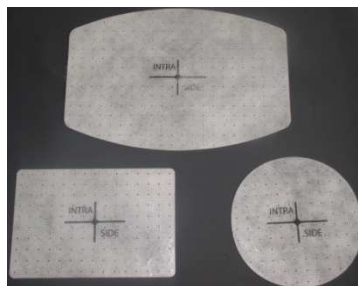




# MICROVAL INTRA IMPLANTS TECHNICAL DATASHEET

Permanent implant for eventrations, wall repairs and umbilical hernia



## 1. Administrative information about MICROVAL



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## 2. Device information

2.1 Common name: Synthetic permanent implant for wall reinforcement

2.2 Commercial name: Microval INTRA implant

2.3 Nomenclature code: GMDN 60300  
EMDN P900204

2.4 Class of medical device: IIb according to European Directive 93/42/CEE (2007/47/CE)  
Notified Body number: 1639  
Date of first sale: 2004  
Manufacturer: MICROVAL



Certificate No. : FR19-81843429





























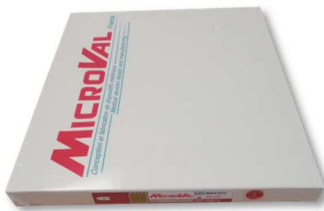

2.5 Device's description:

- ❖ The Microval INTRA implant is specially designed for eventrations, wall repairs and umbilical hernias. Its siliconized surface forms a pseudo peritoneum and thus prevents adhesions with the viscera.
- ❖ The Microval INTRA implant is very flexible, which facilitates its deployment in the intraperitoneal area.
- ❖ Its placement and orientation is eased by the INTRA-SIDE marker.
- ❖ The Microval INTRA implant is macro-perforated to prevent seroma formation and promote drainage.

Characteristics	Value*
Mesh type	Non woven polypropylene + biocompatible silicone
Thickness <sup>1</sup>	0,6 – 1 mm
Weight <sup>2</sup>	70g/m <sup>2</sup>
Pore size	Ø 1mm
Strain at Ultimate Tensile Test <sup>3</sup>	45% (longitudinal) 80% (transverse)
Durability	Permanent
Surgical technique	Laparoscopy or Laparotomy

\*Average values given as an indication

<sup>1</sup> NF EN ISO 5084 (1996) ;  
<sup>2</sup> ISO 3801(1977) méthode 5 ;  
<sup>3</sup> NF EN ISO 13934-1 (2013)

2.6	<div>References:</div> <div><table><thead><tr><th></th><th></th><th>PP NT 70 + Silicone</th></tr></thead><tbody><tr><td></td><td>Circle Ø 12cm</td><td>472012</td></tr><tr><td></td><td>Circle Ø 15,5cm</td><td>472016</td></tr><tr><td></td><td>Rectangle 10*15 cm</td><td>472015</td></tr><tr><td></td><td>Rectangle 20*25 cm</td><td>472025</td></tr><tr><td></td><td>Rectangle 20*30 cm</td><td>472030</td></tr><tr><td></td><td>Rectangle 15*17 cm</td><td>472517</td></tr><tr><td></td><td>Barrel 13/15*17 cm</td><td>472317</td></tr><tr><td></td><td>Barrel 10/15*22 cm</td><td>472522</td></tr><tr><td></td><td>Barrel 15/20*30cm</td><td>472530</td></tr></tbody></table></div> <div>The choice of the size is made according to the morphology of the patient and the importance of the hernia.</div>			PP NT 70 + Silicone		Circle Ø 12cm	472012		Circle Ø 15,5cm	472016		Rectangle 10*15 cm	472015		Rectangle 20*25 cm	472025		Rectangle 20*30 cm	472030		Rectangle 15*17 cm	472517		Barrel 13/15*17 cm	472317		Barrel 10/15*22 cm	472522		Barrel 15/20*30cm	472530
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2.7	<div>Device composition: polypropylene + biocompatible silicone + biocompatible implantable silicon ink for marking</div> <div>✓ No latex</div> <div>✓ No phthalates</div> <div>✓ No products of animal or organic origin</div>																														
2.8	<div>Field of use – Indications: Wall reinforcement. Treatment of umbilical hernias and eventration.</div>																														
3. Sterilization																															
3.1	<div>Sterilized: <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO</div>																														
3.2	<div>Sterilization process: Ethylene oxide according to NF EN ISO11135:2014 and NF EN ISO10993-7:2008(A1:2019)</div>																														
4. Storage conditions																															
<div>Packaging: 1 implant packed in double Tyvek AND filmed cardboard box 240mm x 222mm x 20mm or 365mm x 230mm x 18mm implant ≥ 25 x **cm (non-contractual photograph)</div> <div></div> <div>Expiration: 5 years after sterilization</div> <div>Storage: no particular conditions, store at ambient temperature, please read D130 IFU</div>																															
5. Safety																															
<div>Please read Instructions for Use D130</div>																															
6. Usage																															
6.1	<div>IFU: D130</div>																														
6.2	<div>Indication: Wall reinforcement. Treatment of umbilical hernias and eventration.</div>																														
6.3	<div>Precautions of use: Before operation, please check that all specific instruments for the operation are available and functional. Avoid any contact with objects which could damage the device. The damaged devices and/or that have been in contact with a patient must be isolated and disinfected before cleaning and possible back forwarding. Caution: a defect in the fixing or positioning of the device can induce abnormal stresses and/or reduce the service life.</div>																														
6.4	<div>Contra-indications: Children during their growth, intensive and/or violent physical activities; Allergic reaction. Serious illness inducing a risk of dangerous post-operative complication. Infection and septicemia are absolute contra-indications.</div>																														

## 7. Additional information concerning the product

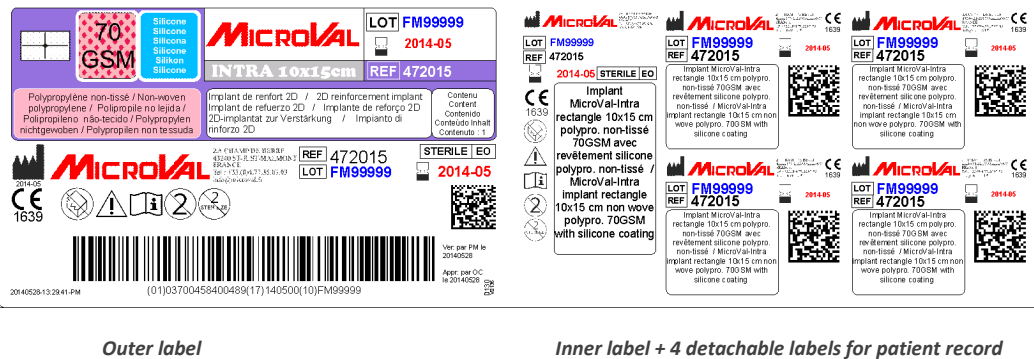
### Bibliography, test reports:

- ❖ 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

## 8. Appendices

### 8.1 IFU: D130

### 8.2 Labelling example:



### 8.3 Symbols used in IFU and/or labels:

