

RUDOLF EasyPort Trocar systems

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Item numbers

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Indication

trocar sheath allows accurate and safe access to the operation situs. Optics and operating instruments are introduced through the trocar sheath.

Contra indication

The products are exclusively intended for the specified method in the indication and contra-indicated for all other applications. This product may only be used in health care facilities by trained medical personnel.

Function check

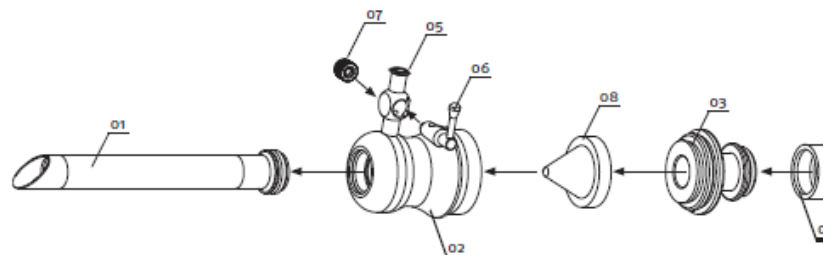
- Following delivery and before each use new instruments must undergo a thorough visual examination and must be tested for functionality.
- If the instrument exhibits any external faults (scratches, breakages, cracks, notches, damaged insulation, bent parts or stiffness) or if they do not function in the way described, please inform us as manufacturer or our sales partners immediately.
- Make sure that before inserting the silicone seal it is free of any cracks or other damages. The use of damaged seals can cause the complete tear during use. This creates the risk that the seal upon insertion of the MIC instrument is pressed by this into the patient.

Warnings and precautions

- Do not use damaged instruments.
- The instrument has only a limited stability. Force applied too strongly can lead to damage and negatively affects its functioning.

First use of new instruments

- EasyPort is delivered non-sterile. The instrument must be cleaned and sterilized before the first use. The instrument can be disassembled and must be cleaned in its disassembled state.



Instructions for disassembly

- 01 Trocar tube
- 02 Casing with stopcock
- 03 Body
- 04 Sealing cap
- 05 Stopcock
- 06 Plug
- 07 Spring cap
- 08 Silicon sealing for single use only

- Please only disassemble instruments that have been pre-washed.
- Remove the sealing cap 04.
- Then open the thread lock on the body 03 by turning it counter-clockwise to the casing 02.
- Remove the silicon sealing (single use only) 08 and dispose of it.
- Unscrew the thread of the trocar tube 01 from the casing 02 by turning it counter-clockwise.
- Unscrew the spring cap 07 and remove the plug 06 from the stopcock.
- The disassembly of the trocar sheath is now complete.

Instructions for assembly

- Put the sealing cap 04 on the body 03.
- Press the new silicon sealing (single use only) 08 into the opposite opening of the body 03.
- Close the thread lock of the casing 02 and body 03 by turning it clockwise.
- The stopcocks are to be lubricated sparingly with grease after each cleaning and before each sterilization.
- Wipe off excess grease with a single-use towel.

- We recommend our oil spray (Item no. RU 8880-00) for all lubrication procedures.

- **Make sure when inserting the plug 06 into the stopcock 05 that the guide pin rotates smoothly in the guidance and the lever, in opened state, points to the opening.**

- Screw together plug 06 with spring cap 07.
- Screw the trocar tube 01 onto the casing 02.
- Check the instrument for proper function.
- The assembly of the trocar sheath is now complete.

Preparation instructions

EasyPort Materials:

01 Trocar sheath	PEEK
02 Casing with stopcock / 03 Body	PPSU
05 Stopcock / 06 Plug / 07 Spring cap	CuZn-Legierung verchromt

Note

- The national regulations and standards for the preparation of medicinal devices are to be met.
- In the case of patients with Creutzfeldt-Jakob disease (CJD), and patients suspected of having CJ disease or possible variations of this disease, current national regulations regarding the preparation of the instruments must be applied.

Warnings and precautions

- EasyPort should not be cleaned with ultrasound.
- During preparation, the temperature affecting the instrument should not exceed 137°C.
- In principle automatic cleaning and disinfection is to be preferred to manual cleaning and disinfection. The automatic cleaning and disinfection procedure is much safer.

- Never use metal brushes/sponges or abrasive cleaning agents for manual cleaning.
- Only clean instruments and instruments of low microbiological contamination enable a successful sterilization.
- In case of damage the devices should undergo the complete reprocessing process before being sent back to the manufacturer for repair.
- Never use cleaning agents with bleaching agents, such as sodium hypochlorite, as it causes severe corrosion.

Restrictions of preparation

- The repeated / frequent preparation according to these instructions has only a small effect on the lifespan of the EasyPort.
- The silicon sealing 08 is intended for single use only.
- The life of a reusable instrument depends mainly on wear out and damages caused by its use.

Application area

- After use, the instruments must be prepared as fast as possible.
- Remove residues and stains on the instrument immediately after use with a single use cloth or tissue.
- Do not use a fixating agents or hot water (>40°C) as this can cause the fixation of residues which may influence the result of the reprocessing process.
- Deposit them preferably in a dry place.
- If necessary; soak the instruments in a solution with a suitable combination of cleaning and disinfecting agents. Please, observe the manufactures' instructions of the cleaning and disinfecting agents.
- Put the instruments in suitable wire baskets.

