

INSTRUCTIONS FOR USE (EN) SHEATHS FOR ENDOSCOPIC ARTHROSCOPY, GYNECOLOGY AND UROLOGY



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D0151 / Rev G / ACR00582 / 2024-03-21



PLEASE READ BEFORE REPROCESSING AND KEEP IT IN A SAFE PLACE

PRODUCT

These instructions for use are valid for RUDOLF Medical diagnostic and operation sheaths.
You are receiving a high-quality product, the proper handling and use of which is described below.



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 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.

INTENDED PURPOSE

Sheaths are intended for suction, irrigation, insufflation and/or the insertion of instruments during minimally invasive surgical procedures.

The instruments are not restricted to a specific population. They should not be used if, in the opinion of the attending physician, the risks for the patient exceed the benefits.



WARNINGS & PRECAUTIONS

- Improper use and overstraining due to twisting / levering can lead to breaks and permanent deformation.
- These medical devices are intended to be used only in medical facilities by trained medical personnel.
- Do not use metal brushes or abrasive cleaners, because they can damage the surface which can lead to corrosion.
- The safe combination of compatible instruments and their compatibility with each other must be checked by the user before clinical use.
- Be careful when handling sharp tips and cutting edges as there is a risk of injury.
- When treating patients with Creutzfeldt-Jakob disease (CJD), or with possible variants of this disease or suspected CJD, please follow the applicable national regulations regarding the disposal and reprocessing of instruments.

PRIOR TO EACH USE: VISUAL AND FUNCTIONAL INSPECTION

Check for:

- External damage (e.g. deformed shaft, dents, burrs, cracks, or sharp edges)
- Correct functioning
- Detergent or disinfectant residues
- Free passage through the working channels



After cleaning and disinfection or before sterilization, we recommend:

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

LOCKING SYSTEM FOR ENDOSCOPES AND INSTRUMENTS

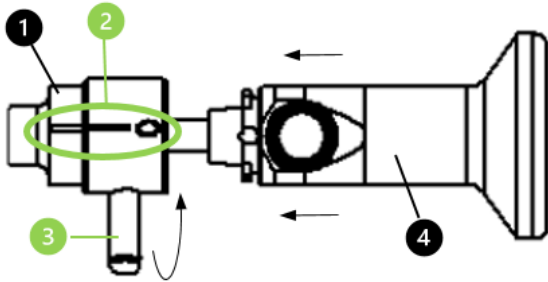
RUDOLF Medical sheaths (operation and diagnostic sheaths), endoscopes and endoscopic instruments are equipped with a special holder and locking system.

1. Shaft holder and locking mechanism (1):

Before an endoscope or instrument inserted in the shaft can be locked, make sure that the locking mechanism is open.

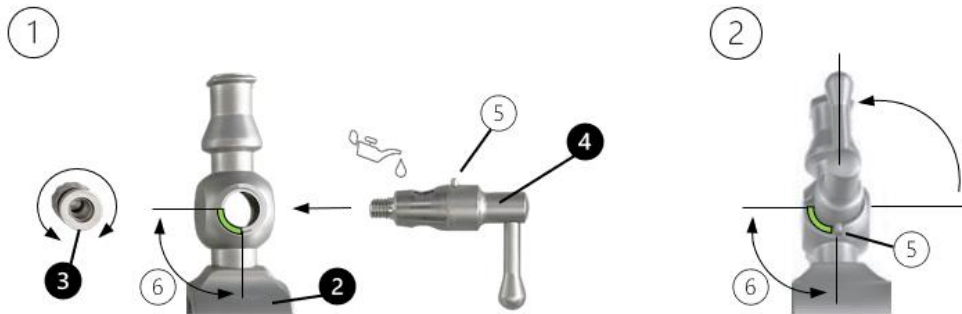
Make sure that the marking lines (2) on the locking mechanism of the shaft are positioned in line with each other (zero position).

