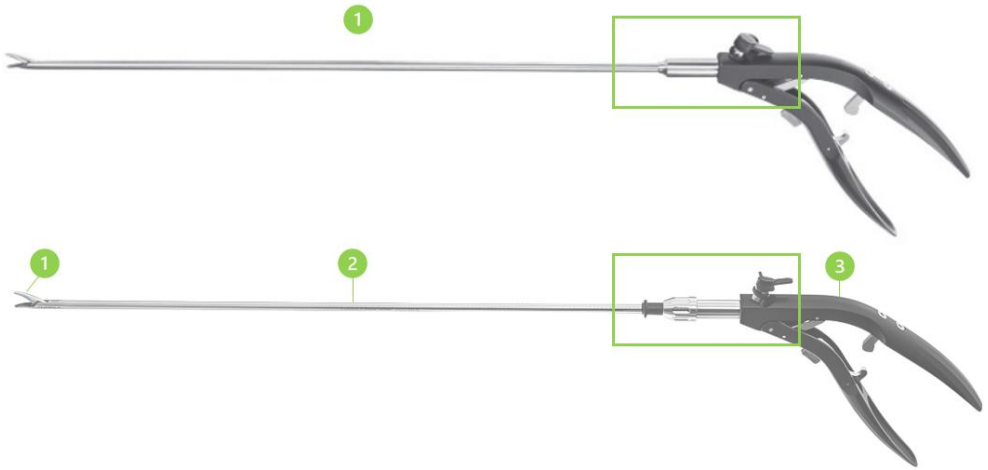
INSTRUCTIONS FOR USE (EN)

LAPAROSCOPY NEEDLE HOLDER – ONE PIECE AND DISMOUNTABLE



RUDOLF Medical GmbH + Co. KG
Zollerstrasse 1, 78567 Fridingen an der Donau,
Germany
Tel. +49 7463 9956-0
Fax +49 7463 9956-56
sales@RUDOLF-med.com
www.RUDOLF-med.com

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PLEASE READ BEFORE REPROCESSING AND KEEP IT IN A SAFE PLACE

PRODUCT

These instructions for use are valid for the RUDOLF Medical laparoscopy needle holder - one piece and dismountable.
The proper handling and use of these high-quality products are described below.

NON STERILE RUDOLF Medical Instruments are delivered non-sterile and must be cleaned, disinfected, and sterilized before first use and immediately after each use. Protective caps and transport packaging must be removed beforehand.

INTENDED PURPOSE

Laparoscopic needle holders are intended for suturing in the pneumoperitoneum. They are intended for grasping and holding surgical suture material.

CONTRAINDICATIONS

– The instrument is contraindicated in the cardiovascular system and central nervous system.
– The use of this instrument is contraindicated if endoscopic interventions are generally contraindicated.

⚠ WARNINGS AND PRECAUTIONS

- Levering, twisting and excessive strain can lead to damage or breakage of parts of the instrument. This can in turn lead to complications such as injury to nerves, vessels or tissue as well as bleeding or infection.
- The flushing channel is for reprocessing and cleaning of the handle lumen (dismountable model), the sheath and the jaw (one-piece model).
- The safe combination of instruments with each other or with implants must be checked by the user before the clinical use.
- Do not use metal brushes or abrasives, because they can damage the surface which can lead to corrosion.
- Alkaline detergents (pH > 12) cause a change in color in instruments made of aluminum. However, they have no impact on the mechanical strength of these instruments.
- Carefully insert the instrument into the trocar to avoid possible damages.
- In the case of patients with Creutzfeldt-Jakob disease (CJD), possible variants of this disease or suspected CJD, the applicable national regulations regarding the disposal and reprocessing of the instruments must be applied.
- Never leave the instruments for too long in the disinfectant solution. Follow the instructions of the disinfectant solution manufacturer.
- Automated cleaning / disinfection should be preferred to manual cleaning / disinfection, since automated processes can be standardized, reproduced, and thus validated.