Transportation

- Safe storage and transportation in a closed container to the reprocessing area to avoid any damage of the instruments and contamination of the environment.

Preparation for decontamination

- The EasyPort must be disassembled for cleaning and disinfection. The instructions for disassembly must be followed.

Cleaning automatic

- Clean and disinfect the instrument only in suitable washers and disinfectors (WD) and with for the WD and the instrument validated procedure / program (EN ISO 15883).
- Suitable WDs are provided with special cleaning baskets / slide-in carts for endoscopy instruments.
- Avoid any rinsing shadows when loading the WD slide-in cart with instruments in order to obtain an ideal rinsing pressure for the entire instrument. Pay special attention to the jaws.
- Put the disassembled instruments on a special key hole surgery rack. Not suitable instruments are to be placed open on an instrument tray.
- Instruments with hollow spaces (tubes, sheaths, tubings) must be connected to special irrigations devices in order to guarantee a complete rinsing of these hollow spaces.
- Do not overload the WD slide-in carts, do not pile them up.
- Please observe the instructions for use and loading indications of the WD manufacturer.
- When choosing the appropriate cleaning agents see the respective lists and recommendations of the Robert-Koch Institute (RKI) of the DGHM Deutsche Gesellschaft für Hygiene und Mikrobiologie (German society for hygiene and microbiology) and consider the instrument's material and characteristics. See additional information of the preparation instructions at hand.

- or 5 min cleaning at 45°C with 0,5 % enzymatic detergent
- Draining
- 3 min. neutralization with warm water (>40°C) and neutralizer
- Draining
- 2 min. rinse with warm tap water (>40°C)
- Draining

Maintenance, Control and Inspection

- After the cleaning and disinfection, the instruments must be inspected visually for cleanness. They must be macroscopically clean (no visible residues/soiling). Pay special attention to grooves, ratchets, closures and other difficult accessible areas.
- Should there still be any visible residues or liquids repeat the cleaning and disinfecting procedure.
- Prior to any sterilization the instruments must be assembled and inspected for function, wear and tear and for damages, and if necessary it has to be exchanged. After the inspection, dismantle the instrument if necessary for sterilization

Packing

- Appropriate packaging for sterilization according ISO 11607 and EN 868.
- Generally adjust the sterilizing accessories and the sterile packing to the content of the packing instrument and the sterilization procedure.
- Please, observe the manufactures' instructions of the sterilizer.

Sterilization

- Sterilization is to be carried out using a steam sterilization procedure validated by DIN EN ISO 13060/ISO 17665 (fractionated vacuum procedure) in a sterilizer in accordance with EN 285/DIN 58946.
- 3 prevacuum phases with at least 60 milli bar pressure
- 134°C, 5 min or 132°C 4min.
- Drying time: minimum 10 min.
- Please, observe the manufactures' instructions of the sterilizer.

Storage

- The reprocessed instruments must be stored in suitable and reusable sterilization containers in accordance with DIN EN 868-1 and DIN EN 868-8, and should be stored until use in accordance with DIN 58953-9.

- The sterilizing container should be designed in such a way that the instrument is safely fixed and protected from damage.
- Storage of sterilized instruments in a dry, dark, low microbiologically contaminated clean and dust free environment at moderate temperatures of 5°C to 40°C.
- The storage area should be free of temperature fluctuations.

Additional Instructions

- If the described chemistry and machines are not available, it is the duty of the user to validate his process.
- It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly. Likewise, any modification by the reprocessor from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.









Repairs

- Even when used as intended surgical instruments are subject to more or less severe wear, depending on how intensely they are used. This wear cannot be avoided due to technical reasons.
- Please do not carry out any repairs yourself. Servicing and repairs may only be carried out by ourselves - the manufacturer - or by other persons we authorized.
- Surgical instruments that are to be sent back for repair have to be cleaned, disinfected and sterilized.



Caution!
Failure to observe the warnings and precautions can lead to death or serious injuries.

Symbols and explanations

	Please read these instructions carefully before using the product for the first time. Always follow the instructions in this manual. Keep these instructions for use in a safe place.
	Batch code
	Order number
	Non sterile
	Indicates a possible danger to persons or property
	CE marking with the identification number of the notified body
	Single use only (Silicon sealing!)
	Symbol for manufacturer

Cleaning agents for automatic cleaning in WD:

Manufacturer	Trade name
Dr. Weigert GmbH & Co. KG	Neodisher FA
Borer Switzerland	Deconex 23 Neutrazym

*the suitability of the cleaning agent as well as subsequently described method has been demonstrated based on preclinical testing / validation by Rudolf Medical.

A - Cleaning program (Miele G 7735):

- 1 min. pre-cleaning with cold water
- Draining
- 3 min. pre-cleaning with cold water
- Draining
- 5 min cleaning at 55°C with 0,5 % alkaline detergent

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Item numbers

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RZ003-100	RZ003-110	RZ003-125