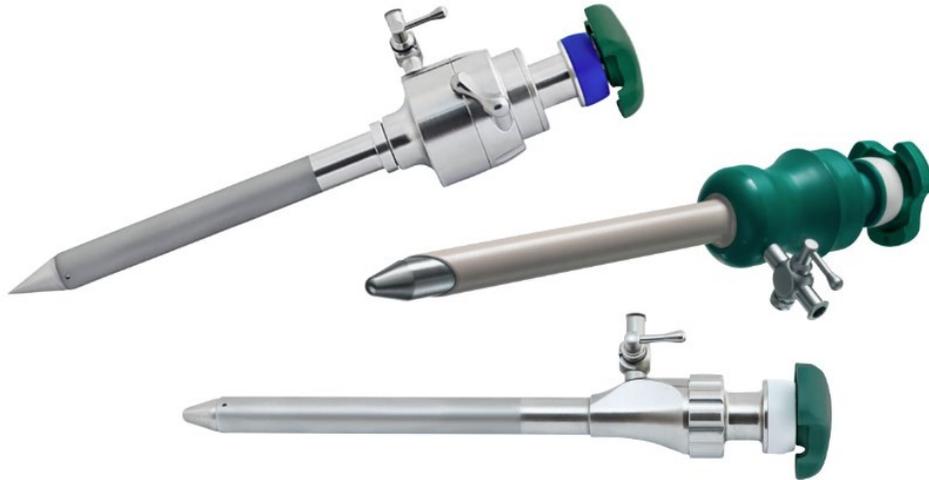


## INSTRUCTIONS FOR USE (EN) TROCAR SYSTEMS



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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 RUDOLF Medical trocar systems.

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.



Please note that the silicone valve is a disposable product. Disposable products must not be reprocessed but must be disposed of after the first use.

Before sterilization, we recommend lubricating the mechanical parts of the instrument with a care oil.

A comprehensive visual and functional inspection of the instruments should be carried out before each use.

#### INTENDED PURPOSE

Trocar spikes are intended to create a controlled entry point for the introduction of endoscopic instruments into the body

#### Contra-indication

The medical devices are not intended for the use on the central nervous and circulatory system.



#### WARNINGS AND PRECAUTIONS

- Incorrect use and overloading due to twisting/levering can lead to fractures and permanent deformation.
- Do not use metal brushes, metal sponges or abrasive cleaners, as corrosion can occur if the surface is damaged.
- The safe combination of instruments with each other or with implants 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.
- 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.
- The trocar systems are not suitable for ultrasonic cleaning.
- Do not use cleaning solutions with bleaching agents such as sodium hypochlorite, as these can cause severe corrosion.

- Do not leave the instruments in the disinfectant for too long. Follow the disinfectant manufacturer's instructions.
- Automated cleaning/disinfection should be preferred to manual cleaning/disinfection, as automated processes can be standardized, reproduced and therefore validated.
- Defective products must not be used and must have undergone the entire reprocessing process before being returned for repair or complaint.
- Gas leakage is possible due to improper fixation of the trocar or insufficient sealing of gas-conducting components, in particular the silicone valve (single-use trocar seal).

### PRIOR TO 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



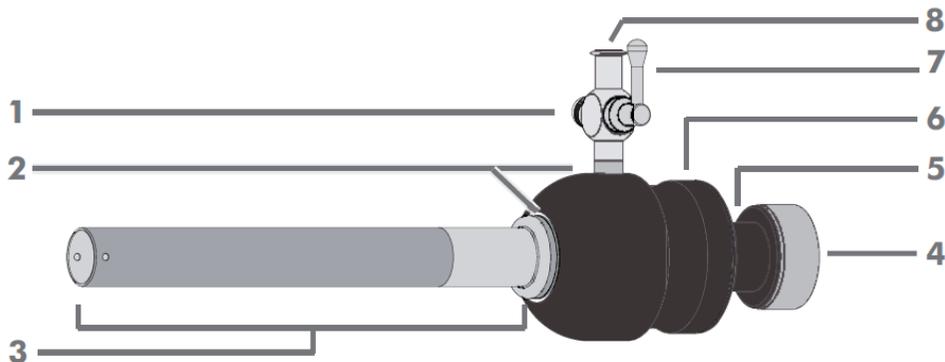
Replace the single-use silicone valve before each sterilization.



After cleaning and disinfection or before sterilization, we recommend lubricating stopcocks and threads with maintenance grease.

### PRODUCT DESCRIPTION

- The trocar is used to introduce instruments and fluids to the surgical site.
- A distinction is made between models with and without a stopcock, which enables insufflation.
- The trocar bodies are generally equipped with a conical silicone valve, which reduces gas loss when the instrument is removed again. The silicone valve is a disposable product.
- Only combine the products with instruments and original accessories that are compatible in terms of their usable length and diameter.
- The trocar systems are not suitable for ultrasonic cleaning.
- Spare parts are available on request.

