

Instructions for use

Reusable Grasping Forceps

1. Intended Use

Grasping forceps are used for foreign body removal from the patient's digestive system.

Patient populations: for adults only.

Use only with an endoscope.

Do not use for any other purpose!

Do not work with damaged instruments!

These instructions are intended to assist the user in using the device as intended, to describe its use and thus provide a higher degree of safety for the patient.

2. Design

Endoaccess GmbH supplies various designs of grasping forceps for various applications. Information on the range of sizes available may be obtained directly from us.

3. Before use

Please study these instructions carefully before using the reusable grasping forceps. The functional principles and handling must be completely understood.

In addition, please also inspect the instrument for any defects or damages after removing it from the packaging. If damages or defects are detected during this inspection the instrument must not be used on the patient and must immediately be returned to **Endoaccess GmbH** for inspection by an expert.

The reusable grasping forceps is not supplied sterile by Endoaccess. It must be inspected for damages before use. Only undamaged devices may be used! The instrument must be sterilized before the first use and after every use.

4. Handling

a. Introducing the grasping forceps into the endoscope:

The grasping forceps must only be introduced into the operating channel of the endoscope with **forceps jaws closed**. For this, appropriate diameters of grasping forceps and working channels must be considered (see "Table 1

b. Types

Endoaccess GmbH offers reusable grasping forceps in different types for various application cases

Table 1: Models

Number	Model Name	Model Spec.
1	Reusable Grasping Forceps (Rat Tooth Type)	EA-R18RG07 EA-R18RG10 EA-R18RG12 EA-R18RG15 EA-R18RG25 EA-R24RG15 EA-R24RG17 EA-R24RG18 EA-R24RG21 EA-R24RG23
2	Reusable Grasping Forceps (Rat Tooth with Alligator Jaws type)	EA-R18RAG07 EA-R18RAG10 EA-R18RAG12 EA-R18RAG15 EA-R18RAG25 EA-R24RAG15 EA-R24RAG17 EA-R24RAG18 EA-R24RAG21 EA-R24RAG23

3	Reusable Grasping Forceps (Alligator type)	EA-R18AG07 EA-R18AG10 EA-R18AG12 EA-R18AG15 EA-R18AG25 EA-R24AG15 EA-R24AG17 EA-R24AG18 EA-R24AG21 EA-R24AG23
4	Reusable Grasping Forceps (Pelican type)	EA-R18PG07 EA-R18PG10 EA-R18PG12 EA-R18PG15 EA-R18PG25 EA-R24PG15 EA-R24PG17 EA-R24PG18 EA-R24PG21 EA-R24PG23
5	Reusable Grasping Forceps (3-Prong type) and Hook type (H)	EA-R18TP07 EA-R18TP10 EA-R18TP15 EA-R18TP25 EA-R24TP15 EA-R24TP16 EA-R24TP17 EA-R24TP21 EA-R24TP23 EA-R18TP07H EA-R18TP10H EA-R18TP15H
6	Reusable Grasping Forceps (5-Prong type) and hook type (H)	EA-R18FP07 EA-R18FP10 EA-R18FP15 EA-R24FP15 EA-R24FP16 EA-R24FP17 EA-R24FP18 EA-R24FP21 EA-R24FP23 EA-R18FP07H EA-R18FP10H EA-R18FP15H EA-R23FP23H
7	Reusable Grasping Forceps (2-Prong Type)	EA-R24DP16 EA-R24DP17 EA-R24DP21 EA-R24DP23
8	Reusable Grasping Forceps (Scissors type)	EA-R24ST16 EA-R24ST17 EA-R24ST18 EA-R24ST21 EA-R24ST23
9	Reusable Grasping Forceps (Rubber Tips type)	EA-R24ST15 EA-R24RT16 EA-R24RT17 EA-R24RT18 EA-R24RT21 EA-R24RT23
10	Reusable Grasping Forceps (Half-Scissors type)	EA-R24HT15 EA-R24HT17 EA-R24HT21 EA-R24HT23

