Reference	*Title*	*Version*	*Device evaluated*
1.6	**Product Technical Form**	**V06**	**I-STOP**

Part 1.6
Product Technical Form
I-STOP device

Content

1. References and characteristics

Reference	Description	Unit	GTIN / UDI
IS-1	- I-STOP sling - Retropubic + transobturator Emmet needles	1	3760151650017
IS-5	- I-STOP sling - Retropubic + transobturator Emmet + helical outside-in needles	1	3760151650048
IS-6	- I-STOP sling - Transobturator helical inside-out needles	1	3760151650055
IS-10	- I-STOP sling - Retropubic + transobturator helical outside-in needles	1	3760151650093
IS-11-RO	- I-STOP sling - Transobturator retro-obturator inside-out needles	1	3760151650109
IS-13	- I-STOP sling - Transobturator helical inside-out / large needles	1	3760151650123
IS-HELICO-01	- I-STOP sling - Transobturator helical outside-in needles	1	3760151650192
IS-HELICO-03	- I-STOP sling - Transobturator helical outside-in / large needles	1	3760151650215
IS-M-1	- I-STOP sling - Retro-obturator needle	1	3760151650185
IS-1-A	- I-STOP sling	1	3760151650338
IS-20-RP	- I-STOP sling - Retropubic needle	1	3760151650000
IS-20-HL	- I-STOP sling - Transobturator helical	1	3760151650147

Designation	Sling for female urinary incontinence
Trade name	I-STOP
GMDN code	47986
EMDN code	P080199
Class	II b
CE mark	HD 1960556-1
Invasive medical device	☑ Yes ☐ No
Contact time	• Sling: ☐ Short term ☑ Long term • Instruments: ☑ Short term ☐ Long term
Date first commercialization EU	2002-07-01

2. Manufacturer information

Name	APIS Technologies Sàrl
Address	Rue de l'Ouriette 141 – 1170 Aubonne - Switzerland
Tel.	+41 21 808 02 05
Website	www.apis.swiss
Email	contact@apis.swiss
Quality certification / Referential	EN ISO 13485 :2016
Certificate number	SX 1960556-1
Notified body	TÜV Rheinland LGA Products GrnbH , 90431 Nürnberg ID number 0197
EC representative	DiLo Médical SAS 4, rue Docteur Pravaz 69110 Sainte Foy Les Lyon - France

3. Device description

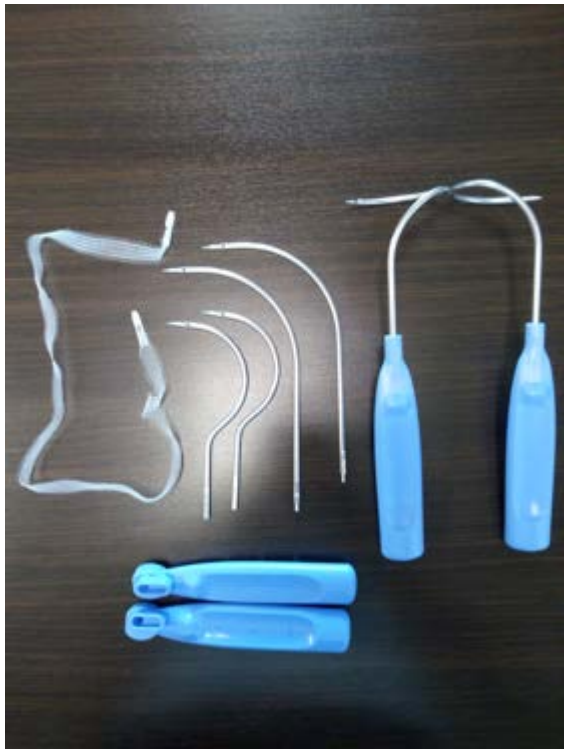
I-STOP is a single-use implant delivered sterile.

The implant is made from a mesh woven with a thread.

The thread used for the implant is 100% synthetic, made exclusively from a non-absorbable raw material (polypropylene monofilament).

The sling is a long-term implantable device used in the treatment of stress urinary incontinence in women and men and prolapse in women.

The sling is delivered with instruments (ancillaries) used to perform the implantation.



(example set ref. IS-5)

4. Implant characteristics

Material	Monofilament of polypropylene non resorbable USP class VI
Length	450 mm
Width	15 mm
Thickness	0,54 mm
Thread diameter	0,15 mm
Manufacturing process	weaving
Gram / surface mass	65 gr/m^2
Gram / lineic mass	1,02 gr/m
Particles release under tension (10N) according to standard NF S 94-801	-0,1 %
Pore size	Type I (classification Amid) Height: 1,17 mm Width: 1,17 mm
Tensile strength	> 66 N
Elasticity	• Elongation at 10 N: 6,1 % • Elongation at break point: 70,4 %

5. Instruments characteristics

Handles / material	Polycarbonate / Bayer Makrolon RX1805
Handles / dimensions	140 x 26 x 20 mm

Needles / material	Stainless steel 316 L / UGIMA 4435 ICH
Needles / diameter	4 mm

Guide / material	Stainless steel 316 L
Guide / dimensions	L 90 mm / l 27.5 mm / w 0.5 mm

Connectors / material	Polyethylene / HDPE Purell GC 7260
Connectors / diameter	5 mm
Connectors / length	24 mm

