LG IMPLANTS TECHNICAL DATASHEET

Synthetic mesh for **inguinal hernia by laparotomy**

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: LG implant

2.3 Nomenclature code: GMDN 60300
EMDN P900202

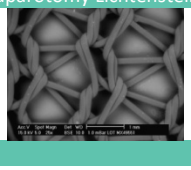
2.4 Class of medical device: IIb according to European Directive 93/42/CEE (2007/47/CE)
Notified Body number: 1639
Date of first sale: 2007
Manufacturer: MICROVAL
Basic UDI-DI 37004584DT011-DIG-LAPWQ

CE 1639

Certificate No. : FR19-81843429

2.5 Device's description:

- These implants can be implanted by Lichtenstein procedure and its derivatives.
- Available in male or female versions (slot for spermatic cord or not).
- These permanent implants and their very high burst strength allow a durable inguinal reinforcement.

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]	102% (longitudinal) 111% (transverse)
Durability	Permanent
Surgical technique	Laparotomy Lichtenstein
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	Destination	Shape	Standard Polypropylene
6 x 12 cm	Woman ♀		413 135
	Man ♂		413 136

2.7 Device composition: 100% polypropylene

✓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.

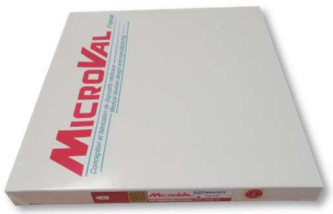
3. Sterilization

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

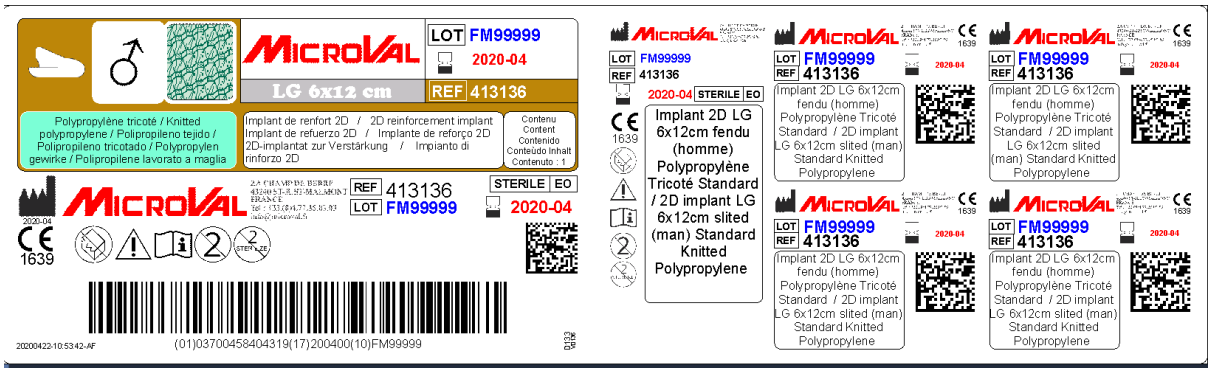
Bibliography, test reports:

- [Ref0510] “Standard polypropylene mesh vs lightweight mesh for Lichtenstein repair of primary inguinal hernia: a randomized controlled trial”, Z DEMTRASHVILI ,K KHUTSISHVILI, I PIPIA, G KENCHADZE, E EKALADZE, Int J of Surgery 2014, 12:1380-1384
- [Ref0509] “Open Mesh Techniques for inguinal hernia repair: a meta-analysis of randomized controlled trials”, G ZHAO, P GAO, B MA, J TIAN, K YANG, Annals of Surgery 2009, 250(1):35-42
- [Ref0020] “Etude rétrospective et analytique du traitement des hernies inguinales de l’adulte sur 130 patients de 1996 à 1997.”, J L DULUCQ and P WINTRINUGER, PMCF study Microval 1998

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