Instructions for use

Reusable Electrical Forceps

NON STERILE

1. Intended Use

The reusable electrical forceps is an important and common-used accessory of alimentary canal scope diagnosis and therapy. It is used for cutting small or medium-sized polyps and coagulate the bleeding wound through high frequency electric in the gastrointestinal tract.

The instruments can only be used with an endoscope.
These instruments are not meant for any other purpose!
Do not use when damaged!
Remove the plastic HF protection before use and before sterilization!

This instruction should only be an aid to help the user to use reusable electrical forceps correctly to guarantee safe procedures and avoid unnecessary risks for the patients.

2. Types

Endoaccess GmbH offers reusable electrical forceps in different lengths, diameters and configurations for different types of endoscopes.
Further information regarding the different types and offers can be found in the main catalog of Endoaccess GmbH.

Product Name	Product Code	Working length	Instrument Diameter in mm
Hot Biopsy Forceps	EA-R18H10	1000	Ø1.8
Hot Biopsy Forceps	EA-R18H12	1200	Ø1.8
Hot Biopsy Forceps	EA-R18H15	1500	Ø1.8
Hot Biopsy Forceps	EA-R18H25	2500	Ø1.8
Hot Biopsy Forceps	EA-R24H15	1500	Ø 2.4
Hot Biopsy Forceps	EA-R24H17	1700	Ø 2.4
Hot Biopsy Forceps	EA-R24H18	1800	Ø 2.4
Hot Biopsy Forceps	EA-R24H21	2100	Ø 2.4
Hot Biopsy Forceps	EA-R24H23	2300	Ø 2.4
Reusable Coagulation Electrode	EA-R18CE10	1000	Ø 1,8
Reusable Coagulation Electrode	EA-R18CE12	1000	Ø1.8
Reusable Coagulation Electrode	EA-R18CE15	1200	Ø1.8
Reusable Coagulation Electrode	EA-R18CE25	1500	Ø1.8
Reusable Coagulation Electrode	EA-R24CE15	2500	Ø1.8
Reusable Coagulation Electrode	EA-R24CE17	1700	Ø 2.4
Reusable Coagulation Electrode	EA-R24CE18	1800	Ø 2.4
Reusable Coagulation Electrode	EA-R24CE21	2100	Ø 2.4
Reusable Coagulation Electrode	EA-R24CE23	2300	Ø 2.4
Reusable Needle Electrode	EA-R18NE10	1000	Ø1.8
Reusable Needle Electrode	EA-R18NE12	1200	Ø1.8
Reusable Needle Electrode	EA-R18NE15	1500	Ø1.8
Reusable Needle Electrode	EA-R18NE25	2500	Ø1.8
Reusable Needle Electrode	EA-R24NE15	1500	Ø 2.4
Reusable Needle Electrode	EA-R24NE17	1700	Ø 2.4
Reusable Needle Electrode	EA-R24NE18	1800	Ø 2.4
Reusable Needle Electrode	EA-R24NE21	2100	Ø 2.4
Reusable Needle Electrode	EA-R24NE23	2300	Ø 2.4

Please refer to the main catalogue of Endoaccess GmbH for available sizes

3. Key material

No	Part	**Material**	**Body contact (yes/no)**
1	Head	Stainless steel	Yes
2	Tube Inner	Stainless steel	No
	Tube outer	Stainless steel + PTFE	Yes
3	Bend protection	PTFE	No
4	Handle	PSF	No

4. Advice before First Application

- Please read carefully and follow all safety operating instructions and warnings information before first application of the device.
- Previous knowledge regarding handling and operation is required and essential.
- Unpack the instrument carefully and examine the devices for any possibility of damage. In case of any damage or missing items contact your distributor immediately.
- The reusable electrical forceps by Endoaccess are not sterile in delivery, all users must complete cleaning and disinfecting before use for every time.

5. Cautions

- Keep away from moisture.
- Refer to package label for minimum working channel size required for this device.
- Rated high-frequency voltage: 700Vp (1.4kVp-p).
- Before using this device, the operator must: pay attention to avoid HF output settings where MAXIMUM OUTPUT VOLTAGE may exceed RATED ACCESSORY VOLTAGE.
- The products were not sterilized before shipment and patients may have risks of being infected or being harm by use of products without cleaned and disinfected according to the instruction before each use, please always clean and disinfect the products before each use.
- 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.
- Stop using the product if the surface of the device is damaged.
- Any electrosurgical accessory constitutes a potential electrical hazard to patient and operator. Possible adverse effects include, but are not limited to: fulguration, burns, nerve and/or muscle stimulation and cardiac arrhythmia.
- Before using this device, follow recommendations provided by electrosurgical unit manufacturer to ensure patient safety through proper placement and utilization of patient return electrode.
- Matching equipment and all other components (in particular, electrode cables and HF ENERGIZED ENDOTHERAPY DEVICES -see IEC 60601-2-18) must be inspected regularly.and checked (e.g., under magnification) for possible damages.
- Ensure that a proper path from patient return electrode to electrosurgical unit is maintained throughout procedure.
- Switch electrosurgical unit to “off” position when not in use.
- The relevant parameters of the HF equipment are as followed
  - Rated voltage: 700Vp.
  - Frequency: 500 KHz;
  - Interface: General standard, high-frequency interface.

