



**Instructions for Use of Disposable
Polypectomy Snare**

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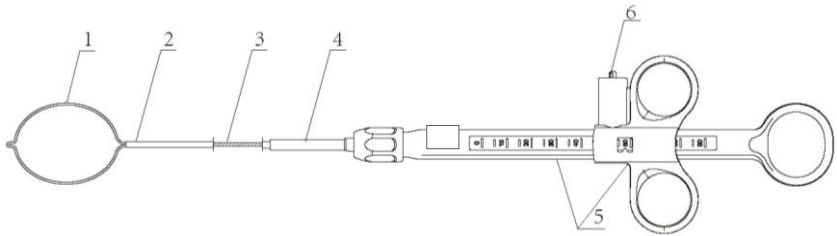
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Instructions for Use of Disposable Polypectomy Snare

【Product Name】

Disposable Polypectomy Snare

【Structure】



1-Loop 2-Outer tube 3-Pulling wire 4-Sheath 5-Handle

6-Electrode connector

【Model】 SD-01 (02,03) 0 (1,2) C5 (D2,D4,E1,E3,F3,F1,F2) - 10 (15, 20, 22, 25, 30, 35, 40, 45, 50)

Code of Loop shape	Shape	Code of endoscope channel: Categorical diameter (mm)	Code of working length: Working Length (mm)	Tolerance (mm)	Code of loop width: Loop width (mm)	Tolerance (mm)
01	Hexagonal	0:2.0 1:2.8	C5:1200 D2:1600	±20	10:10 15:15	±2.0

02	Oval	2:3.2	D4:1800	20:20
			E1:2000	22:22
			E3:2300	25:25
			F3:2500	30:30
03	Crescent		F1:2600	35:35
			F2:2800	40:40
				45:45
				50:50

【Packaging list】

Internal package: Paper-plastic bag, 1 pcs/bag

Middle package: Paper box, 1pcs/box

Outside package: Corrugated box

【Intended use】

The Disposable Polypectomy Snare is used in combined use with endoscope to cutting polyps or other redundant tissues with high-frequency current in digestive tract. Sterile, for single-use.

【Operation environment】

Operating temperature: 5°C-40°C

Operating relative humidity: 30-80%RH

Operating atmospheric pressure:70kPa - 106 kPa

【Method of use】

(1) Preparation :

1. Check if the instrument components are complete and of no damage. Please use the alternative instrument if there are any irregularities;
2. Simulate the operation. Slide the handle back and forth. The loop

should be able to stretch out of and withdraw into the end of the tube completely.

(2) Operations:

1. Select appropriate active cable to connect with the connector in the handle, the other end of the cable is inserted into the appropriate high-frequency generator;

2. Withdraw the loop into the tube completely before inserting the snare into the endoscope;

Warning: Set the high-frequency generator OFF before inserting the snare into the endoscope, so as to avoid patient injured or equipment damaged caused by improper circuit grounding.

Warning: Make sure the patient is grounded properly before using the high-frequency generator and snare, so as to avoid patient injured.

3. Find the location of the polyp and located the endoscope nearby before polypectomy. In order to view the operation clearly and locate the snare accurately, it may need repeated washing or pumping.

4. Push the snare through the endoscope channel until a clear view of the snare under the endoscope. Then perform the polypectomy as per standard techniques.

Warning: if there are marks on the handle, they are only help the operator to determine the approximate location of the withdrawal. The polypectomy should be performed under direct vision of the endoscope all through.

Warning: For the effects of electro surgery is largely influenced by the size and shape of the active electrode, a clear effect of the given control settings can't be defined. It is very important that if the

accurate settings of the generator are not clear, set the power of the generator under recommended range, then increase the power carefully until a desirable effect. As per medical literatures, the power of the generator is generally set as 30-50W.

Warning: It is strongly recommended for operators to reference the latest medical literatures on the monopole setting and technique proposal.

(3)Withdraw of the snare:

1.Make sure the high-frequency generator is set OFF before withdrawing the snare out of the endoscope.

2.Withdraw the snare out of the endoscope slowly and carefully, so as to avoid damaging the endoscope accidentally.

(4) Dispose :

Dispose this device according to recognized hospital standard.

【Notices】

- DO NOT use the product once the internal package is damaged.
- Choose the high-frequency equipment and high-frequency connection cable. The high-frequency equipment of ERBE.MARTIN.STORZ and OLYMPUS is appropriate, and the high-frequency connection cable is also available by these companies. But make sure the appropriate matching with the connection part of this instrument before use.
- No modification of this equipment is allowed.
- Please check the integrity of the device, especially the insulation

part.

