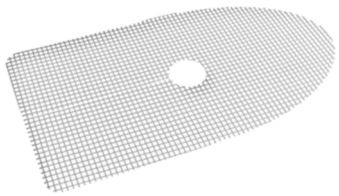
LT IMPLANTS TECHNICAL DATASHEET

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

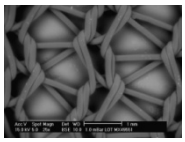
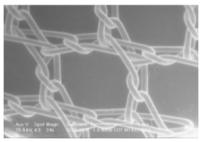
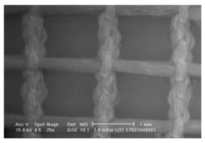
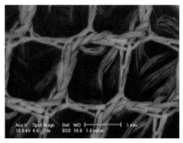
2.2 Commercial name: LT implant

2.3 Nomenclature code: GMDN 60300
EMDN P900202 (polypropylene) / EMDN P900205 (polyester)

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: 2001
Manufacturer: MICROVAL
Basic UDI-DI : 37004584DT011-DIG-LAPWQ
Certificate No. : FR19-81843429

2.5 Device's description:

- These implants can be implanted by Lichtenstein procedure and its derivatives.
- Available in multiple shapes and materials (macroporous monofilament polypropylene –standard or light meshes- or macroporous multifilament polyester -2D or 3D weave-).
- These permanent implants and their very high burst strength allow a durable inguinal reinforcement.

Characteristics	Value*			
Mesh type	Knitted monofilament polypropylene – lock stitch		Knitted multifilament polyester – lock stitch	
Construction	Standard	Lightweight	2D weave	3D weave
Thickness[1]	0.56 mm	0.52 mm	0.50 mm	2.40 mm
Weight[2]	90 g/m²	60g/m²	100g/m²	121g/m²
Max pore size[3]	1.31 mm	1.70 mm	1.25 mm	1.66 mm
Porosity[4]	≥77%	≥84%	≥80%	≥96%
Burst resistance[5] **(max in vivo value ≈ 170mmHg[a])**	≥ 6135mmHg	≥ 4110mmHg	≥ 9030mmHg	≥ 2835mmHg
Strain at Ultimate Tensile Test[6]	102% (longitudinal) 111% (transverse)	104% (longitudinal) 74% (transverse)	33% (longitudinal) 52% (transverse)	75% (longitudinal) 70% (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:

Shape	Size	Standard Polypropylene	Lightweight Polypropylene	2D weave Polyester	3D weave Polyester
	5 x 9 cm	413 095	414 095	416 095	666 095
	5.5 x 10 cm	413 155 *By lot x5:* 413155/05	414 155	416 155	666 155
	6 x 11 cm	413 116 *By lot x05:* 413116/05 *By lot x50:* 413116/50	414 116 *By lot x50:* 414116/50	416 116	666 116
	7 x 11 cm	413 711	414 711	-	666 711
	9 x 13 cm	413 139 *By lot x5:* 413139/05 *By lot x50:* 413139/50	414 139	416 139	666 139

The choice of the size and shape 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. Polyester is hydrophilic and degrades more than polypropylene which is hydrophobic. A higher porosity and/or a larger pore size leads to a faster tissue integration. A monofilament leads to less infection potentially. 3D weave allows a good structural stability over time (cf. shrinkage effect).

2.7 Device composition: 100% polypropylene or 100% polyester

✓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.

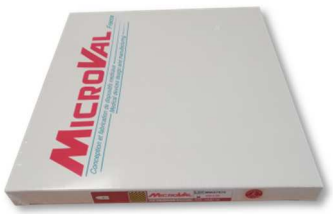
3. Sterilization

3.1 Sterilized: ☒YES ☐NO

3.2 Sterilization process:
Polyester: gamma ray radiation according to ISO 11137-1:2016 (A2:2019) and ISO 11137-2:2015
Polypropylene: 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 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

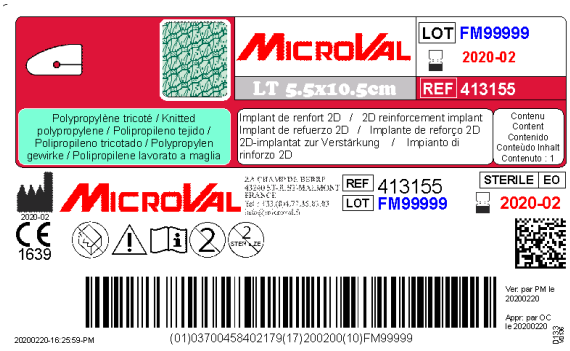
Bibliography, test reports:

- [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
- [Ref0508] “Comparison of polypropylene versus polyester mesh in the Lichtenstein hernia repair with respect to chronic pain and discomfort”, A SADOWSKI, J RODRIGUEZ, R SYMMONDS, J ROBERTS, J SONG,M HASAN RJAB, C CUMMINGS, B HODGES, Hernia 2011; 15:643-654
- [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 (Polypropylene)**

STERILE R **Sterilized with gamma ray radiation (Polyester)**

5 years after sterilization

Single use

Do not re-sterilize