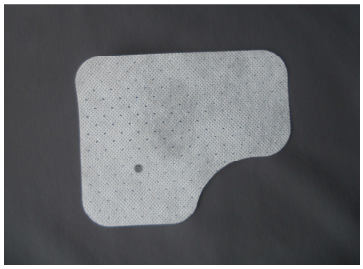
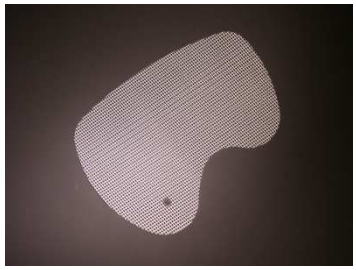
TECHNICAL DATASHEET JP AND CC IMPLANTS





Description

JP and CC implants are IIb[2] class biocompatible[1] devices manufactured for tissue reinforcement during groin hernia repair.

JP and CC implants are indicated for inguinal hernia treatment and are used under laparoscopic surgery.

JP and CC implants are sterilized under gamma rays or EO process and are available 5 years after sterilization. These implants are sold sealed in double 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

⊕ Great mechanical resistance

⊕ Great flexibility permitting easy deployment in the treatment area and providing great comfort for the patient.

⊕ Marking dot permitting easy placement of the implant during surgery.

Materials

MICROVAL's JP and CC implants are made of the following materials:

- Knitted polypropylene standard weight (PPT Std)
- Knitted polypropylene light weight (PPT LW)
- Non Woven polypropylene (PPNT)
- Knitted Polyester (PET)

	Knitted Polypropylene		Non Woven Polypropylene (PPNT)	Polyester (PET)
	Standard Weight (PPT Std)	Light Weight (PPT LW)		
Composition	100% Isotactic Polypropylene Knitted Mono filament double strand Ø 0.15 mm		100% Polypropylene	100% Polyethylene Terephtalate Knitted Multi filament Ø 76dTex 22
Process	Ladder-proof		Extrusion and calendering process	Ladder-proof
Basis weight	90g/m²	60g/m²	50 g/m² (PPNT50) 70 g/m² (PPNT70)	100 g/m²
Thickness	0,6 mm		0.30 mm 0.40 mm	0,6 mm
Pore Size	0,7 mm²	2,3 mm²	Ø 1mm	1,9 mm²

	Knitted Polypropylene		Non Woven polypropylene (PPNT)	Polyester (PET)
	Standard Weight (PPT Std)	Light Weight (PPT LW)		
Burst resistance *ISO 13938 – 1*	>500kPa		-	>500kPa
Strength at breeak *ISO 13934 – 1 (PET, PPT) EDANA 20-2-89 (PPNT)*	>180N (Warp direction) >320N (Fill direction)	>160N (Warp direction) >210N (Fill direction)	>95N (Production direction) >70N (Transverse direction)	>200N (Warp direction) >400N (Fill direction)
Elongation at break *ISO 13934 – 1 (PET, PPT) EDANA 20-2-89 (PPNT)*	>80% (Warp direction) >50% (Fill direction)	>100% (Warp direction) >70% (Fill direction)	>45% (Production direction) >80% (Transverse direction)	>40% (Warp direction) >50% (Fill direction)
Porosity *NF S 94-801 : 2007*	50%	60%	-	60%
Oiling rate *NF S 94 – 167 – 5*	<1,2%		<1,2%	<1,2%
Rejection	-			
Surfactant residue rate *NF EN 1644 - 1*	No residue			

JP AND CC IMPLANTS

References

		PPT Std	PPT LW	PP NT 50	PP NT 70	PET
	JP Implant 14*10 cm	413410	414410	451410	471410	416410
	JP Implant 15*11 cm	413511	414511	-	-	416511
	JP Implant 16*12 cm	413612	414612	451612	471612	416612
	CC Implant 11*15 cm	413115	-	-	-	416115
	CC Implant 15*15 cm	413151	-	-	-	-
	CC Implant 12*15 cm	413215	-	451215	471215	-

Clinical Data / 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

For Single use only

Do not use if damaged packaging

Do not sterilize again

Device sterilized under EO process (PPT, PPNT Implants)

Device sterilized under Gamma rays process (PET Implant)

Available 5 years after sterilization

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