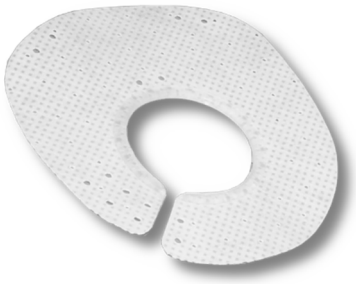
RH IMPLANTS TECHNICAL DATASHEET

Permanent implant for **hiatal hernia repair**



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: RH implant

2.3 Nomenclature code: GMDN 64554
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: 2005
Manufacturer: MICROVAL

CE 1639

Certificate No. : FR19-81843429

2.5 Device's description:

- RH implant is specially manufactured for hiatal hernia repair. Its siliconized face allows the formation of a pseudo peritoneum and thus avoids adhesions with the viscera.
- Its silicone ring ensures a non-aggressive contact between the implant and the esophagus and avoids the risks of adhesion.
- RH implant is macro perforated to avoid seroma formation after implantation and to promote drainage.

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%
Durability	Permanent

Average values given as an indication

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

2.6 References:

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

2.7 Device composition: polypropylene + biocompatible silicone

✓No latex
✓No phthalates
✓No products of animal or organic origin

2.8 Field of use – Indications: Hiatal hernia repair

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 – lots not represented)

Expiration: 5 years after sterilization

Storage: no particular conditions, store at ambient temperature, please read D120 IFU

5. Safety

Please read Instructions for Use D120

6. Usage

6.1	IFU: D120
6.2	Indication: Hiatal hernia repair
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.

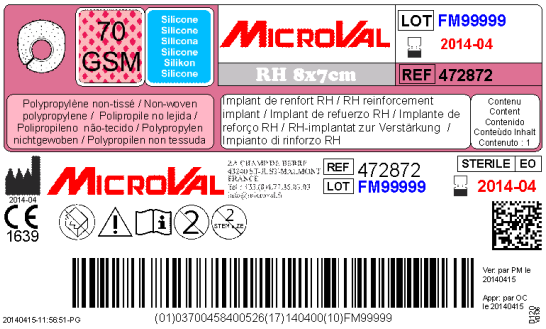
7. Additional information concerning the product

Bibliography, test reports:

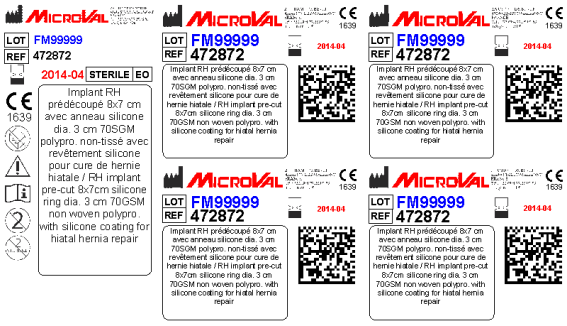
- Etude clinique publiée en 2008 (réf Microval [0388]) « Use of intraperitoneal biface polypropylene/silicone prosthesis Multicentric study on 96 cases » - R. Azoulay, JY. François, Ch. Breton, C. Kupenas, J. Nassa
- La prothèse silpromesh dans le traitement des hernies et éventrations de la paroi antérieure 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: D120
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 D120 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