

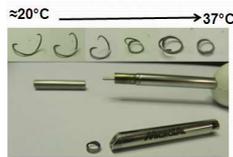
# SPIRE'IT<sup>®</sup> SUTURE APPLIER TECHNICAL DATASHEET



## Description

SPIRE'IT<sup>®</sup> is a mechanical suture used in the fixation of implants or tissue closing. It is used in many surgical procedures such as hernia repair.

SPIRE'IT<sup>®</sup> is manufactured from a shape memory alloy wire, Nitinol. At rest, SPIRE'IT<sup>®</sup> 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 applicator allows the placement of SPIRE'IT<sup>®</sup> sutures and is available in two sizes :

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

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

## Benefits

- ⊕ Ready to use, single-use
- ⊕ Easy to use
- ⊕ Rechargeable
- ⊕ Less traumatic for tissues Very few postoperative pain
  - ➔ Small or no post operative pain

## Material

**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

**Mechanical Characteristics of the SPIRE'IT<sup>®</sup> suture:**

Bulk density	6.5 g/cm <sup>3</sup>
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

Nitinol is a material known for the following characteristics:

- ❖ Super elasticity: Nitinol is able to be deformed up to 10%, in a reversible manner under the effect of a stress;
- ❖ High mechanical strength;
- ❖ Memory effect: the alloy NI-TI is able to recover by heating its original shape after mechanical deformation;
- ❖ Compatible MRI (Magnetic Resonance)
- ❖ Rubbery effect: the Ni-Ti alloy undergoing deformation when released retains a residual deformation;
- ❖ Damping effect: the alloy is capable of damping shocks or reduces mechanical vibration. In fact, the super-elasticity or even simply the elasticity of marten site phase exhibits a phenomenon of hysteresis which causes a dissipation of energy;
- ❖ Biocompatible;
- ❖ Not cytotoxic;
- ❖ Do not turn on "in vitro" the human complement system;
- ❖ Do not induce haemolytic effect;
- ❖ Do not induce significant changes in plasma fibrinogen level;
- ❖ Non-toxic;
- ❖ Not mutagenic;
- ❖ No clastogenic (DNA breakage).

D081 V2  
(En)

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Our technical and medical resources are constantly changing; the information contained in this document is purely indicative and may be subject to change without notice

## 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

## Clinical Data / Bibliographic References

- ❖ [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 Intraoperative Adhesions. K. MEMISOGLU, K. SARIBEOGLU, S. PEKMEZCI, et al
- ❖ Février 2011 - Etude MICROVAL sur résistance des sutures SPIRE'IT

## Symbols used on labels and/or instruction manuals



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



Do NOT use if the packaging is damaged



Single-use



Do NOT Re-sterilize

STERILE R

Device sterilized with GAMMA



2 years after sterilization



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