JG IMPLANTS TECHNICAL DATASHEET

Description

The JG anatomical implant is a biocompatible implant (1) class IIb (2) specifically designed to perfectly cover all areas of weakness of the inguinal regions. JG implant is indicated for inguinal hernia repair under laparoscopic surgery (TEP or TAPP technique).

The implant is valid for 5 years after sterilization, and is sold in blister pack with a lid and Tyvek, packed in a filmed cardboard and sterilized with ethylene oxide.

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

Benefits

⊕ Excellent shape memory

⊕ Flexibility which makes the deployment in the intraperitoneal area

⊕ Setting up and orientation facilitated by the presence of a mark on its lower inner edge

⊕ An anatomical shape for the implant to be placed on the components of the cord

Material

The JG implant range is available in knitted polypropylene.

- Standard Mesh (PPT Std)
- Lightweight Mesh (PPT LW)

	Knitted Polypropylene	
Composition	100% isotactic biocompatible polypropylene double-stranded knitted monofilament Ø 0,15 mm	
Process	Ladder proof knitting	
Surface Mass	Standard Mesh (PPT Std) 90g/m²	Lightweight Mesh (PPT LW) 60g/m²
Thickness	0,6 mm	
Pore sizes	Standard Mesh (PPT Std) 0,7 mm²	Lightweight Mesh (PPT LW) 2,3 mm²

	Knitted Polypropylene	
Resistance to splintering *ISO 13938 – 1*	>500kPa	
Maximum breaking strength *ISO 13934 – 1*	>180N (weft direction) >320N (warp direction)	
Elongation at break *ISO 13934 – 1*	>80% (weft direction) >50% (warp direction)	
Porosity *NF S 94-801 : 2007*	Standard Mesh (PPT Std) 50%	Lightweight Mesh (PPT LW) 60%
Rate of oiling *NF S 94 – 167 – 5*	<1,2%	
Release	-	
Surfactant residue level *NF EN 1644 - 1*	Complete Absence	

References

	Standard Polypropylene (PPT Std)	Light Mesh Polypropylene (PPT LW)
Small right 8*12 cm	411020	412020
Small left 8*12 cm	411021	412021
Medium right 10*14 cm	411040	412040
Medium left 10*14 cm	411041	412041
Large right 12*16 cm	411060	412060
Large left 12*16 cm	411061	412061
Small symmetrical 8*12 cm	411120	412120
Medium symmetrical 10*14 cm	411140	412140
Large symmetrical 12*16 cm	411160	412160

Clinical data / Bibliographic references

- Etude clinique publiée en 2005 (réf Microval [0028]) « Laparoscopic totally extraperitoneal inguinal hernioplastie : the use of a contoured three-dimensional mesh"
- Etude clinique publiée en 2008 (réf Microval [0030]) "Laparoscopic totally extraperitoneal inguinal hernia repair : lessons learned from 3100 hernias repairs over 15 years"
- Etude clinique publiée en 2010 (réf Microval [0033]) "Laparoscopic totally extraperitoneal inguinal hernia repair : non fixation of three-dimensional mesh"
- Etude clinique publiée en 2009 (réf Microval [0133]) "Laparoscopic totally extraperitoneal inguinal hernia repair. Twenty-seven serious complications after 4408 consecutive cases"

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

Please consult the instructions for use D133

Do NOT use if the packaging is damaged

Device sterilized with ethylene oxide

5 years after sterilization

Single use

Do NOT re-sterilize

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