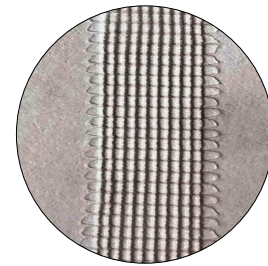


TECHNICAL DATA SHEET : SAFIRE® IMPLANTS



Description

The implant SAFIRE® is a biocompatible⁽¹⁾ implant – Class IIb⁽²⁾ especially designed for the treatment of women stress urinary incontinence.

The implant is valid for 5 years after sterilization, is sold in double Tyvek bag, packaged in filmed cardboard box, and sterilized with ethylene oxide.

- (1) According to ISO 10993 – 1
- (2) According to European Directive 93/42/CEE (2007/47/CE)

Width of tape = 1.2cm

Benefits




- ⊕ Its knitting avoids any particle release
- ⊕ Non aggressive edges for tissues
- ⊕ Macro-porous surface for good tissue integration
- ⊕ The presence of the suture thread and its ends allows an easy and secure attachment to the needle tip* -> facilitates the placement of the tapes




Material

The SAFIRE® sling is available in knitted polypropylene

	Knitted Polypropylene
Composition	100% isotactic biocompatible polypropylene single-stranded knitted monofilament
Process	Ø 0,08 mm Ladder-proof knitting
Surface Mass	< 60g/m ²
Thickness	0,45 mm
Pore sizes	-
	Knitted Polypropylene
Resistance to splintering ISO 13938 – 1	>500kPa
Maximum breaking strength ISO 13934 – 1	>45N
Elongation at break ISO 13934 – 1	>40%
Porosity NF S 94-801 : 2007	65%
Rate of oiling NF S 94 – 167 – 5	<1,2%
Linear density Pr NF 94-801	0.391 g/m
Release	-
Surfactant residue level NF EN 1644 - 1	Complete absence

References

SAFIRE® tape made from Polypropylene and associated instrumentation SINGLE USE				
KIT SAFIRE UG-3S	510130	Tape Lenght = 50 cm Width = 1.2 cm		SAFIRE® tape made from Polypropylene Sterile Right spiral needle / Left spiral needle / Guide
KIT SAFIRE UG-1PS	510160	Tape Lenght = 50 cm Width = 1.2 cm		SAFIRE® tape made from Polypropylene Sterile Small curve needle
KIT SAFIRE UG-1S	510190	Tape Lenght = 50 cm Width = 1.2 cm		SAFIRE® tape made from Polypropylene Sterile Large curve needle

SAFIRE® tape made from Polypropylene			
SAFIRE	510100	Tape Lenght = 50 cm Width = 1.2 cm	SAFIRE® tape made from Polypropylene
Reuse Associated instrumentation			
UG-2 UG-3	952200 952300		Non Sterile Right spiral needle / Left spiral needle Non Sterile Right spiral needle / Left spiral needle / Guide
UG-1P	952600		Sterile Small curve needle
UG-1	952900		Sterile Large curve needle

Clinical data / Bibliographic references

- ❖ [149] Cure d'incontinence urinaire féminine par bandelette de prolène « TVT » : résultats préliminaires d'une enquête multicentrique et rétrospective - M. SOULIE, F. DELBERT-JULHES, X. CUVILLIER, P. MOULY, J. THANWERDAS, P. DUFEUIL, JM. LARROQUE, J. BERNSTEIN, R. SOULIE, C. CHEMASLE, P. BRUCHIER, N. VAZZOLER, P. SEGUIN, F. PONTONNIER, P. PLANTE – Progrès en Urologie (2000), 110, 622-628
- ❖ [155] Incontinence urinaire chez la femme: du nouveau dans la prise en charge et le traitement de l'incontinence urinaire - J. RAIGA, C. SAUSSINE, P. BARAKAT, P. CALMELET, E. CASTEL, D. JACQMIN, JP. BRETTESS
- ❖ [172] La bandelette trans-obturatrice: un procédé mini-invasif pour traiter l'incontinence urinaire d'effort de la femme - E. DELORME - Progrès en Urologie (2001), 11, 1306-1313
- ❖ [174] Traitement de l'incontinence urinaire d'effort pure par bandelette sous-urétrale sans tension (TVT). Résultats à moyen terme d'une étude prospective sur 124 cas - R. VILLET, D. ATALLAH, O. COTELLE-BERNEDE, P. GADONNEIX, D. SALEE-LIZEE, M. VAN DEN AKKER - Progrès en Urologie (2002), 12, 70-76

Symbols used on labels and/or on the instructions for use



Please consult the instructions for use D145



Do NOT use if the packaging is damaged

STERILE EO

Device Sterilized with ethylene oxide



Single use



Do NOT re-sterilize

STERILE R

Device sterilized under Gamma Rays process
(Single Use instruments)



5 years after sterilization



Device non sterile (Re-Usable instruments)



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