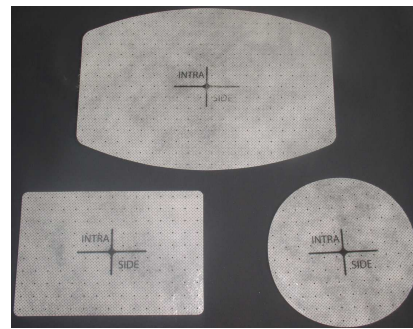


# MICROVAL INTRA IMPLANTS TECHNICAL DATA SHEET



## Description

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

The MICROVAL-INTRA can be implanted either by laparoscopic or open surgery.

The implant is valid for 5 years after sterilization, is sold under 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

⊕ 1 silicone face forming a “peritoneum” in order to avoid adhesions with the viscera

⊕ Flexibility which makes the deployment easy into the intraperitoneal area

⊕ Setting up and orientation facilitated by the presence of a marker "INTRA-SIDE"

⊕ Macro perforations to prevent the formation of seroma and promote drainage



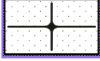
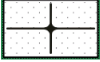
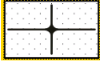


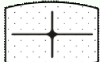

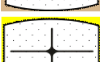
## Material

The Microval-INTRA range is available in non woven polypropylene + silicone:

- Non-woven grammage 50g/m<sup>2</sup> + silicone
- Non-woven grammage 70g/m<sup>2</sup> + silicone

	Non Woven Polypropylene + silicone
<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>Surface Mass</b>	50g/m <sup>2</sup> 70g/m <sup>2</sup>
<b>Thickness</b>	0,6 – 1 mm
<b>Pore size</b>	Ø 1mm
	Non Woven Polypropylene + silicone
<b>Resistance to splintering</b> <i>ISO 13938 – 1</i>	-
<b>Maximum breaking strength</b> <i>ISO 13934 – 1</i>	From 70 to 145N
<b>Elongation at break</b> <i>ISO 13934 – 1</i>	From 45 to 80%
<b>Porosity</b> <i>NF S 94-801 : 2007</i>	-
<b>Rate of oiling</b> <i>NF S 94 – 167 – 5</i>	<1,2%
<b>Release</b>	-
<b>Surfactant residue level</b> <i>NF EN 1644 - 1</i>	Complete Absence

## References

		PP NT 50 + Silicone	PP NT 70 + Silicone
	Circle Ø 12cm	452012	472012
	Circle Ø 15,5cm	452016	472016
	Rectangle 10*15 cm	452015	472015
	Rectangle 20*25 cm	452025	472025
	Rectangle 20*30 cm	452030	472030
	Rectangle 15*17 cm	452517	472517
	Square 30*30 cm	452033	-
	Barrel 13/15*17 cm	452317	472317
	Barrel 10/15*22 cm	452522	472522
	Barrel 15/20*30cm	452530	472530

## 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. 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

STERILE EO

Device sterilized with ethylene oxide



5 years after sterilization



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