

Fascia suture assisting device

Indication

The instrument is used for wound closure following laparoscopic interventions.

Contraindication

This instrument is not designed for use on the central nervous and circulatory system.

Description

The instrument is used for wound closure following laparoscopic interventions. Using a retracting and extending catcher at the distal end, the suture can be securely placed in the subcutaneous tissue to make a subcutaneous knot. The needle guide improves handling and facilitates the setting of the knot in the subcutaneous tissue. /See section „Accessories“.

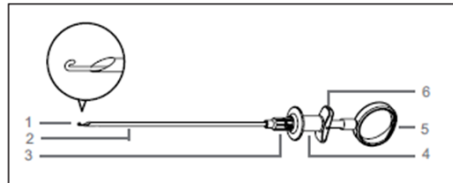


Figure: Suturing aid*

- 1 Catcher
- 2 Outer cannula
- 3 Bayonet catch
- 4 Main part
- 5 Thumb ring
- 6 Finger rest

Lifetime

The lifespan depends on the correct handling of the instrument. Bending or overloading causes damage. Careful reprocessing and proper handling guarantee more than 1000 operations.

If pores, stress cracks or cavities are visible, this instrument must not be used any further.

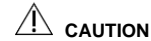
Function check

Following delivery and before each use new instruments must undergo a thorough visual examination and must be tested for functionality.

If the instrument exhibit any external faults (scratches, breakages, cracks, notches, damaged insulation, bent parts or stiffness)

or if they do not function in the way described, please inform us as manufacturer or our sales partners immediately.

The functional test shows whether perfect functioning of the instrument and its components can be ensured. Perform the functional test immediately after assembly.



CAUTION

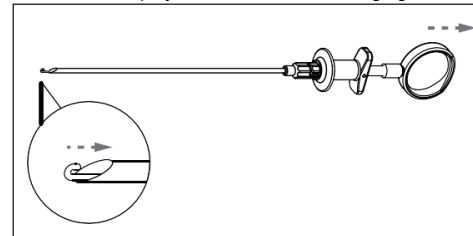
Risk of injury due to damage of product.

▲ Replace the instrument if the catcher cannot move freely.

▲ Replace the instrument if the point of the cannula is damaged.

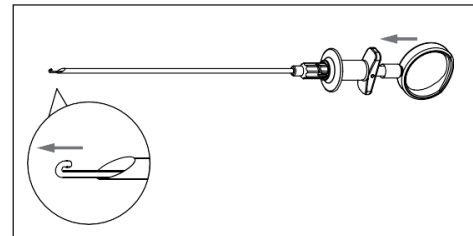
▶ Push the thumb ring against the finger rest.

→ The catcher projects out of the thumb ring again.



▶ Release the thumb ring again.

→ The catcher slides back into the sheath



Warnings and precautions: Handling

- Do not use damaged instruments.
- The instrument has only a limited stability. Force applied too strongly can lead to damage and negatively affects its functioning.
- Please be careful, especially at working ends, if the instrument has sharp cutting edges, teeth, tips, or sharp edges. Don't touch them.

First use of new instruments

- The instrument is delivered non-sterile. It must be cleaned and sterilized before the first use.

Warnings and precautions: Cleaning

- During preparation, the temperature affecting the instrument must not exceed 137°C,
- Automatic cleaning and disinfection is to be preferred to manual cleaning and disinfection. The automatic cleaning and disinfection procedure is much safer.
- Never use metal brushes/sponges or abrasive cleaning agents for manual cleaning.
- Only clean instruments and instruments of low microbiological contamination enable a successful sterilization.
- In case of damage the devices should undergo the complete reprocessing process before being sent back to the manufacturer for repair.
- Never use cleaning agents with bleaching agents, such as sodium hypochlorite, as it causes severe corrosion.

Preparation for cleaning

- After use, the instruments must be prepared as fast as possible.
- Remove residues and stains on the instrument immediately after use with a single use cloth or tissue.
- Do not use a fixating agents or hot water (>40°C) as this can cause the fixation of residues which may influence the result of the reprocessing process.
- Deposit them preferably in a dry place.
- If necessary; soak the instruments in a solution with a suitable combination of cleaning and disinfecting agents. Please, observe the manufactures' instructions of the cleaning and disinfecting agents.
- Put the instruments in suitable wire baskets.

Transportation

- Safe storage and transportation in a closed container to the reprocessing area to avoid any damage of the instruments and contamination of the environment.

