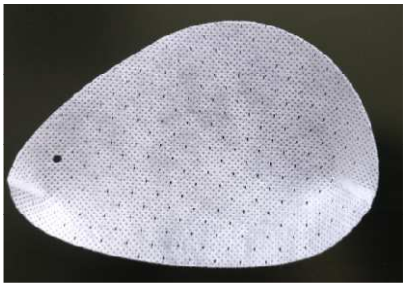
TECHNICAL FILE PS IMPLANTS



Description

PS implant is a IIb[2] class biocompatible[1] device.It is specially manufactured for tissue reinforcement during groin hernia surgery.

PS implant is indicated for inguinal hernia repair and is used under laparoscopic surgery, TAPP or TEP technique with or without fixations. Thank to its flexible properties, PS implant is switchable from right hernias to left hernias by simple pressure on the bumps.

PS implant is sterilized under EO process and is available 5 years after sterilization. The implant is sold in double Tykevk pouches, and packaged filmed in cardboard boxes.

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

Advantages

⊕Good shape memory properties and flexibility for an easy placement in the hernia location. Great flexibility for good conformability left/right.

⊕Anatomic shape for optimal placement and maintain after implantation.

⊕Compatible with fixation-free method, reducing post-operatory pains and discomfort for the patient.

⊕Reference point for easy orientation of the implant during laparoscopic procedure.

Materials

PS implants are available in Non-woven polypropylene:

- 70 GSM (70g/m²)

	Non woven polypropylene (PPNT)
Composition	100% Polypropylène
Process	Non tissé obtenu par extrusion et calandrage
Surface weight	70 g/m² (PPNT70)
Thickness	0,40 mm
Pore size	Ø 1mm
	Non woven polypropylene (PPNT)
Maximal Strength *ISO 13934 – 1*	>95N (sens production) >70N (sens travers)
Elongation at break *ISO 13934 – 1*	>45% (sens production) >50% (sens travers)
Oiling rate *NF S 94 – 167 – 5*	<1,2%
Degradation	-
Surfactant residue rate *NF EN 1644 - 1*	0%

References

	PPNT 70
PS implant 11x15cm	471150
PS implant 10x16cm	471160

Clinical data / Bibliography

- [006] Totally extraperitoneal repair, result of 5,203 hernia repairs. TAMME C, SCHEIDBACH H, HAMPE C, SCHNEIDER C, KÖCKERLING F – Sur Endosc 2003 – Vol. 17, n°2: 190-195
- [072] Tolérance des prothèses herniaires. Caractéristiques de principaux matériaux utilisés - E. ESTOUR – Le Journal de Cardio-chirurgie- N°53, Mars2005
- [447] Five-year results of a randomised controlled multi-centre study comparing heavy-weight knitted versus low-weight, non-woven polypropylene implants in Lichtenstein hernioplasty. M. SMIETANSKI, K. BURY, I. A. SMIETANSKA, R. OWCZUK, T. PARADOWSKI – Hernia (2011) 15:495-501
- [448]A comparison of woven versus nonwoven polypropylene (PP) and Expanded versus Condensed polytetrafluoroethylene (PTFE) on their intraperitoneal incorporation and adhesion formation. Dimitri Aristotle RAPTIS, Barbora VICHOVA, Jan BREZA, James SKIPWORTH, Stephen BAKER – Journal of Surgical Research 169, 1-6 (2011)

Signs used in the labels and in the Instruction 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

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