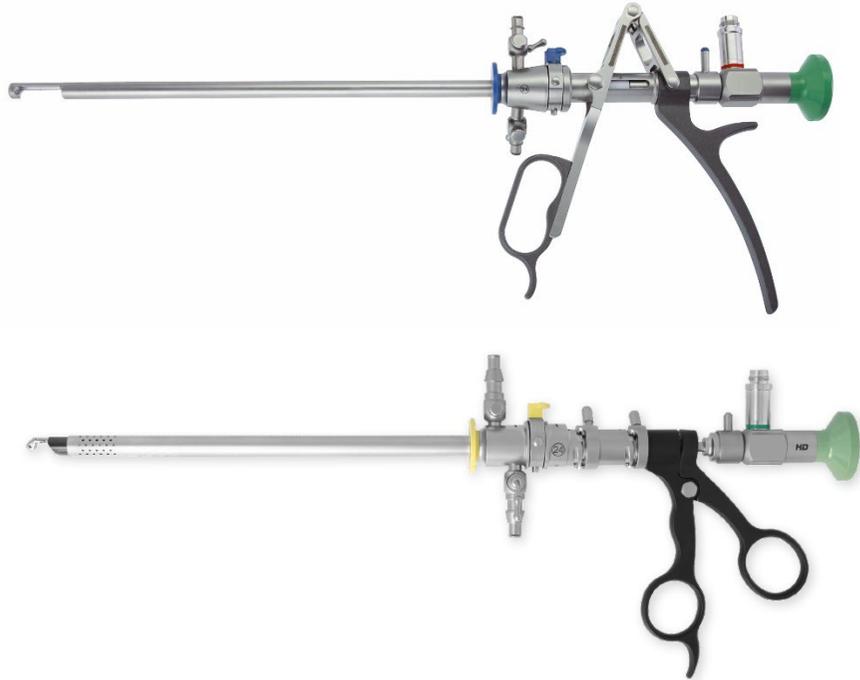


INSTRUCTIONS FOR USE (EN) OPTICAL PUNCHES AND FORCEPS



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PLEASE READ BEFORE REPROCESSING AND KEEP IN A SAFE PLACE

PRODUCT

These instructions for use are valid for RUDOLF Medical optical punches and forceps. You have received a high-quality product, the proper handling and use of which is 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).

Patient population: There are no restrictions concerning the patient population. It may be left to the discretion and experience of the medical professional to decide whether the benefit outweighs the risk in the given population.



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

Detailed instructions on reprocessing can be found in IFU D0462:



RUDOLF Medical instruments are supplied 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

Optical punches and forceps are intended for cutting tissue and removing biopsies in endoscopic gynecology/urology.

CONTRAINDICATIONS

The instrument should not be used in the following cases:

- In the opinion of the attending physician, the risks exceed the benefits for the patient.
- The endoscopic procedure is found to be contraindicated in the patient.
- The medical devices are not intended for the use on the central nervous and circulatory system.
- Acute inflammation in the abdomen
- Urinary tract infection
- Coagulation disorder

⚠️ WARNINGS AND PRECAUTIONS

- These medical devices may only be used in medical facilities by trained medical personnel.
- 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.
- Incorrect use and overloading due to twisting/levering can lead to fractures and permanent deformation.
- Do not use metal brushes or abrasive cleaners, as corrosion can occur if the surface is damaged.
- The safe combination of compatible instruments with each other must be checked by the user before clinical use.
- Take care when handling sharp tips and cutting edges, as there is a risk of injury.

BEFORE EACH USE: VISUAL AND FUNCTIONAL INSPECTION

Check for the following:

- External damage (e.g. deformed sheath, dents, burrs, cracks or sharp edges)
- Correct function
- Cleaning agent or disinfectant residues
- Free passage through working channels

After cleaning and disinfection or before sterilization, we recommend the following:

- Lubricate moving parts with silicone-free, biocompatible medical white oil that is approved for steam sterilization.
- Grease the stopcocks, threads and sealing rings of the sheath with maintenance grease.

LOCKING DEVICE FOR ENDOSCOPES AND INSTRUMENTS

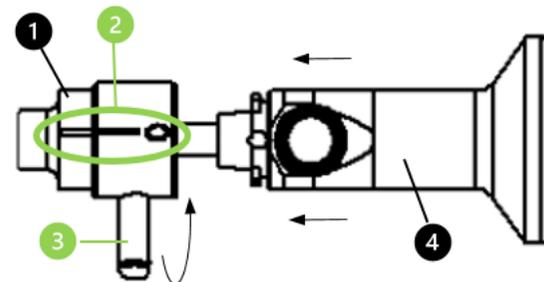
RUDOLF Medical surgical and diagnostic sheaths, endoscopes and endoscopic instruments are equipped with a special holder and locking mechanism.

