



REF

IST1010 - i-stitch
IST1040 - i-stitch up
IST1011 - i-stitch Loading Unit PP 0
IST1021 - i-stitch Loading Unit PDO 2-0
IST1031 - i-stitch Loading Unit PET 0 W
IST1051 - i-stitch Loading Unit PDO 0
IST1020 - i-stitch Cleaning Brush

Operating manual
Gebrauchsanweisung
Manual de instrucciones
Användarhandledning
Kullanma kılavuzu

Mode d'emploi
Manuale operativo
Manual operacional
Bruksanvisning

CE 0297 IST1011, IST1031, IST1021, IST1051

CE IST1010, IST1040, IST1020

1. Product description

General description

A.M.I. i-stitch consists of a surgical instrument that is used for placing suspension sutures on tissue structures (vaginae fixatio sacrospinalis as according to Amreich / Richter) and / or surgical mesh implants during pelvic floor reconstruction in the field of urogynecology. It comprises of a reusable surgical instrument – i-stitch or i-stitch up – which, before use, must be equipped with a sterile, single-use loading unit carrying the surgical suture material. The sterile i-stitch loading units consist of following components: needle slider, cannulated needle, suture dispenser and specially formed surgical suture material designed as a blunt, ball-shaped suture tip. Currently four loading unit options are offered which are basically varying in suture material specifications only. Cleaning devices with different connectors help to mechanically remove debris inside its shaft and rinse the device.

i-stitch / i-stitch up

The i-stitch is a multiple use, surgical stainless steel device for surgical suture attachment. It can be fitted with all variants of i-stitch loading units offered by A.M.I.. Depth markings on the tip serve as a guide to determine insertion depth of the i-stitch tip. The instrument itself is available in two different variants with either dorsal (i-stitch) or ventral (i-stitch up), when considering a patient in lithotomy position, directed jaw-shaped tip.

It is recommended to use the i-stitch up for level III suture attachments at the arcus tendinous fasciae pelvis ligament before the retropubic insertion point.

REF	Name
IST1010	i-stitch
IST1040	i-stitch up

It is suitable for reprocessing by automated cleaning and disinfection and autoclave sterilization. The device is provided with a special cleaning brush, which is used to mechanically remove tissue and / or blood inside its shaft.

i-stitch loading unit

There is a selection of materials available for i-stitch loading units:

REF	Name	Material	Suture size
IST1011	i-stitch Loading Unit PP 0	monofil polypropylene	USP 0

IST1021	i-stitch Loading Unit PDO 2-0	monofil polydioxanone	USP 2-0
IST1031	i-stitch Loading Unit PET 0 W	braided polyester undyed (white)	USP 0
IST1051	i-stitch Loading Unit PDO 0	monofil polydioxanone	USP 0

The i-stitch loading units are provided sterile. The disposable devices comprise of a needle slider (incl. suture clamp), a suture dispenser, a cannulated needle and a suture with a specially formed tip. The cannulated needle is filled with the suture and enables tissue penetration. The suture's tip is aligned to the cannulated needle's distal end and breaches the i-stitch's tip, as soon as the tissue is completely penetrated. The cannulated needle is pushed through the tissue and pulled back via the needle slider.

i-stitch cleaning device

The i-stitch Cleaning Brush is used for mechanical cleaning of the shaft of the i-stitch / i-stitch up.

REF	Name
IST1020	i-stitch Cleaning Brush

2. Intended use

A.M.I. i-stitch / i-stitch up:

Reusable instrument for suture attachment to tissue with or without surgical mesh implants. To be used with A.M.I. i-stitch Loading Units.

A.M.I. i-stitch Loading Units:

Single use sterile Loading Units with polypropylene / polydioxanone / polyester fixation suture to attach to soft tissue and / or surgical mesh implants. To be used with the A.M.I. i-stitch Instrument.

i-stitch Cleaning Brush:

Brush to enable the cleaning of the A.M.I. i-stitch Instrument.