PRIOR TO EACH USE: VISUAL AND FUNCTIONAL INSPECTION

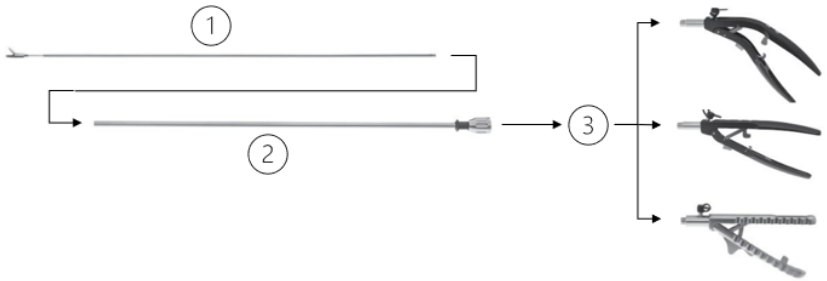
Check for:
- External damage (e.g. scratches, cracks, nicks, dents, deformed parts)
- Correct functioning
- Detergent or disinfectant residues
- Free passage through the working channels

Note: Do not use damaged instruments

⚠ Needle holders are used for sutures with straight or curved needles. Models with a self-righting function are not suitable for straight needles.

ASSEMBLY / DISASSEMBLY

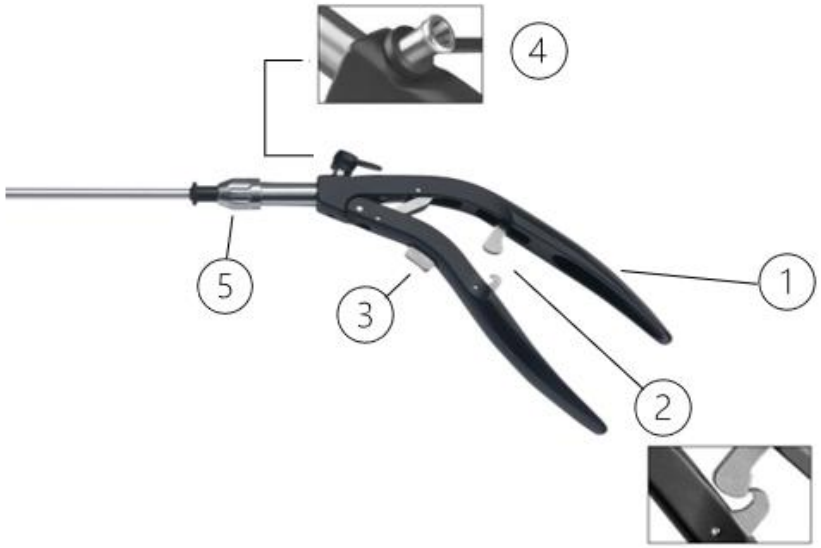
Parts of the dismountable needle holder



Needle holder – components of the dismountable needle holder:

(1) Instrument insert
(2) Tube with union nut
(3) Handle with cap for Luer Lock flushing channel

Operating elements of the dismountable needle holders:



(1) Handle
(2) Ratchet
(3) Lock
(4) Luer Lock flushing channel with cap
(5) Union nut

Application notes

- When closing the handle, the ratchet engages gradually. The ratchet is released by pressing the Lock.
- The Luer Lock flushing channel is used exclusively for the reprocessing and cleaning of the handle.

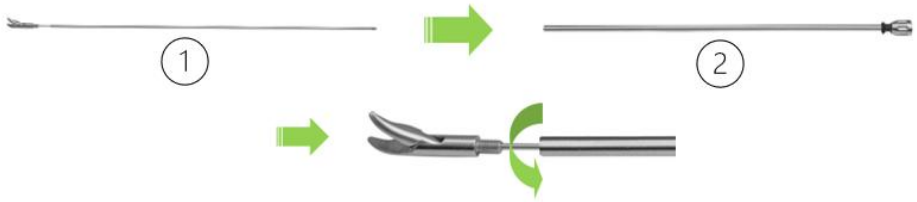
Dismountable needle holder – preparation for reprocessing

- Disassemble the instrument for reprocessing.
- The cap must be removed from the Luer-Lock flushing channel (4) and only reattached after sterilization, but only immediately before use.

