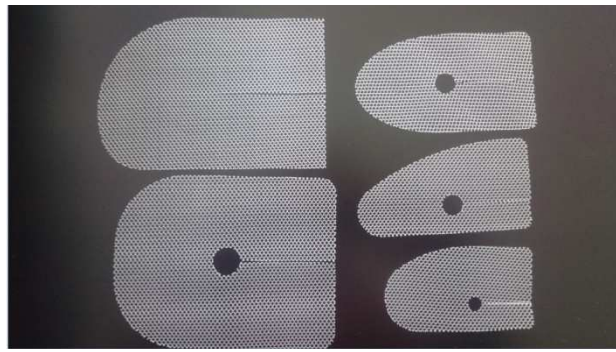


TECHNICAL FILE LT IMPLANTS



MICROVAL France
 Conception et fabrication de dispositifs médicaux
 Medical devices design and manufacturing



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

The range of LT implants is available in :







- ❖ Knitted Polyester (PET)
- ❖ Tridimensional Polyester (TRIMESH)
- ❖ Knitted Polypropylene:
 - Standard Mesh (PPT Std)
 - Light Weight Mesh (PPT LW)
- ❖ Non woven Polypropylene (PPNT)

	Knitted Polyester		Knitted Polypropylene		Non Woven polypropylene (PPNT)
	Bidimensional (PET)	Tridimensional (TRIMESH)	Standard Mesh (PPT Std)	Lightweight Mesh (PPT LW)	
Composition	100% Terephthalate Polyethylene Knitted multifilament Ø 76dTex 22	100% Terephthalate Polyethylene Spacer dTex 50,24	100% isotactic Polypropylene Double-stranded knitted monofilament Ø 0,15 mm		100% Polypropylene
Process	Ladder-proof knitting		Ladder-proof knitting		Non woven by extrusion and calendaring
Surface Mass	100 g/m ²	120g/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	2,25 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
Resistance to splintering ISO 13938 – 1	>500 kPa	>400 kPa	>500kPa		-
Maximum breaking strength ISO 13934 – 1 (PET, PPT) EDANA 20-2-89 (PPNT)	>200N (weft direction) >400N (warp direction)	>160N (weft direction) >160N (warp direction)	>180N (weft direction) >320N (warp direction)	>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)	>40% (weft direction) >50% (warp direction)	>35% (weft direction) >35% (warp direction)	>80% (weft) >50% (warp direction)	>100% (weft direction) >70% (warp direction)	>45% (machine direction) >80% (cross-machine direction)
Porosity NF S 94-801:2007	60%	96%	50%	60%	-
Rate of oiling NF S 94 – 167 – 5	<1,2%		<1,2%		<1,2%
Release	-		-		-
Surfactant residue level NF EN 1644 - 1	Complete Absence		Complete Absence		Complete Absence

D032 V4
(UK)




Approbation : 16/10/2017 [PM] [MDN] [AAK][OC][MR]
 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

		TRIMESH	PET	PPT Std	PPT LW	PP NT 50	PP NT 70	PP NT 90
	5.5*10 cm	666155	-	413155 413155/05 ^(*)	414155	451155	471155	-
	6*11 cm	666116	-	413116 413116/50 ^(**)	414116	451116	471116 471116/05 ^(*)	491116
	5*9 cm	666095	416095	-	-	-	-	-
	7*11 cm	666711	-	413711	414711	-	-	-
	9*13 cm	666139	416139	413139 413139/05 ^(*) 413139/50 ^(**)	-	451139	471139	491139
	10*13 cm	666013	-	413013	-	-	-	-

(*)5 units kit ; (**)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



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



Device sterilized under Gamma rays process
(PET & TRIMESH Implants)



Available 5 years after sterilization