3. Definition



Figure 1: i-stitch

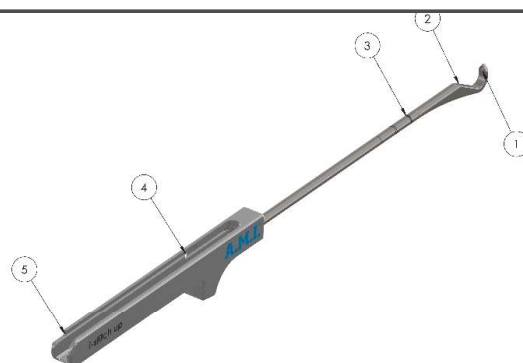


Figure 2: i-stitch up

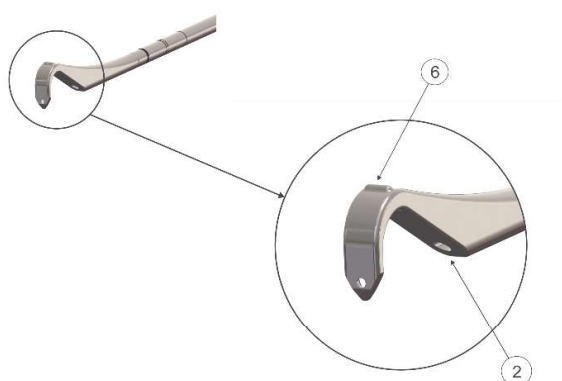


Figure 3: i-stitch tip

Pos.	Description
1	Blunt instrument tip
2	Needle opening
3	Depth marking
4	Guiding slot end
5	Guiding slot
6	Reference marking

Table 1: Legend figures 1-3

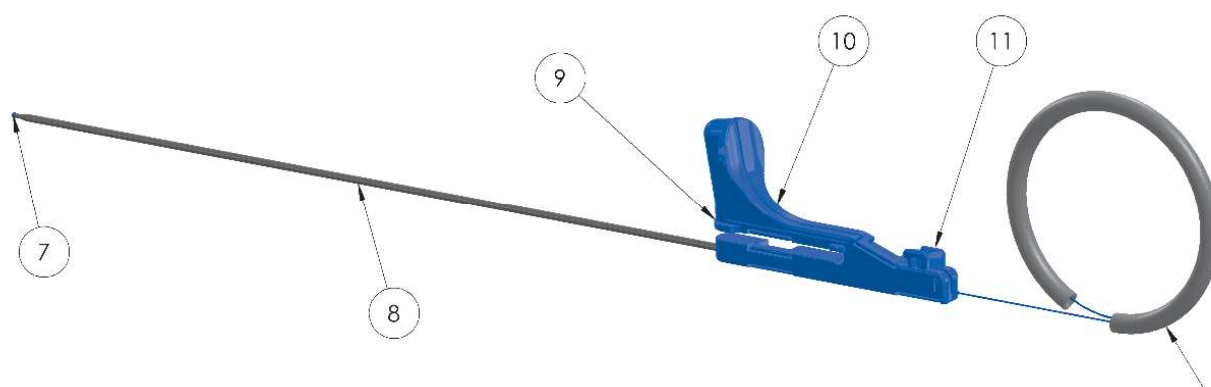


Figure 4: i-stitch Loading Unit

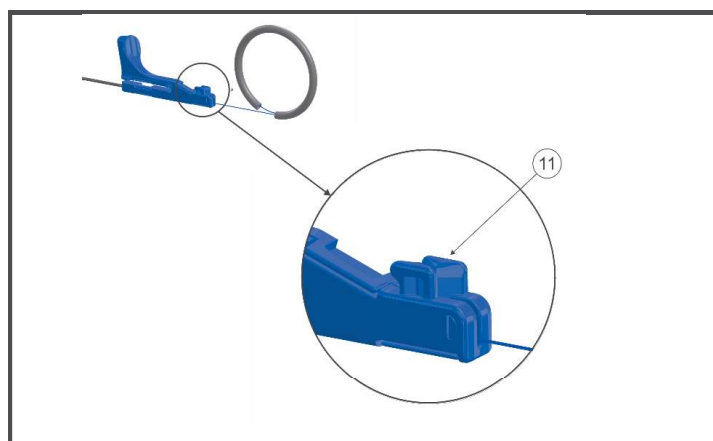


Figure 5: i-stitch Loading Unit - suture clamp

Pos.	Description
7	Blunt suture tip
8	Cannulated needle
9	Sliding guide
10	Needle slider
11	Suture clamp
12	Suture dispenser

