

## Instructions for use

### 1. Intended Use

The disposable electrical knife is an important and commonly used accessory of alimentary canal scope diagnosis and therapy.

Disposable electrical knives are 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 under an endoscope.**

**These instruments are not meant for any other purpose!**

**Do not operate with damaged instruments!**

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

### 2. Types

Endoaccess GmbH offers disposable electrical knives in different types for various applications:

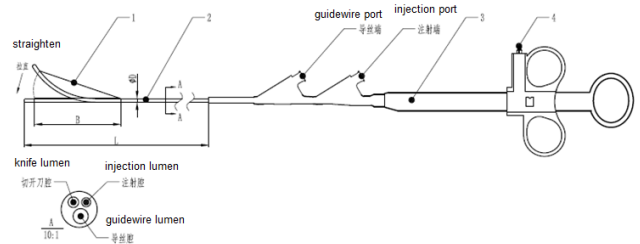
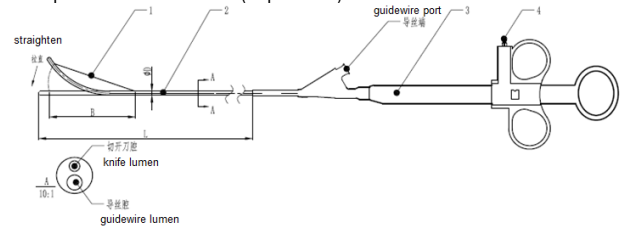
- Papillotome (Double Lumen/Triple Lumen),
- Sphincterotomes (needle knife),
- Cylindrical type (Rotatable),
- Ball type (Rotatable),
- Cylindrical type (Square knife).
- Ball Type (IT Knife)

Model's list:

| Product Name                                                              | Product Code | Working length in mm | Instrument Diameter in mm | Remark          |
|---------------------------------------------------------------------------|--------------|----------------------|---------------------------|-----------------|
| Disposable Double Lumen Papillotome                                       | EA-S0720EPM2 | 2100                 | Ø 2,4                     | ERCP Instrument |
|                                                                           | EA-S0725EPM2 | 2100                 | Ø 2,4                     | ERCP Instrument |
|                                                                           | EA-S0730EPM2 | 2100                 | Ø 2,4                     | ERCP Instrument |
| Disposable Triple Lumen Papillotome                                       | EA-S0720EPM3 | 2100                 | Ø 2,4                     | ERCP Instrument |
|                                                                           | EA-S0725EPM3 | 2100                 | Ø 2,4                     | ERCP Instrument |
|                                                                           | EA-S0730EPM3 | 2100                 | Ø 2,4                     | ERCP Instrument |
| Disposable Needle Electrode (double lumen)                                | EA-S24NE212  | 2100                 | Ø 2,4                     | ERCP Instrument |
| Disposable Needle Electrode triple lumen                                  | EA-S24NE213  | 2100                 | Ø 2,4                     | ERCP Instrument |
| Disposable Cylindrical Type ESD-Instrument                                | EA-S24ST18   | 1800                 | Ø 2,4                     | ESD Instrument  |
|                                                                           | EA-S24ST23   | 2300                 | Ø 2,4                     | ESD Instrument  |
| Disposable Ball Type ESD-Instrument                                       | EA-S24BT18   | 1800                 | Ø 2,4                     | ESD Instrument  |
|                                                                           | EA-S24BT23   | 2300                 | Ø 2,4                     | ESD Instrument  |
| Disposable Ball Type (IT Knife) ESD-Instrument without Irrigation Channel | EA-S24B3T18  | 1800                 | Ø 2,4                     | ESD Instrument  |
|                                                                           | EA-S24B3T23  | 2300                 | Ø 2,4                     | ESD Instrument  |
| Disposable Shield Type (Square Knife) ESD-Instrument                      | EA-S24S2T18  | 1800                 | Ø 2,4                     | ESD Instrument  |
|                                                                           | EA-S24S2T23  | 2300                 | Ø 2,4                     | ESD Instrument  |

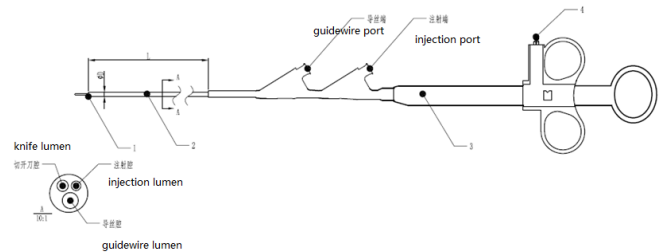
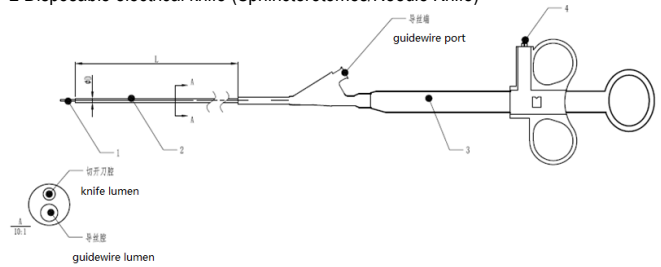
Please refer to the drawing for technical information:

