



PLUG-P



PLUG-S



PB IMPLANT

(PLUG & PATCH)

Description

All MICROVAL's plug systems are IIB⁽²⁾ class biocompatible⁽¹⁾ devices, and are manufactured for tissue reinforcement in crural hernia treatment and inguinal hernia treatment during open Lichtenstein procedure.

Plug systems are sterilized under Ethylene Oxide process. These implants are available 5 years after sterilization, and are sold in double Tyvek pouches or in simple blister, and packaged in filmed cardboard boxes.

(1) According to ISO 10993 – 1

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

Advantages

- ⊕ Optimal conformability due to its flexibility
- ⊕ Good flexibility and good mechanical properties.
- ⊕ For PLUG-P & PLUG-S, opening mechanism intended to optimize the insertion of the implant in the hernia location.




Materials

All plug systems are made of knitted polypropylene:

- Standard weight (PPT Std)
- Light weight (PPT LW)

	Knitted polypropylene	
Composition	100% Isotactic Polypropylene Knitted Mono filament double strand Ø 0.15 mm	
Process	Ladderproof	
Basis weight	Standard (PPT Std) 90g/m ²	Light Weight (PPT LW) 60g/m ²
Thickness	0,6 mm	
Pore Size	Standard (PPT Std) 0,7 mm ²	Light Weight (PPT LW) 2,3 mm ²
	Knitted polypropylene	
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)	>160N (Warp direction) >210N (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)	>100% (Warp direction) >70% (Fill direction)
Porosity <i>NF S 94-801 : 2007</i>	Standard (PPT Std) 50%	Light Weight (PPT LW) 60%
Oiling rate <i>NF S 94 – 167 – 5</i>	<1,2%	
Rejection	-	
Surfactant residue rate <i>NF EN 1644 - 1</i>	0%	

References

		Standard (PPT Std)	Light Weight (PPT LW)
	PLUG-S Ø7cm	411700	-
	PLUG-S Ø9cm	411900	-
	PLUG-P Ø7cm	411007	-
	PLUG-P Ø9cm	411009	-
 (*)	Patch 10x5cm Plug Ø5cm	411105	412105
	Patch 12x6cm Plug Ø6cm	411126	412126
	Patch 14x8cm Plug Ø8cm	411148	412148

(*) For further information about this implant, please refer to Technical File D044 (PB implants)

Clinical Datas / Bibliography

- ❖ [050] The Millikan Modified Mesh-Plug Hernioplasty- K.W. MILLIKAN, B. CUMMINGS, A. DOOLAS – Arch Surg. 2003;138:525-530
- ❖ [067] Mesh plug and mesh patch versus tension-free. Hernioplasty in the repair of recurrent inguinal hernias- M. HILMY – Sci. Med. J. ESCME, Vol 16, no4, Oct 2004
- ❖ [078] The mesh plug technique for recurrent groin herniorrhaphy: a nine-year experience of 407 repairs- I.M. RUTKOW, A.W. ROBBINS – Surgery 1998;124:844-7
- ❖ [079] Mesh plug hernia repair: a follow up report - I.M. RUTKOW, A.W. ROBBINS, Surgery 1995, 117:597-8

Signs used in the label and in the Instructions For Use



Refer to IFU D133



For Single use only



Do not use if damaged packaging



Do not sterilize again

STERILE EO

Device sterilized under EO process



Available 5 years after sterilization

