

# Disposable Electrical Knife

## IFU

(Please read this manual carefully before usage)

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Revision	Date	Description	Author	Approval
C/0	Jun.2005	Created	Yujun CHEN	Changhui HE
C/1	Jan. 2017	Update	Vivian LI	Haoxiang HE
C/2	July.2021	Update	Vivian LI	Jianwen LU
C/3	Aug.2021	Update	Vivian LI	Jianwen LU

## Instruction for Use

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Dear customer:

Thank you for using our products. Please read the manual carefully before you use our products so that you can use and maintain the products accurately.

### 1. Intended Use

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

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

### 2. Types

**Alton (Shanghai) Medical instruments Co., LTD** offers 9 different types disposable

electrical knives suffix with DJ2/DJ3/DZ2/DZ3/EN/EB/ EN-2/ EB-2/ EB-3, they are including:

- *Papillotome (Double Lumen/Triple Lumen),*
- *Sphincterotomes (needle knife),*
- *Cylindrical type (Rotatable),*
- *Ball type (Rotatable),*
- *Cylindrical type (Square knife),*
- *IT knife type (with spray), and*
- *IT knife type (without spray)*

(See the "Table 1" model list of disposable electrical knife attached)

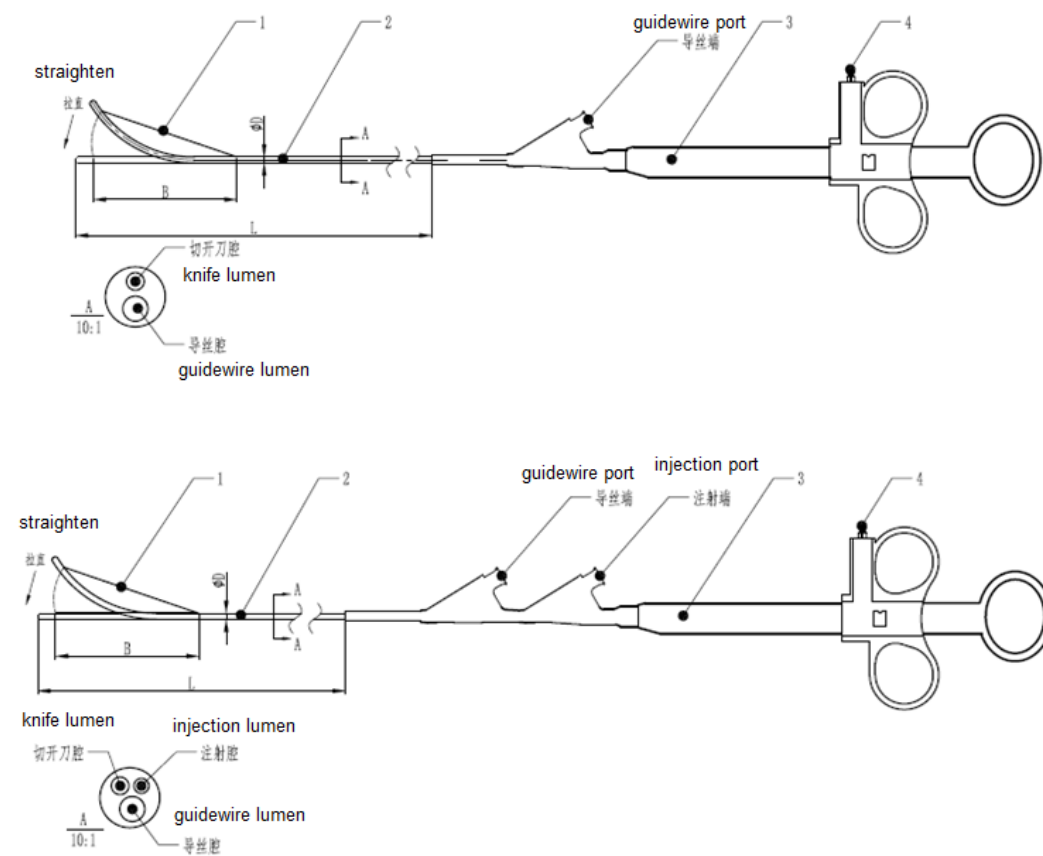
**Table 1: the model list of disposable electrical knife**