Disassembly

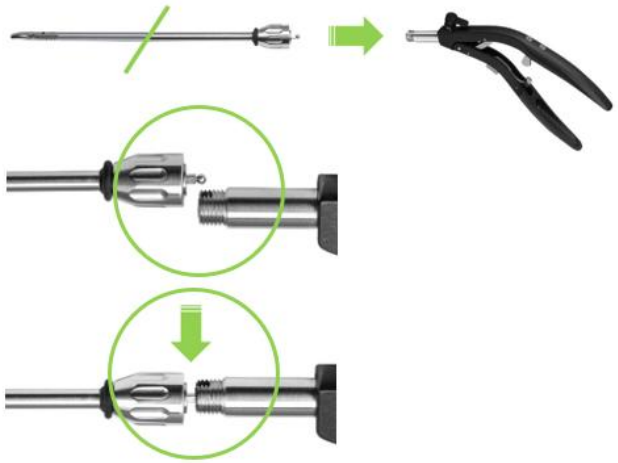
1. Remove the cap of the Luer Lock flushing channel.
2. Unscrew the union nut from the handle.
3. Remove the insert including the tube from the handle adaptor groove.
4. Remove the insert from the tube by rotating it counterclockwise.

Assembly



1. Screw the insert (1) into the tube (2) clockwise and tighten the insert manually.
2. Position the insert with jaws closed into the handle adaptor groove. Press the handle (3) slightly so that the insert is positioned against the handle groove.

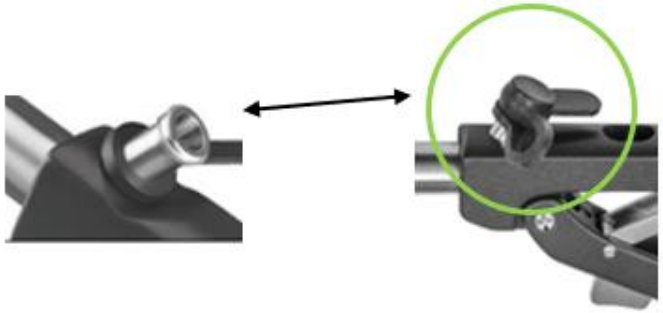
   Note:
   The jaw must open upwards. For orientation, use the mark “TOP” at the working end.



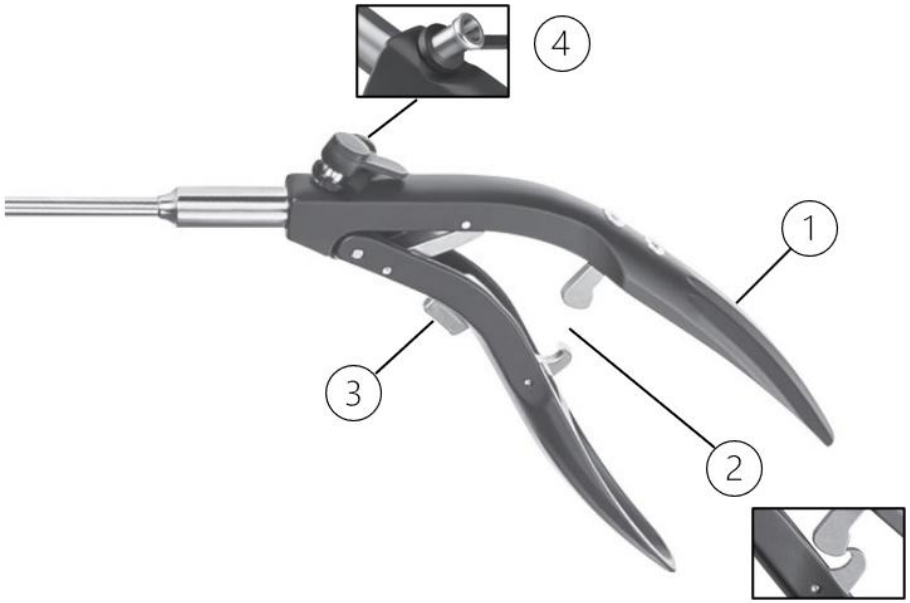
3. Tighten the union nut manually.

