Instruction for Use

Suture Passer and Suture Passer Needle

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Made in Germany

Products: Suture Passer (instrument) with the item numbers STS-ART-400-170SP until STS-ART-403-170SP Suture Passer Needle STS-ART-430-170NN

Read this before using Strauss Surgical LLC. instruments and/or accessories.

General information
Please read these instructions carefully before using the surgical instruments. Improper and/or incorrect handling can have far-reaching consequences for the patient and/or user or may cause premature wear and tear.
The user is ultimately responsible for checking the instrument's functioning and sterility. Surgical instruments and accessories that are damaged and/or not fully functional must not be used. This instrument is a high-quality product, the proper handling and use of which are shown below. In order to keep the risks for patients and users as low as possible, we ask you to follow the instructions for use carefully. The usage, disinfection, cleaning and sterilization of the instruments may only be carried out by trained specialists.
Surgical instruments and accessories may only be used by people who have appropriate knowledge of how to use and apply them. Strauss Surgical LLC. assumes no liability for direct damage and/or consequential damage in the event of incorrect handling, improper use and non-observance of the intended use, as well as improper preparation and maintenance.

Indication
The Suture Passer in combination with the Suture Passer needle is suitable for guiding threads and reattaching tissue when repairing the rotator cuff.

Contraindication
The instrument must not be used on bones or hard tissues of a similar nature.

Warning
Whether used arthroscopically or in open surgery, the suture passer must be used under direct visualization.
CAUTION: The suture passer and suture passer needle may only be used in patients who have reached the age of 18.
CAUTION: Improper use may result in undesirable side effects and complications. These include needle breakage and failure to penetrate tissue.
CAUTION: The suture passer needle is supplied in a sterile state and is INTENDED FOR SINGLE USE ONLY. If the packaging is damaged, or the expiry date or sterility are questionable for any reason, the product should not be used. DO NOT clean, re-sterilize, or re-use the product, as this may damage the equipment or impair performance, and may expose the patient to infectious diseases.
CAUTION: There is a small risk of sensitization or irritation from nitinol in hypersensitive patients.

The suture passer (instrument) is not supplied in a sterile state. Sterilize the suture passer (instrument) with steam in accordance with the instructions in the **Sterilization** section of this instruction manual.

Preparation for use
Read the instruction manual in its entirety prior to using the instrument.
1. Inspect for damage to the suture passer, or sterile barrier in the case of the disposable needle. Do not use if product is damaged or sterile barrier is compromised.
2. Inspect the suture passer prior to use to ensure proper mechanical function.
3. Sterilize the suture passer with steam in accordance with the instructions in the **Sterilization** section of this instruction manual.
4. To insert the suture passer needle into the suture passer, remove the protective cap and insert the sharp end into the rear of the handle.
5. Clip the needle's plastic tip into the deployment lever.
6. With the jaw closed, actuate the needle deployment lever ONCE to confirm that the needle deploys and retracts.
7. CAUTION: Extending the needle in the air (dry) can affect the lifespan of the suture passer and/or the needle.

Instructions for use
1. With the jaw open, insert the suture into the tip of the instrument, making sure that it is pulled fully to the proximal end of the slot on the instrument's tip. It is recommended that one of the tails be at least 2cm long to improve suture management.
   CAUTION: Use only size #2 braided surgical sutures with the suture passer and suture passer needle from Strauss Surgical LLC.

   If the instrument is used in the open surgery, dampen the distal end of the instrument with sterile water.

   <u>If being used in an open procedure, omit the following references to the arthroscopic cannula:</u>

2. With the suture loaded and the needle retracted, pass the suture passer through the cannula into the surgical site under direct visualization.

   PLEASE NOTE: The suture passer should be used with a cannula of 6mm or larger.

