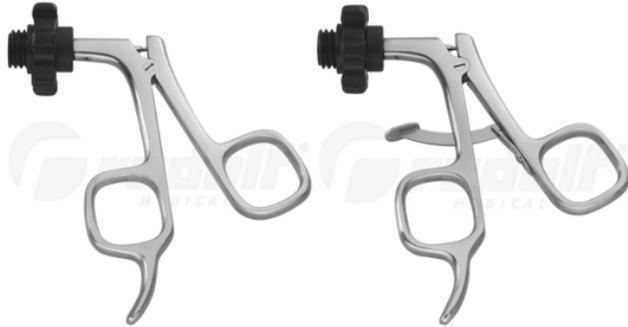


INSTRUCTIONS FOR USE (EN) HANDLES FOR THE LAPAROSCOPY INSTRUMENTS “SCREW-IN” WITHOUT HIGH-FREQUENCY CONNECTION



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PLEASE READ BEFORE REPROCESSING AND KEEP IT IN A SAFE PLACE

PRODUCT

These instructions for use refer to the assembly and disassembly of the RUDOLF Medical handles for the laparoscopic instruments “Screw-In” without a high-frequency connection. You are receiving a high-quality product whose proper handling and use are described below.

For professional use only: The instruments are intended for use by the professional users only (surgeons, operating room nurses, medical device reprocessing technicians).



The following instructions refer to the disassembly of the instrument after surgery and assembly after the cleaning and disinfection process.

Detailed instructions for reprocessing can be found in the IFU D0462:



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.

We recommend treating the mechanical parts of the instrument with a lubricant before sterilization.

A thorough functional and visual check should be carried out before each use.

INTENDED PURPOSE

Handles without HF connection are used in combination with a tube and an instrument insert.

WARNINGS AND PRECAUTIONS

- Do not use defective instruments.
- Improper use and overstraining due to twisting / levering can lead to breaks and permanent deformation.
- Do not use metal brushes or abrasives, because they can damage the surface which can lead to corrosion.
- The safe combination of instruments with each other or with implants must be checked by the user before the clinical use.
- Be careful when handling sharp tips and cutting edges as there is a risk of injury.
- For patients with incurable infections such as CJD (Creutzfeldt-Jakob disease), hepatitis, HIV, possible variants of these infections, or suspected infections, the applicable national regulations regarding the disposal and reprocessing of the medical devices 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., dents, burrs, cracks or sharp edges)
- Correct functioning
- Detergent or disinfectant residues

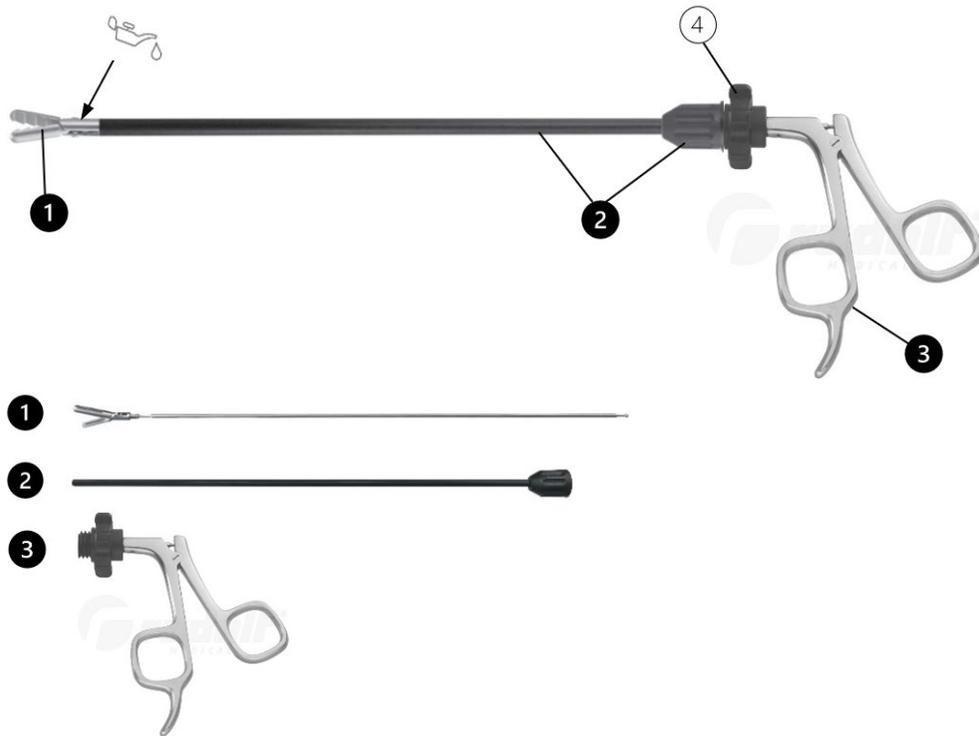
The lifespan of the product is influenced by several factors, including:

- The number of uses and the frequency of reprocessing cycles
- The quality of care, handling, and maintenance
- The continued legibility of any direct product markings

PRODUCT DESCRIPTION OF THE “SCREW-IN” SYSTEM

- The RUDOLF Medical laparoscopic “Screw-In” system consists of three-part dismantable instruments whose components can be combined among each other. The instruments come in various models (jaw inserts, handles, tubes) and designs (tube diameter, working length).
- The “Screw-In” system makes it possible that tubes (with compatible jaw inserts) can be combined with all the handles of the system.
- The instruments are not restricted to any population.

