

2D IMPLANTS TECHNICAL DATASHEET



Description

The 2D implant is a biocompatible device (1) class IIb (2) specifically designed for tissues reinforcement in the treatment of hernias and eventrations. 2D is indicated in cases of hernias and eventrations and has to be implanted by laparoscopy or open surgery. The implant is valid for 5 years after sterilization, and is sold under Tyvek bag packaging in a cardboard box filmed, and sterilized by gamma radiation or ethylene oxide.

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

Benefits

- ⊕ Very high mechanical strength
- ⊕ Excellent flexibility that facilitates its deployment in the treatment area
- ⊕ Excellent flexibility provides comfort to the patient

Material

The range of 2D implants is available in :

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

	Knitted Polyester (PET)	Knitted Polypropylene		Non Woven polypropylene (PPNT)
		Standard Mesh (PPT Std)	Lightweight Mesh (PPT LW)	
Composition	100% Terephthalate Polyethylene Knitted multifilament Ø 76dTex 22	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 calendering
Surface Mass	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 Mesh (PPT Std)	Lightweight Mesh (PPT LW)	
Resistance to splintering ISO 13938 – 1	>500 kPa	>500kPa		-
Maximum breaking strength ISO 13934 – 1 (PET, PPT) EDANA 20-2-89 (PPNT)	>200N (weft direction) >400N (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)	>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%	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

D054 V5
(En)

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 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

	PET	PPT Std	PPT LW	PP NT 50	PP NT 70	PP NT 90
Square 15*15 cm	416515	413515 413515/50* 415515***	414515 414515/50*	451515	471515	491515
Square 20*20 cm	416020	-	-	-	-	-
Square 30*30 cm	416030	413030 413030/25**	414030 414030/25**	451030	471030	491030
Rectangle 6*11 cm	-	413611 413611/50* 415611***	414611 414611/50*	-	-	-
Rectangle 7,5*15 cm	416715	413715 413715/50* 415715***	414715	-	-	-
Rectangle 9*13 cm	416913	413913 413913/50* 415913***	414913 414913/50*	451913	471913	491913
Rectangle 10*15 cm	416015	413015	-	-	-	-
Rectangle 15*17 cm	-	-	-	451517	471517	491517
Rectangle 15*30 cm	416530	413530	414530	-	-	-
Rectangle 17*30 cm	-	-	-	451730	471730	491730
Rectangle 25*35 cm	-	413535	-	-	-	-
Rectangle 30*50 cm	-	413050	-	-	-	-

*50 units packaging **25 units packaging ***3 units packaging

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 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

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



Please consult the instructions for use D133



Single use



Do NOT use if the packaging is damaged



Do NOT re-sterilize

STERILE EO

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

STERILE R

Device sterilized with GAMMA (Implant PET)



5 years after sterilization



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