1. Sheath holder and locking mechanism (1):

Before an endoscope or instrument inserted in the sheath can be locked, it must be ensured that the lock is open.

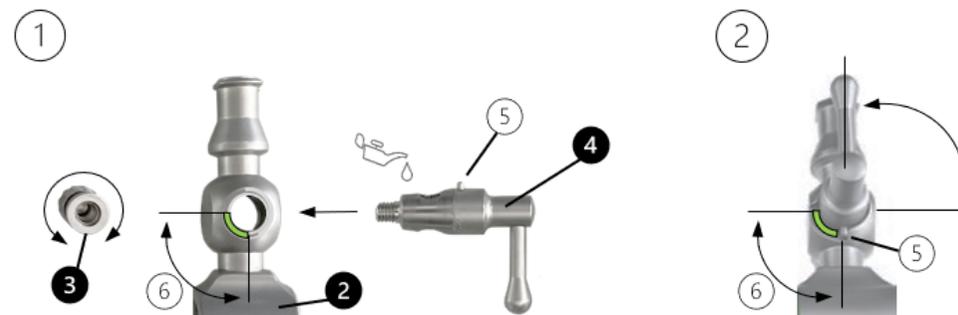
Make sure that the marking lines (2) on the locking mechanism of the sheath are positioned in line with each other (zero position).

2. Now insert an obturator, an endoscope (4) or an endoscopic instrument with the groove into the hub of the sheath and lock it by turning the locking lever (3) clockwise by 90°.



STOPCOCKS FOR INFLOW AND OUTFLOW - DISASSEMBLY/ASSEMBLY

⚠️ The stopcocks must be removed from the sheath system for reprocessing.



Disassembly

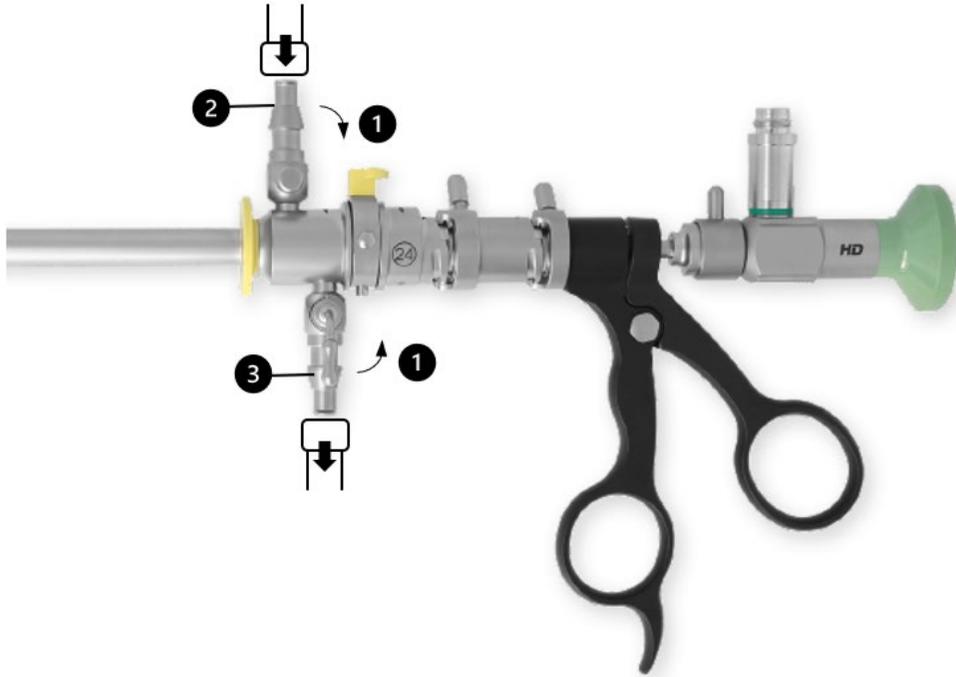
Unscrew the spring cap (3) and remove the stopcock plug (4) from the stopcock.

Assembly

1. Insert the stopcock plug (4) into the stopcock holder (2). Make sure that the guide pin (5) of the stopcock plug runs in the recess (6) of the stopcock holder (2).
2. Then screw the spring cap (3) on the opposite side of the stopcock to the stopcock plug.
3. Check the mobility of the stopcock plug.
4. The stopcock must be open for sterilization. To do this, swivel the lever of the stopcock plug towards the opening of the Luer lock connection.

