

1. Administrative information about MICROVAL



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2. Device information

2.1 Common name: Synthetic Mid Urethral Sling

2.2 Commercial name: SAFIRE implant

2.3 Nomenclature code: GMDN 47986
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 : 37004584DT003-INCONZC



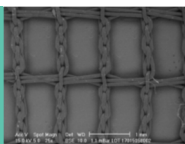
CE
1639

Certificate No. : FR19-81843429

2.5 Device's description:




























- ❖ These implants are macroporous meshes to mechanically reinforce native tissues.
- ❖ Especially designed for Stress Urinary Incontinence using TOT (in-out or out-in) or TVT (ascending retropubic) approaches.
- ❖ Polyester suture wires are fixed at the implant's edges making the handling easier especially using the optional ancillaries. These wires and their heat shrinkable sleeves are removed before wound closing.
- ❖ Atraumatic edges for erosion limitation.



Characteristics	Value* according to NF S94-801:2007
Mesh type	Knitted monofilament polypropylene – lock stitch
Construction	Ultra lightweight
Thickness ¹	0.35 mm
Fiber diameter	0.08 mm
Weight ²	33g/m ²
Max pore size ³	1.55 mm
Mean porosity ⁴	≥87%
Ultimate Tensile Test ⁵	65N
Strain at Ultimate Tensile Test ⁵	40%
at 10N ⁵	4%
Durability	Permanent
Surgical technique	TOT or TVT
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	<div>References:</div> <table><thead><tr><th>Name</th><th>Shape</th><th>Size</th><th>Ultra Lightweight Polypropylene</th></tr></thead><tbody><tr><td>SAFIRE</td><td></td><td rowspan="4">1.2 x 45 cm</td><td>510 100</td></tr><tr><td>UG-3S TOT kit</td><td></td><td>510 130</td></tr><tr><td>UG-1PS TOT kit</td><td></td><td>510 160</td></tr><tr><td>UG-1S TVT kit</td><td></td><td>510 190</td></tr></tbody></table> <table><thead><tr><th colspan="4">Re-usable instrumentation (not sterile)</th></tr><tr><th>Name</th><th>Shape</th><th>Description</th><th>Reference</th></tr></thead><tbody><tr><td>UG-2 TOT</td><td></td><td>Right/left Spiral needle for TOT</td><td>952 200</td></tr><tr><td>UG-3 TOT</td><td></td><td>Right/left Spiral needle for TOT + Guide</td><td>952 300</td></tr><tr><td>UG-1P TOT</td><td></td><td>Small curvature needle for TOT</td><td>952 600</td></tr><tr><td>UG-1 TVT</td><td></td><td>High curvature needle for TVT</td><td>952 900</td></tr></tbody></table>	Name	Shape	Size	Ultra Lightweight Polypropylene	SAFIRE		1.2 x 45 cm	510 100	UG-3S TOT kit		510 130	UG-1PS TOT kit		510 160	UG-1S TVT kit		510 190	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
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2.7	<div>Device composition: 100% polypropylene (implant) or medical stainless steel (instrumentation)</div> <div>✓No latex</div> <div>✓No phthalates</div> <div>✓No products of animal or organic origin</div>																																									
2.8	<div>Field of use – Indications: SAFIRE implant is indicated for the treatment of female stress urinary incontinence as a urethral support tape.</div>																																									
3. Sterilization																																										
3.1	<div>Sterilized: <input checked="" type="checkbox"/>YES <input type="checkbox"/>NO</div>																																									
3.2	<div>Sterilization process:</div> <div>Instrumentation: Gamma ray radiation according to ISO 11137-1:2016 (A2:2019) and ISO 11137-2:2015</div> <div>Implant: Ethylene Oxide according to NF EN ISO11135:2014 and NF EN ISO10993-7:2008(A1:2019)</div>																																									
4. Storage conditions																																										
<div>Packaging: 1 implant packed in a PETG tube AND sealed double Tyvek bags AND filmed cardboard box 240mm x 220mm x 20mm or filmed cardboard box 224mm x 152mm x 48mm for kits (non contractual photo)</div> <div><div>or</div></div> <div>Expiration: 5 years after sterilization</div> <div>Storage: no particular conditions, store at ambient temperature, please read D145 IFU</div>																																										
5. Safety																																										
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6.2	<div>Indication: SAFIRE implant is indicated for the treatment of female stress urinary incontinence as a urethral support tape.</div>																																									
6.3	<div>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.</div> <div>Warning: a defect in the positioning of the device may induce abnormal stresses and/or shorten the life of the device.</div>																																									
6.4	<div>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.</div>																																									

7. Additional information concerning the product

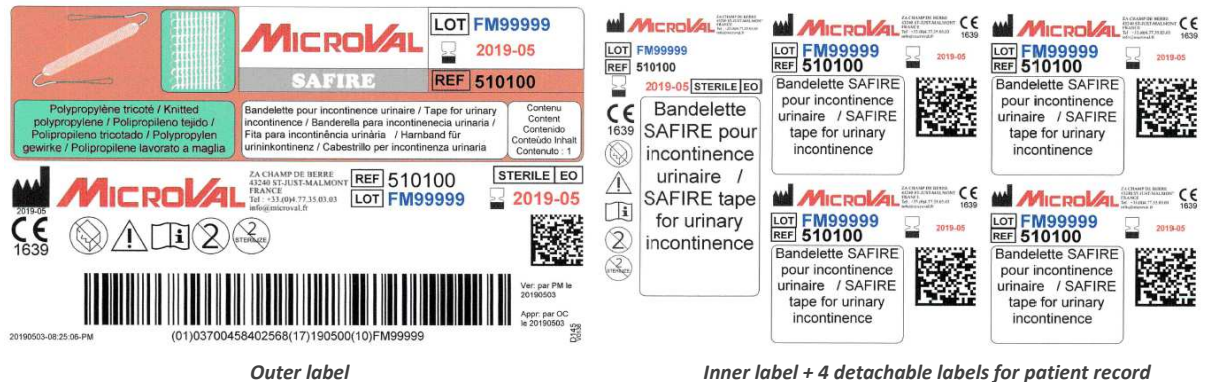
Bibliography, test reports:

- ❖ [Ref0498] "Outpatient mid-urethral tissue fixation system sling for urodynamic stress urinary incontinence: 3-year surgical and quality of life results" - R NAKAMURA, M YAO, Y MAEDA, A FUJISAKI, Y SEKIGUCHI - Int Urogynecol J. 2017 Nov;28(11):1733-1738
- ❖ [Ref0499] "Contemporary diagnostics and treatment options for female stress urinary incontinence" - A M DE VRIES, JPFA HEESAKKERS - Asian J Urol. 2018 Jul; 5(3): 141-148
- ❖ [REF0500] "Consensus Statement of the European Urology Association and the European Urogynaecological Association on the Use of Implanted Materials for Treating Pelvic Organ Prolapse and Stress Urinary Incontinence" – CR Chappel et al. - Eur Urol. 2017 Sep;72(3):424-431

8. Appendices

8.1 IFU: D145

8.2 Labelling example:



8.3 Symbols used in IFU and/or labels:

