

Disposable Polypectomy Snares

Instruction for Use

【Product name】 Disposable Polypectomy Snares

【Product description】

The components of Disposable Polypectomy Snares are Cutting ring (06Cr19Ni10), Sheathing tube (PTFE), Connector (06Cr19Ni10), Protective sleeve (PTFE), Rod head (ABS), Limit block (ABS), Slide bar (ABS), Electrode interface (CU) and Slide ring (ABS).

The Disposable Polypectomy Snares sterilized using Ethylene Oxide. Shelf life is 2 years. Only single use.

【Specification and type】

ATE-QTQ-TY-18×(1200, 1600, 1800, 2300)×(10, 15, 20, 25, 30, 35)

ATE-QTQ-TY-23×(1200, 1600, 1800, 2300)×(10, 15, 20, 25, 30, 35)

ATE-QTQ-LJ-18×(1200, 1600, 1800, 2300)×(10, 15, 20, 25, 30, 35)

ATE-QTQ-LJ-23×(1200, 1600, 1800, 2300)×(10, 15, 20, 25, 30, 35)

ATE-QTQ-BY-23×(1200, 1600, 1800, 2300)×(10, 15, 20, 25, 30, 35)

【Usage】 The Disposable Polypectomy Snares are indicated for use endoscopically for the removal and/or cauterization of diminutive polyps , sessile polyps , pedunculated polyps and tissue from within the gastrointestinal tract.

【Installation and use instructions or graphic】

1. Prepare and check before use

Preparation: 1.1 the instruction manual of the respective prepare all for use with this product equipment and personal protective equipment. Appropriate personal protective equipment including: goggles, masks, waterproof clothing and chemical protective gloves. Should be ready to spare snare.

1.2 inspection: every time when using this instrument needs to check whether the sterilized packing is broken, the sealing is lax or flooding. If there are any abnormal packaging, this product aseptic may have been destroyed. Please change to use spare snare.

A. confirm snare ever fall off or loose connection parts.

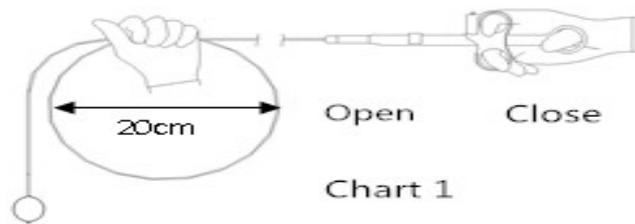
B. a finger brush the entire surface of the outer tube inserted into the department, make sure no crush, excessive damage of bending, breakage, etc.

C. insert confirmed the apex of the head no sharp bumps, angular, or other damage.

D. as shown in figure 1, holding the snare and handle, to insert the formation of a diameter of about 20 cm ring. Operating slide handle back and forth, to determine whether the trap shape consistent with the selected models; Pull the sliding handle, confirm trap apex department can completely recover the outer casing.

E. confirm the handle component no cracks.

F. confirmed the high frequency cable not damaged or wire part.



2. According to the high frequency equipment specifications will be neutral electrode plug connected to the device.

3. Turn the neutral electrode close to its maximum stick on near the operation area on the same side of the body on the upper arm or leg. Please pay attention to the following matters.

3.1 neutral electrode do not use in the following parts: injury, inflammation of the skin, bone area, the surface of the metal buried, the surface of the thickness of subcutaneous fat;

3.2 pay attention to prevent skin contact with the skin;

3.3 when used to prevent and other electrode output circuit;

3.4 patients not with metal objects, patients do not contact with other metals.

4. Insert the product into endoscopic, please pay attention to the following matters.

4.1 insert the snare endoscopy, should be close to clamp the hole opening valve, and as far as possible unbend. Otherwise, may damage the insert part;

4.2 slowly inserted into the snare. Sudden insertion can be damaged by endoscopy or snare;

4.3 if resistance when the insert, please do not forcibly inserted. Reduce the endoscope Angle and lowered scope lifting clamp device, until the snare can smoothly through. Forcibly insert can be damaged by endoscopy and snare;

4.4 only when the snare out from endoscopic apex of completely, can inspect the system. Otherwise, may damage the endoscopy and snare;

4.5 trap and endoscopic apex department contact, please do not to the output. Otherwise, can be damaged by endoscopy and snare;

4.6 insert the snare endoscopy, should maintain the sliding handle. Otherwise, may damage the endoscopy and snare;

4.7 trap has not yet recovered all the tube, please do not insert the snare or taking endoscopy. Otherwise, may damage the endoscopy and snare;

4.8 this instrument and have double duct endoscopy supporting when using, do not use other accessories at the same time. Otherwise, can lead to patients, the operator or assistant burns;

5. According to the high frequency equipment specifications will be a high frequency cable head inserted into the high-frequency equipment, insert the other end product electrode in the joint;

6. Promote the sliding handle, open the trap;

7. According to the need to adjust the Angle of endoscope inserted into the department, forward snare or rotate trap, in order to set the target groups;

8. With trap will target groups;

9. Pull the sliding handle, the target tissue trapping, please pay attention to the following matters.

9.1 please do not push the sliding handle abruptly. Otherwise, trap suddenly stretched out, perforation, bleeding or mucosal damage which can lead to patients.