Connecting the irrigation hoses

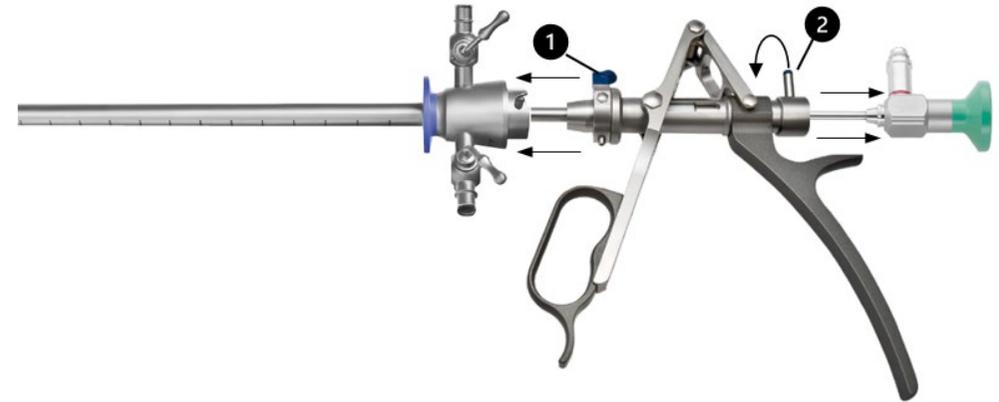
1. Close the irrigation stopcocks (1).
2. Connect the inflow tube to the inflow stopcock (2) via the Luer Lock connection.
3. Connect the outflow tube to the outflow stopcock (3) via the Luer Lock connection.



LITHOTRIPSY PUNCH - DISASSEMBLY/ASSEMBLY

The Click System is an automatic locking mechanism.

Disassembly



Click system for disassembling the outer sheath

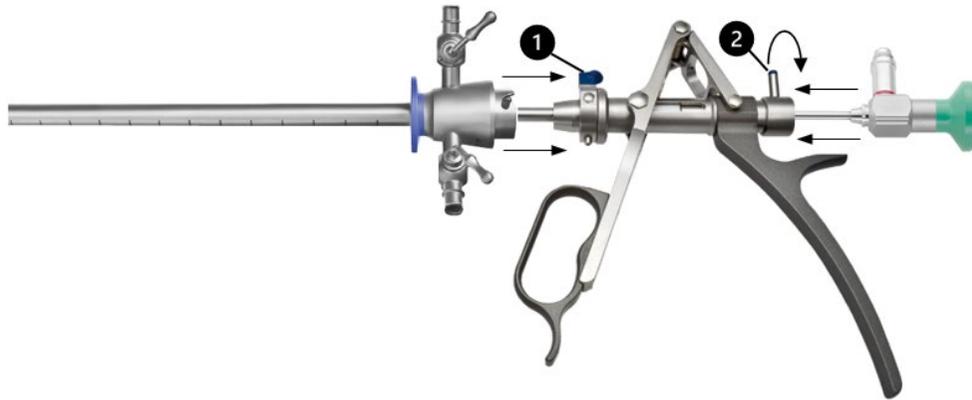
- The outer sheath is unlocked by simply pressing the adapter (1). The instruments can then be separated from each other.

Bayonet lock for removing the endoscope

- The endoscope can be separated from the working element by releasing the lever (2).
- The color coding of an endoscope represents its viewing angle and may therefore differ from the color coding of the sheaths/closures.

Note: Only combine compatible RUDOLF Medical instruments with the same locking mechanism.

Assembly



Click system for assembling the outer sheath

- The outer sheath is locked to the holder with a "click" by simply pressing the adapter (1).

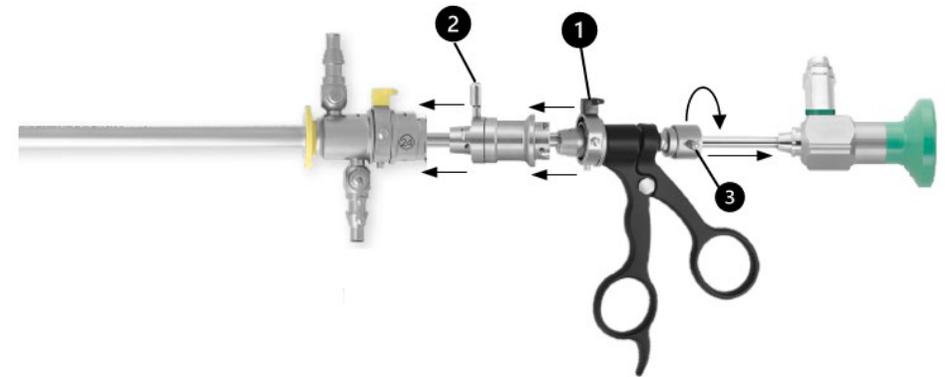
Bayonet lock for assembling the endoscope

- With the bayonet locking system, the endoscope is locked to the working element. The adapter must be positioned by turning the lever (2) so that its claws can be inserted into the threaded groove of the holder and locked using the lever (2).

