-	-	-	-	-
	7*11 cm	-	413711	414711	-	-	-
	9*13 cm	416139	413139 413139/50 ^(*)	-	451139	471139	491139
	10*13 cm	-	413013	-	-	-	-

^(*)50 units kit

Kit references with Plug

	With 	PPT Std
	4.5*10 cm PLUG Ø5 cm	413005
	10*13 cm PLUG Ø7 cm	413007

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 label and in the Instructions For Use



Refer to IFU D133



Do not use if damaged packaging



For Single use only



Do not sterilize again

STERILE EO

Device sterilized under EO process
(PPT Std, PPT LW , PPNT Implants)

STERILE R

Device sterilized under Gamma rays process
(PET Implant)



Available 5 years after sterilization



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