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11	Reusable Fold Angular Basket (Stainless steel)	EA-R18BS07xx EA-R18BS10xx EA-R18BS16xx EA-R18BS25xx EA-R24BS15xx EA-R24BS17xx EA-R24BS19xx EA-R24BS21xx EA-R24BS23xx
12	Reusable Basket without Tip (Nitinol)	EA-R18BM07xx EA-R18BM10xx EA-R18BM16xx EA-R18BM25xx EA-R24BM15xx EA-R24BM17xx EA-R24BM21xx EA-R24BM23xx
13	Reusable Spirality Basket (Nitinol)	EA-R18SB07xx EA-R18SB10xx EA-R18SB16xx EA-R18SB25xx EA-R24SB15xx EA-R24SB17xx EA-R24SB21xx EA-R24SB23xx

Information about the offered dimensions may be obtained from the **Endoaccess GmbH** main catalogue.

c. Product structure

The reusable grasping forceps is composed of four components: head, tube, sliding handle and hand holder. Please select the respective instrument according to the planned operation. Selection includes: Rat Tooth type, Rat Tooth with Alligator Jaws type, Alligator type, Pelican type, 3-Prong type, 3-Prong Hook type, 5-Prong Hook type, Scissors type, Rubber Tips type, Half-Scissors type, Fold Angular Basket type with stainless steel, Basket without Tip type with Nitinol, Spirality Basket type with Nitinol, and Spirality Basket type with Stainless steel, please see figure 1.

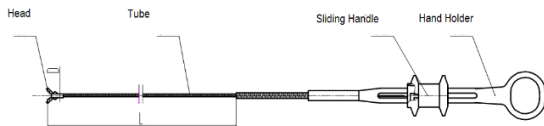


Figure1 : Components of the reusable grasping forceps

No.	Product components	Material	Materials of body contact (Yes/No)
1	Head	Stainless steel	Yes
2	Head (only for basket model)	Stainless steel, or Nitinol	Yes
3	Tube	Stainless steel, or Stainless steel and PTFE	Yes
4	Bend protection	Stainless steel, or PTFE	No
5	Handle	PSF, or Stainless steel	No

Conclusion: Body contact: stainless steel 304: Nitinol and PTFE
Without body contact: stainless steel, PTFE and PSF

5. Contraindication

- Only to be used by trained and specialized surgeons
- Do not use this device should the procedure endanger the patient's life.
- Avoid any of unsafe situations for the patient while using this device.

6. Cautions

- Check the sealing of single pouch
- Do not use in case the sealing is damaged and contact Endoaccess or your distributor for exchange
- Check the instrument for any damages or defects
- Keep away from moisture
- The reusable instruments are not delivered sterilized and must therefore be sterilized before the first use and after every use
- To be stored indoors and kept dry
- Only to be used with an endoscope. It cannot be used independently.
- Please consider type, function and working channel diameter of the forceps. The diameter of the working channel must be larger than the outer diameter of the tube of the instrument. E.g.: the reusable grasping forceps model EA-R24RT23: the outer diameter of the tube is for 2.4mm, and it fits an endoscope with a working channel of 2.8mm or bigger, length 2300mm.

Please refer to table 2 for specification

Model	Scope range	Note
EA-R24RG23	Working channel diameter > or = 2.8mm	24 17/23 Working Length (17: 1700mm; 23 and other: ×100mm) External Diameter of forceps head (×0.1mm)

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7. Operation

7.1 Insertion into the endoscope

Jaws of the grasping forceps must be completely closed; baskets or snare with bag must be completely retracted into the tube during insertion. Please pay attention to compatibility of the forceps and the endoscope's working channel diameter.

