

Instructions for use

1. Intended Use

The disposable electrical snare is an important and commonly used accessory for diagnosis and therapy of the gastrointestinal tract, e.g., for cutting small or medium-sized polyps and coagulation of the bleeding wounds by high frequency electricity in the gastrointestinal tract.

Only to be used with an endoscope.

Do not use for any other purpose!

Do not use if damaged!

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

2. Types

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

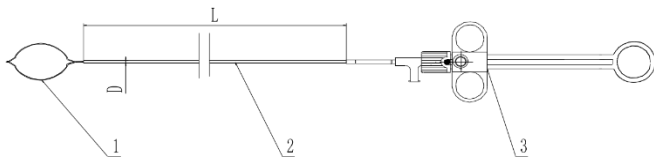
- Oval Type
- Hexagonal Type
- Half-Moon Type
- Oval Type, monofil
- Oval Type, monofil, rotatable.

Model list:

(available with opening width of 10, 15, 20, 25, 30 and 35mm, depending on Ø of the working channel, please refer to catalog)

| No. | Product Name | Model Name |
|-----|---|----------------|
| 1 | Disposable Electrical snare (oval type), rotatable | EA-SxxOSxxxx |
| | Disposable Electrical snare (oval type), Non-Rotatable | EA-SxxOSNxxxx |
| 2 | Disposable Electrical snare (hexagonal type, rotatable) | EA-SxxHSxxxx |
| | Disposable Electrical snare (hexagonal type) | EA-SxxHSNxxxx |
| 3 | Disposable Electrical snare (half-moon type) | EA-SxxHMxxxx |
| 4 | Disposable Electrical snare (oval type, monofil) | EA-SxxOSMxxxx |
| 5 | Disposable Electrical snare (oval type, monofil, rotatable) | EA-SxxOSMxxxxR |
| 6 | Disposable Electrical Snare (Cold Snare Type, with clip for electrode connection) | EA-SxxOSCxxxx |

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

Disposable Electrical Snare

3. Raw material

Raw material of disposable 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 | Yes |
| | | Outer: PTFE | |
| 3 | Bend protection | PTFE | No |
| 4 | Handle | ABS | No |

4. Advice before first application

Please read carefully and follow all safety operating instructions and warning information before first application of the device. Previous knowledge regarding handling and operation is required and essential. Unpack the instrument carefully and examine the device for any possible damage. In case of any damage or missing items contact your distributor immediately. The disposable electrical forceps are sterile on delivery. For single use only.

5. Cautions

- Keep away from moisture.
- Refer to package label for minimum channel size required for this device.
- Before using this device, the operator must pay attention to avoid HF output settings where MAXIMUM OUTPUT VOLTAGE may exceed RATED ACCESSORY VOLTAGE.
- In the event of inadequate sterilization due to reuse or reprocessing of the product or intolerance to a product component, infection or injury to the patient may occur.
- After use, dispose of products and packaging in accordance with hospital, administrative and/or local government policies.
- Do not use the device if the packaging or 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 the electrosurgical unit manufacturer to ensure patient safety through proper placement and utilization of patient return electrode.
- Before using this device, the operator must regularly inspect the matched equipment and all components of the device. In particular, the electrode cables and the HF ENERGIZED ENDOTHERAPY DEVICE (see IEC 60601-2-18) should be checked (e.g., under magnification) for possible damages.
- Ensure 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: 500KHz
 - 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 performed in conjunction with the electric snare

7. Potential adverse events

The use of electrical snare may pose a potential risk for bleeding, perforation of the duodenal wall and acute pancreatitis.

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8. Precautions

- If the correct setting of the generator is not known, it is recommended to set the device to the lowest power and then carefully increase it until the desired effect is achieved.
- Patient discharge currents from the endoscope and from the energized device are additive. Contact the manufacturer of the endoscope for the correct grounding of the endoscope.
- Forceps with Ø 2.4mm tube require a working channel with minimum Ø 2.8mm

9. Product Key Principle

To open and close the head of the disposable electrical forceps, the handle is pushed forward or pulled backwards. Pushing opens the head, and pulling, on the other hand, is used to close it. One end of the handle connects to the plug of the high frequency device. The handle sliding from top to bottom can hold the polyps, then cut the polyps and coagulate the bleeding wound by high frequency

10. Operation

- Wear personal protective equipment when operating the equipment to protect against infection from blood, mucosa, and other potential hazards. Appropriate personal protective equipment helps to ensure that skin exposure is reduced to a minimum risk.
- The instruments may only be used if the visible part of the endoscope or a significant part of the distal end is clearly visible. Otherwise, injuries to the patient or damage to the endoscope may occur
- 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 tube to facilitate insertion
- Pull the instrument back slowly after the operation to avoid damaging the mucous membranes. If pulled with too much force, it may become difficult to grip the instrument.
- The head of the disposable electric forceps must be closed when pulling it out. Make sure that the working channel is not bent to ensure easy extraction.
- Operations with this type of disposable electric forceps should be performed carefully to avoid injury to the mucous membranes of cavities. If too much force is applied, the instrument may be damaged.
- Remove the instrument carefully and slowly after surgery to avoid injury to the cavities, especially the cardia, pharynx or other narrow areas.

11. Sterilization

Disposable electrical snares are delivered sterilized by ETO gas. For single use only. To be destroyed after use according to hospital guidelines.

12. Repairing and Maintenance

- Do not use when sterilization validity is exceeded
- Disposable instruments must not be repaired

13. The period of sterilization validity is three years

14. Storage and transport conditions

Products are not to be stored under heavy pressure in order to avoid distortion.

Storage conditions include:

- To be stored in clean and dry environment
- Avoid direct or indirect sunlight or other ultra-violet rays
- Using general transport: protect from shocks and vibrations during transport, must not be exposed to rain or snow
- do not put any objects on instruments or packaging
- do not store close to aggressive chemical substances

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Improper storage voids all warranty claims.

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. Dispatches for repair and claims

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 application 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.

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20. Symbols

| | | | |
|---|---------------------------|---|----------------------------------|
|  | Do not reuse |  | EO-Gas sterilized |
|  | Expiration date |  | Lot number |
|  | Manufacturer |  | Date of manufacture |
|  | keep dry |  | Do not use if package is damaged |
|  | Give attention to the IFU |  | Product code |
|  | Do not resterilize |  | Do not expose to direct sunlight |
|  | Medical Device |  | Type BF Applied Part |

21. Disposal

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

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