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



STOPCOCKS FOR INFLOW AND OUTFLOW

! The stopcock levers must be removed from the sheath for reprocessing.



Disassembly

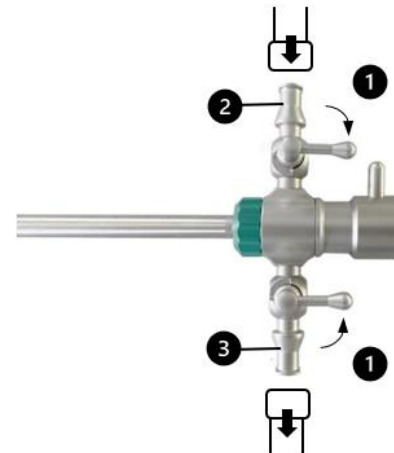
Unscrew the spring caps (3) and remove the stopcock lever (4) from the stopcock.

Assembly

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

Connecting the flushing hoses

1. Close the flush stopcocks (1).
2. Connect the inflow tube (Luer lock connection) to the inflow stopcock (2).
3. Connect the drain hose or the Luer lock connection to the outflow stopcock (3).



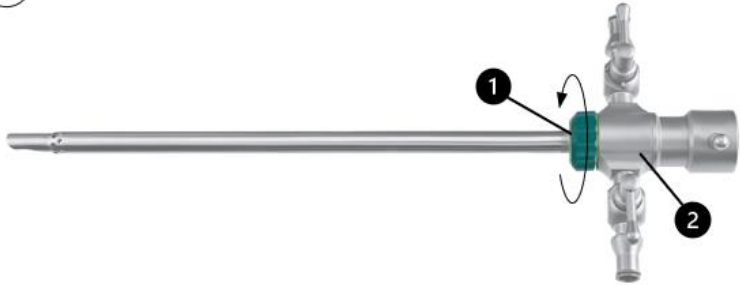
SHEATH FOR ENDOSCOPIC ARTHROSCOPY

Disassembly

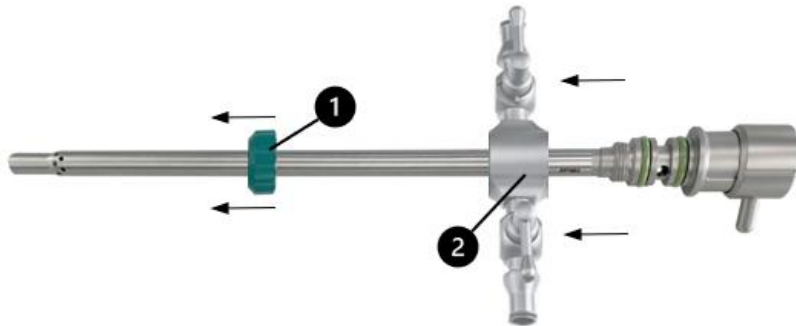
 Only pre-cleaned instruments can be disassembled.

