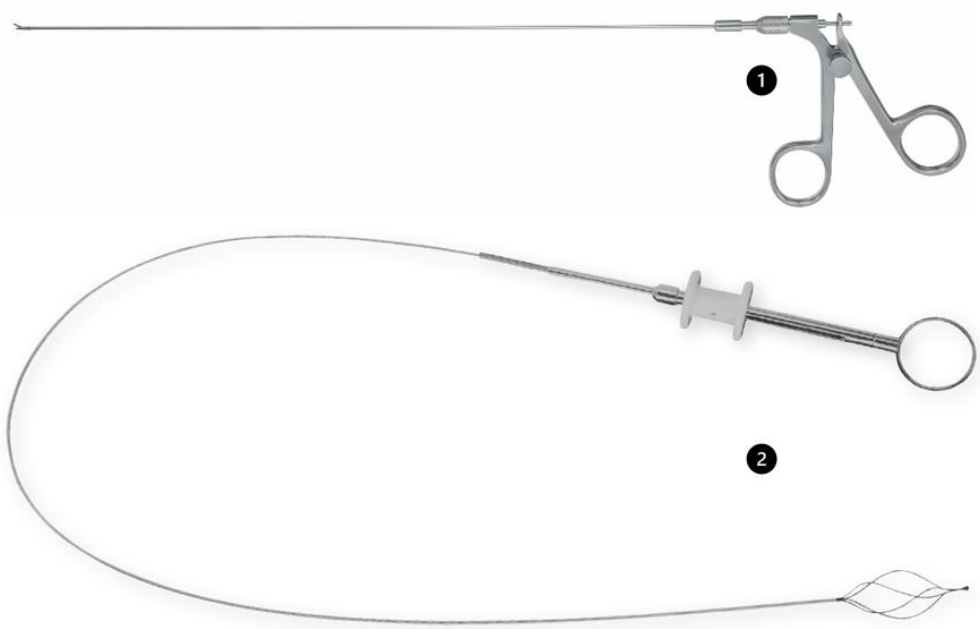
INSTRUCTIONS FOR USE (EN)

SEMI-RIGID AND FLEXIBLE BIOPSY FORCEPS, GRASPING FORCEPS, SCISSORS AND FLEXIBLE STONE EXTRACTOR



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PLEASE READ BEFORE REPROCESSING AND KEEP IN A SAFE PLACE

PRODUCT

These instructions for use are valid for the RUDOLF Medical semi-rigid and flexible biopsy forceps, grasping forceps, scissors and the flexible stone extractor.
You have received a high-quality product, the proper handling and use of which is described below. The instruments are used in urology, nephroscopy and hysteroscopy.
The products must only be used in medical facilities by trained and qualified medical personnel.

NON STERILE 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

Semi-rigid and flexible biopsy forceps, grasping forceps, scissors, and flexible stone removers are intended for cutting, grasping and removing biopsies or stones in endoscopic gynecology/urology.

⚠ WARNINGS AND PRECAUTIONS

- Improper use and overstraining due to twisting / levering can lead to breaks and permanent deformation.
- Do not touch the mandrel of the gripping forceps with a mandrel, as there is a risk of injury and infection.
- 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.
- In the case of patients with Creutzfeldt-Jakob disease (CJD), possible variants of this disease or suspected CJD, the applicable national regulations regarding the disposal and reprocessing of instruments 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 the following:

- External damage (e.g., deformed sheath, dents, burrs, cracks or sharp edges)
- The jaws of the forceps must open and close smoothly and correctly without applying too much force.
- Correct functioning
- Cleaning agent or disinfectant residues

APPLICATION

Inserting the forceps

Insert the instrument with closed jaws into the instrument channel as follows:

1. Make sure that the instrument used matches the diameter of the instrument channel.
2. Operate the handle to close the jaws of the forceps and insert the instrument into the endoscope with the jaws closed.
3. Hold the instrument as axially as possible when inserting it into the instrument channel.
4. Grasp the instrument approx. 3 cm in front of the jaw/working end before you insert the forceps into the instrument channel. Push the forceps forward slowly and carefully with the jaw closed until the forceps is clearly visible.
5. Hold the handle firmly when inserting the instrument into the instrument channel.