#### 1 Disposable Electrical Knife (Papillotome)



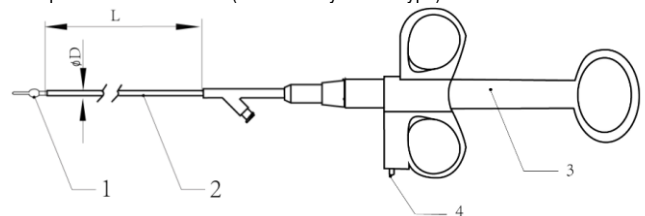
1- knife tip; B line length when flex tube is straightened; 2-flex tube; 3-handle; 4-inlet for connection of HF generator; L-effective length; D-Max. outer diameter of flex tube

#### 2 Disposable electrical knife (Sphincterotomes/Needle Knife)



1-knife tip; 2-flex tube; 3-handle; 4-inlet for connection of HF generator; L-effective length; D-Max. outer diameter of flex tube

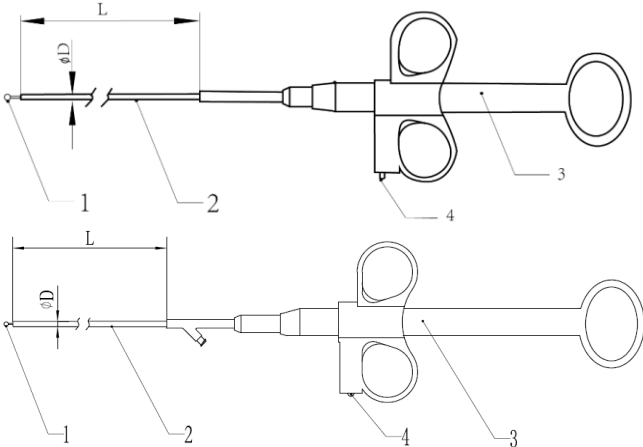
#### 3 Disposable electrical knife (Rotatable Cylindrical type)



1-knife tip; 2-flex tube; 3-handle; 4-inlet for connection of HF generator; L-effective length; D-Max. outer diameter of flex tube

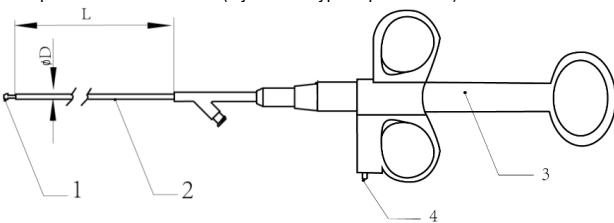
## Instructions for use

### 4 Disposable electrical knife (Rotatable Ball type)



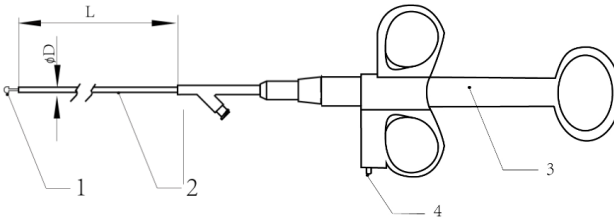
1-knife tip; 2-flex tube; 3-handle; 4-inlet for connection of HF generator; L-effective length; D-Max. outer diameter of flex tube

### 5 Disposable electrical knife (Cylindrical type/Square Knife)



1-knife tip; 2-flex tube; 3-handle; 4-inlet for connection of HF generator; L-effective length; D-Max. outer diameter of flex tube

### 6 Disposable Electrical Knife (IT knife Type)



1- knife tip; 2-flex tube; 3-handle; 4-inlet for connection of HF generator; L-effective length; D-Max. outer diameter of flex tube

Information about the offered dimensions you can refer to the main catalogue by **Endoaccess GmbH**

### 3. Key material

Key material disposable electrical knife (see template 1)

| No | Part            | Material                                         | Body contact (Yes/No) |
|----|-----------------|--------------------------------------------------|-----------------------|
| 1  | Head            | Stainless steel with Nylon                       | Yes                   |
| 2  | Tube            | Inner: stainless steel                           | No                    |
|    |                 | Out: stainless steel + PTFE coated, or Out: PTFE | Yes                   |
| 3  | Bend protection | PTFE                                             | No                    |
| 4  | Handle          | ABS                                              | No                    |

### 4. Before use

- 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.

### 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

### 6. Contraindication

- Contraindications include those specific to the Endoscopic surgery of digestive tract treatment, such as cutting, coagulopathy but are not limited to these.
- Contraindications include those specific to ERCP and ESD procedure performed in conjunction with the electric knife.

### 7. Potential adverse events

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

### 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.
- Knives with  $\varnothing$  2.4mm tube require a working channel with minimum  $\varnothing$  2.8mm

### 9. Product Key Principle

To open and close the head of the disposable electrical knife, the handle is pushed forward or pulled backwards. Pushing opens the head, and pulling, on the other hand, is used to close it.

### 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 knife closed during insertion into the endoscopic working channel. Insert the knife 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 knife front and tube to facilitate insertion

## Instructions for use

- 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 knife 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 knife 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. Cleaning / Sterilization

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

### 12. Period of Validity

Three years after sterilization date.

### 13. Instructions for Storage

Before storing, apply some lubricant (company dedicated) to the joints of electrical knife after drying and sterilization.

### 14. 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.

### 15. Repairing and Complaints

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

### 16. Legal foundation

The Law of the European Union is applied

### 17. 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.

### 18. 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

## 19. 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             |



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**Disposable Electrical Knife**  **STERILE EO**