SPIRE'IT® SUTURE APPLIER TECHNICAL DATASHEET

1. Administrative information about MICROVAL

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2. Device information

2.1 Common name: SPIRE'IT® suture applier

2.2 Commercial name: SPIRE'IT

2.3 Nomenclature code: GMDN 59873 (for applier) / GMDN 35615 (for sutures)
EMDN H.02.99 (for applier) / EMDN H.01.99 (for sutures)

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 : 37004584DT002-SPIREITHW

CE 1639

Certificate No. : FR19-81843429

2.5 Device's description:

SPIRE'IT® is a mechanical suture used in implant fixation or tissue approximation. It is used in numerous surgical procedures such as hernia cures or repair.

SPIRE'IT® is manufactured from a shape memory alloy wire, Nitinol. At rest, SPIRE'IT®has the shape of a spring with two turns of approximately 4 mm diameter. Sutures 10 are placed straight in a barrel and return to their original shape when implanted.

The applier allows the placement of SPIRE'IT® sutures and is available in two sizes :

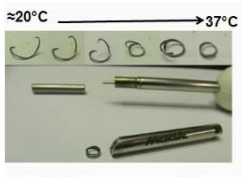
- A short applier of 7cm for open surgery
- A long applier of 30 cm for laparoscopic surgery

The diameter of each instrument allows the passage into 5 mm trocar.

Mechanical Characteristics* of the SPIRE'IT®suture:

Bulk density	6.5 g/cm^3
Maximum breaking strength	>1000MPa
Elongation at break	>10%
Spire Diameter	4mm
Dimension of wire	0.35 x 0.55 mm
Spire mass	<0.03g
Average pullout strength of a spire placed at a body temperature of 37 ° C	Between 10 et 15N

Average values given as an indication



2.6 References:

	SPIRE'IT® Suture applier
Short applier (7cm) + 10 sutures	943050
Short applier (7cm) + 20 sutures	943052
Long applier (30cm) + 10 sutures	943300
Long applier (30cm) + 20 sutures	943302

2.7 Device composition:

Physicochemical composition of SPIRE'IT nitinol sutures according to ASTM F 2063 (in %):

TI	Ni	O	H	C	Fe	Cu	Co	Nb	Cr
Balance	56.2	0.03	0.0010	0.0027	< 0.005	< 0.005	< 0.005	< 0.005	< 0.005

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

2.8 Field of use – Indications: MICROVAL's Spire'it® suture applier is used in general endoscopic or open surgery for meshes fixation, during hernia repair and approximation of tissues in various surgical specialties.

3. Sterilization

3.1 Sterilized: ☒YES ☐NO

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

4. Storage conditions

Packaging: 1 applier packaged in a single PETG blister and protective lid AND filmed cardboard box 483mm x 168 mm x 23.5mm (non contractual photo)


Or


or


Expiration: 2 years after sterilization
Storage: Store at room temperature. Avoid prolonged exposure to elevated temperature.

5. Safety

Please read IFU D128 (943050, 943300) or D132 (943052, 943302)

6. Usage

6.1 IFU: D128 (943050, 943300) and D132 (943052, 943302)

6.2 Indication: MICROVAL's Spire'it® suture applier is used in general endoscopic or open surgery for meshes fixation, during hernia repair and approximation of tissues in various surgical specialties.

6.3 Precautions for use: Excessive pressure on the tip of the applier during use, may cause jam and/or block it. After any implantation of SPIRE IT suture, always check carefully for haemostasis. The bleeding can be treated by electrocoagulation or manual suture. It is not advisable to recharge the Spire'it® applicator more than once during the same surgical procedure, otherwise the integrity of the fixation would not be guaranteed. The Spire'it® applier is designed for multiple use during one and single operation.
For safety reasons, any applier that has to be returned to MICROVAL must be decontaminated if it has been soiled.

6.4 Contra-indications: Do not use Spire'it® suture applier on vascular, nervous tissues nor on hard bodies (bones). It is however possible to place Spire'it® sutures above underlaying bones, vessels or viscera, but there must be a distance of not less 4.5 mm from the surface of the tissue to the underlaying structure. Do not use Spire'it® suture applier to perform haemostasis. Do not use Spire'it® suture applier on a site where it is impossible to visualy check haemostasis.

7. Additional information concerning the product

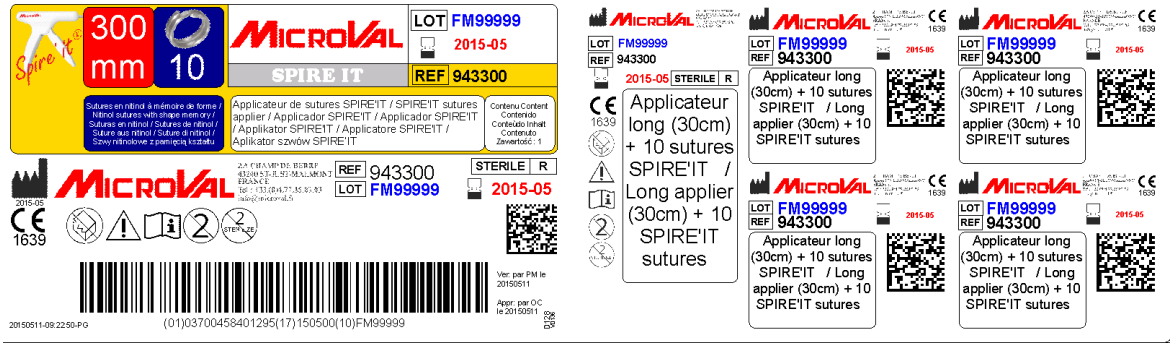
Bibliography, test reports:

- [296] A new porous titanium-nickel alloy: Part 1. Cytotoxicity and genotoxicity evaluation - M. ASSAD, A. CHERNYSHOV, M.A. LEROUX, C.H. RIVARD
- [297] Biocompatibility and corrosion resistance of NiTi - C. TREPANIER, A. PELTON -Source NDC
- [299] Medical Uses of Nitinol -A.R. PELTON, D. STOCKEL, TW. DUERIG - Materials Science forum Vols. 327-328 (2000) pp.63-70
- [300] Status of Nitinol as a Biomaterial - S.A. SHABALOVSKAYA- Journal of Biomedical Materials Research
- [307] The shape memory effect - Phenomenon, Alloys, Applications - Dieter Stockel - NDC, Nitinol Devices & Components, Inc., Fremont, CA
- [358] Evaluation of staples and protheses for use in laparoscopic inguinal hernia repair. Powell, Murray et al.
- [361] Assessment of usefulness exhibited by different tacks in laparoscopic ventral hernia repair. Smietański M, Bigda J et al
- [362] Mesh Fixation Devices and Formation of Intraperitoneal Adhesions. K. MEMISOGLU, K. SARIBEYOGLU, S. PEKMEZCI,et al
- Février 2011 - Etude MICROVAL sur résistance des sutures SPIRE'IT

8. Appendices

8.1 IFU: D128 (943050, 943300) and D132 (943052, 943302)

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 the instructions for use D128 (943050, 943300)
Please check the instruction for use D132 (943052, 943302)

Do not use if packing has been damaged

STERILE R **Sterilized with gamma ray radiation**

2 years after sterilization

Single use

Do not re-sterilize