⚠ Do not insert the instrument when there is resistance and never push the instrument forward abruptly. Otherwise, the instrument and/or the endoscope may be damaged. It may also result in injury to the patient, such as perforations, bleeding or mucosal injuries.

Removal of tissue samples or foreign bodies using forceps

1. Guide the forceps to the point where the sample or foreign body is to be removed.
2. Open the jaws and grasp the tissue or object to be removed.

⚠ Do not press the instrument too firmly into the tissue, as this can lead to injuries to the patient such as perforations, bleeding or mucosal injuries.

Cutting tissue or suturing with scissors

1. Guide the instrument to the point where the tissue or suturing is to be cut.
2. Open and close the instrument to cut and separate the tissue or suturing.

⚠ Do not press the scissors too hard into the tissue, as this can lead to injuries to the patient such as perforations, bleeding or mucous membrane injuries.

Extracting tissue or foreign bodies with a stone extractor

1. Guide the basket to the site where the tissue is to be taken, or foreign body is to be removed.
1. Open the basket by pushing the slider on the handle forwards.
2. Grasp the tissue or foreign body to be removed.
3. Carefully close the basket by pulling the slider on the handle towards you.

⚠ Do not press the stone extractor too firmly into the tissue, as this can lead to injuries to the patient such as perforations, bleeding or mucosal injuries.

Pulling the instrument out of the instrument channel

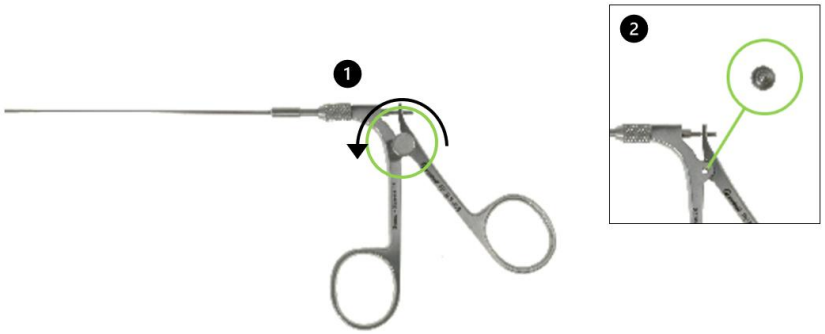
1. Operate the handle to close the jaws of the instrument.
2. When the instrument is closed, pull it slowly and carefully out of the instrument channel.

⚠

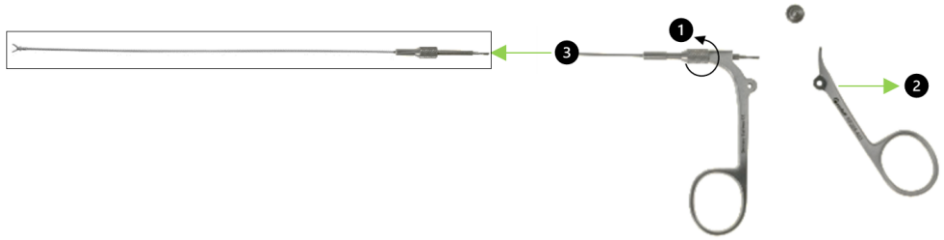
– Be careful when removing the instrument. Otherwise, blood, mucus and other secretions may come out, which could be a risk of infection.
– If you feel resistance, reduce the bending angle until the instrument can be pulled back easily. The instrument and/or the endoscope may be damaged if it is pulled back forcibly. If the instrument can no longer be closed completely, remove the endoscope with the instrument.
– Make sure that no infectious material is left behind, otherwise there is a risk of infection for the patient and user.

DISASSEMBLY OF THE BIOPSY FORCEPS, GRASPING FORCEPS, SCISSORS

1. Loosen the screw (1) counterclockwise and remove it (2).
2. Loosen the knurled nut from the handle (1) counterclockwise.

