Disposable hot polypectomy snare

[PRODUCT NAME]

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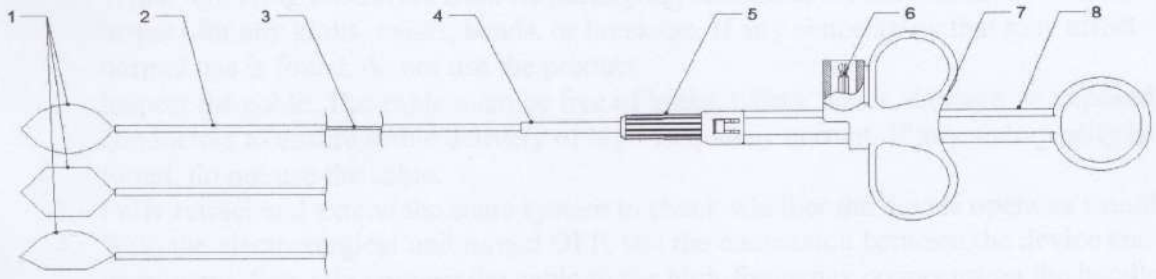
[PRODUCT STRUCTURE]

The disposable hot polypectomy snare consists of a loop assembly that can be extended and retracted from the outer tube of the device by operating the handle.



No.	Component Name	Material	No.	Component Name	Material
1	Metal loop	SUS304	5	Shaft sleeve	ABS
2	Outer tube	PTFE	6	Electrical connector	Copper
3	Cable	SUS304	7	Sliding ring	ABS
4	Conduit	PVC	8	Core rod	ABS

[MAIN TECHNICAL FEATURES]

1. The product is EO sterilized, sterile, and for single use only.
2. Snares with outer tube diameters of 1.8 mm and 2.4 mm shall be used with gastrointestinal endoscopes with working channels $\geq$ 2.0 mm and $\geq$ 2.8 mm respectively.
3. The device shall withstand a tensile force of 20 N for 10 seconds without loosening or breaking.
4. The snare shall be able to extend and retract continuously for 50 cycles without jamming.
5. The resistance between the snare and the high-frequency connector shall be $< 20\ \Omega$.

[MATERIALS]

The disposable hot polypectomy snare is composed of a snare loop, outer tube, cable, shaft sleeve, high-frequency connector, sliding ring, and core rod.

The snare loop and cable are made of 06Cr19Ni10 in accordance with GB/T 1220.
The outer tube is made of PTFE in accordance with GB/T 35748.
The shaft sleeve, sliding ring, and core rod are made of ABS in accordance with GB/T 12672.
The high-frequency connector is made of H62 in accordance with GB/T 5231.

[INTENDED USE]

This product is used in conjunction with a high-frequency electrosurgical unit to perform endoscopic resection of gastrointestinal polyps.

[INSTRUCTIONS FOR USE]

1. When removing the device from its packaging, straighten the instrument and carefully inspect for any kinks, twists, bends, or breakage. If any abnormality that may affect normal use is found, do not use the product.
2. Inspect the cable. The cable must be free of kinks, twists, bends, damage, or exposed conductors to ensure stable delivery of high-frequency current. If any abnormality is found, do not use the cable.
3. Fully retract and extend the snare system to check whether the device operates smoothly.
4. With the electrosurgical unit turned OFF, test the connection between the device and the instrument. Securely connect the cable to the high-frequency connector on the handle and to the electrosurgical unit. Place the patient return electrode and connect it to the electrosurgical unit in accordance with the manufacturer's instructions.

Notes:
a. Place the return electrode on the area with the largest contact surface on the upper arm or thigh, on the same side as the intervention site.
b. Do not place the return electrode on damaged skin, inflamed areas, bony prominences, areas with metal implants, or areas with thick subcutaneous fat.
c. If the electrosurgical unit is operating normally at standard settings but the output power decreases or is interrupted, it may be due to improper placement or poor contact of the return electrode. Check the electrode and all connections before increasing the power.

5. When the polyp is visible within the endoscopic field of view, the snare must be fully retracted into the outer tube. Then insert the outer tube into the working channel of the endoscope until the tip of the device emerges from the distal end of the endoscope.

WARNING:
To ensure patient safety, only activate the electrosurgical unit after the snare has been properly positioned around the polyp.

6. Advance the sliding ring until the snare loop is fully extended from the outer tube, position the snare to firmly encircle the target polyp, and tighten the sliding ring

Note:
The plane of the snare loop should be kept perpendicular to the polyp stalk to ensure effective cutting performance.

WARNING:
Only activate the electrosurgical unit when the snare loop has been securely positioned around the polyp.

7. Check the required device parameters and activate the electrosurgical unit in accordance with the manufacturer's instructions.
8. **Note:** The rated voltage of the product is 800 V in cutting mode and 1550 V in coagulation mode.
9. Perform polypectomy.
10. After completing the polypectomy, turn off the electrosurgical generator, retract the snare into the outer tube, and withdraw the device from the endoscope.
11. Retrieve the polyp and handle the specimen according to hospital procedures.
12. After the procedure, disconnect the cable from the electrode on the handle and dispose of the device in accordance with medical hazardous waste regulations.
13. Disconnect the cable from the electrosurgical unit, clean any dirt or fluids with a damp cloth, and loosely coil the cable for storage.

[CONTRAINDICATIONS]

To ensure safety, the patient's condition must be evaluated prior to the procedure. Absolute contraindications for endoscopic gastrointestinal polypectomy include (but are not limited to):

1. Polyps with obvious malignant features under endoscopy.
2. Patients with pacemakers or metallic implants.
3. Other contraindications to endoscopic procedures.

