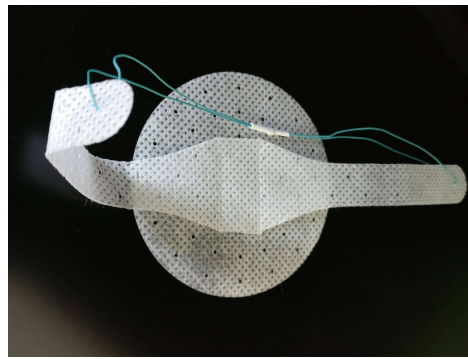


# TECHNICAL DATA SHEET INTRA-OMBILI IMPLANT



## Description

INTRA-OMBILI implant is a biocompatible device<sup>(1)</sup> class IIb<sup>(2)</sup> specifically designed for umbilical hernia repairs.

INTRA-OMBILI implant is used under open surgery and is placed on the intraperitoneal wall.

The implant is valid for 5 years after sterilization, is sold under double Tyvek bag packaged in a filmed cardboard box, and sterilized with ethylene oxide.

(1) According to ISO 10993 – 1

(2) According to European directive 93/42/CEE (2007/47/EC)

## Benefits

- ⊕ Excellent shape memory properties, allowing optimal placement on the intraperitoneal wall.
- ⊕ Excellent flexibility, allowing easy deployment.
- ⊕ Anti-adhesive silicone coating preventing visceral adhesion phenomena.

## Material

The INTRA-OMBILI implant is available in the following material:

- Non-woven polypropylene (PPNT) 70g/m<sup>2</sup> + silicone coating

	Non Woven Polypropylene 70g/m <sup>2</sup> + silicone (PPNT 70)
<b>Composition</b>	100% Biocompatible non woven polypropylene coated of one side of biocompatible silicone
<b>Process</b>	Non woven obtained by extrusion, bursting of fibers on a surface and calendering with welding spots (17% of the surface is welded)
<b>Base weight</b>	70g/m <sup>2</sup>
<b>Thickness</b>	0,6 – 1 mm
<b>Pore size</b>	∅ 1mm
<b>Resistance to splintering</b> ISO 13938 – 1	-
<b>Maximum breaking strength</b> ISO 13934 – 1	>95 N (production direction) >70 N (Transverse direction)
<b>Elongation at break</b> ISO 13934 – 1	>45% (production direction) >80% (Transverse direction)
<b>Porosity</b> NF S 94-801 : 2007	-
<b>Rate of oiling</b> NF S 94 – 167 – 5	<1,2%
<b>Release</b>	-
<b>Surfactant residue level</b> NF EN 1644 - 1	Complete Absence







## References

		PPNT 70 + silicone coating
	Disk Ø7 cm	472070
	Disk Ø9 cm	472090

## Clinical Data / Bibliography 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. Kuppenas, 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		Single use
	Do NOT use if the packaging is damaged		Do NOT re-sterilize
	Device sterilized with ethylene oxide		5 years after sterilization