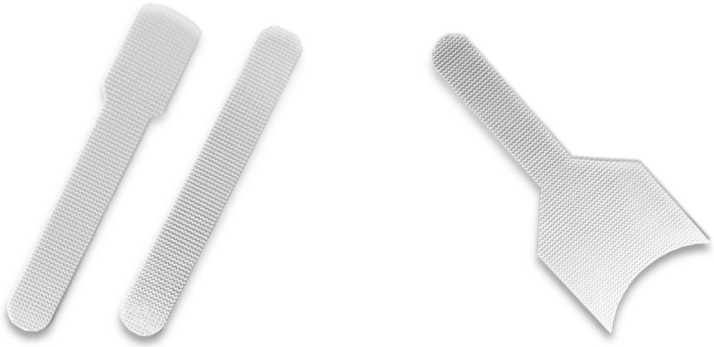
PROLAFIX TECHNICAL DATASHEET

Synthetic mesh for **Pelvic Organ Prolapse (POP) – Abdominal approach**



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: Implant for Pelvic Floor reinforcement

2.2 Commercial name: PROLAFIX implant

2.3 Nomenclature code: GMDN 60842
EMDN P900202 (polypropylene) / EMDN P900205 (polyester)

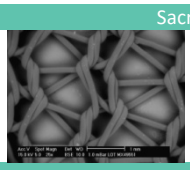
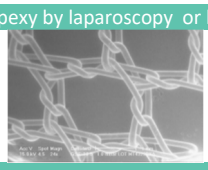
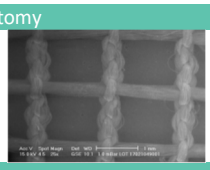
2.4 Class of medical device: IIb according to European Directive 93/42/CEE (2007/47/CE)
Notified Body number: 1639
Date of first sale: 2004
Manufacturer: MICROVAL
Basic UDI-DI : 37004584DT004-PROLA62

CE 1639

Certificate No. : FR19-81843429

2.5 Device's description:

- These implants are macroporous meshes to mechanically reinforce native tissues.
- Available in multiple sizes and materials (macroporous monofilament polypropylene –standard or light meshes- or multifilament polyester).
- Especially designed for abdominal surgery of prolapse (sacrocolpopexy) in coelioscopy or laparotomy.

Characteristics	Value* according to NF S94-801:2007					
Mesh type	Knitted monofilament polypropylene – lock stitch		Knitted monofilament polypropylene – lock stitch		Knitted multifilament polyester – lock stitch	
Construction	Standard		Lightweight		2D weave	
Thickness[1]	0.56 mm		0.52 mm		0.50 mm	
Fiber diameter	0.15 mm		0.15 mm		Ø 76 dTex 22	
Weight[2]	90 g/m²		60g/m²		100g/m²	
Max pore size[3]	1.31 mm		1.70 mm		1.25 mm	
Mean porosity[4]	≥77%		≥84%		≥80%	
	longitudinal	*transverse*	*longitudinal*	*transverse*	*longitudinal*	*transverse*
Ultimate Tensile Test[5]	324N/5cm	289N/5cm	227N/5cm	367N/5cm	342N/5cm	570N/5cm
Strain at Ultimate Tensile Test[5]	102%	111%	104%	74%	33%	52%
at 10N[5]	4%	5%	17%	9%	1.1%	1.1%
Durability	Permanent					
Surgical technique	Sacrocolpopexy by laparoscopy or laparotomy					
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 13934-1 (2013)

2.6 References:

Name	Shape	Size	Standard Polypropylene	Lightweight Polypropylene	2D weave Polyester
K3 - kit		2.5/8 x 19 cm 2.5 x 18 cm 2.5/3.5 x 18 cm	413 803	414 803	416 803
K3+ - kit		2.5/8 x 24 cm 2.5 x 18 cm 2.5/3.5 x 18 cm	-	414 813	416 813
A4 - anterior		4.5 x 18 cm	-	-	416 881
P4 - posterior		4.5/8 x 20 cm	-	-	416 891

Kits are available with two anterior implants so that the surgeon can choose the one that fits the best the patient. The choice of the size and shape is made according to the morphology of the patient. 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.

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: PROLAFIX implants are indicated for women with advanced apical pelvic organ prolapse (POP-Q ≥ stage 2) in abdominal surgery. These implants can be used in women with or without uterus and concomitant surgical procedures can be performed if necessary at the discretion of the surgeon.