3. When ready to pass the suture, open the jaw and position the jaws of the suture passer at the desired location to pass the suture. Close the jaw by carefully pressing the trigger, without activating the movement of the needle. If more room is required to open the jaw, pull the cannula proximally once the instrument is inside the rotator cuff.
4. To deploy the needle through the tissue, push the deployment lever as far as is necessary to create enough of a suture loop through the tissue.
5. After passing the suture, let go of the deployment lever so that the needle can retract completely. Open the jaw and grasp the loop of suture that has already passed through tissue with a hook or grasper from another portal. Alternatively, the tip of the suture passer can be used as a grasper for the suture. Remove the suture passer from the cannula.

   CAUTION: If the needle is not fully retracted, it will not be possible to remove the instrument from the tissue.

6. Remove the needle by taking the needle's plastic tip out of the deployment lever and pulling the needle back out of the instrument. Remove the disposable needle immediately after the operation, place the protective cap on the sharp end of the needle, and dispose of it in the sharps container for medical waste.
   <u>The suture passer needle is INTENDED FOR SINGLE USE ONLY</u>.

Storage
The instruments must be stored and handled with care. It is recommended that you remove the instruments from their plastic bags before storage to avoid condensation. Store the instruments with care in a suitable clean, dry place. Do not store in contact with or near products that can have a corrosive effect.
Store sterilized needles in a clean, dry, dust-free environment at moderate temperatures.

Information on reprocessing the suture passer (instrument)
Due to the product design and the materials used, 100 reprocessing cycles may be carried out. Due to wear-and-tear and damage from use and reprocessing, the instruments must be inspected before re-use and, if necessary, disposed of before 100 reprocessing cycles have been reached.

Manual reprocessing of the suture passer (instrument)
Manual reprocessing methods are unsuitable because a brush must be used. In the event of heavy soiling or improper handling during the cleaning process, this can lead to surface damage or damage to the medical products, thus affecting patient safety. Manual cleaning/disinfection does not guarantee consistent, reproducible cleaning results. For this reason, machine reprocessing methods must be used.

Instructions for the machine reprocessing of the suture passer (instrument)
(SMP validation project no. 02511013701)

General
The validation was carried out using the values/parameters of the processes described here, which are to be applied accordingly, depending on the existing conditions on site.
Remove coarse dirt from the instruments immediately after use. Do not use fixing agents or hot water (>40°C), as this leads to the fixing of residues and can affect the success of the cleaning process.

Preparing the suture passer (instrument) for reprocessing
The instruments may need to be opened for reprocessing.

Transporting the suture passer (instrument)
Safe storage in a closed container and transport of the instruments to the reprocessing site to avoid damage to the instruments and contamination to the environment.

Manual pre-cleaning of the suture passer (instrument)
1. The suture passer is placed in cold water for 5 minutes and then brushed with a nylon brush.
2. Then the hard-to-reach areas are rinsed with a water gun (with a static water pressure of at least 3.8 bar).
3. The instruments are then placed in an ultrasonic bath with a mildly alkaline cleaner (neodisher Mediclean, Dr. Weigert Hamburg) at 45° for 10 minutes.

Machine cleaning of the suture passer (instrument)
Now place the suture passer in an instrument sieve. Then start the following process:

Cleaning and disinfection device: G 7735 CD (Miele)

Cleaning program: Vario TD

Step	Time (min.)	Process step	Reagents	Temp. (C°)
1	2	Pre-cleaning	Tap water	Cold
2	-	Drain water	-	-
3	5	Cleaning	Tap water Dosage: 0.5% Neodisher Mediclean (Dr. Weigert, Hamburg)	55
4	-	Drain water	-	-
5	3	Neutralizing	Tap water	10-25
6	-	Drain water	-	-
7	2	Rinsing	Tap water	10-25
8	-	Drain water	-	-

Disinfecting the suture passer (instrument)
Machine thermal disinfection must be carried out taking into account the national regulations and the A0 value = 3000.

Drying the suture passer (instrument)
The outside of the instrument is dried using the drying cycle of the cleaning/disinfection device. If necessary, manual drying can also be carried out using a lint-free cloth. Dry the instrument's cavities using sterile compressed air.