9.2 set of living tissues, do not force or pressure. Otherwise, can lead to bleeding or mucosal damage patients.

9.3 connection device, please confirm whether high frequency power supply equipment in the closed position, otherwise, can lead to the operator or assistant burns.

10. Pull the sliding handle, start the output, electric coagulation before cutting (alternating electric coagulation, electric cutting application 3 ~ 4 seconds/times), repeated several times gradually smooth to remove excess tissue.

10.1 warning

A. suction cavity adhesion in a trap and a tissue fluid, such as mucus. If the liquid attached to the electricity cut, can lead to patients with perforation, bleeding, mucous membrane damage or tissue burns.

B. when high frequency equipment operation, try to use the minimum needed to complete the operation output values and the shortest time. Excessive output can lead to patients with perforation, bleeding, mucous membrane damage.

C. during resection, confirm this equipment electricity. To be the time when an unpowered excision bleeding or mucosal damage may lead to patients.

10.2 pay attention to

A. when the instrument to turn on the high frequency current use, please do not contact in this instrument and normal body cavity tissues when start the output. Otherwise, you will burn a target organization.

B. if a lumen bilge gas, with a combustible gases (e.g., CO₂) to replace it. Otherwise, bilge gas will cause the combustion or explosion, leading to tissue burns.

C. to avoid burns healthy tissue, please do not in trap start output when in contact with a target organization.

D. when the target tissue (such as polyps head) when in contact with the goal of any part of the organization do not start the output. Otherwise, it may burn a target organization.

E. endoscopic apex of body cavity organization too close, or contact with, please do not start the output. Otherwise, it may burn tissue and damage the endoscopy.

F. endoscopic apex of the metal parts of the trap is too close, or contact with, please do not start the output.

G. the patient's skin contact with each other (e.g., bare arms and lateral thoracic contact), please do not start the output. Otherwise, may result in patients with burns.

H. patients when the clothes are wet, please do not start the output. Otherwise, may result in patients with burns.

I. the patient contact with the metal part of the work station or other device, please do not start the output. Otherwise, it may lead to patients, the operator or assistant burns.

J. output, please do not contact wire and make it come into contact with others. Otherwise, can lead to patients, the operator or assistant burns.

11. Close the high frequency switch equipment, will take on high frequency cable plug from the electrode interface.

12. Pumped from endoscopic snare, please pay attention to the following matters.

A. do not use snare quickly pulled out from the endoscopy. Otherwise, clastic spitting blood, mucus, or other patients, the infection risk.

B. trap has not yet recovered all the tube, please do not take out from endoscopic snare. Otherwise, can be damaged by endoscopy and snare.

【Note, warning and prompt content】

1. This equipment by ethylene oxide sterilization for sterile products, valid for two years. Destroyed the disposable use, after use, it is forbidden to reuse;

2. Please check the bags in the sterilization when using effective date, please use within a prescribed period of time.

3. This equipment does not contain the user can repair parts. Please do not remove, modified, or try to repair, otherwise it will lead to the patient or operator injury or equipment damage.

4. Before the endoscope and its attachments to the patient's body, to check that the endoscope and exposing the electrode have rough edges or sharp corners or any highlights, if may bring harm to patients, should be replaced immediately or stop using;

5. Please do not attempt to the instrument disinfection, which can lead to infection and the patient's risk of infection control, equipment damage or failure;

6. Check before using aseptic packaging is being torn bad, or the seal is not good, or whether be affected with damp be affected with damp. If the bag there is any abnormal, the aseptic packaging has been damaged, do not use the equipment, please change to use the standby equipment;

7. Do not use this product for plant on patients with cardiac pacemaker. Otherwise, from the product, the high frequency signal of high frequency equipment, cable and spark discharge interference or damage may result in ventricular fibrillation pacemaker of electronic components, lethal damage;

8. Surgery should prevent electrode contact caused by combustible gas combustion, try to avoid using nitrous oxide and oxygen gas as anesthesia. Also avoid electrode contact with combustible material (such as cotton, gauze, wood, asperse essence, etc.) in oxygen combustion;

9. With endoscope used to prevent electrode cable insulation damage.

10. Snare electrode connected to the high frequency equipment, the following should be paid attention to.

10.1 according to the high frequency equipment manual insert high-frequency wire snare electrode in the joint, until a click is heard.

10.2 confirm the snare electrode plug tightly in place.