3. Sterilization

3.1 Sterilized: ☒YES ☐NO

3.2 Sterilization process:
Polyester: gamma ray radiation according to ISO 11137:2019
Polypropylene: Ethylene Oxide according to NF EN ISO11135:2014 and NF EN ISO10993-7:2019

4. Storage conditions

Packaging: 1 to 3 implants packed in sealed double Tyvek bags AND filmed cardboard box 240mm x 220mm x 20mm (non contractual photo)


Expiration: 5 years after sterilization
Storage: no particular conditions, store at ambient temperature, please read D134 IFU

5. Safety

Please read Instructions for Use D134

6. Usage

6.1 IFU: D134

6.2 Indication: PROLAFIX implants are indicated for women with advanced apical pelvic organ prolapse (POP-Q ≥ stage 2) in abdominal surgery. These implants can be used in women with or without uterus and concomitant surgical procedures can be performed if necessary at the discretion of the surgeon.

6.3 Precautions of use: Before the operation, check that the instruments specific to the installation of the device are available and functional. Avoid contact with objects that may damage the device. Damaged devices and/or devices that have been in contact with a patient must be isolated and decontaminated before cleaning and possible reshipment.
Warning: a defect in the fixing, positioning or assembly of the device may induce abnormal stresses and/or reduce the service life of the device. In women with increased risk of complications related to a synthetic implant (chronic steroid use, smoking, etc.), other surgeries should be considered. For patients with medical co-morbidities that prevent them from undergoing more invasive and longer surgery (heart disease, chronic obstructive pulmonary disease or thromboembolic disease), a vaginal approach (with a different implant) should be considered. The placement of a preventive posterior implant in the context of primary surgery should not be systematic.

6.4 Contra-indications: Pregnant woman or those considering a future pregnancy. Child during their growth. Intense physical activities. Allergic reactions. Serious illness containing a risk of dangerous post-operative complications. Infection and sepsis are absolute contraindications.

7. Additional information concerning the product

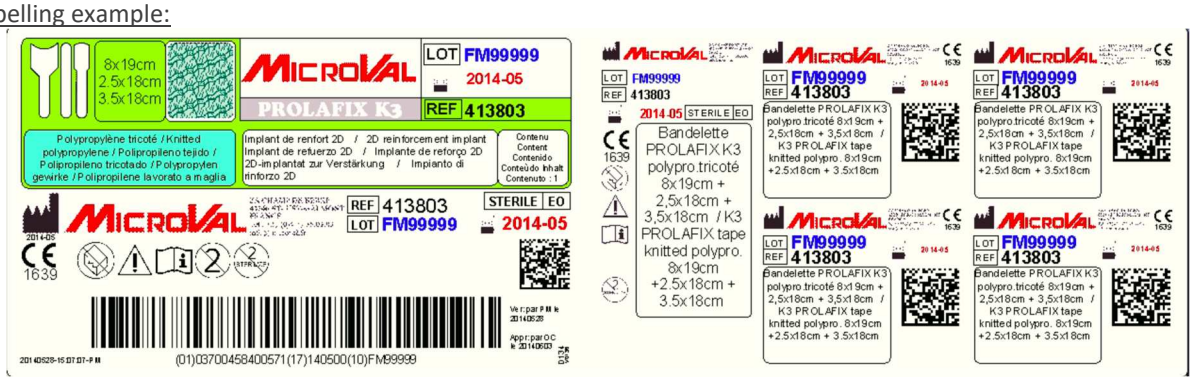
Bibliography, test reports:

- [Ref0494] “The Use of Uro-Gynaecological Mesh in Surgical Procedures” - CHIEF MEDICAL OFFICER OF THE IRISH REPUBLIC – Report to the Minister for Health 2018
- [Ref0496] “A long-term cohort study of surgery for recurrent prolapse comparing mesh augmented anterior repairs to anterior colporrhaphy” - N CURTISS, J DUCKETT - Gynecol Surg. 2018;15(1):1
- [Ref0497] “Laparoscopic promontofixation for pelvic organ prolapse: A 10-year single center experience in a series of 501 patients “ -J BACLE, AG PAPATSORIS, P BIGOT, AR AZZOUZI, PE BRYCHAET, J PIUSSAN, E MANDRON -Int J Urol. 2011 Dec;18(12):821-6

8. Appendices

8.1 IFU: D134

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 D134 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