Polypectomy Snare
Instructions for 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.
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. The Polypectomy Snares are used endoscopically in the removal of diminutive polyps, sessile polyps, and pedunculated polyps within the GI tract.
2. Single or multiple gastrointestinal polyps with diameter less than 2cm;
3. Non-infiltration type polyp(s) confirmed by histopathology and multiple polyps with quantity less than 30 pieces;
4. Early stage cancer only confined in mucous layer.

CONTRAINDICATIONS

Contraindications include, but may not be limited to:
1. Poor physical fitness, with serious heart or/and lung disease, and can’t tolerate endoscopy and endoscopic treatment;
2. Bleeding tendency, an extended bleeding and prolonged coagulation time, or thrombocytopenia or lack of prothrombin which couldn’t be treated
3. A polyp / polyps with a large base more than 2cm for gastric poly and 1.5cm for normal polyp.
4. A polypoid cancer which has infiltrated into tissue or organ and has deteriorated;
5. Patients with implanted pacemaker or implanted with a metal valve / values (It is classified as relative contraindication);
6. Diabetes, regardless of whether blood sugar is normal (poor healing capacity) (It is classified as relative contraindication);
7. Uncooperative patients or family members.

POTENTIAL COMPLICATIONS

• Bleeding, perforation, trans-mural burn, thermal injury, respiratory depression or apnea, arrhythmia or cardiac arrest;
• Infection, septicaemia, etc.;
• Complications which may exist and 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. When applied to a patient with a pacemaker implanted, the instrument may cause malfunction or failure of the pacemaker, seriously affecting the patient. Consulting cardiologist or the manufacturer of the pacemaker is recommended before instrument application.

9. When using the instrument in the vicinity of the heart, be sure to use it with the minimum necessary output. Spark discharge during operation may affect the heart.

10. When using an electrocardiograph or other physiological monitoring equipment simultaneously with the instrument, any monitoring electrodes should be placed as far away as possible from the electrodes used with the electrosurgical unit. Needle monitoring electrodes should not be used. Physiological monitoring equipment incorporating high-frequency current limiting device is recommended.

11. When the endoscope is used with the device, the leakage currents may be relatively increased. Ensure a proper path from patient return electrode to electrosurgical unit is connected and maintained throughout the procedure.

12. Before use, please check the insertion patient's body parts, ensure that no sharp edge.

13. Do not touch energized handle components (e.g. the high-frequency applied mandrel) and do not contact with conductive object as shown in Fig.1 and Fig.2 below.
14. Operation without strictly following instructions from electrosurgical unit manufacturer could cause the Snare invalid, patient or user injury.

15. The applicable electrosurgical unit should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the electrosurgical devices should be observed to verify normal operation in the configuration in which it will be used.

16. The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the electrosurgical unit manufacturers replacement parts for internal components, may result in increased emissions or decreased immunity of the electrosurgical unit.

17. Since supporting the use of Olympus endoscopic system, Olympus endoscopic system’s light source may affect Polypectomy Snare’s temperature to exceed 41°C, to minimize the risk of injury, please ensure the correct use of it according to Olympus endoscopic system and the manufacturer’s instructions.

【Product Name】Polypectomy Snare
【Packaging】Packed in Pouch
【Production Date】See packaging
【Sterilization】Sterilized by EO (ethylene oxide) gas
【Shelf Life】3 years
【Compatible Working Channel】≥ φ 2.8 mm

【Applicable Electrosurgical Unit】
High-frequency Electrosurgical unit that which is legal listing in USA is recommended such as CONMED Electrosurgery 60-8200-230 and its matched 474-L active cord.

【Rated High-Frequency Voltage】
DO NOT use higher repeated peak voltage than the Cut -1200Vp (2400Vp-p)
STRUCTURE

The Polypectomy Snare consists of a loop assembly which can be extended and retracted from the snare’s outer tube by manipulating the handle assembly. (Refer to Fig.3).

![Fig.3 Structural Sketch of Sterile Snare with type II handle](image)


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.
7. Before use, operate the slider back and forth to observe whether the
INSTRUCTIONS FOR USE

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...
Cold 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. Operate the handle to extend the Snare loop and snare the target tissue gently. 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.
4. Repeat steps 3 & 4 as required.
5. Retract the snare prior to removing the instrument from the endoscope.

**EMC CONDITIONAL**

Guidance and manufacturer’s declaration - electromagnetic emissions - for all ME EQUIPMENT and ME SYSTEM.

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>The Polypectomy Snare uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class A</td>
<td>The Polypectomy Snare is suitable for use in all establishments other than domestic establishments and those directly connected to the public low -voltage power supply network that supplies buildings used for domestic purposes</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000 -3-2</td>
<td>A</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/ Flicker emissions IEC 61000 -3-3</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>
Guidance and manufacturer’s declaration – electromagnetic immunity - for all ME EQUIPMENT and ME SYSTEM.