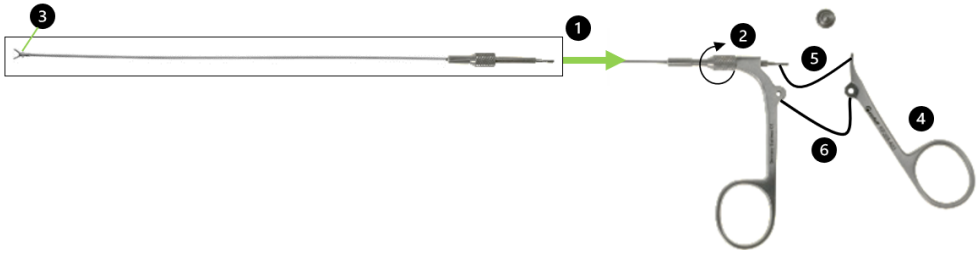


3. Remove the thumb-operated handle (2) and pull the instrument insert out of the handle (3).

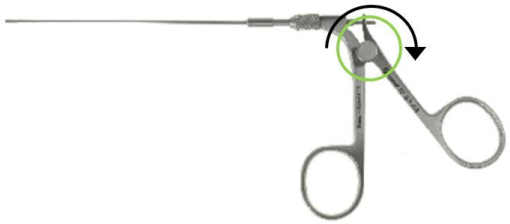


ASSEMBLY OF THE BIOPSY FORCEPS, GRASPING FORCEPS, SCISSORS

1. Insert the instrument insert (1) into the opening of the front handle and screw on the knurled nut clockwise (2)
2. Position the working end (3) before tightening the screw.
3. Insert the thumb-operated handle (4) with the fork into the groove (5) of the instrument insert and into the screw lock (6).



4. Tighten the screw on the handle clockwise.



REPROCESSING INSTRUCTIONS

Restrictions

- The product service life depends on the following:
  - Number of applications and the associated reprocessing cycles
  - Care and maintenance
- Do not use fixing agents or hot water (> 40°C), as this can lead to hardening of residues and thus impair the cleaning success. The cleaning agents must be aldehyde-free.

⚠ Provided the stone extractor is undamaged and with appropriate care, the stone extractor can be reused up to 60 times. Any further use beyond this is the responsibility of the user. The use of damaged and/or contaminated instruments may result in injury to the patient and user.

Material resistance

When selecting cleaning agents and disinfectants, make sure that they **do not** contain the following ingredients:

- Strong organic, mineral and oxidizing acids (minimum permissible pH value 5.5)
- Strong alkaline solutions (maximum permissible pH value 11, neutral/enzymatic or slightly alkaline cleaning agent recommended)
- Organic solvents (e.g., ethers, ketones, benzenes), fluorinated alcohols
- Oxidizing agents (e.g., hydrogen peroxides)
- Halogens (chlorine, iodine, bromine)
- Aromatic/halogenated hydrocarbons
- Formamide
- Trichloroethylene/perchloroethylene

Initial treatment at the place of use

- Defective instruments must be labelled as such. They have to be reprocessed before being disposed of or returned.
- The instruments must be reprocessed within one hour after use to prevent contamination from drying.
- Heavy contamination on the instrument must be removed immediately after use with a disposable cloth.

Transportation

- Safe transport of the instruments to the reprocessing site should be carried out in a closed receptacle / container system to avoid damage to the instruments and contamination of the environment.

Preparation before cleaning

- The forceps and scissors must be disassembled for reprocessing. See the "Disassembling the biopsy forceps, grasping forceps and scissors" section.

Manual pre-cleaning

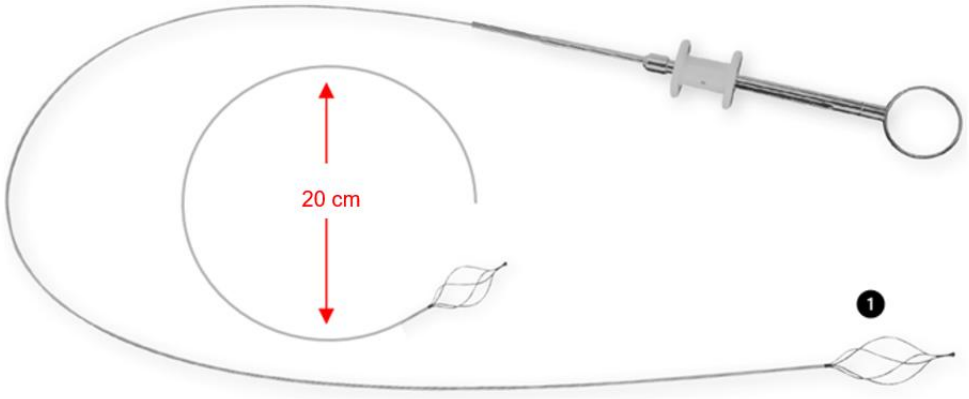
- Observe the manufacturer’s instructions for the cleaning agent (concentration, temperature, and sonication time).