1. Unscrew the union nut (1) from the sheath and pull off the holder (2).

①

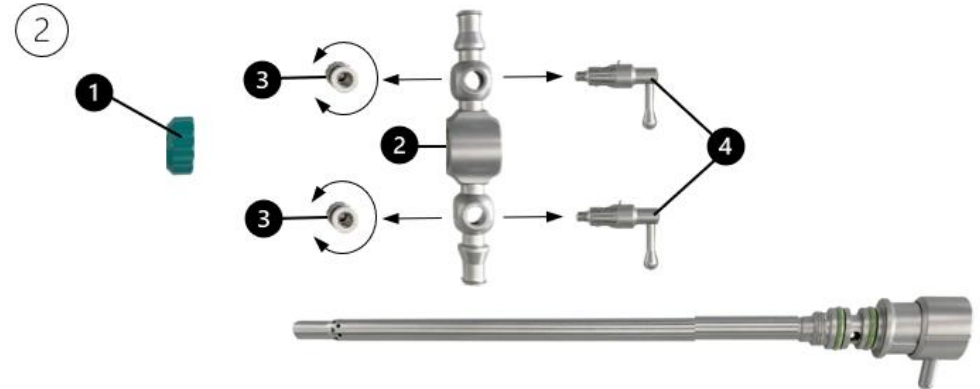


①



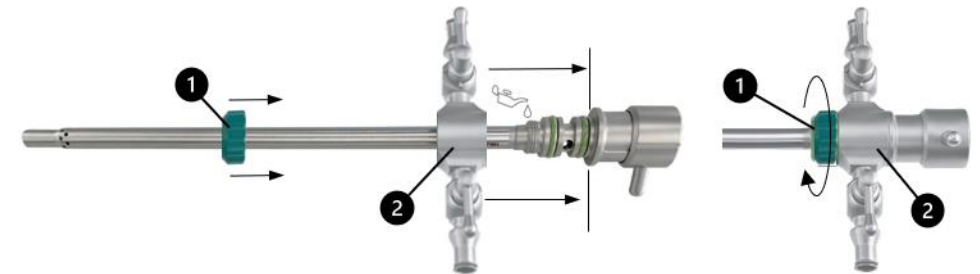
2. Unscrew the spring caps (3) and remove the stopcock lever (4) from the stopcock.

②



Assembly

1. Assemble the stopcocks. See section "STOPCOCKS FOR INFLOW AND OUTFLOW".
2. Slide the holder (2) with the assembled stopcocks over the shaft and push the holder up to the stop of the connection part.
3. Then screw the holder tight with the union nut (1).



SHEATHS FOR ENDOSCOPIC GYNECOLOGY (HYSTEROSCOPY) AND UROLOGY (CYSTOSCOPY)

Sheaths for endoscopic gynecology (hysteroscopy)

The instruments are used in combination with compatible instruments (endoscopes, flexible and semi-rigid instruments, flexible monopolar HF electrodes). Continuous flow sheaths (hysteroscopes) allow both the examination and surgical interventions in the uterus or cervix under endoscopic view.

Sheaths for endoscopic urology (cystoscopy)

The instruments are used in combination with compatible instruments (endoscopes, flexible and semi-rigid instruments, flexible monopolar HF electrodes).

Endoscope bridges for cysto-urethroscope sheaths

An endoscope bridge must also be connected to the cysto-urethroscope sheaths, as otherwise the compatibility with the endoscope cannot be guaranteed. Furthermore, it is not possible to use flexible and semi-rigid instruments without an endoscope bridge.

Note: Note the locking system for the shaft system during assembly. See the click system (1) in the following illustration. A bayonet lock is always fitted on the endoscope side.



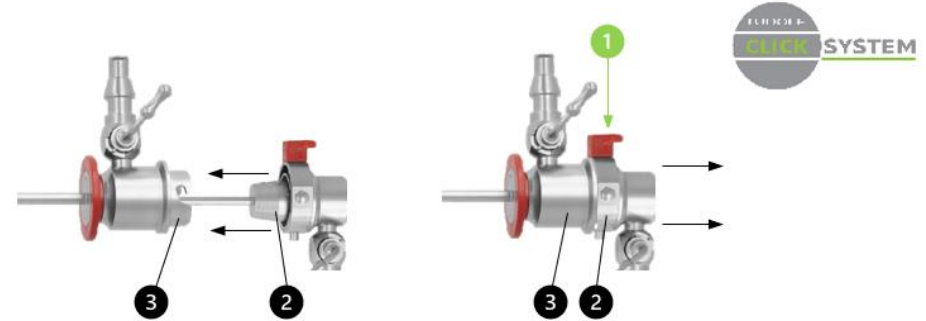
CLICK SYSTEM / BAYONET LOCKING SYSTEM

Depending on the version, RUDOLF Medical sheaths are equipped with a click system and/or a bayonet lock.