Functional testing, maintenance, and care of the suture passer (instrument)
Optical inspection for cleanliness; care and functional testing. If necessary, repeat the reprocessing process until the instrument is optically clean.

Packaging of the suture passer (instrument) (SMP validation project no. 02511022601)
Standard packaging for sterilized instruments in accordance with EN ISO 11067 and EN 868. Instruments double-packed in sterilization bags (VP Stericlin).

Preparing and sterilizing the suture passer (instrument)
(SMP validation project no. 02511022601)
Before preparing the instrument components for sterilization, the surface and especially all moving parts should be carefully lubricated. We recommend grease-free and temperature-resistant silicone lubricants. This helps to keep the moving parts and threads accessible and also protects the entire instrument surface from mineral deposits, which can later lead to functional impairments. The lubricants must be biocompatible and approved for medical devices. Please note that lubrication of the instrument should be carried out routinely after each cleaning (ultrasound etc.) and before each sterilization.
Product sterilization using the fractional pre-vacuum process (EN ISO 17665) taking into account the respective national requirements.

- 3 pre-vacuum phases with at least 60 millibar pressure
- Heating to a sterilization temperature of 132°C
- Hold time: 3 to 5 min.
- Drying time: 10 min.

If you suspect contamination with prions (CJD), prepare and dispose of the instrument.

Additional instructions
If the chemicals and machines described here are not available and the reprocessing process cannot be carried out as described, it is the responsibility of the user to validate the process accordingly. It is the user's responsibility to ensure that the reprocessing process, including resources, materials and personnel, is appropriate to achieve the required results. The state of the art and national laws require compliance with validated processes.

Further information on the reprocessing of medical devices

- Internet: http://www.a-k-i.org
- Hygiene requirements for the reprocessing of flexible endoscopes and additional endoscopic instruments Recommendation of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI), Internet: http://www.rki.de
- Recommendation of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Requirements for hygiene in the reprocessing of medical devices".
- For information, as the product is re-sterilizable: DIN EN ISO 17664 Sterilization of medical devices. Information to be provided by the manufacturer for the preparation of sterilizable medical devices

Warranty Limitation

Strauss Surgical LLC. guarantees to manufacture your products with the greatest possible care.

THIS IS THE ONLY VALID WARRANTY AND IT REPLACES ALL OTHER WARRANTY STATEMENTS GIVEN.

It should be noted that due to the biological differences of the persons to be treated, no product is always effective under all conditions. Strauss Surgical. has no influence on the application of the product, on the diagnosis of the patients and on the handling of the product outside the company. Strauss Surgical. can neither guarantee a good effect nor a complication-free application of the product. Therefore, Strauss Surgical. does not assume any liability for damages and costs. Strauss Surgical. will replace products that show a defect that has been accepted by Strauss Surgical.

Employees of Strauss Surgical. are not entitled to change the above-mentioned conditions, to extend liability or to enter additional product-related obligations.

Products are subject to changes.

Instruction for Use

Suture Passer and Suture Passer Needle

Explanation of the symbols used
The symbols depicted on the medical device, medical device label, or instructions for use have the following meaning in accordance with DIN EN ISO 15223-1:

Suture passer (instrument)		Suture passer needle	
REF	Item number	REF	Item number
LOT	Batch number	LOT	Batch number
	Follow the instructions for use		Follow the instructions for use
	Caution! Follow the instructions in the accompanying documents		Caution! Follow the instructions in the accompanying documents
	Product is not sterile	STERILE EO	EO sterilized
	Manufacturer		Manufacturer
	Date of manufacturing		Date of manufacturing
	Do not use if packaging is damaged		Do not use if packaging is damaged
	Store in a dry place		Protect from light
			Store in a dry place
Rx Only	To be used by professionals only		
MD	Medical device	Rx Only	To be used by professionals only
			Do not reuse
			Do not re-sterilize
			Expiration Date
		20°C 15°C	Storage temperature