No.	Product Name	Model Name	Size
1	Disposable Electrical Knife (Papillotome Type)	AF-D0720DJ2	Φ2.4*2100mm
2	Disposable Electrical Knife (Papillotome Type)	AF-D0725DJ2	Φ2.4*2100mm
3	Disposable Electrical Knife (Papillotome Type)	AF-D0730DJ2	Φ2.4*2100mm
4	Disposable Electrical Knife (Papillotome Type)	AF-D0720DJ3	Φ2.4*2100mm
5	Disposable Electrical Knife (Papillotome Type)	AF-D0725DJ3	Φ2.4*2100mm
6	Disposable Electrical Knife (Papillotome Type)	AF-D0730DJ3	Φ2.4*2100mm
7	Disposable Electrical Knife (Sphincterotomes / Needle knife Type)	AF-D2421DZ2	Φ2.4*2100mm
8	Disposable Electrical Knife (Sphincterotomes / Needle knife Type)	AF-D2421DZ3	Φ2.4*2100mm
9	Disposable Electrical Knife (Cylindrical Type, Rotatable)	AF-D2416EN	Φ2.4*1600mm
10	Disposable Electrical Knife (Cylindrical Type, Rotatable)	AF-D2418EN	Φ2.4*1800mm
11	Disposable Electrical Knife (Cylindrical Type, Rotatable)	AF-D2423EN	Φ2.4*2300mm
12	Disposable Electrical Knife (Ball Type, Rotatable)	AF-D2416EB	Φ2.4*1600mm
13	Disposable Electrical Knife (Ball Type, Rotatable)	AF-D2418EB	Φ2.4*1800mm

14	Disposable Electrical Knife (Ball Type, Rotatable)	AF-D2423EB	Φ2.4*2300mm
15	Disposable Electrical Knife (Cylindrical Type / Square knife)	AF-D2416EN-2	Φ2.4*1600mm
16	Disposable Electrical Knife (Cylindrical Type / Square knife)	AF-D2418EN-2	Φ2.4*1800mm
17	Disposable Electrical Knife (Cylindrical Type / Square knife)	AF-D2423EN-2	Φ2.4*2300mm
18	Disposable Electrical Knife (IT knife Type, with spray)	AF-D2416EB-2	Φ2.4*1600mm
19	Disposable Electrical Knife (IT knife Type, with spray)	AF-D2418EB-2	Φ2.4*1800mm
20	Disposable Electrical Knife (IT knife Type, with spray)	AF-D2423EB-2	Φ2.4*2300mm
21	Disposable Electrical Knife (IT knife Type, without spray)	AF-D2416EB-3	Φ2.4*1600mm
22	Disposable Electrical Knife (IT knife Type, without spray)	AF-D2418EB-3	Φ2.4*1800mm
23	Disposable Electrical Knife (IT knife Type, without spray)	AF-D2423EB-3	Φ2.4*2300mm

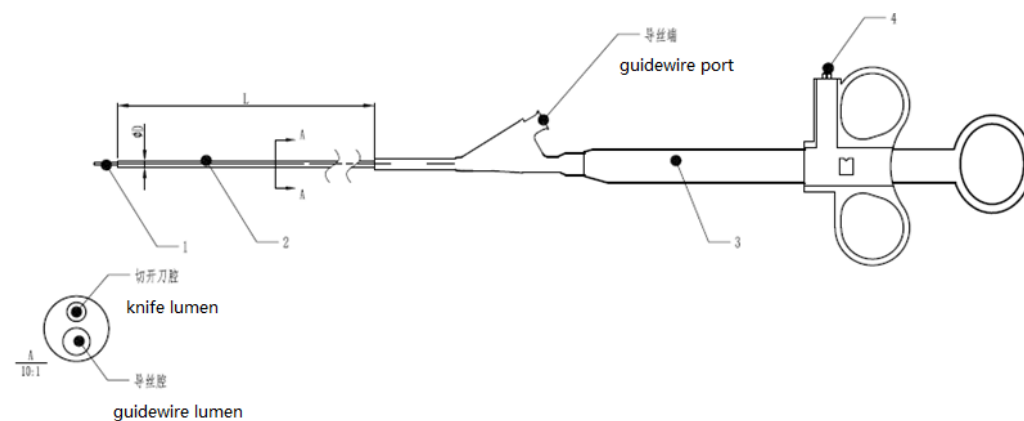
Please refer to the drawing example as followed:

