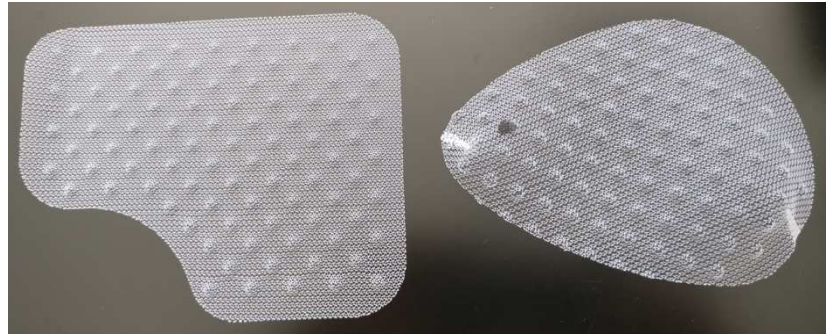


TECHNICAL DATASHEET BULMESH IMPLANTS



Description

BULMESH implants are IIb⁽²⁾ class biocompatible⁽¹⁾ devices specially manufactured for tissue reinforcement during groin hernia repair.

BULMESH implants are indicated in inguinal hernia treatment and are used under laparoscopic surgery.

BULMESH implants are sterilized under EO process. These implants are available 5 years after sterilization, are sold sealed in blisters and packaged in filmed cardboard boxes.

(1) According to ISO 10993 – 1

(2) According to European Directive 93/42/CEE (2007/47/CE)

Advantages

⊕ Great mechanical properties.

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

⊕ Surface shaping providing good maintain during surgery.

Materials

BULMESH implants are made of the following materials :

- ❖ Standard Weight Knitted Polypropylene (PPT Std)





	Knitted polypropylene Standard (PPT Std)
Composition	100% Isotactic Polypropylene Knitted Mono filament double strand Ø 0.15 mm
Process	Tricot indémaillable
Basis weight	90g/m ²
Thickness	0,6 mm
Pore Size	0,7 mm ²
	Knitted polypropylene Standard (PPT Std)
Burst resistance <i>ISO 13938 – 1</i>	>500kPa
Maximal strength <i>ISO 13934 – 1 (PET, PPT)</i> <i>EDANA 20-2-89 (PPNT)</i>	>180N (Warp direction) >320N (Fill direction)
Elongation at break <i>ISO 13934 – 1 (PET, PPT)</i> <i>EDANA 20-2-89 (PPNT)</i>	>80% (Warp direction) >50% (Fill direction)
Porosity <i>NF S 94-801 : 2007</i>	50%
Oiling rate <i>NF S 94 – 167 – 5</i>	<1,2%
Rejection	-
Surfactant residue rate <i>NF EN 1644 - 1</i>	No residue

D057 V1
(En)

Approval : 14/09/2016 [PM] [OC] [AAK] [MR][MDN]

Because of the constant evolution of our technique and medical means, data in this document are given for informational purpose only.
These data can be updated and modified without prior notice.

References

		PPT Std
	CC BULMESH Right 12*15 cm	601150
	CC BULMESH Left 12*15 cm	601151
	PS BULMESH Right 10*16 cm	601160
	PS BULMESH Left 10*16 cm	601161

Clinical Data / Bibliography

- ❖ 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
- ❖ [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
- ❖ innovation, vol 12, no 1 (march), 2005: pp63-69

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

STERILE EO

Device sterilized under EO process



Available 5 years after sterilization