6. Validation based on specifications

Title	Specification	Tests results	Tests results
Resistance of the sling	Traction test: 40N tolerance + ∞ N / - 5 N	Batch 191212CL: • 45.2 N • 44.4 N • 47 N • 57.3 N • 47.4 N Validated ✅	Batch 191012CL: • 58 N • 51.8 N • 53.8 N • 54.8 N • 51.2 N Validated ✅
Resistance of the connector to the sling	Traction test: 40N tolerance + ∞ N / - 5 N	Batch 191212CL: • 51.4 N • 45 N • 41 N • 59.1 N • 48.7 N Validated ✅	Batch 191012CL: • 54.5 N • 49.2 N • 51.2 N • 54.2 N • 48 N Validated ✅
Resistance of the connector to the needle	Traction test: 70N tolerance + ∞ N / - 5 N	Batch 191212CL: • 77.1 N • 88.7 N • 87.3 N • 83.9 N • 80 N Validated ✅	Batch 191012CL: • 89.5 N • 72.7 N • 82.8 N • 83.8 N • 82.1 N Validated ✅

7. Components of the device and nature of the materials

Sling	Monofilament of polypropylene
Connectors	Polyethylene
Handles	Polycarbonate
Needles	Stainless steel 316 L

Substances actives substances	☐ Yes	✅ No
Presence of latex	☐ Yes	✅ No
Presence of PVC	☐ Yes	✅ No
Presence of phthalates	☐ Yes	✅ No
Presence of DEHP	☐ Yes	✅ No
Presence of Bisphenol A	☐ Yes	✅ No
Presence of animal or biological product	☐ Yes	✅ No

8. Indication

Application aera	Gynecology - Urology
Indication	I-STOP® is intended to be used for the treatment of female urinary incontinence.

9. Instructions

Instructions for use	Refer to the Instructions For Use
Contraindications	Refer to the Instructions For Use
Warnings	Refer to the Instructions For Use
Precautions	Refer to the Instructions For Use
Adverse Reactions	Refer to the Instructions For Use

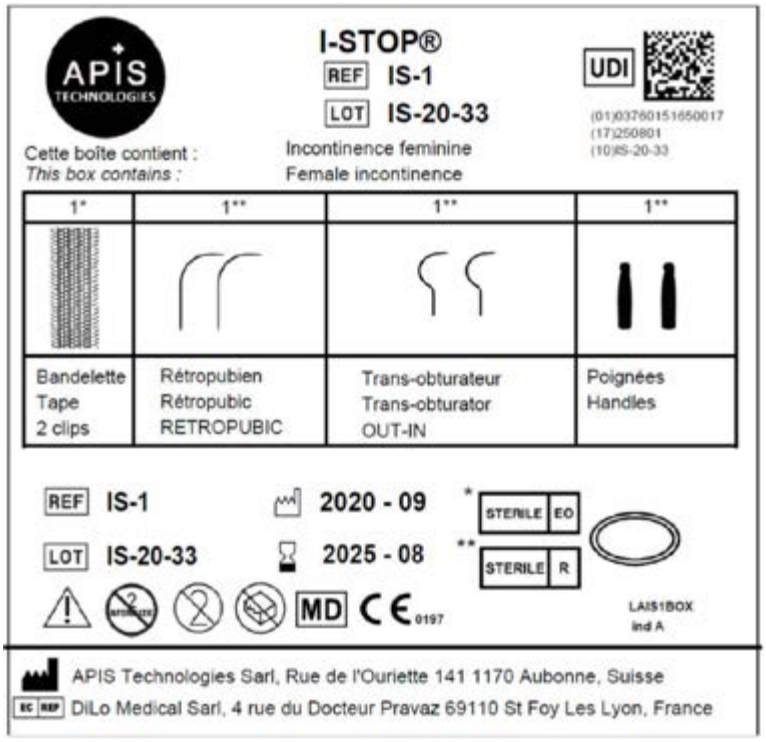
10. Sterilization process

Single Use	✅ Yes ☐ No
Sterile	✅ Yes ☐ No
Sterilization method	• Sling (implant): ethylene oxide • Ancillaries (instruments): Gamma
Sterilization site ETO	STERLAB 2720 Chemin de Saint-Bernard, 06220 Vallauris, France
Sterilization site Gamma	IONISOS Route de Balan, 01120 Dagneux, France
Validation sterilization ETO	✅ Yes ☐ No
Validation sterilization Gamma	✅ Yes ☐ No

11. Storage conditions

Conservation and storage	Standard conditions, keep dry and clean
Shelf life	5 years

12. Labeling

Sling	
Ancillaries	
Traceability	
Box	

13. Packaging

Sling:
- Double PETG blister

Ancillaries:

- Primary: PA/PE pouch
- Secondary: Tyvek pouch

Traceability labels

Box with external label:
- Cardboard box
- Dimensions:
  320 x 140 x 60 mm
- Protection wrapping

14. Document revision history

Ind.	Date	Made by	Update
V01	08/10/2020	VG	Creation
V02	22/10/2020	VG	Add GTIN codes
V03	07/06/2021	VG	Update ISO + CE certificates numbers
V04	26/08/2021	VG	Add traction tests results (§6), connector and guide dimensions
V05	22/12/2021	VG	EMDN codes
V06	11/02/2022	VG	Additional references