

## Instructions for use

### 1. Intended Use

The reusable biopsy forceps is used to take biopsy tissue from alimentary canal mucous membrane to provide the pathologic basis for diagnosis. Patient populations: for adults only.

**Only to be used with an endoscope.  
Do not use for any other purpose!  
Do not use when damaged!**

This instruction is intended to assist the user in using the biopsy forceps as intended, to describe their use and thus provide a higher degree of safety for the patient.

### 2. Design

Endoaccess GmbH supplies various designs of biopsy 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 biopsy forceps. The functional principles and handling must be completely understood.

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

**Please note that you do not need to exert much force on the handle to carry out the biopsy. The amount of strength to be used is the equivalent of a gentle handshake.**

**The reusable biopsy forceps is not supplied sterile by Endoaccess GmbH. It must be inspected for damage before use. Only undamaged biopsy forceps must be used! The instrument must be sterilized before first and after every following use.**

### 4. Handling

#### 4.1 Introducing the biopsy forceps into the endoscope.

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

#### 4.2 Types

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

Table 1: Models of reusable biopsy forceps

No.	Model Name	Model spec.	Size
1	Reusable Biopsy Forceps (Standard type )	EA-R18S10	Ø 1.8*1000mm
		EA-R18S12	Ø 1.8*1200mm
		EA-R18S15	Ø 1.8*1500mm
		EA-R18S16	Ø 1.8*1600mm
		EA-R24S16	Ø 2.4*1600mm
		EA-R24S17	Ø 2.4*1700mm
		EA-R24S18	Ø 2.4*1800mm
		EA-R24S21 EA-R24S23	Ø 2.4*2100mm Ø 2.4*2300mm
2	Reusable Biopsy Forceps (Alligator, single moving cup type)	EA-R18OP10	Ø 1.8*1000mm
		EA-R18OP12	Ø 1.8*1200mm
		EA-R18OP15	Ø 1.8*1500mm
		EA-R24OP16	Ø 2.4*1600mm
		EA-R24OP17	Ø 2.4*1700mm
		EA-R24OP18	Ø 2.4*1800mm
		EA-R24OP21	Ø 2.4*2100mm
		EA-R24OP23	Ø 2.4*2300mm
3	Reusable Biopsy Forceps (Oval Fenestrated Cups type)	EA-R18C10	Ø 1.8*1000mm
		EA-R18C12	Ø 1.8*1200mm
		EA-R18C15	Ø 1.8*1500mm
		EA-R24C16	Ø 2.4*1600mm
		EA-R24C17	Ø 2.4*1700mm
		EA-R24C18	Ø 2.4*1800mm
		EA-R24C21	Ø 2.4*2100mm
		EA-R24C23	Ø 2.4*2300mm
4	Reusable Biopsy Forceps (Oval Fenestrated Cups with Needle type)	EA-R18OW10	Ø 1.8*1000mm
		EA-R18OW12	Ø 1.8*1200mm
		EA-R18OW15	Ø 1.8*1500mm
		EA-R24OW16	Ø 2.4*1600mm
		EA-R24OW17	Ø 2.4*1700mm
		EA-R24OW18	Ø 2.4*1800mm
		EA-R24OW21	Ø 2.4*2100mm
		EA-R24OW23	Ø 2.4*2300mm
5	Reusable Biopsy Forceps (Alligator Jaws type)	EA-R18A10	Ø 1.8*1000mm
		EA-R18A12	Ø 1.8*1200mm
		EA-R18A15	Ø 1.8*1500mm
		EA-R24A16	Ø 2.4*1600mm
		EA-R24A17	Ø 2.4*1700mm
		EA-R24A18	Ø 2.4*1800mm
		EA-R24A21	Ø 2.4*2100mm
		EA-R24A23	Ø 2.4*2300mm
6	Reusable Biopsy Forceps (Alligator Jaws with Needle type)	EA-R18AW10	Ø 1.8*1000mm
		EA-R18AW12	Ø 1.8*1200mm
		EA-R18AW15	Ø 1.8*1500mm
		EA-R24AW16	Ø 2.4*1600mm
		EA-R24AW17	Ø 2.4*1700mm
		EA-R24AW18	Ø 2.4*1800mm
		EA-R24AW21	Ø 2.4*2100mm
		EA-R24AW23	Ø 2.4*2300mm