Table 2: Legend figure 4-5

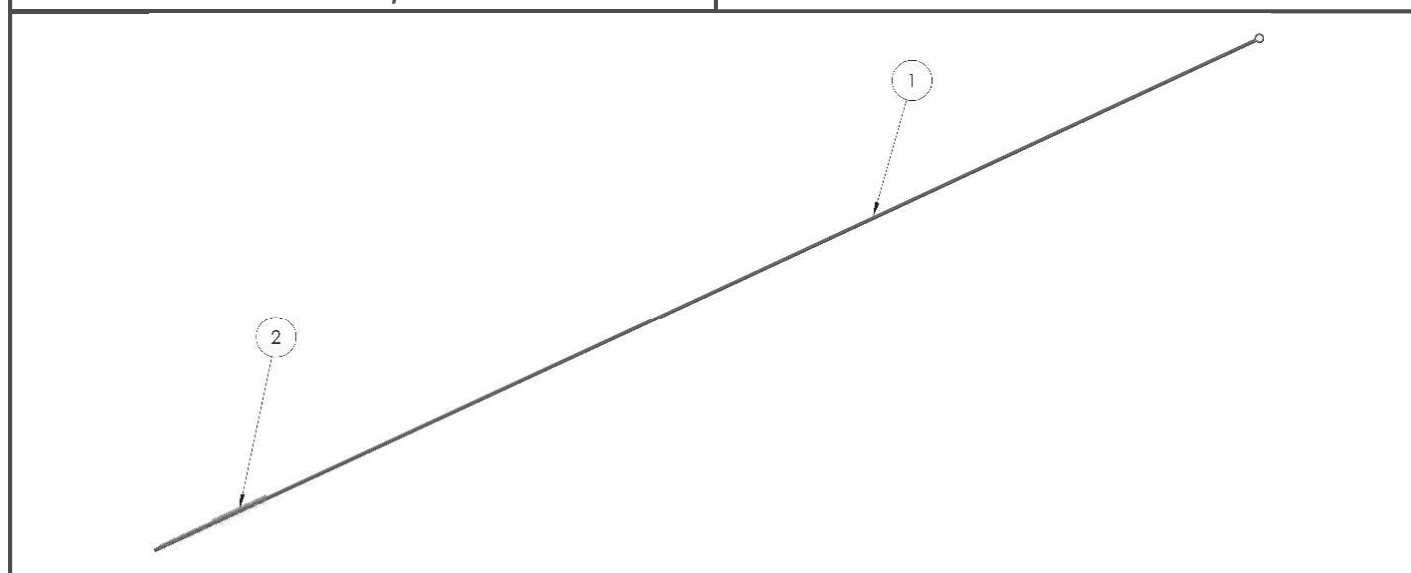


Figure 6: i-stitch Cleaning Brush

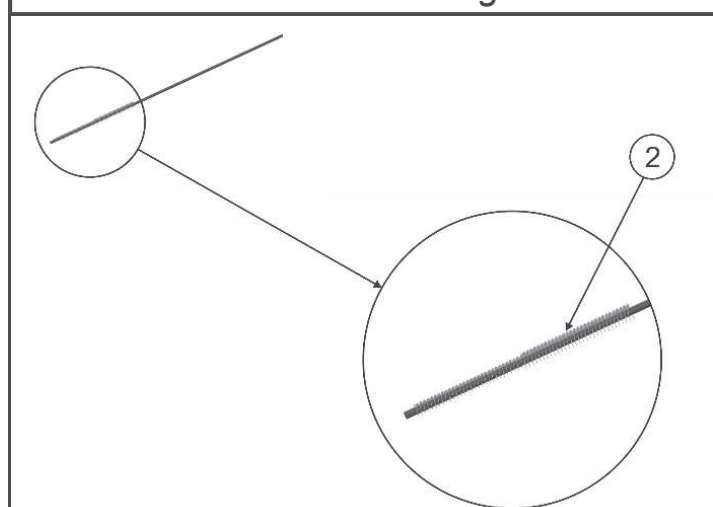


Figure 7: i-stitch Cleaning Brush - brush

Pos.	Description
1	Wire
2	Brush

Table 3: Legend figure 6-7

4. Product features and Clinical benefits

- easy application of sutures to tissue structures that are difficult to access
- blunt, non-cutting suture tip
- loading units with resorbable and non-resorbable suture material
- suitable cleaning accessories

5. Patient group

Patients of 18 years and older.

6. Indications

i-stitch is indicated for pelvic floor reconstruction; for native tissue repair or synthetic mesh placement.

7. Contraindications

Contraindications associated with the use of the product are, but not limited to:

- infection (active or latent)
- allergies to the materials used
- benign or malignant changes
- anticoagulation disorders
- autoimmune connective tissue disorders
- for placing sutures into or through bone

The use of the product is generally contraindicated if the treatment or the procedure as such is not suitable in the opinion of the treating physician, for example, due to the general condition of the patient.

8. Patient information

The surgeon performing the procedure should ensure that the patient or his legal representative, is correctly and comprehensively informed on the benefits and risks associated with the use of an i-stitch. Before the procedure, the patient or his legal representative must be informed of the following additional issues:

- specific complications / residual risks associated with the proposed procedure
- suitability of the patient's condition for the procedure
- evidence / level of experience of the performing surgeon with the surgical procedure

9. Possible complications / Adverse Events

Possible complications and / or adverse events connected with use of i-stitch are (but not limited to):

- bleeding, hematoma
- pain (ongoing or transient)
- infection
- nerve damage
- acute inflammatory tissue reaction
- post-operative bleeding, vaginal discharge
- transitory local irritation

10. Safety related information

Danger The keyword „**danger**“ indicates a hazard with a potentially high risk, which if the hazard is not avoided, the consequences are severe injuries or death.