10.3 insert the plug of the other end of the high frequency line, high-frequency equipment cutting/electric coagulation (CUT/COAG) socket.

10.4 confirm hear a clicking sound and plug tightly in place.

10.5 remove the high frequency cable plug.

10.6 as for the above steps found any abnormal, please find out the reason or switch to standby snare.

10.7 note:

A. choose high frequency equipment and high frequency cable, ERBE, MARTIN, STORZ and push around the company's high frequency equipment is appropriate, high frequency cable generally these companies offer, but it must be confirmed before use to match the device interface.

B. it is recommended to use 300 ~ 500 KHZ frequency, maximum peak voltage is less than 1000 v high frequency equipment, high frequency electric excision polyp should according to different situation specific polyp to choose the appropriate current affected different output power (usually 15-35 w electric coagulation and cutting).

C. please set limits the output power of high frequency equipment, to ensure the safety of patients and prevent inadvertently tissue thermal damage, and prevent the equipment and high-frequency equipment in the case of started electrode contact with other metal equipment damage caused by high frequency current is too high,

D. high frequency power supply equipment is opened, please do not connect any equipment or check any connection. Otherwise, will lead to the operator or assistant burns.

E. such as high frequency equipment with monitoring circuit, please refer to the use of high frequency equipment specifications are compatible,

F. in normal use should be down as far as possible when the output power of high frequency

equipment. If you need higher power output should check each component connection is correct.

G. unplug electrode plug or don't pull when high frequency cable connections. Otherwise, can lead to high frequency cable damage.

10.8 warning:

A. electrode should be placed in isolation and patients when not in use.

B. do not use the high frequency cable tie or with other medical devices (such as electrocardiograph, endoscopic system, etc.) of wires bundled together. Otherwise, the work of the high frequency signal and the spark discharge interference can cause dysfunction of other medical equipment, have a negative effect on the patients.

C. high frequency generator regulation must not more than the output voltage is specified in the specifications, the largest peak voltage.

D. when using this instrument operation area is absolutely cannot use the explosive gas.

E. pay attention to the instrument when used with endoscope may have potential hazards, want the user to pay attention to and try to avoid.

F. if high frequency equipment failure may result in unexpected increase output.

G. unless device equipped with electrodes to monitor circuit, unreliable don't contact with patients, potentially dangerous.

11. The equipment the operator must be a doctor or medical personnel under the supervision of a physician, they must be trained in enough clinical endoscopic technique can operate.

【Contraindications】

1. Have a digestive endoscopy contraindications;

2. Have a bleeding tendency, out of, and clotting time extended, thrombocytopenia or lengthen prothrombin time, unable to correct treatment;

3. Type polyps carcinoma has been infiltrating with worsening;

4. Easy piercings banned;

5. The basal parts for polyps is too large (greater than 2 cm in diameter), confirmed to be removed;

6. Other specific by professional doctor according to the actual condition of the patient.

7. Possible complications: trap the possible complications of surgery (including but not limited to) : bleeding, perforation, burns, sepsis, infection, blood pressure (hypotension).

【 Product maintenance and maintenance method, special storage and transportation conditions, methods 】

1. This apparatus single packaging USES paper-plastic bag, packing with carton, the outer packing use cartons. Transportation should maintain clean, dry and closed transportation, transportation conditions: temperature - 20 °C ~ 70 °C; Humidity 10% ~ 90%. Transportation when not with sand, broken during metal, glass, or sharp objects, more not with toxic and corrosive or flammable mixture, avoid by all means throwing during loading and unloading, it is forbidden to exposure in the sun or rain.

2. This instrument is a sterile disposable products, storage mode: temperature - 20 °C ~ 60 °C; Humidity 10% ~ 90%. Stored in ventilated and dry, and avoid direct sunlight indoors.

3. Please do not place the asepsis packing products in packaging damage easily, be affected with damp be affected with damp or sealing easy open place. Otherwise, it will harm the product aseptic, leading to infection control risk exists or the patient's infection.

【 Marking instruction 】

Symbol	Title of Symbol	Symbol	Title of Symbol
	Manufacturer		Authorized representative in the European Community
	CE marking		Date of manufacture
	Catalogue number		Batch code
	Use-by date		Sterilized using ethylene oxide
	Do not re-use		Caution
	Working diameter		Logo



Jiangsu Ate Medical Technology Co.,Ltd.
No.8, Lanxiang Road, Wujin Economic Development Zone, 213161 Jiangsu,
China

Tel: 0086-519-85288988 Fax: 0086-519-85288060



ZOUSTECH S.L.
Pso. Castellana, 141 - Planta 19, 28046 - Madrid, Spain
Tel: + 34694426446 Fax: + 34917915466



0197 TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany

Document number: ATE/IFU-QTQ-0001, version: A/1