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

#### 4.3 Product structure

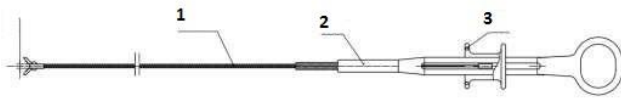
The reusable biopsy forceps is composed of head, tube and handle. The instruments differ in the design of cups and are to be selected according to application. please see figure 1.





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Figure1 : Components of the reusable biopsy forceps



Note:

- 1 - tube
- 2 - bend-protection
- 3 - handle

### The material list of Reusable Biopsy Forceps

No.	Product components	Material	Materials of body contact (Yes/No)
1	Head	Stainless steel	Yes
2	Tube	Stainless steel	Yes
3	Bend protection	Stainless steel	No
4	Handle	PSF or Stainless steel	No
Conclusion: Body contact: stainless steel 304 Without body contact: stainless steel 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

- Keep away from moisture
- Must be sterilized after every use
- To be stored in clean and dry environment
- 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.
- The reusable biopsy forceps is not sterilized upon delivery. The shelf life of the reusable biopsy forceps is 10 years. Maximum number of sterilization procedures: 30. To be sterilized before first use and after every following use. Pay attention to correct sterilization and keep the product in a dry storage. The device must be used in conjunction with an endoscope only, it cannot be used independently.
- Please consider the type, function and working channel diameter of the forceps. The diameter of working channel must be larger than the outer diameter of the reusable biopsy forceps' head. Example: reusable biopsy forceps EA-R24S23: the outer diameter of the tube is 2.4mm. Thus, the diameter of the endoscope's working channel must be 2.8mm or more with a working length of min 2300mm.

Please refer to table 2 for more information.

Table 2: Specifications

Model	Scope range	Note
EA-R24S23	Working channel diameter > or = 2.8mm	

### 7. Operation

- Position the biopsy forceps in front of targeted site
- Push the plastic spool gently forward to open the jaws of the forceps
- Introduce the forceps into the tissue, then pull back the plastic spool (causing the forceps jaws to close) and carefully remove the tissue sample
- Hold the forceps jaws in a closed position and slowly withdraw the entire instrument
- The tissue sample thus obtained may now be prepared for further examination.

### 8. Cleaning, Drying and Desinfection

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

- I. 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 ≤15us/cm (25 °C) to rinse for 30 seconds in final step.

#### 8.3 Drying

Dry products at 50 ±5°C for 120 mins.

#### 8.4 Disinfecting

8.4.1 Use purified water (conductivity ≤5.1us/cm (25°C)) to dilute glutaraldehyde solution to 2.5%

8.4.2 Add sodium bicarbonate to adjust pH (7.5 ≤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 ≤15us/cm (25°C) for 30 seconds

8.4.5 Finally, dry for 120 min at, 50 ±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.

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

### 10. Validity period

- Ten years after production date or
- Sterilization procedures max 30 times



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### 11. Storage

- Store only after sterilization and drying process has been completed
- To be stored indoors.
- Keep dry

### 12. User

The users of instruments of Endoaccess GmbH must be specialists in their fields. An appropriate and specific training for preparation, care and maintenance of the flexible instruments is required.

### 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 the local distributors 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

### 16. Symbols

	Non sterile		Do not expose to direct sunlight
	Use by		Lot number
	Manufacturer		Date of manufacture
	Keep dry		Do not use if package is damaged
	Give attention to IfU		Product code
			Medical Device

### 17. Disposal

After the products have been used for specific times required in the shelf life, dispose of products and packaging in accordance with hospital, administrative and/or local government policies.



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