Warning The keyword „**warning**“ indicates a hazard with a medium risk, which if the hazard is not avoided, the consequences are severe injuries.



Caution The keyword „**caution**“ indicates a hazard with a low risk, which if the hazard is not avoided, the consequences are minor or moderate injuries.



Note The keyword „**note**“ indicates a safety information which shows a condition which has to be complied, information for understanding, as well as tips and recommendations for the effective use of the product.



User group/ user qualifications:





















The products are intended for use by qualified and expert medical specialists. An understanding of the principles of the appropriate surgical techniques is a prerequisite.



Checklist before use:

The product has to undergo a visual check before use whereby attention must be paid to the following:

- Integrity of the sterile barrier packing
- Expiry date on the sterile barrier packing
- Damage due to inappropriate transport or storage

11. Warnings and precautions

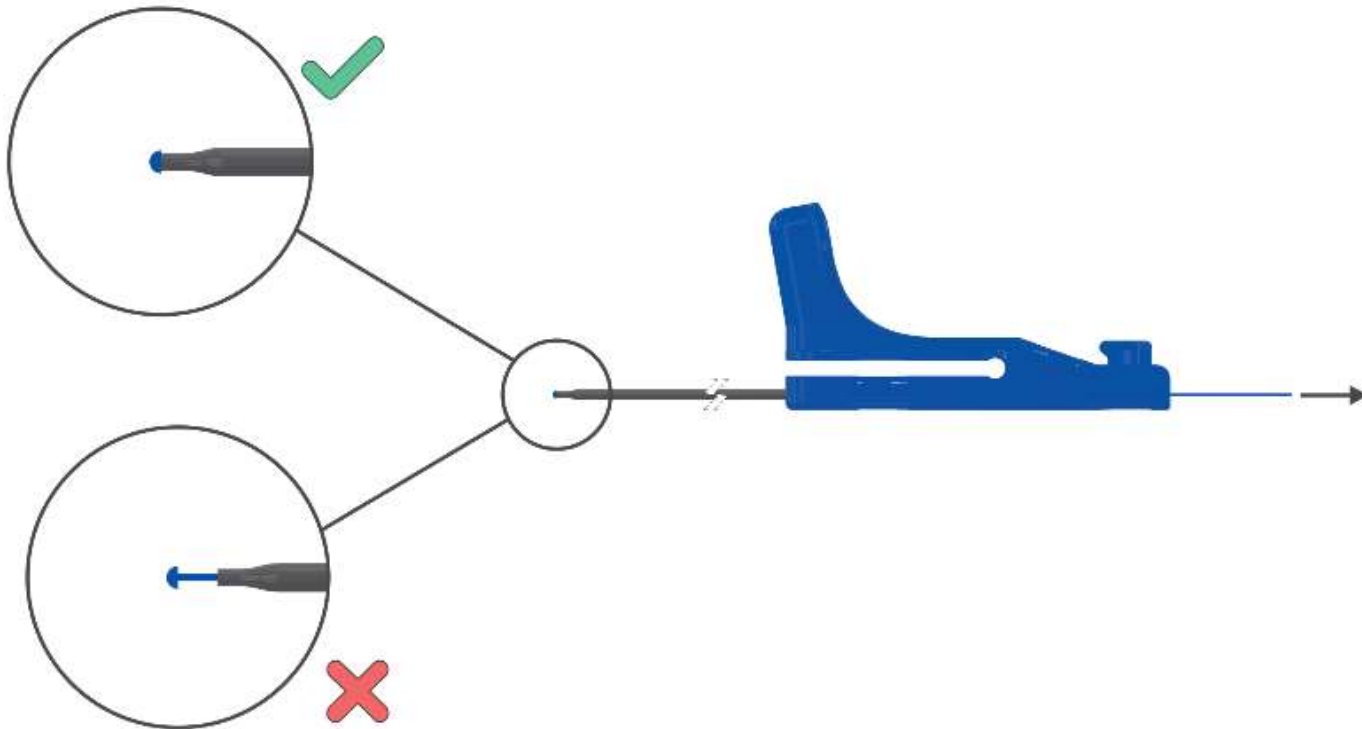
Warning 	The instructions for use at hand has to be stored to be available for the entire lifetime of the product.	
Warning 	The information in the current instructions for use, as well as the information accompanying the products used in combination must be adhered to.	
Warning 	The product must not be used for any purposes other than the purpose mentioned above.	
Warning 	Do not attempt to alter this product in any way. Doing so may endanger the patient and / or user.	
Warning 	The use of damaged products or products which do not function perfectly is to be avoided.	
Warning 	The product has to be reprocessed prior to each clinical application. Use sterile products only.	
Warning 	Do not re-sterilize or reuse disposable products.	 
Warning 	Do not use the product after the expiry date.	
Warning 	Do not use products that have open or defective sterile barrier packaging.	
Warning 	Use of product by medical personnel only.	
Warning 	Only the products and components specified by A.M.I. are to be used for the i-stitch / i-stitch up instrument.	
Warning 	If the product comes into contact with non-sterile objects or similar, contamination is to be expected and a change to a sterile product must be made.	
Warning 	The markings on i-stitch sheath are not suitable for measurements. They only serve to visualize how deep the tip of the i-stitch is in situ.	
Warning 	Use of the i-stitch / i-stitch up may damage blood vessels, nerves, other organs and structures that require immediate surgical repair.	
Warning 	To avoid unintentional puncture of the tissue, confirm proper instrument tip positioning. See surgical instruction.	