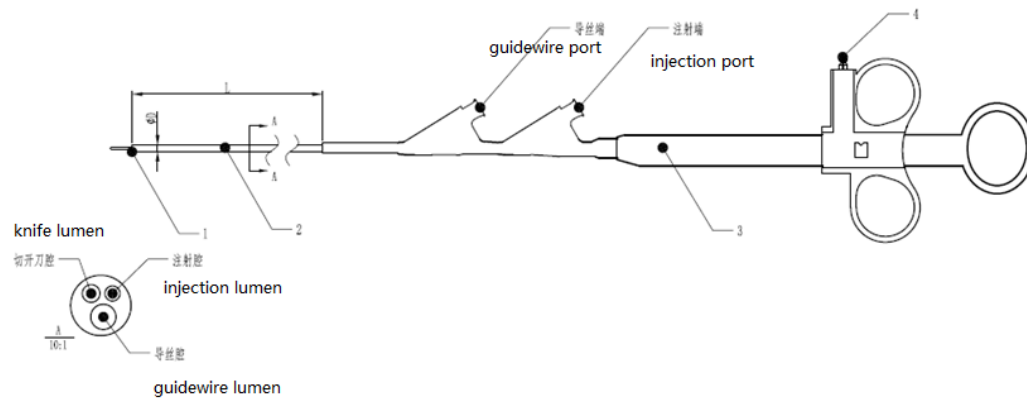
### 1 Disposable Electrical Knife (Papillotome)



- 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

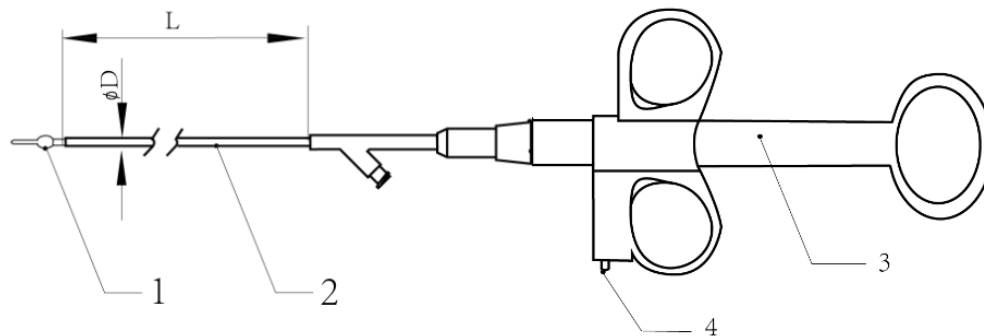
### 2 Disposable electrical knife (Sphincterotomes/Needle Knife)





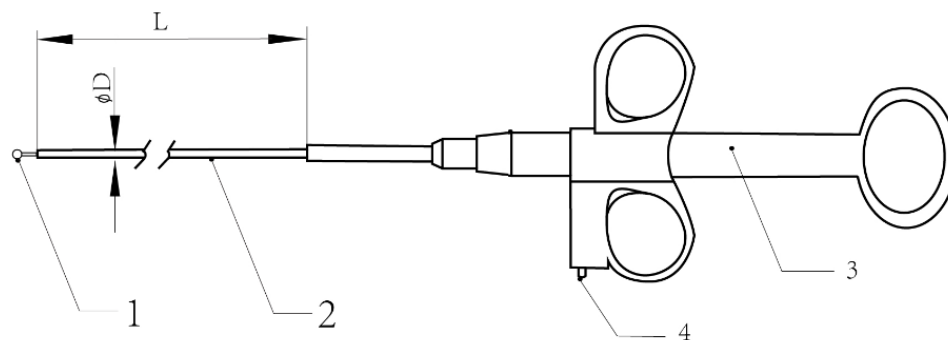
1-knife tip; 2-flex tube; 3-handle; 4-inlet for connection of HF generator; L-effective length; D-Max. outer diameter of flex tube

