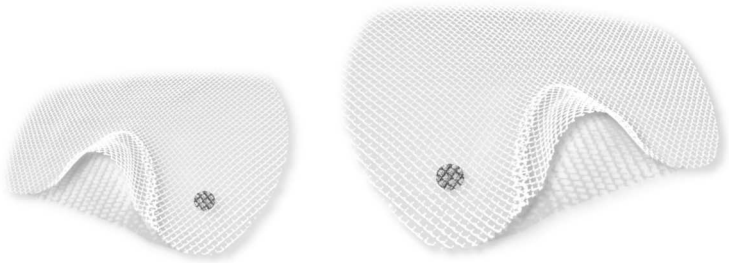
JG IMPLANTS TECHNICAL DATASHEET

Synthetic mesh for **inguinal hernia by laparoscopy**



1. Administrative information about MICROVAL

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2. Device information

2.1 Common name: Synthetic permanent implant for abdominal wall reinforcement

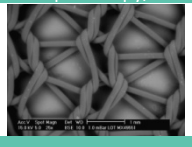
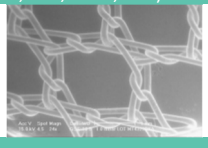
2.2 Commercial name: JG anatomic implant

2.3 Nomenclature code: GMDN 60300
EMDN P900202

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: 2008
Manufacturer: MICROVAL
Basic UDI-DI : 37004584DT010-DIG-COEV8
Certificate No. : FR19-81843429

2.5 Device's description:

- These implants are macroporous, monofilament, medical grade polypropylene meshes build in three dimensions.
- Their anatomical shape perfectly fits the anatomical region which reduces the migration phenomenon.
- These permanent implants and their very high burst test resistance allow a durable inguinal reinforcement.
- A medical black ink marker allows the surgeon to easily identify the internal inferior edge in order to ease the implant's placement.
- These implants can be implanted with all laparoscopic/coelioscopic available techniques including robotic surgery (TAPP, TEP, eTEP, etc.)

Characteristics	Value*	
Mesh type	Knitted monofilament polypropylene – lock stitch	
Construction	Standard	Lightweight
Thickness[1]	0.56 mm	0.52 mm
Weight[2]	90 g/m²	60g/m²
Max pore size[3]	1.31 mm	1.70 mm
Porosity[4]	≥77%	≥84%
Burst resistance[5] **(max in vivo value ≈ 170mmHg**[a]**)**	≥ 6135mmHg	≥ 4110mmHg
Strain at Ultimate Tensile Test[6]	102% (longitudinal) 111% (transverse)	104% (longitudinal) 74% (transverse)
Durability	Permanent	
Surgical technique	Laparoscopy/Coelioscopy (TAPP, TEP, eTEP, etc.)	
Microscopic view of the mesh		

Average values given as an indication

[1] NF EN ISO 5084 (1996); [2] ISO 3801(1977) method 5
[3] NF S94-801 (2007) method B; [4] NF S94-801 (2007) method A
[5] NF EN ISO 13938-1(2019) ; [6] NF EN ISO 13934-1 (2013)

[a] Pott et al. 2012, « Mechanical Properties of Mesh Materials Used for Hernia Repair and Soft Tissue Augmentation », PLoS ONE 7(10): e46978. doi:10.1371/journal.pone.0046978

2.6 References:

Size	Shape	Side	Standard Polypropylene	Lightweight Polypropylene
10 x 14 cm		right	411 040	412 040
		left	411 041	412 041
		symmetrical	411 140	412 140
11 x 15 cm		right	411 050	412 050
		left	411 051	412 051
		symmetrical	411 150	412 150
12 x 16 cm		right	411 060	412 060
		left	411 061	412 061
		symmetrical	411 160	412 160

The choice of the size is made according to the morphology of the patient and the importance of the hernia. The choice of material is made regarding the mechanical properties and the handling that best fits the surgeon. A higher porosity and/or a larger pore size leads to a faster tissue integration. The choice of a left or right implant is made according to the laterality of the pathology.

2.7 Device composition: 100% polypropylene + biocompatible implantable silicon ink for marking

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

2.8 Field of use – Indications: Abdominal wall reinforcement. Treatment of hernias and eventration.

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 simple PETG blister with protective cover AND filmed cardboard box 224mm x 152mm x 30mm (non-contractual photograph)

Expiration: 5 years after sterilization
Storage: no particular conditions, store at ambient temperature, please read D133 IFU

5. Safety

Please read Instructions for Use D133

6. Usage

6.1 IFU: D133

6.2 Indication: Abdominal wall reinforcement. Treatment of hernia and eventration.

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

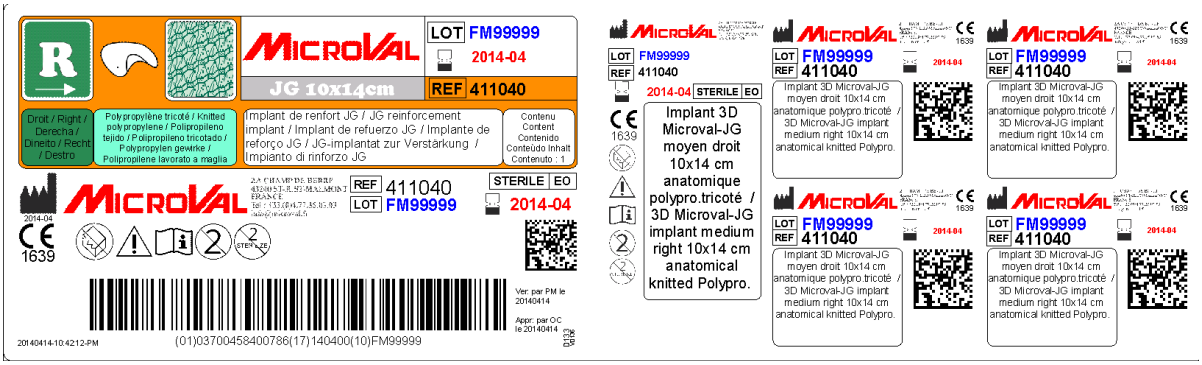
Bibliography, test reports:

- [Ref0438] “Laparoscopic totally extraperitoneal inguinal repair. Twenty-seven serious complications after 4408 consecutive cases”, P BLANC, J G BALIQUE, M KITAMURA, A MEYER, R TRULLENQUE JUAN, F DELACOSTE, J ATGER, Revista do Colégio Brasileiro de Cirurgiões, 2013, 40(1):32-36
- [Ref0033] “Laparoscopic Totally Extraperitoneal Inguinal Hernia Repair: Nonfixation of Three-Dimensional Mesh”, A L MEYER, D M BELLANDI, F DELACOSTE, J ATGER, E BERGER, M A A RANOYA, O MONTEIRO, P A ALONSO, L M V GUIMARAES, Bras. J. Video-Sur. 2010, 3(1): 019-023
- [Ref0511] “Post Clinical Follow up from 2011 to 2013 over 28 patients in France and Japan JG implants”, Microval PMCF study, 2013
- [Ref0512] “Post Clinical Follow up from 2010 to 2013 over 90 patients in France and Japan JG implants”, Microval PMCF study, 2013
- [Ref0513] “Test report from Dr JG Balique over 2400 hernias JG implants”, Microval test report, 2013

8. Appendices

8.1 IFU: D133

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 D133 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