Example: Grasping forceps with a tube diameter of 5mm, working length 330mm, handle without a ratchet.



Combination parts and components:

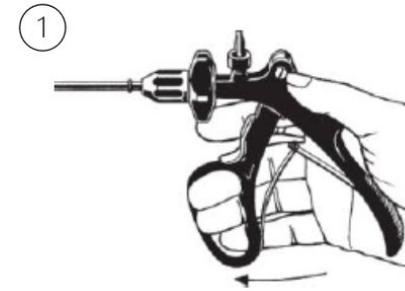
- (1) Jaw insert – example above with grasping forceps.
- (2) Tube with fastening screw nut. The fastening screw nuts come in various colors.
- (3) Handle – example above shows a model without a ratchet.
- (4) Rotatable adapter, 360° rotatable, with 10 latches (comfort handle: 12 latches).

ASSEMBLY / DISASSEMBLY

 Jaw inserts can be combined only with tubes of the same system diameter and working length.

The images in the following assembly and disassembly instructions may differ from the model you have because there are different models. However, the mechanics and the handling are the same.

Disassembly

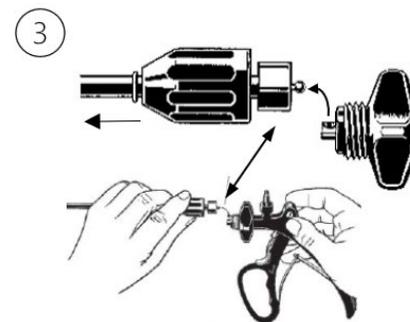


To unscrew the tube, open the instrument or the handle.

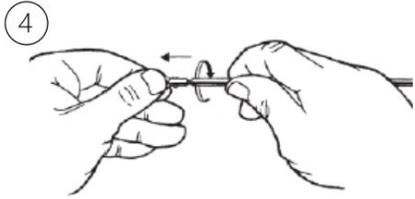
Built-in springs (see figure) in handles support automatic opening.



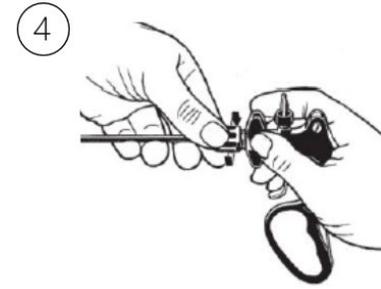
1. Hold firmly the rotatable adapter by the handle.
2. Loosen the fastening screw nut of the tube by rotating it counterclockwise.



1. Pull back the fastening screw nut over the metal cylinder of the tube.
2. Remove the tube including the jaw insert out of the ball socket of the handle.



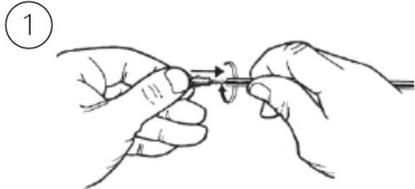
1. Unscrew the tube from the jaw insert by rotating it counterclockwise.
2. Pull the jaw insert out of the tube.



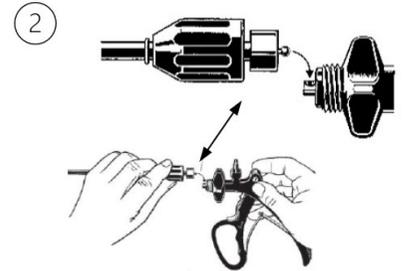
1. Screw the fastening screw nut clockwise onto the threaded socket of the handle and tighten it while holding the rotatable adapter by the handle.
2. After the assembly, perform a functional check.

For more information, see the "Prior to each use: visual and functional inspection" section.

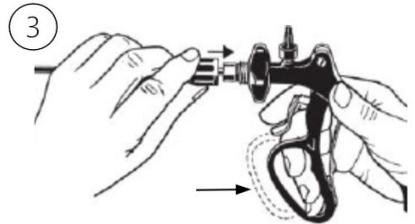
Assembly



1. Slide the jaw insert into the tube and screw the tube onto the jaw insert by rotating it clockwise.
2. Fasten the tube only that much that the jaw insert cannot come loose during usage.



1. With its ball end first, insert the tube with the screwed-in jaw insert into the ball socket of the handle.
2. Make sure that the jaw is completely closed. The handle must be open. Do not operate it.



1. Operate the handle only so far until the metal cylinder of the tube rests against the threaded socket of the handle.
2. Then, slide the fastening screw nut over the metal cylinder of the tube towards the threaded socket of the handle. This makes it easy and safe to screw the fastening screw nut to the handle.

SYMBOLS

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