# PROLAFIX-V TECHNICAL DATASHEET

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

## 1. Administrative information about MICROVAL


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## 2. Device information

2.1 Common name: Implant for Pelvic Floor reinforcement

2.2 Commercial name: PROLAFIX V implant

2.3 Nomenclature code: GMDN 60842
EMDN P900202

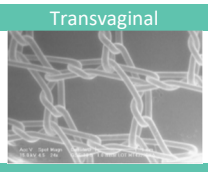
2.4 Class of medical device: IIb according to European Directive 93/42/CEE (2007/47/CE)
Notified Body number: 1639
Date of first sale: 2009
Manufacturer: MICROVAL
Basic UDI-DI : 37004584DT014-PROLAVRT

CE 1639

Certificate No. : FR19-81843429

2.5 Device's description:

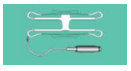
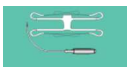
- These implants are macroporous meshes that mechanically reinforce native tissues.
- Especially designed for vaginal surgery of prolapse using TOT (in-out or out-in) or TVT (ascending retropubic) approaches. The implant is placed into the vesico-vaginal wall.
- Polyester suture wires are fixed at the implant's edges making the handling easier especially using the optional ancillaries. Theses wires and their heat shrinkable sleeves are removed before wound closing.
- This implant must be placed by specialist surgeons that have been appropriately trained.

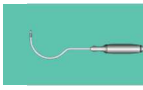
| Characteristics | Value* according to NF S94-801:2007 | |
|---|---|---|
| Mesh type | Knitted monofilament polypropylene – lock stitch | |
| Construction | Lightweight | |
| Thickness[1] | 0.52 mm | |
| Fiber diameter | 0.15 mm | |
| Weight[2] | 60g/m² | |
| Max pore size[3] | 1.70 mm | |
| Mean porosity[4] | ≥84% | |
| | *longitudinal* | *transverse* |
| Ultimate Tensile Test[5] | 227N/5cm | 367N/5cm |
| Strain at Ultimate Tensile Test[5] | 104% | 74% |
| Strain at 10N[5] | 17% | 9% |
| Durability | Permanent | |
| Surgical technique | Transvaginal | |
| 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 | Lightweight Polypropylene |
|---|---|---|---|
| V2 |  | 5 x 7 cm | 512 002 |
| V2 TOT kit |  | | 512 062 |
| V2 TVT kit |  | | 512 092 |
| V4 |  | 6 x 10 cm | 512 004 |
| V4 TOT kit |  | | 512 064 |
| V4 TVT kit |  | | 512 094 |

| Re-usable instrumentation (not sterile) | | | |
|---|---|---|---|
| **Name** | **Shape** | **Description** | **Reference** |
| UG-2 TOT |  | Right/left Spiral needle for TOT | 952 200 |
| UG-3 TOT |  | Right/left Spiral needle for TOT + Guide | 952 300 |
| UG-1P TOT |  | Small curvature needle for TOT | 952 600 |
| UG-1 TVT |  | High curvature needle for TVT | 952 900 |

The choice between PROLAFIX V2 (2 arms) vs. PROLAFIX V4 (4 arms) can be made regarding (i) the type and level of prolapse (2 arms = less pronounced prolapse), (ii) the possible duration of operation (2 arms = faster operation), (iii) the surgeon's preference (2 arms = simpler but less accurate tensioning). The choice between TOT vs. TVT technique can be made mainly regarding surgeon's experience.

2.7 Device composition: 100% polypropylene (implant) or stainless steel (instrumentation)

✓No latex
✓No phthalates
✓No products of animal or organic origin

2.8 Field of use – Indications: PROLAFIX-V implants are indicated for vaginal surgery of anterior prolapse or advanced multi-compartmental pelvic organ prolapse (POP-Q ≥ stage 2) in women with recurrent prolapse or with significant recurrence risk factors. 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:
Instrumentation: Gamma ray radiation according to ISO 11137:2019
Implant: Ethylene Oxide according to NF EN ISO11135:2014 and NF EN ISO10993-7:2019

## 4. Storage conditions

Packaging: 1 implant packed in sealed double Tyvek AND filmed cardboard box 240mm x 220mm x 20mm or filmed cardboard box 224mm x 152mm x 48mm for kits (non contractual photo)


or


Expiration: 5 years after sterilization
Storage: no particular conditions, store at ambient temperature, please read D144 IFU

## 5. Safety

Please read Instructions for Use D144

## 6. Usage

6.1 IFU: D144

6.2 Indication: PROLAFIX-V implants are indicated for vaginal surgery of anterior prolapse or advanced multi-compartmental pelvic organ prolapse (POP-Q ≥ stage 2) in women with recurrent prolapse or with significant recurrence risk factors. 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 positioning or assembly of the device may induce abnormal stresses and/or reduce the service life of the device. Vaginal surgery of prolapse is reserved for complex cases where other surgical procedures have already failed or are likely to fail. In women at increased risk of complications related to a synthetic implant (chronic steroid use, smoking, etc.), other surgeries should be considered. Avoid excessive tension during handling and installation of the implant to avoid damaging the device. Risk factors must be taken into account to determine a patient's eligibility for implant placement: general health (hormone levels, diabetes, obesity, smoking), presence of somatic inflammatory disease, quality of host tissue (prolapse stage, age and genetic characteristics).

6.4 Contra-indications: Pregnant woman or considering a future pregnancy. Female with clinically significant preoperative chronic pelvic pain for which pain may worsen postoperatively (resurgence surgery to relieve pain is more likely to fail in these patients). Child during their growth. Intense physical activities. Allergic reactions. Serious illness containing a risk of dangerous post-operative complications. Infection and sepsis are absolute contra-indications.

## 7. Additional information concerning the product

Bibliography, test reports:


- [Ref0493] "Efficacy and patient satisfaction of pelvic organ prolapse reduction using transvaginal mesh: A Canadian perspective" - AUBÉ M, GUÉRIN M, RHEAUME C, TU LM- Can Urol Assoc J. 2018 Oct;12(10): E432-E437
- [Ref0494] "The Use of Uro-Gynaecological Mesh in Surgical Procedures" - CHIEF MEDICAL OFFICER OF THE IRISH REPUBLIC – Report to the Minister for Health 2018
- [Ref0495] "Long term Follow-up of Transvaginal Anatomical Implant of Mesh in Pelvic organ prolapsed" - DY LUO, TX YANG, H SHEN - Sci Rep. 2018 Feb 12;8(1):2829


## 8. Appendices

8.1 IFU: D144

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 D144 IFU**

**Do not use if packing has been damaged**

STERILE EO — **Sterilized with Ethylene Oxide (implant)**

STERILE R — **Sterilized with gamma ray radiation (instrumentation)**

**5 years after sterilization**

**Single use**

**Do not re-sterilize**