Instructions for use

Reusable Electrical Snare

NON STERILE

1. Intended Use

The reusable electrical snare is an important and common-used accessory of alimentary canal scope diagnosis and therapy.

Reusable electrical snares are used to cut small or medium sized polyps and coagulate the bleeding wound by high frequency current in the gastrointestinal tract.

Only to be used with an endoscope!
Not to be used for other purposes!
Damaged devices must not be used!
Remove the plastic HF protection before use and before sterilization!

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

2. Types

Endoaccess GmbH offers reusable electrical snares in different types such as:

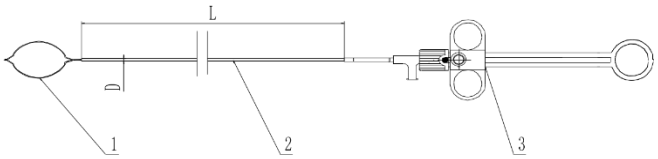
- Oval Type
- Hexagonal Type
- Half-Moon Type
- Oval Type, monofil
- Oval Type, monofil, rotatable.

Model list:

(available with opening width of 10mm, 20mm, or 30mm)

No.	Product Name	Model Name
1	Reusable Electrical snare (oval type), rotatable Reusable Electrical snare (oval type), non-rotatable	EA-Rxx**OS**xx EA-Rxx**OSN**xx
2	Reusable Electrical snare (hexagonal type, rotatable) Reusable Electrical snare (hexagonal type)	EA-Rxx**HS**xx EA-Rxx**HSN**xx
3	Reusable Electrical snare (half-moon type)	EA-Rxx**HM**xx
4	Reusable Electrical snare (oval type, monofil))	EA-Rxx**OSM**xx
5	Reusable Electrical snare (oval type, monofil, rotatable)	EA-Rxx**OSM**xx**R**

Please see illustration for technical information



Note:

- head: selectable depending on application
- tube: selectable depending on application
- handle: same for all models

Please refer to the Endoaccess GmbH main catalogue for further information

3. Raw material

Raw material of reusable electrical snare (see template 1)

Template 1: Raw Materials

No.	Product components	Material	Materials of body contact (Yes / No)
1	Head	stainless steel	Yes
2	Tube	Inner: stainless steel wire Outer: stainless steel & PTEE	No Yes
3	Bend protection	PTEE	No
4	Handle	ABS	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 snares 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

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6. Contraindication

a. Contraindications include those specific to the Endoscopic surgery of Digestive tract Treatment, such as cutting, coagulopathy but are not limited to these

b. Contraindications include those specific to EMR procedure to be performed in conjunction with the electric snares.

7. Potential adverse events

The use of the Electrical snare 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.
- Please pay attention to using the correct Ø of the working channel for example, the snare with Φ2.4 mm sheath tube require an endoscope with a minimum working channel of Φ2.8 mm; and the snare with Ø 1.8mm sheath tube require an endoscope with a minimum working channel of Ø 2.0 mm

9. Product Key Principle

Opening or closing the head of the reusable electric sling is performed by the handle, which moves forward and backward. Pushing the device opens the head, while pulling it closes it.
One end of the handle is connected to the plug of the high-frequency connection. By sliding the handle from top to bottom, the polyps can be tightened, then the polyps are cut off and the bleeding wound is coagulated by high frequency.

10. 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 snare closed during insertion into the endoscopic working channel. Insert the snare 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 snare front and wiring to facilitate insertion.
- When extracting the snare proceed slowly and carefully since otherwise mucosal injuries may occur and, the resulting bleeding might cause infections. Too much force may cause the snare to fall to the floor when being pulled out.
- The snare 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 snare should be handled carefully and cautiously. Applying too much force can otherwise cause the snare head to break off.
- Please extract the snare slowly after the operation to avoid injuries of other areas of the abdominal cavity, e.g., the cardia, throat, or other narrowing

11. Cleaning, Drying and Disinfection

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

11.1. **Preparation before cleaning**

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

11.2. 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.

11.3 Drying

Drying products at 50 ±5ºC for 120 mins.

11.4 Disinfecting

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

11.4.2 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.

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

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

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

11.5 Packing

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

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

12. Sterilization

- The instruments are not sterile upon delivery
- Must be sterilized before first and each following use
- Remove the plastic HF protection before sterilizing the instrument
- Sterilizing method: autoclaving
- Sterilizing conditions: temperature 132°C; pressure 202.7 kPa for 5 min

13. Validity

3 years or max. number of sterilization 30 times

14. Storage

Avoid direct sunlight.

Keep dry.

15. 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

16. 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

17. Legal Foundation

The Law of the European Union is applied.

18. 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

19. 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
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20. Symbols

NON STERILE	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		Do not expose to direct sunlight

21. Disposal

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

CE 0123

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