PS 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: PS implant

2.3 Nomenclature code: GMDN 60300
EMDN P900202

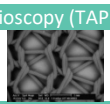
2.4 Class of medical device: IIb according to European Directive 93/42/CEE (2007/47/CE)
Notified Body number: 1639
Date of first sale: 2016
Manufacturer: MICROVAL
Basic UDI-DI : 37004584DT010-DIG-COEV8

CE 1639

Certificate No. : FR19-81843429

2.5 Device's description:

- These implants are macroporous, monofilament, medical grade polypropylene meshes build in three dimensions.
- Can be used for both left or right side by simply pushing up the two bumps (for standard polypropylene).
- Available with Bulmesh treatment for limiting migration phenomenon (+30% friction).
- These permanent implants and their very high burst test resistance allow a durable inguinal reinforcement.
- 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	
Thickness[1]	0.56 mm	
Weight[2]	90 g/m²	
Max pore size[3]	1.31 mm	
Porosity[4]	≥77%	
Burst resistance[5] **(max in vivo value ≈ 170mmHg**[a]**)**	≥ 6135mmHg	
Strain at Ultimate Tensile Test[6]	111% (longitudinal) 102% (transverse)	
Durability	Permanent	
Surgical technique	Laparoscopy/Coelioscopy (TAPP, TEP, eTEP, etc.)	
Microscopic view of the mesh		
Mesh aspect	Standard 	Bulmesh (+30% friction) 

*Average values given as an indication

[1] NF EN ISO 5084 (1996); [2] ISO 3801(1977) method 5
[3] NF 594-801(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	Bulmesh Polypropylene
11 x 15 cm		Left or right	413 150	
10 x 16 cm		Left or right	413 160	
		right		601 160
		left		601 161
11 x 16.5 cm		Left or right	413 165	

The choice of the size is made according to the morphology of the patient and the importance of the hernia. The choice of a left or right implant is made according to the laterality of the pathology. Bulmesh side must be in contact with the muscles.

2.7 Device composition: 100% polypropylene + biocompatible implantable silicon ink for marking (Bulmesh design only)

✓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.

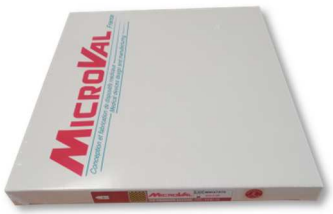
3. Sterilization

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 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 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

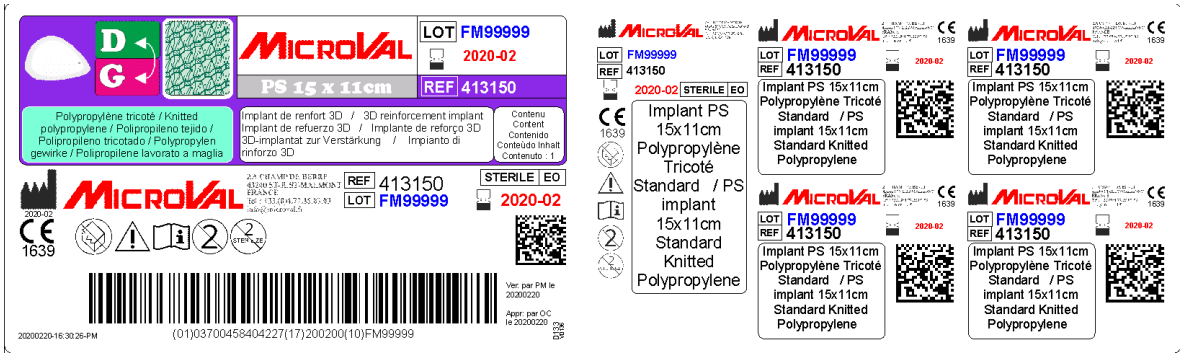
Bibliography, test reports:

- [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
- [Ref0513] “Test report from Dr JG Balique over 2400 hernias JG implants”, Microval test report, 2013
- Internal tests comparing standard versus Bulmesh construction. D229 D-HI-L rev0, 2020

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