

Instructions for use

Dear customer:

Thank you for using our products. Please read the manual carefully before use.

1. Intended Use

The disposable electrical forceps 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 forceps correctly to guarantee safe procedures and avoid unnecessary risks for the patients.

2. Types

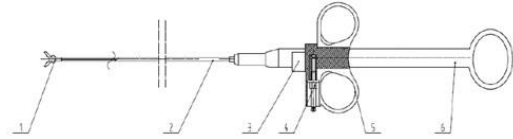
Endoaccess GmbH offers electrical forceps in different types for various applications: (see list below)

Models:

1	Disposable Coagulation (hemostasis) Forceps (Rotatable)	EA-S24HFR18 EA-S24HFR23	Φ2.4×1800mm Φ2.4×2300mm
2	Disposable Dissection Tooth/Hook Type Forceps (Rotatable)	EA-S24DTR18 EA-S24DTR23	Φ2.4×1800mm Φ2.4×2300mm
3	Disposable Dissection Scissor (Rotatable)	EA-S24DSR18 EA-S24DSR23	Φ2.4×1800mm Φ2.4×2300mm
4	Disposable Dissection Forceps (Rotatable)	EA-S24DFR18 EA-S24DFR23	Φ2.4×1800mm Φ2.4×2300mm
5	Disposable Electrical Forceps (Hot Biopsy)	EA-S18H10 EA-S18H12 EA-S18H15 EA-S24H16 EA-S24H18 EA-S24H21 EA-S24H23	Φ1.8×1000mm Φ1.8×1200mm Φ1.8×1500mm Φ2.4×1600mm Φ2.4×1800mm Φ2.4×2100mm Φ2.4×2300mm
6	Disposable Electrical Forceps (Needle Electrode)	EA-S18NE10 EA-S18NE12 EA-S18NE15 EA-S24NE16 EA-S24NE18 EA-S24NE21 EA-S24NE23	Φ1.8×1000mm Φ1.8×1200mm Φ1.8×1500mm Φ2.4×1600mm Φ2.4×1800mm Φ2.4×2100mm Φ2.4×2300mm

Disposable Electrical Forceps **STERILE**

Please refer to the drawing example as followed:



Note:

1. Head (Jaw): select according to purpose
2. Tube: available in different lengths
3. Block: to locate the clip to operation
4. Electrode clip with electrode plug
5. Handle

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

3. Key material

Key material disposable electrical forceps (see template 1)

Template 1 key material of disposable electrical forceps

No	Product components	Material	Materials of body contact (Yes/No)
1	Head	stainless steel	Yes
2	Tube	Inner: stainless steel Out: stainless steel + PPTFE	No
3	Bend protection	PTFE	No
4	Handle	ABS	No

4. Advice before first application

- a. Please read carefully and follow all safety operating instructions and warning information before first application of the device.
- b. Previous knowledge regarding handling and operation is required and essential.
- c. Unpack the instrument carefully and examine the device for any possible damage. In case of any damage or missing items contact your distributor immediately.
- d. 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.

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- 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 forceps.

7. Potential adverse events

The use of electrical forceps 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.
- 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. Check before operation

- Understand the performance of matching endoscope
- Check all other equipment: High-frequency generator, neutral electrode, personal protective equipment including face mask, protection gown, gloves.
- Check the electrical forceps :
 - Check if the surface of the cups is smooth and that they open or close completely when you operate the handle. If not, damage to the working channel may occur.
 - Check if steel wire is flat and the handle is undamaged. If the cups do not open and close smoothly, the instrument must not be used and be replaced.

11. 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.

Disposable Electrical Forceps

- 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.

12. Sterilization

Disposable electrical forceps are delivered sterilized by ETO gas. For single use only. To be disposed of according to hospital guideline after use.

13. The period of sterilization validity is three years

14. Storage and transport conditions

- do not store under heavy pressure to avoid distortion
- store in clean and dry environment
- avoid direct or indirect sunlight or other ultra-violet rays
- store in clean and dry environment
- 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

Incorrect storage of the instruments invalidates any 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. Repairing and Complaints

- Do not use when sterilization validity 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 application error.

20. Product Support

In case of questions or difficulties concerning our instruments please contact your distributor or Endoaccess GmbH directly during regular working hours.

Address: Feldriethe 1, 30826 Germany

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Fax: +49 5131 4422 622

21. Disposal







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

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Disposable Electrical Forceps **STERILE EO**

15. Symbols

-  Do not reuse
-  Expiration date
-  Manufacturer
-  keep dry
-  Give attention to the IfU
-  Do not re sterilize
-  Medical Device
-  Type BF Applied Part

-  EO-Gas sterilized
-  Lot number
-  Date of manufacture
-  Do not use if package is damaged
-  Product code
-  Do not expose to direct sunlight

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