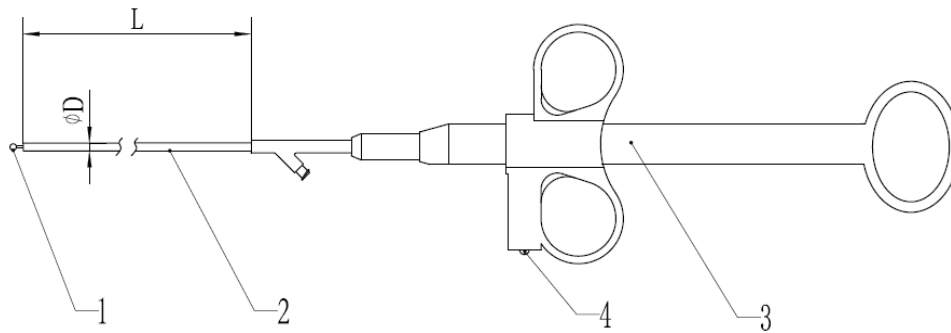
### 3 Disposable electrical knife (Rotatable Cylindrical type)



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

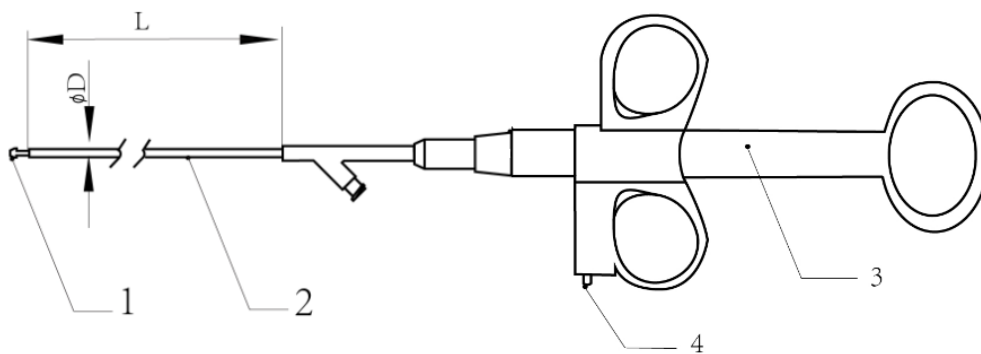
### 4 Disposable electrical knife (Rotatable Ball type)





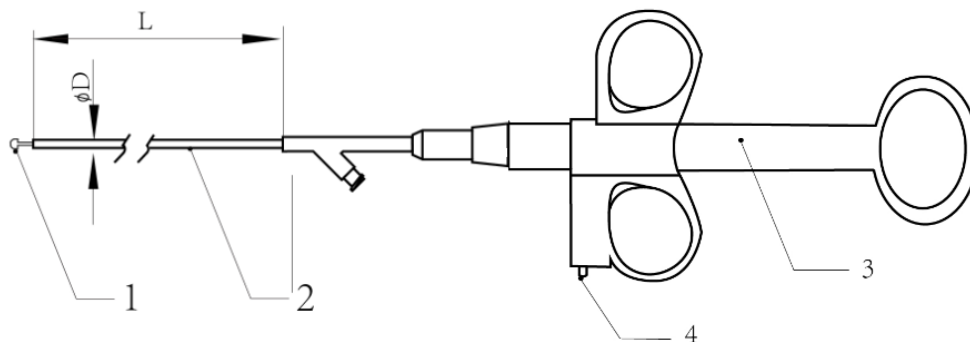
1-knife tip; 2-flex tube; 3-handle; 4-inlet for connection of HF generator; L-effective length; D-Max. outer diameter of flex tube

#### 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 **Alton (Shanghai) Medical Instruments Co., LTD.**

### 3. Key material

The Key material of disposable electrical knife (see template 1)

**Template 1 the key material of disposable electrical knife**

No.	Product components	Material	Materials of body contact (Yes/No)
1	Head	stainless steel	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. Advices before First Application

- Please read carefully and follow all safety operating instructions and warnings information before first application of the device.
- A 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 disposable electrical knives by Alton are sterile in delivery, all devices are only for single use.

#### 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.
- The sterilization or the tolerance of the products may not be enough, patients may have risks of being infected or being harm by the re-using or re-processing products, please use it only once.
- After use, dispose of products and packaging in accordance with hospital, administrative and/or local government policies.
- If the single bag or the surface of the device damaged, don't use it anymore.
- 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.

- i. Before using this device, the operator must regularly inspect the matched equipment and all components of the device. In particular, electrode cables and HF ENERGIZED ENDOTHERAPY DEVICES (see IEC 60601-2-18) should be checked (e.g. under magnification) for possible damage.
- j. Ensure a proper path from patient return electrode to electrosurgical unit is maintained throughout procedure.
- k. Switch electrosurgical unit of “off” position when it is not in use.
- l. The relevant parameters of the HF equipment are as followed
  - Rated voltage: 700Vp;
  - Frequency: 500 KHz;
  - Interface: General standard, high-frequency interface.

