

3D ANATOMICAL IMPLANTS DATASHEET



Description

3D anatomical implant is a biocompatible device (1) class IIb (2) specifically designed to cover perfectly all areas of weakness of the inguinal regions. 3D anatomical implant is indicated in cases of inguinal hernias in laparoscopic surgery by extra peritoneal approach (TEP) or trans-abdominal one (TAPP).

The implant is valid for 5 years after sterilization. It is sold under blister pack with lid and Tyvek, and is packaged in a cardboard box filmed 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
- ⊕ Excellent flexibility that facilitates its deployment in the intraperitoneal area
- ⊕ Setting up and orientation facilitated by the presence of a mark on its lower inner edge.
- ⊕ An anatomical 3D shape perfectly adapted to the inguinal-pelvic area right or left

Material

The 3D anatomical implant range is available in knitted polypropylene, standard mesh (PPT Std).

	Knitted Polypropylene (PPT Std)
Composition	100% isotactic biocompatible Polypropylene Double-stranded knitted monofilament Ø 0,15 mm
Process	Ladder proof knitting
Surface Mass	90g/m ²
Thickness	0,6 mm
Pore size	0,7 mm ²
	Knitted Polypropylene (PPT Std)
Resistance to splintering <i>ISO 13938 – 1</i>	>500kPa
Maximum breaking strength <i>ISO 13934 – 1</i>	>180N (weft direction) >320N (warp direction)
Elongation at break <i>ISO 13934 – 1</i>	>80% (weft direction) >50% (warp direction)
Porosity <i>NF S 94-801 : 2007</i>	50%
Rate of oiling <i>NF S 94 – 167 – 5</i>	<1,2%
Release	-
Surfactant residue level <i>NF EN 1644 - 1</i>	Complete Absence

References

	Knitted Polypropylene (PPT Std)	
	France	Export
Small right 14*10 cm	410000	411000
Small left 14*10 cm	410001	411001
Medium right 16*11 cm	410010	411010
Medium left 16*11 cm	410011	411011

Clinical data / Bibliographic references

- ❖ Etude clinique réalisée par le Dr Dulucq en 1998 « Adult inguinal hernia repair : retrospective and analytic study »
- ❖ Etude clinique publiée en 2005 (réf Microval [028]) « Laparoscopic totally extraperitoneal inguinal hernioplastie : the use of a contoured three-dimensional mesh »
- ❖ Etude Clinique publiée en 2008 (réf Microval [030]) “Laparoscopic totally extraperitoneal inguinal hernia repair : lessons learned from 3100 hernias repairs over 15 years”
- ❖ Etude Clinique publiée en 2010 (réf Microval [033]) “Laparoscopic totally extraperitoneal inguinal hernia repair : non fixation of three-dimensional mesh”
- ❖ Etude Clinique publiée en 2009 (réf Microval [133]) « 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 D121



Single use



Do NOT use if the packaging is damaged



Do NOT re-sterilize

STERILE EO

Device sterilized with ethylene oxide



5 years after sterilization



MICROVAL

ZA Champ de Berre - 43240 Saint Just Malmont, France

Tel : 33 4 77 35 03 03

Fax : 33 4 77 35 03 19

info@microval.fr