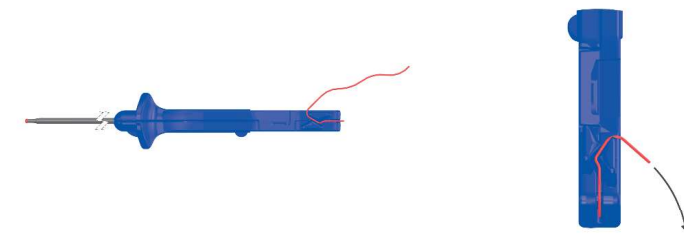
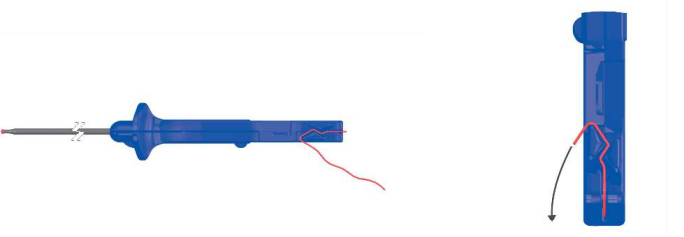

Warning 	Do not use the i-stitch / i-stitch up instrument for placing sutures into or through bone structures and / or cartilage.
Note 	To avoid malfunctions, the assembly and surgical instructions must be followed.

12. Product combinations and accessories

The i-stitch / i-stitch up can only be used in combination with the i-stitch loading units.

13. Assembly instructions

1.	Remove the i-stitch loading unit (Figure 4) from the sterile packaging.
2.	Pull off and remove the suture dispenser [12]. NOTE: If the suture is stuck in the suture dispenser [12], push the thread slightly back into the suture dispenser and then pull it out again.
3.	Gently pull the suture backwards, so that the blunt suture tip [7] is positioned directly at the end of the cannulated needle.
	
4.	As an option the suture can be secured under tension in the suture clamp [11].

		Clamping with right hand
		Clamping with left hand
5.	Insert the i-stitch loading unit into the guiding slot of a sterile i-stitch / i-stitch up (Figure 1 / Figure 2).	
		
	NOTE: Ensure that the blunt suture tip [7] is flush with the end of the cannulated needle [8].	
6.	Push the i-stitch loading unit (Figure 4) forward until the needle slider [10] is at the stop position. NOTE: At this time the blunt suture tip [7] and the cannulated needle [8] are completely covered by the needle opening [2].	

14. Surgical instructions

1.	Determine, by sight or palpation, where the suture is to be placed.
2.	Guide the blunt instrument tip [1] under vision or along the finger to the desired position. WARNING: Confirm proper instrument tip positioning to avoid unintentional puncture of tissue.

