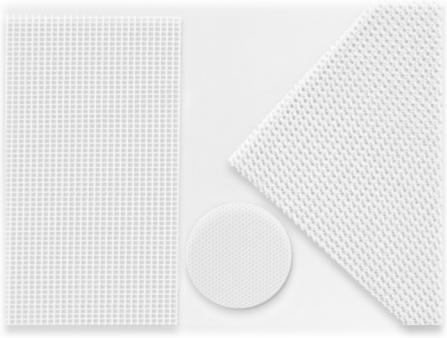
MICROVAL 2D MESH TECHNICAL DATASHEET

Synthetic mesh for **abdominal wall reinforcement**



1. Administrative information about MICROVAL

MICROVAL
ZA CHAMP DE BERRE, 43240 SAINT JUST MALMONT, France
Tel: +33 4 77 35 03 03
Fax: +33 4 77 35 03 19
E-mail: info@microval.fr
Website: www.microval.fr

Medical device vigilance contact: Olivier CUILLERON
Tel: +33 4 77 35 03 03
Fax: +33 4 77 35 03 19
E-mail: info@microval.fr

2. Device information

2.1 Common name: Synthetic permanent implant for abdominal wall reinforcement

2.2 Commercial name: Microval 2D mesh implant

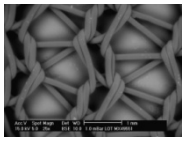
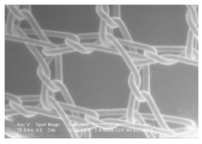
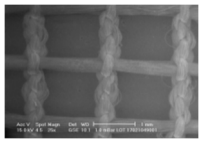
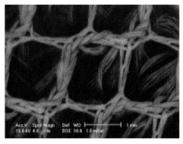
2.3 Nomenclature code: GMDN 60300
EMDN P900202 (polypropylene) / EMDN P900205 (polyester)

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: 1998
Manufacturer: MICROVAL
Basic UDI-DI : 37004584DT010-DIG-COEV8 and 37004584DT011-DIG-LAPWQ

CE 1639
Certificate No. : FR19-81843429

2.5 Device's description:

- These implants can be implanted extraperitoneally for different types of hernias: umbilical, incisional, femoral, etc. In the case of inguinal hernias, Lichtenstein procedure (and derivatives) and laparoscopic procedures can be envisaged.
- 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 or laparoscopy			
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 594-801 (2007) method B; [4] NF 594-801 (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
	15 x 15 cm	413 515 *By lot x3:* 415515 *By lot x5:* 413515/05 *By lot x50:* 413515/50	414 515 *By lot x50:* 414515/50	416 515	666 515
	30 x 30 cm	413 030 *By lot x25:* 413030/25	414 030 *By lot x25:* 414030/25	416 030	666 030
	Ø5 cm	413 500	-	-	-
	Ø7 cm	413 700 *By lot x25:* 413700/05	-	-	-
	Ø9 cm	413 900	-	-	-
	6 x 11 cm	413 611 *By lot x3:* 415611 *By lot x50:* 413611/50	414 611 *By lot x50:* 414611/50	-	-
	7.5 x 15 cm	413 715 *By lot x3: 415715* *By lot x50: 413715/50*	414 715	416 715	666 715
	9 x 13 cm	413 913 *By lot x3: 415913* *By lot x50:* 413913/50	414 913 *By lot x50:* 414913/50	416 913	-
	10 x 15 cm	413 015 *By lot x3: 415015*	-	416 015	666 015
	15 x 30 cm	413 530	414 530	416 530	-

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 ISO11137-2:2015
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 or filmed cardboard box 365mm x 230mm x 18mm implant ≥ 30 x **cm (non-contractual photograph – lots not represented)


ou


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

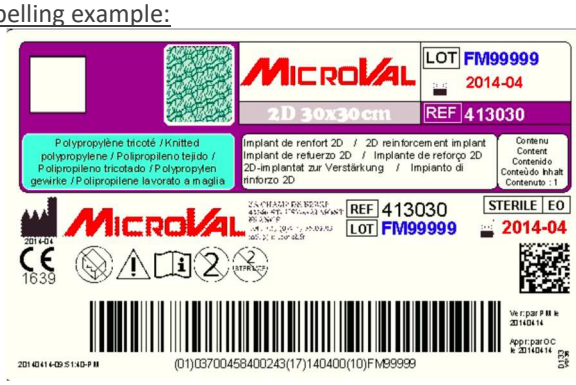
Bibliography, test reports:

- [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
- [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 (Polypropylene)**

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

5 years after sterilization

Single use

Do not re-sterilize