CLICK SYSTEM

- The Click System is an automatic locking mechanism in which combinable instruments are locked together with a "click" by simply pressing the adapter (2) into the holder (3).
- By pressing the push button (1) on the adapter (2) you release the connection to the holder (3). The instruments can now be separated from each other.

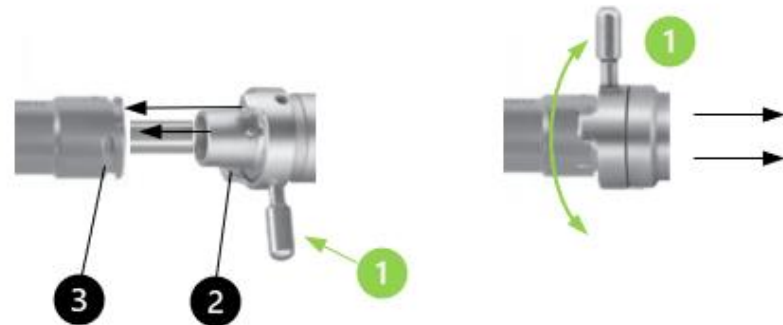
Note: Only combine compatible RUDOLF Medical instruments with the same color coding.



BAYONET LOCKING SYSTEM

- With the bayonet lock, two combinable instruments are locked by means of a lever. The adapter (2) must be positioned by turning the lever (1) so that its claws can be inserted into the threaded groove of the holder (3) and can be locked using the lever (1).
- The instruments can be separated from each other by releasing the lever (1) of the adapter (2) from the holder (3).

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



SHEATHS WITH WORKING CHANNELS FOR THE INSTRUMENTS

Sheaths with working channels are fitted with replaceable rubber caps (1). Compatible instruments can be inserted through the rubber cap into the instrument channel of the respective sheath.

Note: Always ensure that the working channels of the sheaths are fitted with rubber caps (REF RZ200-000) and that these do not show any visible damage. The rubber caps must be removed from the instrument before reprocessing.

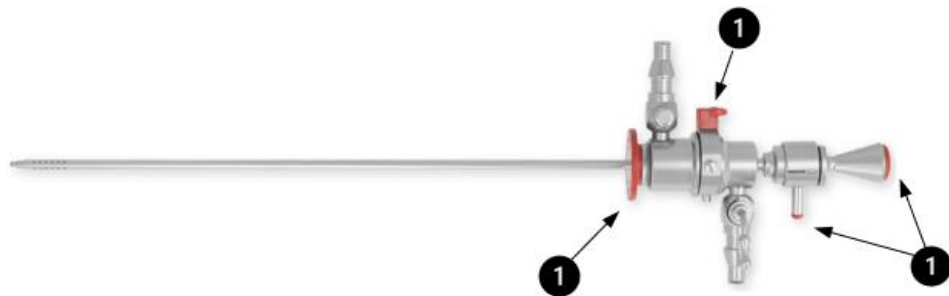
Sheaths with working channel:



COMBINATION OF SHEATHS WITH OBTURATORS OR ENDOSCOPES

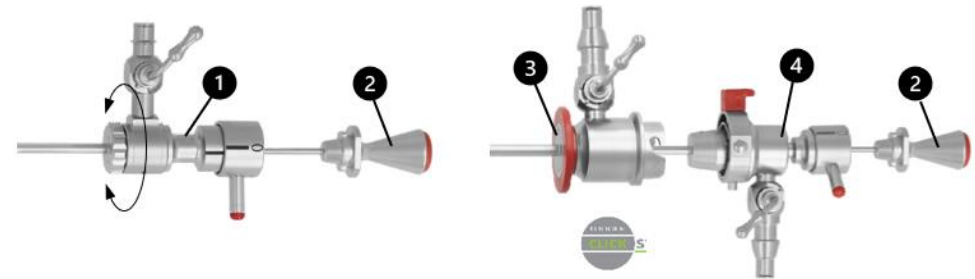
The sheaths and their locking system are color-coded according to their size. When combining compatible RUDOLF Medical endoscopes/obturators, pay attention to their color coding (1).