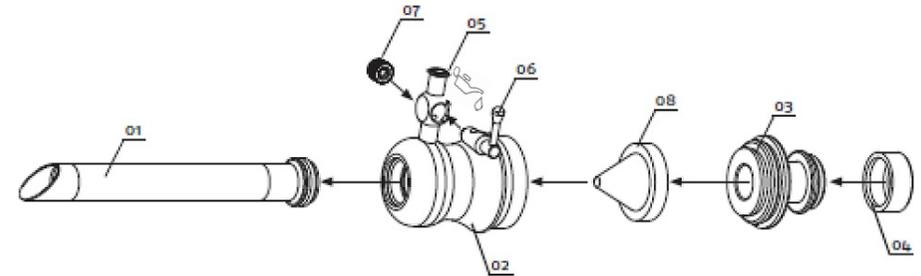


1 Spring cap

- 2 Trocar body (consists of main body + closure part)
- 3 Trocar tube
- 4 Sealing cap
- 5 Closure body with sealing cap
- 6 Main body
- 7 Stopcock plug for insufflation
- 8 Luer Lock connection

**Note:** These instructions for use apply to several trocar models. Design deviations are therefore possible.

The following illustration is helpful for the following sections on assembly and disassembly. The numbers of the individual parts can be found in the continuous text.



The silicone valve (08) in the trocar body is a disposable product. The design of the silicone valve may vary depending on the trocar model.

### ASSEMBLY

1. Place the sealing cap (04) on the sealing part of the trocar body (03).
2. Press the silicone valve (08) into the opposite opening of the closure part (03).
3. Close the threaded closure of the main body (02) and the closure part (03) by turning it clockwise.
4. Screw the trocar tube (01) onto the main body of the trocar (02).  
The trocar is now fully assembled.

### DISASSEMBLY



Only disassemble pre-cleaned instruments.

1. Remove the sealing cap (04).
2. Then open the threaded closure of the main body (02) and the closing part (03) by turning it counterclockwise.
3. Remove the silicone valve (08) and dispose of it.
4. Unscrew the thread of the trocar tube (01) from the main body (02) by turning it counterclockwise.  
The trocar has now been completely disassembled.

## HANDLING OF THE INSUFFLATION STOPCOCKS

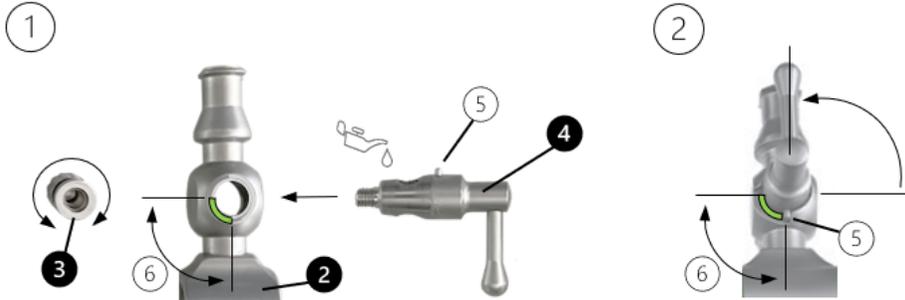
 **The stopcock must be removed from the trocar for cleaning and disinfection. Before sterilization, the stopcock must be mounted.**

### Disassembly

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

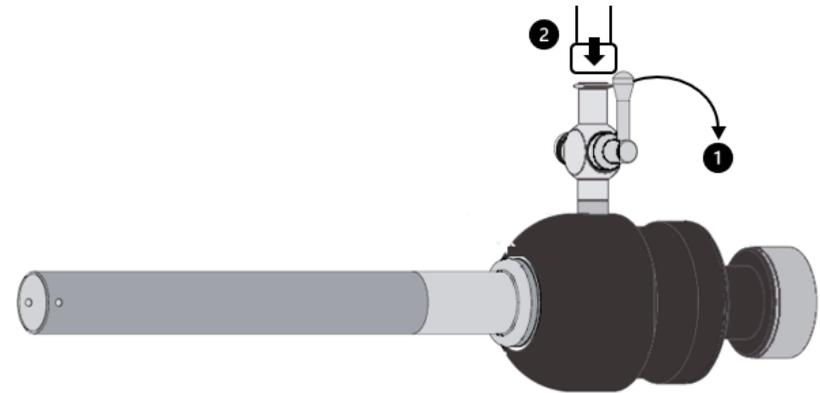
### Assembly

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. Check the mobility of the stopcock plug.
3. 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 insufflation hose

1. Close the stopcock (1).
2. Connect the insufflation hose to the stopcock (2) via the Luer Lock connection.



## SYMBOLS

	Consult instructions for use
<b>LOT</b>	Batch code
<b>REF</b>	Article no.
<b>QTY</b>	No. per package
	Non-sterile
	Caution
	Manufacturer
	Date of manufacture
	Do not re-use
<b>CE</b> <b>0297</b>	CE mark in accordance with Regulation (EU) 2017/745 for medical devices (MDR) with the identification number of the notified body
	Keep dry
	Lubricate with silicone-free, biocompatible white oil approved for medical devices and steam sterilization.
<b>MD</b>	Medical Device