3.	<p>Grasp the tissue with the blunt instrument tip [1]. If necessary, apply pressure to the back of the blunt instrument tip [1] with the finger.</p> <p>NOTE: Existing marking is an orientation aid (6) to identify the distal end of the blunt instrument tip [1].</p> <p>ATTENTION: Existing depth markings (3) help to estimate how deep the blunt instrument tip is in situ.</p>
4.	<p>Push the needle slider [10] down and forward simultaneously until the blunt suture tip [1] has penetrated the desired tissue and has passed through and engaged in the blunt instrument tip [1].</p> <p>NOTE: If the suture is not secured in the suture clamp while advancing the needle slider [10], maintain suture tension by pulling the suture backward, so that the blunt suture tip [7] does not tilt sideways during penetration process (see 3. of assembly instruction).</p> <p>CAUTION: Do not exert any lateral force on the needle tip while advancing the needle slider [10] to ensure proper suture placement.</p> <p>NOTE: Advance the needle slider [10] fully to ensure that the blunt suture tip [7] is securely engaged in the blunt instrument tip [1] of the i-stitch / i-stitch up.</p> <p>NOTE: The final blunt suture tip placement position is confirmed by an audible "click". The needle slider [10] is fully advanced.</p>
5.	<p>If the suture is secured in the suture clamp it must be released now.</p> <p>CAUTION: The suture must be released from the suture clamp before the loading unit is withdrawn out of the i-stitch / i-stitch up (Figure 1 / Figure 2). Otherwise the connection between the blunt suture tip [7] and the blunt instrument tip [1] is loosen again.</p>
6.	<p>Withdraw the needle slider [10] including cannulated needle [8] out of the i-stitch / i-stitch up (Figure 1 / Figure 2) and dispose of it.</p>
7.	<p>Carefully retract the blunt instrument tip [1] from the tissue and pull back the i-stitch / i-stitch up until the two halves of the suture are approximately the same length and can be grasped.</p> <p>NOTE: In order to avoid premature detachment of the blunt suture tip [7], the suture must lie and glide freely in the operating field when removing the i-stitch / i-stitch up (Figure 1 / Figure 2).</p>
8.	<p>7. Separate the i-stitch / i-stitch up from the suture by cutting the blunt suture tip [7]. Now suture is placed in the tissue and ready for further use.</p> <p>CAUTION: After each use of the i-stitch / i-stitch up inspect the site for hemostasis.</p>

15. Disposal of the product

Reusable components (i-stitch / i-stitch up, i-stitch Cleaning Brush):



At the end of life the product has to be reprocessed prior disposal. The product has to be disposed according to current national laws and recommendation guidelines (e.g. RKI recommendations) for clinical waste.

Disposable components (loading units):



After the usage of the product it bears a potential biological hazard and has to be disposed according to current national laws and recommendation guidelines (e.g. RKI recommendations) for clinical waste.

16. Cleaning and Sterilization

The i-stitch loading units are disposable products and must be disposed of after use. They are neither suitable for reprocessing nor for reutilization!



The i-stitch Cleaning Brush is not intended for reprocessing with superheated steam. The product is only to be cleaned to such an extent, that no macroscopic contamination is visible anymore and subsequently to disinfect with a suitable disinfect agent (to prevent damage to the polyamide bristles of the cleaning brush). The i-stitch Cleaning Brush can be cleaned and disinfected in the RDG with the program VarioTD (Miele). Disinfectants must be used in accordance with the manufacturer's instruction (concentration, temperature, exposure time, etc.).

Warning



The instructions described have been validated by A.M.I. for the reprocessing of A.M.I. medical devices. The process is validated only with the mentioned cleaning and disinfection agents. The use of any other process, cleaning and disinfection agents shall be validated by the user himself, and will therefore carry the responsibility.

The following description regarding reprocessing correspond to ISO / EN ISO 17664 and are applicable to the mentioned products:

- i-stitch
- i-stitch up

For these products no manual disinfection is intended, as the cleaning and disinfection in the RDG shows significantly better results and thus ensures that the product will be sterile.

**Note**

The country-specific regulations and standards for the reprocessing of medical devices must be observed. For patients with Creutzfeldt-Jakob Disease (CJD), suspected CJD or possible variants of this disease, the applicable country-specific regulations regarding reprocessing of instruments must be applied.

**Note**

In those cases, where not specified in more detail, holding or exposure times of individual processing steps listed below refer to minimum values. In principle, the instructions of the manufacturers of the cleaning agents and disinfectants used must always be observed.

Application site	<p>Prevent any blood or other bodily secretions from drying on the surface:</p> <ul style="list-style-type: none"> • use a soft lint-free cloth to wipe off all the surfaces • rinse with cold, deionized water • flushing the i-stitch / i-stitch up sheath
Storage & transport	<p>Implementation of the treatment process within the shortest possible time, contamination should not dry out. Maximum time between application and treatment 6h.</p>
Preparation for cleaning	<p>Soak in alkaline cleaning solution for 10min</p> <p>Scrub off any dried-on blood or other bodily secretions with a soft brush and cold fully demineralized running water</p> <p>Clean the i-stitch / i-stitch up sheath with the help of the i-stitch Cleaning Brush (Figure 6)</p> <p>No macroscopic stains are visible (valid for all parts which are reprocessed)</p>