Note:
Perform a function test by opening and closing the jaws using the handle and the ratchet

4. Attach the cap on the Luer Lock flushing channel.



Operating elements of the one-piece needle holder



(1) Handle
(2) Ratchet
(3) Lock
(4) Luer Lock flushing channel with cap

Application notes

- When closing the handle, the ratchet (2) gradually engages. The ratchet is released by pressing the lock (3).
- The Luer Lock flushing channel is used for reprocessing and cleaning the tubes and jaws.

One piece needle holder – preparation for reprocessing

For the reprocessing, the cap is removed from the Luer Lock flushing channel and is reattached after sterilization, but only immediately before use.

REPROCESSING INSTRUCTIONS

Restrictions

- Due to the product design and the materials used, 100 reprocessing cycles can be carried out.
- Due to wear and damage caused by use and reprocessing, the instruments must be checked before each use and, if necessary, disposed of before the 100 reprocessing cycles have been reached. See section “Prior to each use: visual and functional inspection”.
- Do not use any fixing agents or hot water (>40°C), because this causes a hardening of residues which can impede the cleaning of the instruments.

Initial treatment at the place of use

- Defective instruments must be clearly marked as such. They have to be reprocessed before being disposed of or returned.
- The instruments must be reprocessed within an hour after use to prevent contamination from drying on the instruments.
- Heavy contamination on the instruments must be removed with a disposable cloth immediately after use.
- Working channels and lumen must be flushed through at least 3 times immediately after use to avoid blockages.

Transportation

- The safe transportation of the instruments to the reprocessing site should be carried out in a closed receptacle / container system to avoid damage to the instruments and contamination of the environment.

Preparation before cleaning

- The instruments must be disassembled or opened for reprocessing as far as possible without using tools.

Manual pre-cleaning

1. Rinse the sheath with a water gun at a static pressure of 3.8 bar for 10 seconds.
2. Place the instruments in cold water for 5 minutes.
3. Brush the instruments with a soft brush until all visible residues are removed.
4. Rinse every opening and difficult to access surfaces, holes and threads with a water gun at a static pressure of 3.8 bar for 5 seconds. Rinse the cavities with the water gun at the same pressure for 10 seconds.
5. Prepare an ultrasonic bath with the cleaning agent neodisher MediClean forte. Temperature: 40°C; concentration 0.5%.
6. Place the instruments in the ultrasonic bath for 10 minutes.
7. Rinse then the cavities with a water gun at a static pressure of 3.8 bar for 10 seconds.

Automated cleaning and disinfection

- Clean and disinfect the instrument only in suitable washers and disinfectors (WD) with a procedure / program validated for the WD and this type of instrument (EN ISO 15883).
- Observe the operating and loading instructions of the washer-disinfector manufacturer.
- For cleaning, instruments with joints must be opened by approximately 90 degrees.
- Instruments with lumen (tubes, shafts, slots) must be connected to a rinsing system to ensure a flush of the lumen.
- When choosing the cleaning agent, consider the material and properties of the instrument, the cleaning agents recommended by the WD manufacturer for the respective application and the relevant recommendations of the Robert Koch Institute (RKI) and the German Society for Hygiene and Microbiology (Deutsche Gesellschaft für Hygiene und Mikrobiologie, DGHM).

Cleaning agent and washer for automated cleaning / disinfection

Cleaning agent for the automated cleaning/disinfection	Dr. Weigert neodisher® MediClean forte, alkaline
Washer/disinfector	Miele G 7836
Cleaning program	Oxivario
Disinfection method	Thermal disinfection When carrying out an automated thermal disinfection, consider the national requirements regarding the A0 value in ISO 15883-1 (A0 = 3000).

Automated cleaning program with thermal disinfection in the WD

Process	Reagents	Time / min	Temp. / °C
Pre-cleaning	Drinkable tap water	2	Cold
Draining	---	---	---
Cleaning	Drinkable tap water Concentration of the cleaning agent: 0.5%	5	55
Draining	---	---	---
Neutralization	Deionized water	3	10-25
Draining	---	---	---
Rinsing	Deionized water	2	10-25
Draining	---	---	---
Drying	---	> 20	Max. 93
If necessary, manual drying with a lint-free cloth can also be carried out. Dry instrument cavities with sterile compressed air.			