## **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 ERCP and ESD procedure to be performed in conjunction with the electric knife.

## **7. Potential adverse events**

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

## **8. Precautions**

- a. 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.
- b. Patient leakage currents from endoscope, as well as energized polypectomy snare, are additive. Consult the endoscope manufacturer about the proper grounding of the endoscope.
- c. The knives with  $\Phi 2.4$  mm sheath tube require an endoscope with a minimum working channel of  $\Phi 2.8$  mm.

## **9. Products Key Principle**

Opening or closing of the head of disposable electrical knives 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. Operation**

- 1) Wear personal protective equipment in the operation of equipment, or you would be infected from the patient's blood, mucus and other potential dangers. Appropriate personal protective will help your skin not be exposed as much as possible.
- 2) Instruments can be used only if there is a clear vision in the visible range of endoscope and can see the end of endoscope or significant part of the distal end of insertion in monitor image. Otherwise it will injure patients. For example, it would make a thorn hole bleeding, mucosal damage, or damage the endoscopic equipment.
- 3) Close the device head before insert the disposable electrical knife into the endoscopic working channel. Operating should smoothly to insert the knife, light and appropriate way with not too fierce force, quickly act. The device is transferred through the valve. Fingers should be as close to entrance as possible to avoid an excessive distance and bend steel coat. Special attention to the smooth conditions when the head of knife through the bend department of endoscope. If there is any block feeling in through bending angle in the device, angle button should be released to restore the original bending angle and look for the target. If not, it is easy to damage the working channel of endoscope. The knife head should be closed during the above the insertion process. To make it easier to insert, front of knife and wire coat should wipe appropriate silicone oil to reduce friction.
- 4) Do not draw too fast to pull out the knife or it is easy to make the mucosal injury caused infection by bleeding. Too much force will make failure to grasp the head even fall to the ground and damage the knife.
- 5) The knife head should always be closed when exiting the electrical knife. Endoscope insertion part should be put straight in order to smoothly out the electrical knife.
- 6) The movement for this type of disposable electrical knife to do surgery in front of endoscopic should be light, so as not to bruise cavity mucosal tissue. Heart of electrical knife is easy to be broken off if too much force.
- 7) Do not exit too fast after surgery, so as not to bruise the other organizations of cavity, especially in the cardia, throat and other narrows.

## **11. Sterilization**

Disposable electrical knives are delivered sterilized by ETO gas. The disposable instruments must only be used once. So after use, the disposable electrical knife have to be destroyed by the local hospital.

**12. The period of sterilization validity is for three years.**

### **13. Storage**

Drop some lubricant (company dedicated) on the joints of electrical knife after dry and sterilization, then storage after dried.

Temperature: 0-40 °C, Relative humidity: 30-85%, air pressure: 50.0-106.0KPa.

### **14. User**

The users of instruments of the **Alton (Shanghai) Medical Instruments Co., LTD** 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**

All instruments are not allowed:

- a. To be changed if the sterilization validity date exceed than the date printed on labels;
- b. To be repaired if for single use device.

### **16. Legal Foundation**

The Law of the European Union is applied.

### **17. Disclosure of residual risks**

The product may contain the following residual risks:

- a. Bacterial or virus infection to the patient or other persons;
- b. Re- or cross-infection;
- c. Operational hazards caused by use error.















### **18. Product Support**

In case of questions or difficulties concerning our instruments please contact your distributor or the **Alton (Shanghai) Medical Instruments Co., LTD** directly during regular working hours.

Version: C/3

**Date: 2021.8.4**

## 19. Symbols

NO.	Description	Symbols on labels
1	CATALOGUE NUMBER	
2	MANUFACTURER	
3	DATE OF MANUFACTURE	
4	USE BY	
5	BATCH CODE	
6	STERILIZED USING ETHYLENE OXIDE	
7	DO NOT REUSE	
8	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	
9	Notified body number	 0123
10	KEEP DRY	
11	KEEP AWAY FROM SUNLIGHT	
12	TEMPERATURE LIMITATION	
13	Do not use the packing breakage	
14	Refer to instruction manual	
15	Type BF APPLIED PART	