Preparation

 Note	Please see our general preparation instruction A0462 for reusable instruments (thermostable). If you do not have these, please request them from us.
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Cleaning

Automated cleaning

- Clean and disinfect the instrument only in suitable washers and disinfectors (WD) and with for the WD and the instrument validated procedure / program according to EN ISO 15883.
- Suitable WDs are provided with special cleaning baskets / slide-in carts for sensitive instruments.
- Avoid any rinsing shadows when loading the WD slide-in cart with instruments in order to obtain an ideal rinsing pressure for the entire instrument. Pay special attention to the jaws.
- Do not overload the WD slide-in carts, do not pile them up.
- Please observe the instructions for use and loading indications of the WD manufacturer.
- When choosing the appropriate cleaning agents see the respective lists and recommendations of the Robert-Koch Institute (RKI) of the German society for hygiene and microbiology (Deutsche Gesellschaft für Hygiene und Mikrobiologie - DGHM) and consider the instrument's material and characteristics. See additional information of the preparation instructions at hand.

Cleaning agents for automatic cleaning in WD:

Manufacturer	Trade name
Dr. Weigert GmbH & Co. KG	Neodisher FA
Borer Switzerland	Deconex 23
	Neutrazym

*the suitability of the cleaning agent as well as subsequently described method has been demonstrated based on preclinical testing / validation by RUDOLF Medical.

A - Cleaning program (Miele G 7735):

- 1 min. pre-cleaning with cold water
- Draining
- 3 min. pre-cleaning with cold water
- Draining
- 5 min cleaning at 55°C with 0,5 % alkaline detergent
- or 5 min cleaning at 45°C with 0,5 % enzymatic detergent
- Draining
- 3 min. neutralization with warm water (>40°C) and neutralizer
- Draining
- 2 min. rinse with warm tap water (>40°C)
- Draining

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Maintenance, Control and Inspection

- After the cleaning and disinfection, the instruments must be inspected visually for cleanness. They must be macroscopically clean (no visible residues/soiling). Pay special attention to grooves, ratchets, closures and other difficult accessible areas.
- Should there still be any visible residues or liquids repeat the cleaning and disinfecting procedure.
- Prior to any sterilization the instruments must be assembled and inspected for function, wear and tear and for damages, and if necessary it has to be exchanged.

Packaging

- Appropriate packaging for sterilization according ISO 11607 and EN 868.
- Generally, adjust the sterilizing accessories and the sterile packing to the content of the packing instrument and the sterilization procedure.
- Please, observe the manufactures' instructions of the sterilizer.

Sterilization

- Sterilization is to be carried out using a steam sterilization procedure validated by DIN EN ISO 13060 / ISO 17665 (fractionated vacuum procedure) in a sterilizer in accordance with EN 285, DIN 58946.
- 3 pre-vacuum phases with at least 60 mbar pressure
- 134°C - 5 min or 132°C - 4min.
- Drying time: minimum 10 min.
- Please, observe the manufactures' instructions of the sterilizer.

Storage

- Only transport and store the instrument with appropriate protection
- The reprocessed instruments must be stored in suitable and reusable sterilization containers in accordance with DIN EN 868-1 and DIN EN 868-8, and should be stored until use in accordance with DIN 58953-9.
- The sterilizing container should be designed in such a way that the instrument is safely fixed and protected from damage.
- Storage of sterilized instruments in a dry, dark, low microbiologically contaminated clean and dust free environment at moderate temperatures of 5°C to 40°C.

- The storage area should be free of temperature fluctuations.

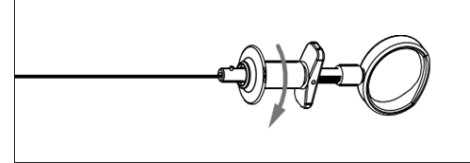
Additional Instructions

- If the described chemistry and machines are not available, it is the duty of the user to validate his process.
- It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly. Likewise, any modification by the reprocessor from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.

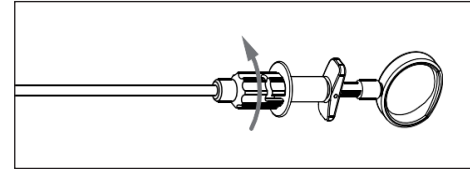
Assembly and disassembly of the instrument

Assembly of the instrument

- ▶ Insert the main part and screw on the finger rest.



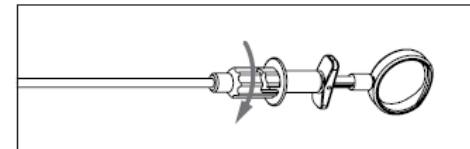
- ▶ Attach the outer cannula and close the bayonet catch



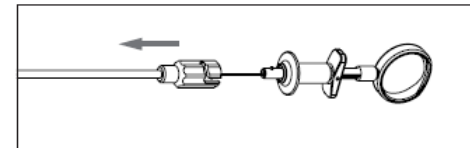
- ▶ Perform functional test.
/See chapter „Perform functional test“.

Disassembly of the instrument

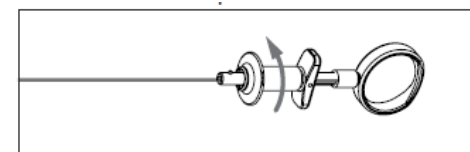
- ▶ Open the bayonet catch.