[POTENTIAL COMPLICATIONS]

1. General endoscopic complications may include (but are not limited to): perforation, bleeding, aspiration, fever, infection, hypotension, drug allergy, respiratory depression or apnea, arrhythmia, or cardiac arrest.
2. Polypectomy-related complications may include (but are not limited to): gastrointestinal bleeding, perforation, burns, serositis, etc.

[WARNINGS]

1. This instrument must not be used in patients with pacemakers or metallic implants. High-frequency signals may cause ventricular fibrillation, pacemaker malfunction, or electric shock, potentially leading to serious injury or death.
2. Do not allow the snare to contact or entangle with other instruments such as electrosurgical knives, ECG leads, or cables in the endoscopic system, as this may cause interference, short circuits, or device damage.

3. The output power of the electrosurgical unit should be kept as low as possible. Excessively high-frequency current is not required and should be limited to the minimum necessary for effective treatment.
4. Do not bend the outer tube to a diameter smaller than 20 cm to avoid permanent deformation.
5. Avoid twisting the outer tube during device preparation.
6. The output voltage of the electrosurgical unit must not exceed the maximum peak voltage specified in its instructions for use.
7. Accessories shall be inspected regularly, especially the electrode cables and connection cables used with the endoscope.
8. Do not use the product in environments containing flammable or explosive gases.

WARNING

1. This product shall only be used by physicians who have received adequate professional and technical training, or under the supervision of experienced medical personnel.
2. Do not operate the product before thoroughly reading the entire instructions for use. Improper operation may affect the success of the procedure.
3. After use, the device must be disposed of in accordance with hospital procedures and applicable medical waste management regulations.
4. When this product is connected to and used with the intended compatible equipment, it does not affect the compliance of the equipment with YY9706 standards. No special consideration is required regarding the manufacturer or model of the connected equipment. The transmission frequency range, bandwidth, modulation type, frequency characteristics, and effective radiated power depend on the technical specifications of the associated electrosurgical unit.

[NOTES]

1. Carefully check the packaging and product labeling. If any damage to the packaging is found or the product is expired, it must not be used.
2. Refer to the product label to determine the minimum compatible endoscope channel size for using this device.
3. The coil diameter of the device must not be less than 20 cm.
4. Before use, the patient neutral electrode must be properly placed and used in accordance with the recommendations of the high-frequency electrosurgical unit manufacturer, in order to ensure patient safety and maintain a stable connection throughout the procedure.
5. The procedure must be performed under direct endoscopic visualization.
6. This device must not be used for any purpose other than its intended use.
7. The product is sterilized and intended for single use only. After use, it must be disposed of in accordance with national or local regulations on infectious medical waste. Reuse is strictly prohibited.
8. The level of protection against electric shock depends on the high-frequency generator used in conjunction with the product.

9. The high-frequency connection cable is provided by the manufacturer of the high-frequency generator; however, before use, it must be checked to ensure that the connector is compatible with the interface of this device.

[PACKAGING]

Upon delivery, the inner packaging of the product is sealed in a paper–plastic pouch to maintain sterility until opened. The intermediate packaging is a paper box containing a quality inspection certificate and instructions for use. The outer packaging is a carton box.
Packaging configuration includes: Paper–plastic pouch (1 piece/pouch), intermediate box, and outer carton.

[DATE OF MANUFACTURE]

See the label on the paper–plastic pouch.

[EXPLANATION OF SYMBOLS, MARKINGS AND ABBREVIATIONS USED ON PACKAGING AND LABELS]

	Manufacturer		CE mark and Identification number of Notified Body
	Authorised Representative in the European community		Batch code
	Caution		Date of manufacture
	Do not reuse		Use by
	Dot not re-sterilize		Keep dry
	Do not use if package is damaged		Keep away from sunlight
	Sterilized Using Ethylene Oxide		Consult instructions for use
	Type BF Applied Part		

[ENVIRONMENTAL REQUIREMENTS]

1. Transportation and Storage
   Ambient temperature: -40°C to 55°C
   Relative humidity: 20% ~ 80%
   Atmospheric pressure: 500 hPa ~ 1060 hPa
2. Operation
   Ambient temperature: 5°C to 40°C

Relative humidity: 20% ~ 80%
Atmospheric pressure: 860 hPa ~ 1060 hPa

[CLEANING, DISINFECTION AND STERILIZATION]

This device has been sterilized using ethylene oxide (EO) prior to leaving the factory.
The product is for single use only and must be discarded after use. Users shall not clean, disinfect, or re-sterilize the device.

[INSTALLATION REQUIREMENTS]

Before use, the user shall connect the device to the electrosurgical unit using a high-frequency connection cable; no additional installation is required.
This device does not contain user-serviceable parts.
Do not disassemble or repair the device, as this may cause harm to the patient or operator.

[STORAGE]

The product shall be stored in a cool, dry, clean, and well-ventilated environment free of corrosive gases. Do not expose the packaging to organic solvents, ionizing radiation, or ultraviolet radiation.
The shelf life of the product is 3 years.

[REVISION]: A/0

[PRODUCTION INFORMATION]

Manufacturer

Jiangsu Rui Tian Medical Technology Co., Ltd.
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EC REP

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Người đại diện hợp pháp của cơ sở
Ký tên (Ghi họ tên đầy đủ, chức danh)
Xác nhận bằng dấu hoặc chữ ký

CÔNG TY TNHH LONGTECH MEDICAL VIỆT NAM
THÀNH PHỐ HÀ NỘI

GIÁM ĐỐC
Nguyễn Thị Huyền Trang