MAINTENANCE, CONTROL, AND INSPECTION

- After cleaning and disinfection, the instruments must be inspected visually and for functionality. See also section “Prior to each use: visual and functional inspection”.
- The instruments must be macroscopically clean (free of visible residues). Particular attention should be paid to slots, ratchets, locks, and other areas that are difficult to access.
- If residues / liquids are still visible, the cleaning and disinfection process must be repeated.
- Before sterilization, the instrument must be assembled and checked for function, wear & tear, and damage (cracks, rust) and replaced, if necessary.
- After each cleaning and before sterilization, the moving parts (e.g. joints, locks) must be lubricated with a silicone-free, biocompatible, vapor-permeable, medical white oil.
- Defective products must have gone through the entire reprocessing cycle before being returned for repair or complaint.

PACKAGING

- The standardized packaging of the instruments for sterilization is according to standards DIN EN ISO 11607 and DIN EN 868.
- In case of individual packaging, care must be taken to ensure that the packaging is large enough to hold the product without putting tension on the sealing seam or tearing the packaging. Pointed tips and sharp cutting edges must not perforate the sterilization packaging.

STERILIZATION

- The sterilizers are validated according to DIN EN 13060 and DIN EN 285.
- The steam sterilization method (fractionated vacuum method) is validated according to DIN ISO 17665-1.
- Observe the instructions of the manufacturer of the sterilizer.

3 Pre-vacuum phases	Sterilization temperature	Minimum holding time	Drying time
Minimum of 60mbar pressure	132°C – 137°C	5 minutes	Minimum of 10 minutes

STORAGE

- Store the sterilized instruments in a dry, clean and dust-free environment at approx. 25°C without major temperature fluctuations.

INFORMATION REGARDING THE VALIDATION OF THE REPROCESSING PROCEDURE

The following materials and machines were used in the validation:

Manual pre-cleaning	Ultrasonic bath Dr. Weigert neodisher MediClean forte; temperature: 40°C; concentration 0.5%
Cleaning agent for the automated cleaning/disinfection	Dr. Weigert neodisher® MediClean forte, alkaline
Washer/disinfector	Miele G 7836
Cleaning program	Oxivario
Disinfection method	Thermal disinfection When carrying out an automated thermal disinfection, consider the national requirements regarding the A0 value in ISO 15883-1 (A0 = 3000).
Sterilization	Steam sterilization
Sterilizer	Selectomat HP 666-1HR
Sterile packaging	The validation was performed with the following packaging: Sterile pouch according to EN ISO 11607-1 (Wipak STERIKING flat rolls type R43 / type R44)

ADDITIONAL NOTES

- If the specified cleaning agents and machines are not available, the user needs to validate their process.

DISPOSAL

- The products should be disposed of accordingly only after they have been cleaned and disinfected properly.
- Comply with national regulations and applicable hospital guidelines when discarding or recycling the product / components.
- Be careful with sharp tips and cutting edges. Use suitable protective caps or containers to prevent third parties from being injured.

REPAIRS & RETURNS

- Never carry out repairs yourself. Service and repairs should only be carried out by appropriately instructed and qualified persons. If you have any questions, contact RUDOLF Medical or your medical technology department.
- Defective products must have gone through the entire reprocessing cycle before being returned for repair or complaint.

PROBLEMS / EVENTS

- The user should report any problems with our products to the respective distributor.
- In the event of serious incidents with the products, the user must report this to RUDOLF Medical as the manufacturer and the competent authority of the member state in which the user resides.

WARRANTY

- The instruments are made of high-quality materials and are subjected to a strict quality control before delivery. If there are any discrepancies, please contact RUDOLF Medical.

SYMBOLS

	Consult instructions for use
LOT	Batch code
REF	Article no.
QTY	No. per package
	Non-sterile
	Caution
	Manufacturer
	Date of manufacture
CE 0297	CE marking according to the Medical Device Regulation (EU) 2017/745 (MDR) with the ID of the notified body
	Keep dry
	Lubricate with silicone-free, biocompatible white oil approved for medical devices and steam sterilization.
MD	Medical Device