

LesionHunter™ Rotatable Nitinol Cold Snare

Instructions for Use



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

The LesionHunter™ Rotatable Nitinol Cold Snare is indicated for use endoscopically for the removal of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the gastrointestinal tract.

CONTRAINDICATIONS

Contraindications for these devices are those specific to endoscopic polypectomy and tissue resection.

POTENTIAL COMPLICATIONS

Include, but may not be limited to:

- Perforation, immediate or delayed bleeding.
- Infection or septicemia, etc.
- Respiratory depression or apnea, arrhythmia or cardiac arrest.
- 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 Snare is made from Nitinol. Do not use on a patient who is severely allergic to metals, including but not limited to nickel.
5. **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.
6. Do not insert the instrument into the endoscope unless you have a clear endoscopic field of view. Insertion without a clear endoscopic field of view could cause patient injury, such as perforation, hemorrhage or mucous membrane damage. It may also damage the endoscope and/or instrument.
7. Care should be exercised when grasping tissue to avoid inadvertently grasping tissue not intended for retrieval.

【 Product Name 】 LesionHunter™ Rotatable Nitinol Cold Snare

【 Packaging 】 Packed in Pouch

【 Production Date 】 See packaging

【 Sterilization 】 Sterilized by EO (ethylene oxide) gas

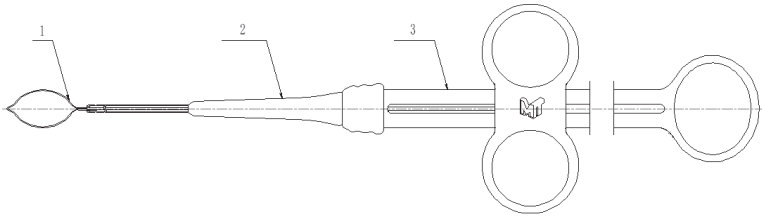
【 Shelf Life 】 See packaging

【 Compatible Working Channel 】 $\cong \varnothing 2.8 \text{ mm}$

Device is not made with natural rubber latex.

STRUCTURE

Cold Snare mainly includes a loop assembly, outer tube assembly, handle assembly. (Fig. 1).



1、 Loop assembly 2、 Outer tube assembly 3、 Handle assembly

Fig.1 Schematic diagram of cold snare

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 the 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, operate the slider back and forth to confirm function. The snare loop should be free of distortion, deformation, frayed wires, disconnections, and sharp protrusions. If this device shows any signs of damage, do not use. Do not attempt to repair a non-functional or damaged device.

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. Slowly advance the catheter through the endoscope channel until the tip appears in the endoscopic view and the lesion is clearly identified and targeted.
3. Operate the handle to extend the Snare loop and gently snare the target tissue.
Note: The Snare loop can be rotated if desired by holding the outer sheath assembly and rotating the handle.
4. Confirm appropriate tissue is captured and proceed to resect by gently pulling

the slider.

5. Repeat steps 3 & 4 as required.

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

PREPARATION

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.

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 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.**



Manufacturer

Micro-Tech (Nanjing) Co., Ltd.

No.10 Gaoke Third Road, Nanjing National Hi-Tech Industrial
Development Zone, Nanjing 210032 ,Jiangsu Province, PRC

TEL:+ 86 25 58609879, 58646393

FAX:+ 86 25 58744269

Email: info@micro-tech.com.cn

www.micro-tech-medical.com;

Distributed By

Micro-Tech USA Inc.

2855 Boardwalk Drive, Ann Arbor, MI 48104 USA

Tel: 734-259-3768

Toll free: 877-552-4027

info@micro-tech-usa.com