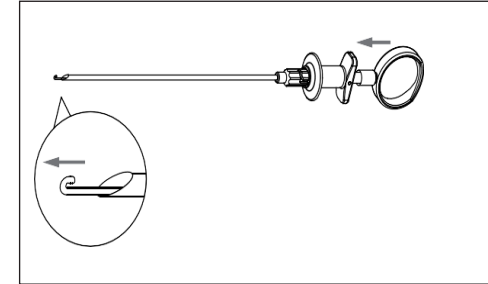
- ▶ Pull out the outer cannula.



- ▶ Hold the instrument by the finger rest and unscrew the main part

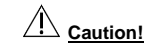


- ▶ Release the thumb ring again.
→ The catcher slides back into the sheath



Repairs

- Even when used as intended surgical instruments are subject to more or less severe wear, depending on how intensely they are used. This wear cannot be avoided due to technical reasons.
- Please do not carry out any repairs yourself. Servicing and repairs may only be carried out by ourselves - the manufacturer - or by other persons we authorized.
- Surgical instruments that are to be sent back for repair have to be cleaned, disinfected and sterilized.



Caution!
Failure to observe the warnings and precautions can lead to death or serious injuries.

Disposal

Environmentally sound disposal enables valuable raw materials to be recycled. Dispose of the product in an environmentally friendly manner in accordance with the valid hospital guidelines.

Application



WARNING

Risk of infection from non-sterile instruments.
▲ Reprocess the instrument before each use.



WARNING

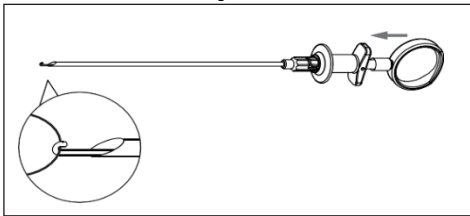
Risk of injury from the use of incompatible instruments.
▲ Only use original accessories.
/ See section „Accessories“.

CAUTION

Risk of injury from the sharp edges and tips.
▲ Do not touch the distal end.

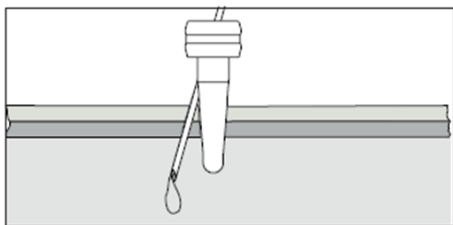
Prerequisite: The instrument is assembled.

- ▶ Push the thumb ring against the finger rest.
- ▶ Thread the suture into the middle of the catcher and release the thumb ring.



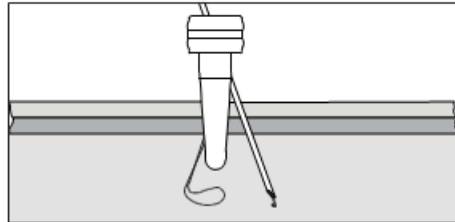
→ The catcher slides back into the sheath.

- ▶ Insert the needle guide.
- ▶ Place the instrument in the subcutaneous tissue through one of the openings provided by the the needle guide.

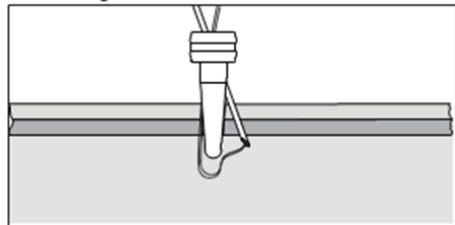


- ▶ Push the thumb ring against the finger rest to allow the suture to slide out of the catcher.
- ▶ Release the thumb ring to allow the catcher to move back into the outer sheath.

- ▶ Remove the instrument.
- ▶ Insert the instrument into the subcutaneous tissue through another one of the openings provided by the needle guide.
- ▶ Catch the free end of the thread with the catcher and pull into the instrument sheath.



- ▶ Pull the instrument with the suture out of the needle guide.



- ▶ Pull out the needle guide.
Knot the suture tightly in the subcutaneous tissue

Accessories











WARNING

Risk of injury from the use of incompatible instruments.
▲ Only use original accessories.

- Needle guide for trocar sleeves, dia. 10 – 20 mm.

Symbols and explanations

	Please read these instructions carefully before using the product for the first time. Always follow the instructions in this manual. Keep these instructions for use in a safe place.
	Manufacturer of the medical device.
	Batch code
	Article number
	Non sterile
	Indicates a possible danger to persons or property
	CE marking
▲	Specifies measures to reduce risks.
▶	You are requested to take action here.
→	You find out the result of the action taken here.
/	This symbol indicates additional information.
	CAUTION: Federal law in the USA restricts the device to sale by or on the order of a physician or other licensed practitioner.