Table 2: Guidance and manufacturer’s declaration – electromagnetic immunity

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 Test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic Discharge (ESD) IEC 61000-4-2</td>
<td>±6 kV contact ±8 kV air</td>
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<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical fast transient/burst IEC 61000-4-4</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines</td>
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<td>Mains power quality should be that of a typical commercial or hospital environment</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>±1 kV lines to earth</td>
<td>±1 kV lines to lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</td>
<td>&lt;5% UT (&gt;95% dip in UT) For 0.5 cycle 40% UT (60% dip in UT) For 5 cycle 70% UT (30% dip in UT) For 25 cycle &lt;5% UT (&gt;95% dip in UT) For 5 cycle</td>
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<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of Polypectomy Snare requires continued operation during power mains interruptions, it is recommended that the Polypectomy Snare be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td>Power frequency (50/60Hz) magnetic field IEC 61000-4-8</td>
<td>3A/m</td>
<td>3A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment</td>
</tr>
</tbody>
</table>

Note: UT is the a.c. mains voltage prior to application of the test level.
Guidance and manufacturer’s declaration – electromagnetic immunity for ME EQUIPMENT and ME SYSTEM that are not LIFE-SUPPORTING.

Table 3: Guidance and manufacturer’s declaration – electromagnetic immunity

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<th>Immunity test</th>
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| Conducted RF  | IEC 61000-4-6        | 3 Vrms 150 kHz to 80 MHz | Portable and mobile RF communications equipment should be used no closer to any part of the SYSTEM, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance

\[
d = \left[ \frac{3.5}{P} \right]^1 \quad \text{80 MHz to 800 MHz}
\]

\[
d = \left[ \frac{3.5}{E_1} \right]^1 \quad \text{800 MHz to 2.5 GHz}
\]

Where \( P \) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and \( d \) is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol: ✖️

Radiated RF | IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3V/m |
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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.

### 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 3 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.
Limited Warranty and Disclaimers:

1. Limited Warranty to Buyer. Micro-Tech USA warrants to Buyer that, for the earlier of one (1) year from the date of purchase, or until the product is used by Buyer, the products will be free from defects in materials and workmanship when stored and used in accordance with the instructions for storage and use provided by Micro-Tech USA and in accordance with applicable regulatory requirements. Descriptions or specifications appearing in Micro-Tech USA’s literature are meant to generally describe the products and do not constitute any express warranties. In the event that Micro-Tech USA gives technical advice with respect to the product, it is agreed that such advice is given without any liability on Micro-Tech USA’s part. Any guarantee of specific properties of or in the products shall only be effective if and to the extent specifically confirmed by Micro-Tech USA in writing. These warranties shall not apply for product failure or deficiency due to improper storage, alteration, or the consequences of uses for which the products were not designed or that adversely affect the products’ integrity, reliability, or performance.

2. Disclaimer and Release. THE WARRANTIES, OBLIGATIONS, AND LIABILITIES OF Micro-Tech USA AS SET FORTH HEREIN ARE EXCLUSIVE. BUYER HEREBY WAIVES ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, ARISING BY LAW OR OTHERWISE, WITH RESPECT TO THE PRODUCTS AND ANY OTHER GOODS OR SERVICES DELIVERED BY BUYER, INCLUDING, BUT NOT LIMITED TO: (1) ALL OTHER EXPRESS AND IMPLIED WARRANTIES, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND (2) ANY IMPLIED WARRANTY ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING, OR USAGE OF TRADE.

3. Implied Warranties. The purchase of products may be subject to laws in the territories applicable to the sale of the products by Micro-Tech USA to Buyer that impose implied warranties, conditions, or obligations that cannot be excluded, restricted, or modified, or can only be excluded, restricted, or modified to a limited extent. The provisions of Paragraphs 2 and 4 shall apply to the greatest extent allowed by such laws.

4. Limitation of Liability. EXCEPT TO THE EXTENT PROHIBITED BY APPLICABLE LAW, Micro-Tech USA’S LIABILITY UNDER THIS WARRANTY IS LIMITED TO: (a) THE REPLACEMENT OF THE PRODUCTS OR THE RE-SUPPLY OF EQUIVALENT PRODUCTS; (b) THE REPAIR OF THE PRODUCTS OR PAYMENT OF THE COST OF REPAIRING THE PRODUCTS; or (c) PAYMENT
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OF THE COST OF REPLACING THE PRODUCTS OR ACQUIRING EQUIVALENT PRODUCTS. MICRO-TECH USA SHALL HAVE NO OBLIGATION OR LIABILITY, WHETHER ARISING IN CONTRACT (INCLUDING WARRANTY), TORT (INCLUDING ACTIVE, PASSIVE, OR IMPUTED NEGLIGENCE, STRICT LIABILITY, OR PRODUCT LIABILITY) OR OTHERWISE, FOR ANY SPECIAL, CONSEQUENTIAL, PUNITIVE, INCIDENTAL, OR INDIRECT DAMAGES, OR FOR LOSS OF USE, LOSS OF REVENUE, LOSS OF BUSINESS, LOST PROFIT, OR OTHER FINANCIAL LOSS ARISING OUT OF OR IN CONNECTION WITH ANY PRODUCT OR OTHER GOODS OR SERVICES FURNISHED BY MICRO-TECH USA, EVEN IF MICRO-TECH USA WAS AWARE OF THE POSSIBILITY OF SUCH DAMAGES OR LOSS.
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