6. Contraindication

- Do not use it to treat patients who will be in peril of their life
- To avoid any unsafe situations using the device for patients, such as the Rated high-frequency voltage of the device to connect with.
- According to the operation standard in “5-operation” strictly.
- To storage this device in the place where is far away to patients before use it

7. Potential adverse events

The use of the Electrical Forceps may cause a potential risk for bleeding, perforation of duodenal wall, and acute pancreatitis

8. Precautions

- It is very important that if the proper setting of the generator is not known, one should set the unit at a power setting lower than the recommended range and
- cautiously increase the power until the desired effect is achieved.
- Patient leakage currents from endoscope, as well as energized polypectomy snare, are additive. Consult the endoscope manufacturer about the proper grounding of the endoscope.
- Using the forceps require an endoscope with matching working channel for example, the forceps with Φ2.4 mm sheath tube require an endoscope with a minimum working channel of Φ2.8 mm; and the forceps with Φ1.8mm sheath tube require an endoscope with a minimum working channel of Φ2.0 mm.

9. Products Key Principle

Opening or closing of the head of reusable electrical forceps are controlled by the slide handle moving fore and aft. To push the device is for opening the head, and opposite to pull, it is for closing.
One end of the handle connects to the plug of the high-frequency link. The handle's sliding from top to bottom can handle the polyps tightening, then cut the polyps and coagulate the bleeding wound through high frequency.

10. Check before operation

Make sure to check by the following methods every time before each use

1. Understand the performance of matching endoscope
2. Check other equipment: functionality of the high-frequency generator, the forceps plate contact with the patient, personal protective equipment including face mask, surgical clothes, surgical gloves.
3. Check the electrical forceps
   a) Check that the head moves smoothly and opens fully when the push handle is operated. Check that the head does not malfunction when closing the forceps, otherwise it will damage the working channel.
   b) Check the tube of the instrument for deformations. The push handle should operate properly. If the head does not open and close smoothly, stop using the instrument and replace it with a new one.be opened and closed smoothly, please stop to use and replace it with a new one.
   c) Place the instrument rolled up around the spring tube in a 20cm ring to check whether the forceps head opens and closes. If it does not, please replace it

11. Operation

- Wear personal protective equipment when operating the equipment, as otherwise, you may become infected with the patient's blood and mucus or be exposed to other potential hazards.
  Proper personal protective equipment will help minimize your skin exposure.
- Instruments may be used only if vision is clear or a significant part of the distal end of insertion is seen in the monitor image.
- Keep the head of the forceps closed during insertion into the endoscopic working channel. Insert the forceps through the valve. Insertion should be smooth and light without force using short strokes. Keep your hands close to the entrance to avoid bending. If resistance is met due to excess angulation of the endoscope decrease the angulation to allow passage. Silicone oil can be applied to forceps front and wiring to facilitate insertion.
- When extracting the forceps proceed slowly and carefully since otherwise mucosal injuries may occur and, the resulting bleeding might cause infections. Too much force may cause the forceps to fall to the floor when being pulled out.
- The forceps head should always be closed when pulling out.
  The insertion part of the endoscope should be held straight so that the instrument can be pulled out smoothly.
- To avoid injury to mucous membranes in the abdominal cavity, the electric forceps should be handled carefully and cautiously. Applying too much force can otherwise cause the forceps head to break off.
- Please extract the forceps slowly after the operation to avoid injuries of other areas of the abdominal cavity, e.g., the cardia, throat, or other narrowing

12. Cleaning, Drying and Disinfection

It is recommended to use a temperature below 30 ºC for cleaning and disinfection of reusable products.

12.1. **Preparation before cleaning**

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

12.2. Cleaning

I. Washing: Wash the products with drinking water at a temperature not higher than 45ºC for 30 seconds.
II. 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.

12.3 Drying

Drying products at 50 ±5ºC for 120 mins.

12.4 Disinfecting

12.4.1 Use purified water (conductivity ≤5.1us/cm (25ºC)) to dilute glutaraldehyde solution to 2.5%

12.4.2 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.

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

12.4.4 After 45 min. wash the instruments with purified water (conductivity ≤15us/cm (25ºC) for 30 seconds

12.4.5 Finally, dry for 120 min at, 50 ±5ºC

12.5 Packing

12.5.1 After the disinfection has been finished completely wrap the instruments in medical gaze.
12.5.2 Place the sterilized products flat in a sterilization basket lightly on top of each other. Handle with care.

13. Sterilization

a) The instruments are not sterile upon delivery
b) Must be sterilized before first and each following use
c) Sterilizing method: autoclaving
d) Sterilizing conditions: temperature 132°C; pressure 202.7 kPa for 5 min
e) Remove the plastic HF protection before use and before sterilization**!**

14. Validity

10 years or max. number of sterilization 30 times

15. Storage

- Apply lubricant (company dedicated) to the joints of the electrical forceps before storage.

16. User

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

17. Repairing and complaints

- Instruments must not be used if sterilization validity date (printed on label) is exceeded
- Disposable instruments must not be repaired

18. Legal Foundation

The Law of the European Union is applied

19. 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 use error

20. Product support

In case of questions or difficulties concerning our instruments please contact the local distributors or the **Endoaccess GmbH** directly during regular working hours.

21. Symbols

	Non sterile		Do not expose to direct sunlight
	Use by	LOT	Lot number
	Manufacturer		Date of manufacture
	Keep dry		Do not use if package is damaged
	Give attention to IfU	REF	Prodcut code
MD	Medical Device		Type BF applied part

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