OPTICAL FORCEPS - DISASSEMBLY/ASSEMBLY

The Click System is an automatic locking mechanism.

Disassembly



Click System

- The connection adapter (2) is unlocked from the holder with a "click" by simply pressing the instrument adapter (1).

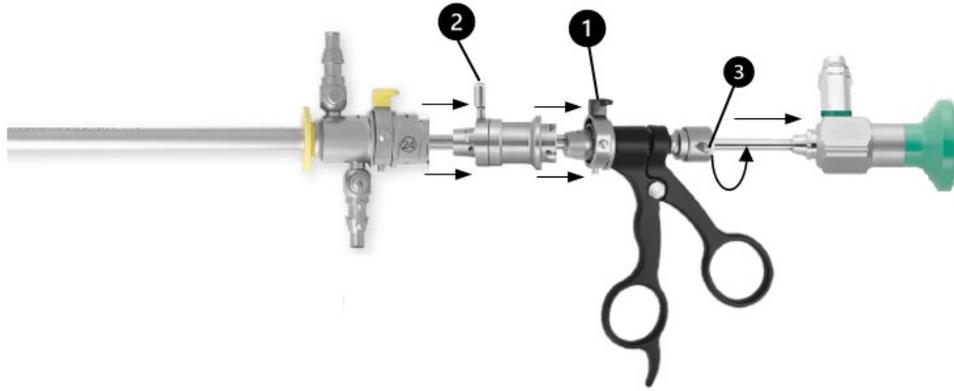
Bayonet lock

- The sheath system is separated from the working element by releasing the lever (2).
- The endoscope is separated from the working element by releasing the lever (3).

Notes:

- If you use working elements in combination with cysto-urethroscope sheaths size 19 - 26 Fr./Charr. you **do not** need an additional adapter.
- The working elements are available with both a click system and a bayonet lock. The disassembly is always based on the same principle.

Assembly



Click System

- The connection adapter (2) is locked in the holder with a "click" by simply pressing the instrument adapter (1).

Bayonet lock for assembling the endoscope

- With the bayonet locking system, the endoscope is locked to the working element. The adapter must be positioned by turning the lever (2) so that its claws can be inserted into the threaded groove of the holder and locked using the lever (2).
- The working elements are available with both a click system and a bayonet lock. The assembly is always based on the same principle.

CLICK SYSTEM OR BAYONET LOCK FOR ASSEMBLY AND DISASSEMBLY OF THE ADAPTERS

Note:

There are different adapters for the working elements when combining them with resectoscope sheaths. When selecting the adapter, pay attention to the connection type of the working element and the connection type of the sheath system.

<p>CY040-401</p> <p>Image showing the adapter CY040-401 and its assembly with the instrument adapter. The adapter is a cylindrical component with a lever. The assembly shows the adapter being inserted into the instrument adapter.</p>	<p>CY040-400</p> <p>Image showing the adapter CY040-400 and its assembly with the instrument adapter. The adapter is a cylindrical component with a lever. The assembly shows the adapter being inserted into the instrument adapter.</p>	<p>Image showing the adapter CY040-400 and its assembly with the instrument adapter. The adapter is a cylindrical component with a lever. The assembly shows the adapter being inserted into the instrument adapter.</p>
<p>CY040-412</p> <p>Image showing the adapter CY040-412 and its assembly with the instrument adapter. The adapter is a cylindrical component with a lever. The assembly shows the adapter being inserted into the instrument adapter.</p>	<p>CY040-411</p> <p>Image showing the adapter CY040-411 and its assembly with the instrument adapter. The adapter is a cylindrical component with a lever. The assembly shows the adapter being inserted into the instrument adapter.</p>	<p>Image showing the adapter CY040-411 and its assembly with the instrument adapter. The adapter is a cylindrical component with a lever. The assembly shows the adapter being inserted into the instrument adapter.</p>

To guide yourself, you can also observe the arrow markings on the instrument lock. If these arrows have the same dimensions or contour, compatibility is guaranteed.



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 mark in accordance with Regulation (EU) 2017/745 for medical devices (MDR) with the identification number of the notified body
	Lubricate moving parts with silicone-free, biocompatible white oil approved for medical devices and steam sterilization. Lubricate stopcocks, threads and sealing rings with instrument grease approved for medical devices and steam sterilization.
MD	Medical Device