7.2 Foreign Body Capture and Removal

Once the foreign body is located proceed as follows:

7.2.1 Grasping forceps

- Insert the grasping forceps into the endoscope through the working channel.
- Place the forceps in front of the object to be removed and open the jaws by pushing the handle spool and capture the object.
- Close the jaws as much as the object allows and remove object and forceps by gently withdrawing the endoscope. Always keep the jaws closed.

8. Cleaning and Disinfection

Recommended ambient temperature for cleaning and disinfection of reusable products < 30 °C.

8.1. Preparation before cleaning

Prepare all related items including water tub, soft brush, gauze, multi-enzyme cleaning solution, dry duster, and others if necessary.

8.2. Cleaning

- Washing: Wash the products with drinking water at a temperature not higher than 45°C for 30 seconds.
- II. rinsing: put the products into the 40HZ ultrasonic cleaning machine; add 0.5% Multi-enzyme washing liquid for ultrasonic cleaning of 2 minutes; then ultrasonic rinse again with drinking water for 3 times for 5 minutes each time.
- III. Final Rinsing: Place products into purified water with conductivity $\leq 15\mu\text{s}/\text{cm}$ (25 °C) to rinse for 30 seconds in final step.

8.3 Drying

Dry products at 50 \pm 5°C for 120 mins.

8.4 Disinfecting

8.4.1 Use purified water (conductivity $\leq 5.1\mu\text{s}/\text{cm}$ (25°C)) to dilute glutaraldehyde solution to 2.5%

8.4.2 Add sodium bicarbonate to adjust pH (7.5 \leq 8.0) to the 2.5% glutaraldehyde disinfectant; Then add 0.5% sodium nitrite to prevent rust from forming on the instruments.

8.4.3 Cover instruments completely in the disinfectant and leave in sealed container for 45 min.

8.4.4 After 45 min. wash the instruments with purified water (conductivity $\leq 15\mu\text{s}/\text{cm}$ (25°C) for 30 seconds

8.4.5 Finally, dry for 120 min at, 50 \pm 5°C

8.5 Packing

8.5.1 After the disinfection has been finished completely wrap the instruments in medical gaze.

8.5.2 Place the sterilized products flat in a sterilization basket lightly on top of each other. Handle with care.

9. Sterilization

Endoaccess reusable instruments are not sterile when delivered. They must be sterilized before the 1st use, as well as after each use.

- not sterile on delivery
- sterilized before the first use
- method: autoclaving
- sterilization conditions: at a temperature of 132 °C and a pressure of 202.7kPa for 5 minutes.

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10. Validity period

- Ten years after production date
- Max. number of sterilizations procedures: 30.

11. Storage

- Store only after sterilization and drying process has been completed
- Keep dry

To be stored indoors Improper storage voids all warranty claims

12. User

The user of the instruments of Endoaccess GmbH must be specialized in the field of endoscopy. He should have special training in handling and reprocessing of flexible endoscopy instruments

13. Repairing and Complaints

In the interest of our employees' health, only sterilized or disinfected instruments will be accepted as returns. They should be labelled as such; otherwise, they cannot be handled further

14. Legal Foundation

The Law of the European Union is applied.

15. Disclosure of residual risks

The product may contain the following residual risks:











- ✓ Bacterial or virus infection to the patient or other persons;
- ✓ Re-or cross-infection
- ✓ Operational hazards caused by application error

16. Product Support

In case of questions or difficulties concerning our instruments please contact your distributor or Endoaccess GmbH directly during regular working hours.

Address: Endoaccess GmbH, Feldriethe 1, 30826 Garbsen, Germany
Tel: +49 5131 4422 60 Fax: +49 5131 4422 622

17. Symbols

	Non sterile		Lot number
	Expiration date		Date of manufacture
	Manufacturer		Do not use if package is damaged
	keep dry		Product code
	Give attention to the IfU		Medical Device

18. Disposal

After use, dispose the instrument and packaging according to the regulations of the hospital, or local waste law



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