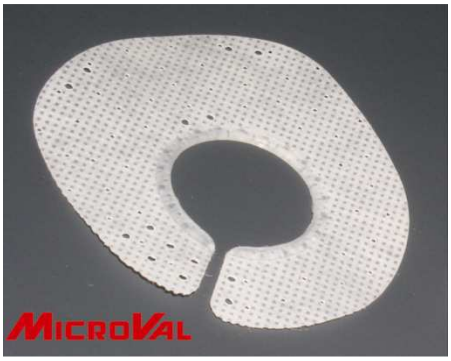
TECHNICAL DATASHEET RH IMPLANT



Description

RH implant is a IIb class[2)] biocompatible[(1)] medical device specially manufactured for hiatal hernia repair.

RH implant is sterilized under Ethylene Oxyde process. This implant is available 5 years after sterilization and sold in double Tyvek pouches, packaged in filmed cardboard boxes.

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

Advantages

⊕ 1 siliconed face avoiding visceral adhesion after implantation.

⊕ Central silicone ring providing soft contact between the implant and the esophagus and avoiding risks of adhesion to the esophagus cord.

⊕ Macro perforations avoiding seroma formation after implantation.

Materials

RH implant is available in silicone coated non-woven polypropylene (70g/m²).

	Silicone coated non –woven polypropylene
Composition	100% Biocompatible non woven polypropylene coated of one side of biocompatible silicone
Process	Non woven obtained by extrusion, bursting of fibers on a surface and calendering with welding spots (17% of the surface is welded)
Base weight	70g/m²
Thickness	0,6 – 1 mm
Pore Size	Ø 1mm

	Silicone coated non –woven polypropylene
Burst resistance *ISO 13938 – 1*	-
Maximal Tensile strength *EDANA 20-2-89*	>95N
Elongation at break *EDANA 20-2-89*	>45%
Porosity *NF S 94-801 : 2007*	-
Oiling rate *NF S 94 – 167 – 5*	<1,2%
Rejection	-
Surfactant residue level *NF EN 1644 - 1*	Total absence

References

		PP NT 70 + Silicone
	8x7 cm Diameter 3 cm	472872

Clinical data / Bibliographic references

- Etude clinique publiée en 2008 (réf Microval [0388]) « Use of intraperitoneal biface polypropylene/silicone prosthesis Multicentric study on 96 cases » - R. Azoulay, JY. François, Ch. Breton, C. Kupenas, J. Nassa
- La prothèse silpromesh dans le traitement des hernies et éventrations de la paroi antérieure à l'abdomen.
  Résultats à long-terme à propos de 145 observations – P. Blanc, Y. Laborde, D. Lechaux, GF. Begin, G. Moulin, JP. Monatte, A. Gariant, B. Cartoux, A. Lippa – 2005/2006

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


Please consult the instructions for use D130


Do NOT use if the packaging is damaged


For Single use only


Do NOT sterilize again

Device sterilized under ethylene oxide process


Available 5 years after sterilization

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