Machine cleaning	<p>Positioning the product in the cleaning and disinfecting machine (WD).</p> <p>Caution:</p> <ul style="list-style-type: none"> • all surfaces must be fully accessible to the alkaline cleaning solution • drainage of all blind holes, recesses etc. must be ensured • it is recommended to use the i-stitch Rinsing Needle (IST1050 or IST1060) for machine cleaning (for detailed description refer to IFU IST1050, IST1060) <p>The maximum load of the WD must not exceed. Use validated devices (ISO / EN 15883) only.</p> <p>Pre-rinse:</p> <ul style="list-style-type: none"> • soft water at 20°C for 6min <p>cleaning 1:</p> <ul style="list-style-type: none"> • de-ionized water at 40°C for 5min, with cleaning agent MediClean forte 0,5% • do not pump of the water between cleaning 1 and cleaning 2 <p>cleaning 2:</p> <ul style="list-style-type: none"> • water reused from cleaning 1, heat up to 55°C • cleaning for 6min <p>mid-cycle rinse:</p> <ul style="list-style-type: none"> • de-ionized water at 20°C for 1min <p>Cleaning agent: Validated detergents: Neodisher MediClean forte (Dr. Weigert) 0.5%; if alternative alkaline cleaning agents for machine cleaning are used follow instructions given by the manufacturer (pH ≥10,5).</p>
Machine disinfection	<p>Thermal disinfection:</p> <ul style="list-style-type: none"> • de-ionized water at 90°C for 5min • min. A₀ 3000
Drying	Drying at 95°C for 16min

Control, maintenance & examination	Visual inspection for cleanliness. If necessary, perform reprocessing process again until the instruments are visibly clean.
Packaging	Appropriate packaging for sterilization according ISP 11607 and EN 868.
Sterilization	<p>Sterilization in the autoclave by fractionated pre-vacuum process</p> <p>3 pre-vacuum phases with at least 60 mbar. Exposure time: 18 min. Sterilization temperature 134°C (max. 137°C)</p> <p>The maximum load of the autoclave must not exceed. Use validated device and process (ISO 17665) only.</p>
Storage	<p>See chapter transportation and storage</p> <p>Dry, clean and low-dust environment</p> <p>Valid storage duration and environmental conditions consult information given by the manufacturer of the used packaging.</p>

The person in charge of reprocessing is responsible for ensuring that the reprocessing actually performed achieves the desired results, taking into account the equipment, materials, and staff. This may require verification and / or validation and routine monitoring of the process.

Any deviation from the instructions provided by the person in charge of reprocessing should be carefully evaluated for its effectiveness and any possible adverse events.

17. Reprocessing documentation

The following table has to be filled out correctly after every sterilization process. If the table is not used another suitable method of documentation has to be used which indicates the same information shown in the table.

The user of the medical device is fully responsible for a complete documentation. The warranty expires if the documentation of the reprocessing cycles is not complete or not available.

seq. Nr.	LOT	S/N	cleaning method	used cleaningagent	serilizationmethod	applied sterilization cycle (temperature / time)	date	performed by
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								

seq. Nr.	LOT	S/N	cleaning method	used cleaningagent	serilizationmethod	applied sterilization cycle (temperature / time)	date	performed by
1	123456	001	WD, vario TD	Neodisher MediClean forte 0,5% Neodisher Z	steam autoclave	134°C/18 min	01.01.2018	John Smith

18. Maintenance and Inspection

A.M.I. recommends an annual inspection by the user. This inspection should include:

- visual inspection of i-stitch / i-stich up for any damages (e.g. bended i-stitch / i-stitch up sheath)
- other signs of wear that indicate the end of the product's service live, e.g. cracks which do not permit clean reprocessing or similar

19. Operating conditions

Temperature: +10°C to +25°C
Ambient pressure: 500 bis 1060hPa

20. Storage and Transport conditions

Avoid strong vibrations during transport. Transport and storage should be in a dry and clean environment, protected from water and other fluids, sunlight, dust, salt and other substances.

Storage (IST1011, IST1031):

Temperature: +10°C to +25°C
Ambient pressure: 500 bis 1060hPa
Rel. humidity: 30-75%

Storage (IST1021, IST1051):

Temperature: max. +25°C
Ambient pressure: 500 bis 1060hPa
Rel. humidity: 30-75%

Transport (IST1011, IST1021, IST1031, IST1051):

Temperature: -20°C to +60°C
Ambient pressure: 500 bis 1060hPa
Rel. humidity: 10-75%

21. Return and Repair

Return consignments are only accepted if all components have been cleaned and sterilized beforehand. Contaminated components must be correspondingly labeled for the return consignments.

RETURNS:

Returns will only be accepted if all components have been previously cleaned and

sterilized. Contaminated components must be marked accordingly upon returns. In the event of a defect, the entire product including the description of the defect must be sent back to the MANUFACTURER.

REPAIRS:



You may not carry out any product repairs on your own accord. This could endanger the user, patient or third parties and cause the warranty to become invalid.