Note: The color coding of an endoscope represents its viewing angle and can therefore differ from the color coding of the sheaths/locking system.



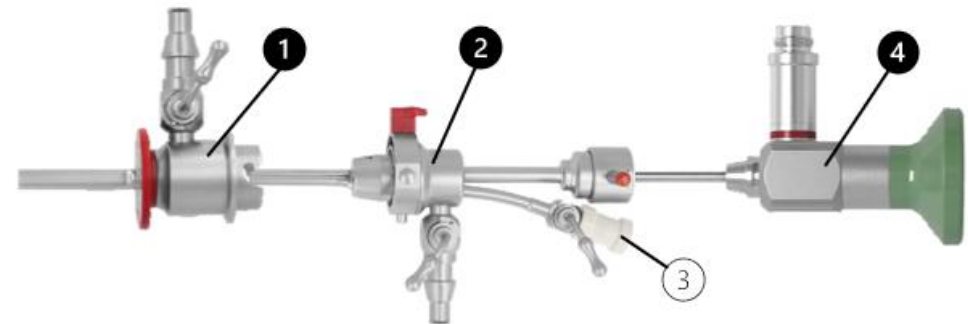
DIAGNOSTIC SHEATHS

- Diagnostic sheath (1) with rotatable stopcock and bayonet lock, obturator (2).
- Diagnostic sheath with outer sheath Click System (3) and inner sheath Click System (4) with bayonet lock, obturator (2).
- When using a sheath for diagnosis, the obturator is replaced by a compatible RUDOLF Medical endoscope.