Manual pre-cleaning of forceps and scissors

1. Immerse the instrument in the cleaning solution and remove any contamination visible on the outside of the jaws using a clean, soft brush that is only used for this purpose. Do not use steel wool or metal brushes.
2. Open and close the jaws of the instrument immersed in the cleaning solution at least three times.
3. Disassemble the forceps and scissors. See section "Disassembling the biopsy forceps, grasping forceps and scissors".
4. Place the instruments with open jaws and the handle directly into an ultrasonic bath filled with cleaning solution (duration, concentration and sonication time according to the manufacturer's instructions)
5. Then rinse the instruments under running water for at least one minute: temperature < 35C / 95 °F.

Manual pre-cleaning of the stone extractor

1. Immerse the stone extractor in the cleaning solution and remove all visible contamination using a clean, soft brush that is only used for this purpose. Do not use steel wool or metal brushes.
2. Open and close the working end (1) of the stone extractor immersed in the cleaning solution at least three times.
3. Place the stone extractor wound up (not less than Ø 20 cm) with the working end open directly into an ultrasonic bath filled with cleaning solution (duration and concentration as well as sonication time according to the manufacturer's instructions).



Cleaning agent for the manual pre-cleaning in an ultrasonic bath

Process type	Cleaning agent	pH value	Manufacturer
Enzymatic	0.2% neodisher® MediZym	8,2	Dr. Weigert

Automated cleaning and disinfection

- Clean and disinfect the instruments only in suitable washer-disinfectors (WD) and with a procedure / program validated for the WD and surgical instruments (EN ISO 15883).
- The operating and loading instructions of the WD manufacturers must be observed.
- When selecting the cleaning agent, consider the material and properties of the instrument, the cleaning agents recommended by the WD manufacturer for the respective application and the relevant recommendations of the Robert Koch Institute (RKI) and the German Society for Hygiene and Microbiology (Deutsche Gesellschaft für Hygiene und Mikrobiologie, DGHM).

Cleaning agents for machine cleaning in the WD

Process type	Cleaning agent	pH value	Manufacturer
Enzymatic	0.2% neodisher® MediZym	8,2	Dr. Weigert

Procedure

1. Insert the disassembled forceps and scissors with open jaws or the stone extractor wound up (not less than Ø 20 cm) with the working end extended into the washer-disinfector. Make sure that the instruments do not touch each other.
2. Place handle parts in a small parts basket in the washer/disinfector.
3. Start the program.
4. Remove the instruments after the program is finished.

Automated cleaning program with thermal disinfection in the WD using the enzymatic process

Process	Reagents	Time / min	T / °C
Pre-cleaning	Deionized water	5	< 25°C
Draining	---	---	---
Cleaning	Deionized water Enzymatic cleaning agent (1)	5	40
Draining	---	---	---
Draining	---	---	---
Flushing (2)	Deionized water	3	Cold
Draining	---	---	---
Disinfection (3)	Deionized water	10	> 90
Drying (4)	---	> 20	Max. 93

- (1) The recommended concentrations for admixture can be found in the data sheet of the cleaning agent.
- (2) Note: Only use sterile (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water for rinsing.
- (3) For mechanical thermal disinfection, observe the national requirements for the A0 value from ISO 15883-1 (A0 = 3000).
- (4) If necessary, manual drying can also be carried out using a lint-free cloth. Dry instrument cavities with sterile compressed air.

MAINTENANCE, CONTROL AND INSPECTION

- Instrument oils and instrument greases must not be used.
- After cleaning and disinfection, the instruments must undergo a visual and functional inspection. The instruments must be macroscopically clean (free of visible residues). Particular attention should be paid to slots, ratchets, joints and other areas that are difficult to access.
- If residues / liquids are still visible, the cleaning and disinfection process must be repeated.
- Before sterilization, the instrument must be assembled and checked for function, wear and damage (cracks, rust) and, if necessary, replaced. See the "Assembly of biopsy forceps, grasping forceps, scissors" section.
- Defective products must have undergone the entire reprocessing process before being returned for repair or complaint.
- See also "Prior to each use: visual and functional inspection" in these instructions.

