Cold Snare
Instructions for Use

Micro-Tech (Nanjing) Co., Ltd
IMPORTANT INFORMATION

Caution: Federal law restricts this device to sale by or on the order of a physician. Read all instructions carefully before use. They contain essential information on using this device safely and effectively. Keep these instructions in a safe, accessible location, as you may need to refer to them again. If you have any questions or comments about any information in these instructions, please contact Micro-Tech.

INTENDED USE

1. Cold Snare is intended to be used without electro-cautery for the endoscopic resection of diminutive polyps (≤9mm) in the gastrointestinal tract.
2. Single or multiple polyps in digestive tract, the diameter should generally being ≤9mm, the number of the multiple polyps being ≤30.
3. Pathologic histology confined that polyp is non-infiltration.
4. Early cancer confined to a mucosa and the polyp(s) suitable for endoscopic removal.

CONTRAINDICATIONS

Contraindications include, but may not be limited to:
1. People who have poor physical fitness, and a serious heart or/and lung disease, and cannot tolerate to endoscopy and endoscopic treatment.
2. People who have a bleeding tendency, an extended bleeding and coagulation time, or thrombocytopenia or prolonged prothrombin, which cannot be corrected by treatment.
3. People who have a polyp / polyps with a too large base, the base of a polyp >9mm.
4. People who have a polypoid cancer which has infiltrated a tissue or organ and has deteriorated.
5. People who have diabetes, regardless of whether whose blood sugar is normal should be classified as relative contraindications (poor healing capacity).
6. Uncooperative patients or family members.
POTENTIAL COMPLICATIONS

1. Bleeding, perforation, infection, septicemia, etc.
2. Respiratory depression or apnea, arrhythmia or cardiac arrest.
3. Potential complications that are not known or observed.

WARNINGS

1. The product is intended for single use only! DO NOT re-use, re-sterilize, and/or reprocess. Re-use re-sterilization or reprocessing may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Re-use re-sterilization or reprocessing may also create a risk of contamination of the device and/or cause patient infectious disease(s). Contamination of the device may lead to injury, illness or death of the patient. Micro-Tech assumes no liability with respect to instruments reused, re-sterilized or reprocessed.
2. Do not use this instrument for any purpose other than its intended use.
3. The product is only intended for adult populations.
4. This device is not made with natural rubber latex.
5. Patients should be informed of the potential risks and complications, which may lead to injury, illness or death of the patient.
6. The instrument is intended for use under the direct supervision of a suitably trained physician only. A thorough understanding of the technical principles, clinical applications, and associated risks is expected before usage.
7. Confirm that the endoscopy view is clear before use. Do not insert the instrument into the endoscope unless you have a clear endoscopic field of view. Insertion without clear endoscopic field of view could cause patient injury, such as perforation, hemorrhage or mucous membrane damage. Damage to the endoscope and/or the instrument may also occur.
8. Do not insert the instrument into the endoscope unless you have a clear endoscopic field of view. If you cannot see the distal end of the insertion portion in the endoscopic field of view, do not use it. Insertion without clear endoscopic field of view could cause patient injury, such as perforation, hemorrhages or mucous membrane damage. It may also damage the endoscope and/or instrument.
9. The operator of the snare must be a physicians with sufficient training.
10. If polyps cannot be removed, and don’t force operation, Please changing cold snare or using other methods.
11. For multiple polyps patients, after repeated procedures, please observe whether loop is distorted or not, if distortion, please use another one.
12. For less than 3mm polyps in the digestive tract is not recommended.

【Product Name】Cold Snare
【Packaging】Packed in Pouch
【Production Date】See packaging
【Sterilization】Sterilized by EO (ethylene oxide) gas
【Shelf Life】5 years
【Compatible Working Channel】≥ φ 2.8 mm

STRUCTURE

Cold Snare mainly includes a snare loop, wire cable, outer tube and handle. (Fig. 1).


Fig.1 Schematic diagram of cold snare

Note: This is the sketch map of one kind of loop, the other loop shapes are not shown here.
PREPARATION

1. Reference the product label and choose the appropriate device.
2. Contents supplied STERILE.
3. Inspect the package before use for any damage. Do not use if package is damaged. Open the package carefully after verifying the shelf life.
4. Carefully remove the device from its packaging and uncoil it. Do NOT use excessive force as this may damage the device and affect performance.
5. Before use, please check the insertion patients body parts, ensure that no sharp edge.
6. If this device shows any signs of damage, do not use. Do not attempt to repair a nonfunctional or damaged device.

INSTRUCTIONS FOR USE

1. Cold Snare is compatible with an endoscope channel of 2.8mm or larger.
2. Retract the handle in order to make sure the snare loop is inside the outer tube (as shown in Fig.2). And insert the snare into the working channel of the endoscope. Via the endoscope view, make sure that the tube projects out of the distal end of the channel (as shown in Fig. 3).

![Image of incorrect and correct positioning of snare loop](image1)

Incorrect

Correct

Fig. 2

![Image of working channel of endoscope](image2)

Fig. 3

3. Extend the snare loop, trap the polyps gently (as shown in Fig. 4).
4. Pull back the slider to removing polyps.
5. Retract the handle in order to make sure the snare loop is inside the outer tube, and pull out cold snare Repeat the procedure as necessary.
6. Upon completion of the procedure, remove the instrument from the endoscope.

**STORAGE**

The product should be stored in a cool, dry, clean, well-ventilated, non-corrosive gas environment.
Do not expose the package to organic solvent, ionizing radiation or ultraviolet radiation.
The product shelf life is 5 years.

**PRODUCT DISPOSAL**

After use, this product may be a potential biohazard. Handle and dispose of in accordance with hospital, local and administrative laws and regulations.

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Hot Snare Use:

1. Retract the handle of the Snare and confirm that the Snare loop is fully retracted into the catheter prior to inserting the catheter into the endoscope.

2. Advance the catheter through the endoscope channel until the lesion is clearly identified and targeted. Snare loop could be rotated if rotatable function is available.

3. With electrosurgical unit off, securely connect the active cord to the Snare handle and electrosurgical.

4. Turn the electrosurgical unit ON.

**NOTE:** the device should be installed and put into service according to the EMC information provided in the electrosurgical unit accompanying documents.

**NOTE:** In strict accordance with the applicable electrosurgical device operational mode and Input feature during operation.

Take the CONMED Electrosurgery 60-8200-230 as an example:

Operational mode: intermittence 15s open/30s close;

The rated Input: 100~240V, 4A max. 50/60Hz.

5. Operate the handle to extend the Snare loop and snare the target tissue gently. Press the foot switch to active output. Pull the slider and resect the target tissue. Do not apply excessive force when snaring the tissue. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage or thermal injury.

6. Retract the snare prior to removing the instrument from the endoscope.

7. Upon completion of the procedure, disconnect the active cord from the Snare handle and dispose of the device according to the institutional guidelines for biohazard medical waste and local regulatory requirements.