- When the loop contacts with the endoscope tip, don't allow the output, otherwise, it may result in damage to endoscope and this instrument.
- Do not make an abrupt push to the sliding handle, otherwise, it would make the loop reach out abruptly, which would result in perforation, hemorrhage or mucous membrane damage
- Do not use too much power when attempt to enclose the tissue, otherwise, it may result in patient hemorrhage or mucous membrane damage.
- Aspirate the liquids that adhered to the loop and body cavity tissues (such as mucilage). If electrical cutting is executed when these liquids are adhered, it would result in patient perforation, hemorrhage, mucous membrane damage or burning to tissue.
- When operating the high-frequency equipment, try to use the minimum output and time needed by the operation. Excessive output would result in patient perforation, hemorrhage or mucous membrane damage.
- When cutting, make sure this instrument is connected with electricity. It may result in patient hemorrhage or mucous membrane damage if this instrument is disconnected with electricity when cutting.
- When this instrument is connected with high-frequency electricity currency, don't start up the output when this instrument is in contact with the normal body cavity tissue, otherwise, the non-target tissue will be burned.

- If swelling air formed in intestinal cavity, change it with unflammable air (such as CO₂), otherwise, the swelling air could result in burning or explosion, then cause burning to patient's tissue.
- When the metal part in the tip portion of endoscope is too close to loop part, or they are in contact, do not start up output.
- When patient's skins are in contact (i.e. bare arm are in contact with chest side), do not start up output, otherwise, it may result in burning to patient.
- When patient's clothing is wet, do not start up output, otherwise, it may result in burning to patient.
- When patient is in contact with the metal part of operation platform or other equipment, do not start up output, otherwise, it may result in burning to the patient, operator or assistant.
- Do not withdraw the instrument from the endoscope quickly. This could scatter blood, mucus or other patient debris and cause risk of infection.
- When the loop is not completely retracted to its outer tube, do not withdraw the instrument from the endoscope, otherwise, it may result in damage to endoscope or the instrument.
- Temporarily unused ACTIVE ELECTRODES should be stored in a location that is isolated from the PATIENT.
- For patients with cardiac pacemakers or other active implants, a possible hazard exists due to interference with the action of pacemaker or pacemaker may be damaged, and when in doubt, approved qualified advice should be obtained.

- The device must be used with the endoscope, the insulation of the device tube parts is provided by the endoscope, during use, the insulated electrode cables must be paid attention.
- It is recommended to use high frequency electricity equipment with rated frequency of 300-600KHz and rated voltage less than 1000V. It shall select appropriate current and rated output power according different polyps conditions, generally, rated output power of 20-50W is advised to electrocoagulation and electrocision.

【Contraindications】

- Patients who have the contraindications for digestive endoscopic examination;
- Patients with the trend of hemorrhage, time elongated of hemorrhage or cruor, hemoblast reduction, or elongated time of thrombin, cannot recover after medical therapy;
- Patients with deteriorated polyp cancer;
- The places easy for perforation;
- Basilar part of polyp is too large (with its diameter $>2\text{cm}$), which is confirmed not be able to be excised.

【Potential complications】





- Potential complications of snare operation include (but not limited to).
- Hemorrhage, perforation, burning, blood poisoning, infection, hypotension.







【Storage and transportation】

- The single package is paper-plastic bag, middle is the box, and outer is the carton. When in transport, it should be kept clean, dry and sealed. The transport condition should be of the temperature of $-20^{\circ}\text{C}\sim 70^{\circ}\text{C}$, and the humidity of $10\%\sim 90\%$. It could not be transported together with sand, metal fragments, glasses, or keen-edged stuff, nor with the poisonous, corrosive or flammable stuff. Slings of packages when loading and unloading, insulation under the sun or drenching in rain are all prohibited.
- This instrument is sterilized product, for single use only. Store the sterile package at the temperature of $-20^{\circ}\text{C}\sim 60^{\circ}\text{C}$ and the humidity is not greater than 80%. Store the instrument at the dry room of good ventilation. Do not store it in direct sunlight.

Warning: Do not store the sterile package containing the instrument in places where it will become damaged, wet or improperly sealed. Otherwise, the sterility of the instrument may be compromised, which could cause risk of infection control or patient's affected part infection.

【Explanation for used symbols】

	CE certified by TUV SUD		Lot number
	Single use		Date of manufacture

	Sterilized by EO		Manufacturer
	Read the IFU		European union representative
	BF type device		Validity of device

【Validity Period】 3 years

【Manufacturer】 Jiangsu Changmei Medtech Co., Ltd.

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