PACKAGING

- Standardized packaging of instruments for sterilization is carried out according to DIN EN ISO 11607 and DIN EN 868.
- In the case of individual packaging, ensure that the packaging is large enough to hold the product without causing tension on the seal seam or tearing the packaging. Sharp tips and edges must not perforate the sterilization packaging.

STERILIZATION

- The sterilizers are validated according to DIN EN 13060 and DIN EN 285.
- The steam sterilization process (fractionated vacuum process) is validated according to DIN EN ISO 17665-1
- The following sterilization procedures must not be used: flash sterilization, hot air sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization and plasma sterilization.

Sterilization temperature	Minimum holding time	Drying time
132°C (270°F) - 134°C (273°F)	5 minutes	At least 20 minutes
121°C (250°F)	20 minutes	At least 20 minutes

The manufacturer's instructions for the sterilization device must be observed.

STORAGE

- Store the sterilized instruments in a low-germ, dry, clean and dust-free environment at room temperature.

INFORMATION ON THE VALIDATION OF THE REPROCESSING

The following tools and machines were used in the validation:

Manual pre-cleaning in an ultrasonic bath	• Detergent: 0.2% neodisher® MediZym from Dr. Weigert, enzymatic, pH value: 8.2 • Ultrasonic bath
Automated cleaning and disinfection	• Thermal disinfection • Detergent: 0.2% neodisher® MediZym from Dr. Weigert, enzymatic, pH value: 8.2
Washer / disinfector	Miele G 7836 CD
Sterilization	• Steam sterilization 1: triple pre-vacuum; 132°C/134°C • Sterilizer 1: ZIRBUS technology HST 6x6x6
	• Steam sterilization 2: pre-vacuum triple; 121°C • Sterilizer 2: MMM Euro-Selectomat

ADDITIONAL NOTES

- If the specified cleaning agents and machines are not available, the user needs to validate their process.

DISPOSAL

- The products should be disposed of accordingly only after they have been cleaned and disinfected properly.
- Comply with national regulations and applicable hospital guidelines when discarding or recycling the product / components.
- Be careful with sharp tips and cutting edges. Use suitable protective caps or containers to prevent third parties from being injured.

REPAIRS AND RETURNS

- Never carry out repairs yourself. Service and repairs must only be carried out by trained and qualified persons. If you have any questions, contact RUDOLF Medical, your distributor or your medical technology department.
- Defective products must have undergone the entire reprocessing process before being returned for repair or complaint.

PROBLEMS / EVENTS

- The user should report all problems with RUDOLF Medical products to their respective distributor.
- In the event of serious incidents with the products, the user must report them to RUDOLF Medical as the manufacturer and to the competent authority of the member state in which the user resides.

WARRANTY

- The instruments are made of high-quality materials and undergo strict quality control before delivery. If there are any discrepancies, please contact your respective distributor or RUDOLF Medical.

REPROCESSING - APPLICABLE STANDARDS

- AAMI/ANSI ST77:2006 Containment Devices for Reusable Medical Device Sterilization
- Hygiene requirements for the reprocessing of medical devices, status: 10/2012, KRINKO/RKI/BfArM
- DIN EN 285 Sterilization - Steam sterilizers - Large sterilizers
- DIN EN 868 Packaging materials and systems for medical devices to be sterilized - Part 8: Reusable sterilization containers for steam sterilizers according to EN 285; requirements and test methods
- DIN EN ISO 11607: Packaging for medical devices to be sterilized in the final packaging - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- DIN EN 13060: Small steam sterilizers
- DIN EN ISO 15883: Washer/disinfectors - Part 1: General requirements, terminology and test methods
- DIN EN ISO 17664: Reprocessing of health care products - Information to be provided by the medical device manufacturer for the reprocessing of medical devices
- ISO 17665-1 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and control of the application of a sterilization procedure for medical devices
- Medical Device Services - for steam sterilization: Reports #146159-10 and #052360-10
- Medical Device Services - for automated cleaning: Reports #146158-10-A, #146158-10-B, #146158-10-C

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
	Keep dry
	Keep away from sunlight
MD	Medical Device