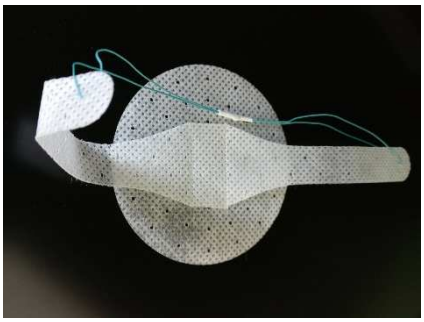
INTRA-OMBILI IMPLANTS TECHNICAL DATASHEET

Permanent implant for **umbilical hernia**



1. Administrative information about MICROVAL

MICROVAL SAS
ZA CHAMP DE BERRE, 43240 SAINT JUST MALMONT, France
Tel: +33 4 77 35 03 03
Fax: +33 4 77 35 03 19

E-mail: info@microval.fr
Website: www.microval.fr

Medical device vigilance contact: Olivier CUILLERON
Tel : +33 4 77 35 03 03
Fax : +33 4 77 35 03 19
E-mail : info@microval.fr

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: 2017
Manufacturer: MICROVAL

CE 1639

Certificate No. : FR19-81843429

2.5 Device's description:

- The INTRA-OMBILI implant is specially designed for tissue reinforcement in the treatment of umbilical hernias. Its siliconized surface prevents visceral adhesion. The Microval INTRA implant is very flexible, which facilitates its deployment in the intraperitoneal area.
- Its excellent shape memory allows it to adapt optimally to the peritoneum after insertion in the intraperitoneal area, an insertion eased by its excellent flexibility.

Characteristics	Value*
Mesh type	Non woven polypropylene + biocompatible silicone
Thickness[1]	0,6 – 1 mm
Weight[2]	70g/m²
Pore size	Ø 1mm
Strain at Ultimate Tensile Test[3]	45% (longitudinal) 80% (transverse)
Durability	Permanent
Surgical technique	Laparotomy

Average values given as an indication

[1] NF EN ISO 5084 (1996) ; [2] ISO 3801(1977) méthode 5 ; [3] NF EN ISO 13934-1 (2013)

2.6	References: PPNT 70 + silicone Ø7 cm disc — 472070 Ø9 cm disc — 472090 The choice of the size is made according to the morphology of the patient and the importance of the hernia.
2.7	Device composition: polypropylene + biocompatible silicone ✓No latex ✓No phthalates ✓No products of animal or organic origin
2.8	Field of use – Indications: Umbilical hernia
3. Sterilization	
3.1	Sterilized: ☒YES ☐NO
3.2	Sterilization process: Ethylene oxide according to NF EN ISO11135:2014 and NF EN ISO10993-7:2008(A1:2019)
4. Storage conditions	
	Packaging: 1 implant packed in double Tyvek AND filmed cardboard box 240mm x 222mm x 20mm (non-contractual photograph)  Expiration: 5 years after sterilization Storage: no particular conditions, store at ambient temperature, please read D130 IFU
5. Safety	
	Please read Instructions for Use D130
6. Usage	
6.1	IFU: D130
6.2	Indication: Umbilical hernia
6.3	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.
6.4	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.

7. Additional information concerning the product

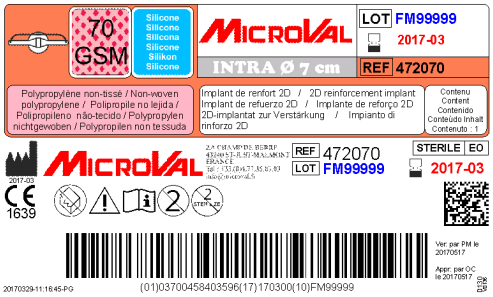
Bibliography, test reports:

- 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. 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

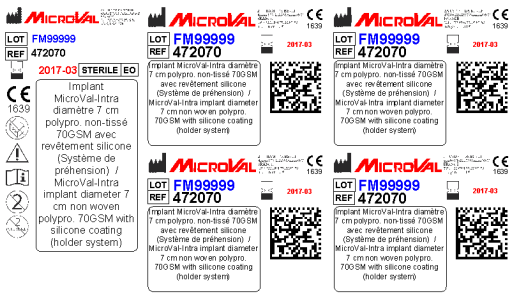
8. Appendices

8.1 IFU: D130

8.2 Labelling example:



Outer label



Inner label + 4 detachable labels for patient record

8.3 Symbols used in IFU and/or labels:

Please check D130 IFU

Do not use if packing has been damaged

STERILE EO — **Sterilized with Ethylene oxide**

5 years after sterilization

Single use

Do not re-sterilize