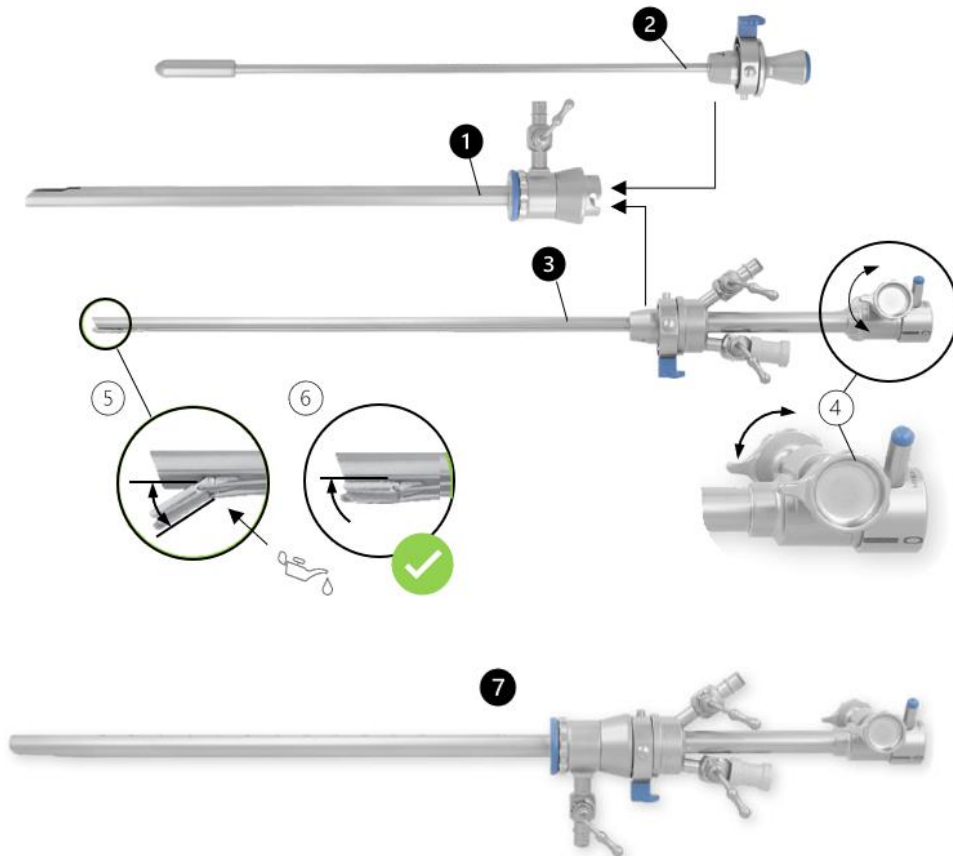
OPERATION SHEATHS

- Operation outer sheath Click System (1), operation inner sheath Click System (2) with working channel (3) and bayonet lock, endoscope (4).
- Before using a suitable endoscope with an operation sheath, the obturator must be replaced with a compatible RUDOLF Medical endoscope.



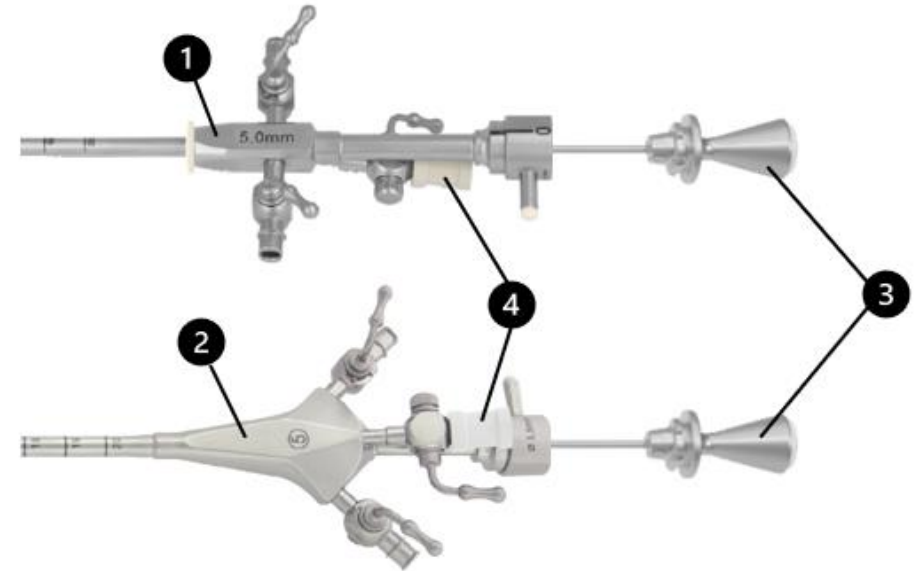
Operation sheaths for continuous flow, with Albarran lever

- Outer operating sheath for continuous irrigation (1), can be combined with the Obturator Click System (2) or with the sheath Click System with bendable Albarran lever (3) and bayonet lock.
- The Albarran lever (5) is adjusted by turning the adjusting wheels (4). The Albarran lever is used to guide and steer a flexible or semi-rigid instrument (forceps, scissors, monopolar HF electrode) inserted through the working channel.
- Outer operation sheath (7) with integrated Albarran sheath.
- When using an operation sheath, the obturator is replaced by a compatible RUDOLF Medical endoscope.
- When inserting and removing the Albarran sheath through the outer operation sheath, the Albarran lever must be in the rest position (6).
- Always insert the flexible or semi-rigid instruments through the working channel of the sheath with their jaws closed.









High-flow sheaths

- High-flow sheaths (1) with working channel and rubber cap (4), with two rotatable stopcocks, bayonet lock for obturator (3) or endoscope.
- High-flow sheath (2) with working channel and rubber cap (4), two diagonally positioned stopcocks, bayonet lock for obturator (3) or endoscope.
- When using a high-flow sheath, the obturator is replaced by a compatible RUDOLF Medical endoscope.



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 that is approved for medical devices and steam sterilization. Lubricate stopcocks, threads and sealing rings with maintenance lubricant.
MD	Medical Device