22. Additional Information

This description is only a guide for the proper and safe use of this product by the user (medical staff / surgeon or their representation in the form of a health care facility). It does not constitute as a recommendation for surgical procedures. By using this product, the user declares and warrants that it is familiar with the operating method described here and that all regulations applicable in the country concerned with respect to this method are complied with. Care must be taken to ensure that this product is prepared and used appropriately by qualified staff. Defects and damages due to natural wear and tear, improper use, or modifications to the product which do not correspond to the user information are excluded from warranty. A.M.I. GmbH or its authorized specialist dealers are neither responsible for, nor obliged to compensate the surgeon or health care facility for incidental or causally determined losses, damages, or expenses arising directly or indirectly from the use of this product. A.M.I. GmbH will assume liability for product defects that existed before the product was shipped only if these defects are determined and reported before the product is used. Such cases will constitute only as a claim for replacement of the defective product.

All major incidents in relation to the product must be reported to the manufacturer and the appropriate authorities of the member state in which the user and / or patient is registered/located.

23. Symbols

Symbol	Description
	Refer to instructions for use
	Do not use if packaging is damaged

	Manufacturer
	Date of manufacture AT
	Do not reuse
	Do not re-sterilize
	Sterilized using ethylene oxide
	Batch code (The first two digits indicate the year of manufacture)
	Reference number (order number)
	Medical Device
	Expiry date
	This product complies with the applicable European Directives. The trailing four-digit number identifies the Notified Body.
	This product complies with the applicable European Directives.
	UDI in the HIBC Format
	Keep away from sunlight
	Temperature limit (low – high)



Temperature limit (high)

24. Specifications

i-stitch / i-stitch up

Lifetime /service life		Determined by wear and tear during the intended use of the product, but at least 2 years.
Maintenance		N/A
Dimensions	Total length	284mm
	Length of instrument tip	153,5mm
	Width of the instrument tip	4mm
	Shaft diameter	4mm
	Device weight	85g
Cleaning		Suitable for cleaning with a WD (see chapter 16 Cleaning and Sterilization)
Sterilization		Suitable for sterilization with an autoclave (see chapter 16 Cleaning and Sterilization)

i-stitch Loading Units

Lifetime /service life		For single use only
Maintenance		N/A
Dimensions	Total length	218,95mm
	Diameter cannulated needle	1,5mm
	Suture length	700mm
Sterilization		Sterilization with EO Delivered sterile, no reprocessing allowed

25. Materials

Component	Material	Nature of body contact	Contact duration*
IST1010/ i-stitch, IST1040/ i-stitch up			
Instrument handle	Stainless steel 1.4301	No contact	-
Instrument sheath	Stainless steel 1.4301	External communicating device / tissue, bone, dentin	A
Instrument tip	Stainless steel 1.4301	External communicating device / tissue, bone, dentin	A
IST1011/ i-stitch Loading Unit PP 0			
Loading unit	PBT Crastin S600F40 NC010	No contact	-
	Stainless steel 1.4301	External communicating device / tissue, bone, dentin	A
Suture	PP, monofilament	Implant device/ Tissue/ bone	C
Suture dispenser	PE	No contact	-
IST1031/ i-stitch Loading Unit PET 0 W			
Loading unit	PBT Crastin S600F40 NC010	No contact	-
	Stainless steel 1.4301	External communicating device / tissue, bone, dentin	A
Suture	PET, USP 0, white, braided	Implant device/ Tissue/ bone	C
Suture dispenser	PE	No contact	-
IST1021/ i-stitch Loading Unit PDO 2-0, IST1051/ i-stitch Loading Unit PDO 0			
Loading unit	PBT Crastin S600F40 NC010	No contact	-

	Stainless steel 1.4301	External communicating device / tissue, bone, dentin	A
Suture	PDO, monofilament, USP 2-0/ USP 0, violet	Implant device/ Tissue/ bone	C
Suture dispenser	PE	No contact	-
IST1020 / i-Stitch Cleaning Brush			
Wire	Stainless steel	No contact	-
Bristle	PA (Polyamid)	No contact	-

* According to ISO 10993-1: Limited exposure (A), Prolonged Exposure (B) or Long-term exposure (C)

26. Warranty

A warranty period of 24 months starting on the date of purchase applies to the product. The warranty will be annulled if the products are not used according to the specifications in the instructions for use or any changes at the device are made.

The expiration of the service life does not constitute as a warranty claim. In the event of a malfunction during the warranty period, please contact the supplier immediately.

27. Conformity

IST1020: The product complies with the requirements of REGULATION (EU) 2017/745 and is labelled with the CE mark accordingly.



IST1010/IST1040: The product complies with the requirements of Medical Device Directive 93/42/EEC and is labelled with the CE mark accordingly.



All other products: The product complies with the requirements of Medical Device Directive 93/42/EEC and is labelled with the CE mark accordingly.

CE0297