

1 Product

Name	REF	93/42/EEC	Canadian MDR	Type of Product
i-stitch	IST1010	I 6		medical device
i-stitch Loading Unit PP 0	IST1011	IIb 8	I 3	medical device
i-stitch Cleaning Brush	IST1020	-	-	accessory
i-stitch Loading Unit PDO 2-0	IST1021	III 8	III 3	medical device
i-stitch Loading Unit PET 0 W	IST1031	IIb 8	III 3	medical device
i-stitch up	IST1040	I 6		medical device
i-stitch Loading Unit PET 0 G	IST1041	IIb 8	III 3	medical device
i-stitch Loading Unit PDO 0	IST1051	III 8	III 3	medical device

2 Intended Use

The devices in the A.M.I. i-stitch System are used to fasten sutures to tissue.

3 Clinical Applications

The devices in the A.M.I. i-stitch System enable medial attachment to the sacrospinous ligament during pelvic floor reconstruction and vaginae fixation sacrospinalis.

4 Product Description

The multiple use instruments – i-stitch and i-stitch up – are equipped with a disposable loading unit, which comprises the thumb-slider, a dispenser, a hollow needle and specially formed suture material. Once loaded, the reusable instrument is ready for suture fixation in just three simple steps.

5 Functional Principle

The i-stitch (up), fitted with an i-stitch Loading Unit, is guided along the surgeon's finger to the intended suture fixation point (at the instrument tip is a guide that serves to elicit the distal end). The tissue is grasped by the i-stitch's jaw-shaped tip. The i-stitch Loading Unit is pushed forward until its suture is secured in the i-stitch's tip. While the suture stays in place, the i-stitch Loading Unit is pulled back.

The i-stitch's tip is loosened from the tissue and pulled back. Hence the suture slides through the initially penetrated tissue. As soon as the surgeon has both ends of the suture at hand, the suture can be cut off the i-stitch's tip.

i-stitch

To meet the surgeons' preferences, the i-stitch is available with its jaw-shaped tip away from the thumb-slider (i-stitch) and towards the thumb-slider (i-stitch up). The i-stitch (up) is a multiple use device, designed to be reprocessed in the cleaning automate and sterilization in the autoclave. The device is provided with a special cleaning brush, which may be used to remove debris inside its shaft.

It can be fitted with all types of i-stitch Loading Units offered by A.M.I.

Technical File

The i-stitch serves for:

- a) grasping the tissue intended to fasten the suture.
- b) securing the i-stitch Loading Unit's suture, as soon as penetration of the tissue is completed.
- c) bringing the suture's distal end to the surgeons hand.
- d) length markings serve as a guide to determine how deep the tip of the i-stitch inserted in Situ

i-stitch Loading Unit

The i-stitch Loading Units offered differentiate in the suture contained:

- IST1011 monofile polypropylene USP 0
- IST1021 monofile polydioxanone USP 2-0
- IST1031 braided polyester USP 0 undyed (white)
- IST1041 braided polyester USP 0 green
- IST1051 monofile polydioxanone USP 0

Each i-stitch Loading Unit is provided sterile.

The disposable devices comprise a thumb-slider, a dispenser, a hollow needle and a suture with a specially formed tip.

The hollow needle is filled with the suture and enables tissue penetration. The suture's tip aligns to the hollow needle's distal end and is encased by the i-stitch's tip, as soon as tissue is completely penetrated.

The hollow needle is pushed through the tissue and pulled back vial the thumb-slider.

When removing the i-stitch including the i-stitch Loading Unit the remaining suture slides out of the dispenser.

6 Technical Detail

i-stitch:

Total length:	284 mm
Length of jaw-shaped tip:	14 mm
Max. outer diameter:	10 mm

i-stitch Loading Unit:

Length of suture:	700 mm
Size of suture:	see above

6.1 Materials

Stainless steel, suture (for details see above)

6.1.1 General Material Related Data

- Implanted materials are compatible for MRI use with magnetic field strengths up to 3 Tesla.
- The materials used do not contain latex as intentional additive or ingredient.

Technical File

6.2 Delivery Status

Name	REF	Delivery Status	Method of Sterilization	Shelf Life
i-stitch	IST1010	non sterile	autoclave	not limited
i-stitch Loading Unit PP 0	IST1011	sterile	EO	5 years
i-stitch Cleaning Brush	IST1020	non sterile	-	not limited
i-stitch Loading Unit PDO 2-0	IST1021	sterile	EO	3 years
i-stitch Loading Unit PET 0 W	IST1031	sterile	EO	5 years
i-stitch up	IST1040	non sterile	autoclave	not limited
i-stitch Loading Unit PET 0 G	IST1041	sterile	EO	5 years
i-stitch Loading Unit PDO 0	IST1051	sterile	EO	3 years

6.3 GMDN (Global Medical Device Nomenclature)

37839 / Suture/needle passer, reusable

13908 / Polyglycolic acid suture

13908 / Polyglycolic acid suture

13909 / Polypropylene suture

7 Features

- secure attachment of sutures to structures which are not easily accessible
- blunt, non-cutting suture tip for pushing through tissue
- reduced risk of bleeding from the suture puncture site
- safe and quick, even in hard-to-reach places

Created by

R&D Project Engineer: Simon Schneider

3.8.2015

Date, Signature

Approved by

QM: Alexander Gurnig

3.8.2015

Date, Signature

