



LesionHunter™ Rotatable Nitinol Cold Snare
Instructions for Use

LesionHunter™ Drehbare Nitinol-Kaltschlinge
Gebrauchsanweisung

Boucle de capture à froid nitinol pivotante
LesionHunter™
Mode d'emploi

LesionHunter™ Trappola orientabile
a freddo in nitinolo
Istruzioni per l'uso

Laço frio rodável de nitinol LesionHunter™
Instruções de utilização

LesionHunter™ Asa fría giratoria de nitinol
Instrucciones de uso

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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 devices reused, re-sterilized or reprocessed.
2. Do not use this device for any purpose other than its intended use.
3. Do not insert the device 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 device.
4. Care should be exercised when grasping tissue to avoid inadvertently grasping tissue not intended for retrieval.

DEVICE NAME

LesionHunter™ Rotatable Nitinol Cold Snare

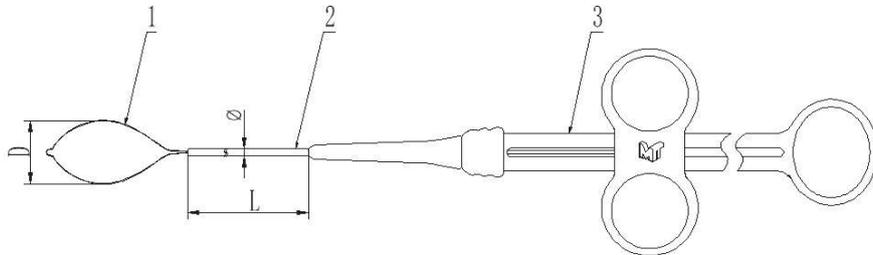
DEVICE DESCRIPTION

[SPECIFICATION]

The specifications of the product are represented by Snare Loop Diameter (D), Maximum outer diameter of the part inserted into endoscope channel (\emptyset) and Working Length (L), as indicated in table 1

Table 1 Specification and parameter

NO	REF	Snare Loop shape	Snare Loop Diameter D(mm)	Maximum outer diameter of the part inserted into endoscope channel \emptyset (mm)	Working Length L(mm)
1	CS2-21023231	Oval	10	≤ 2.5	2300
2	CS2-21523231	Oval	15	≤ 2.5	2300
3	CS2-22023231	Oval	20	≤ 2.5	2300

【STRUCTURE】

1. Snare Loop 2. Outer tube 3. Handle assembly

Fig.1 Schematic diagram of LesionHunter™ Rotatable Nitinol Cold Snare

【USER INFORMATION/TRAINING/QUALIFICATIONS】

This device is intended to be used by physicians, nurses and technicians trained in endoscopic tissue resection procedures.

INTENDED USE / INDICATIONS FOR USE

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.

PATIENT TARGET GROUP

The product is intended for adult and adolescent populations.

CLINICAL BENEFITS

LesionHunter™ Rotatable Nitinol Cold Snare is a dedicated device to grasp and cut sessile polyps, pedunculated polyps and tissue from within the gastrointestinal tract mechanically without the use of cautery. This technique has short procedure times, and low complication rates.

PERFORMANCE CHARACTERISTICS

LesionHunter™ Rotatable Nitinol Cold Snare provides users with a three ring comfortable grip.

LesionHunter™ Rotatable Nitinol Cold Snare offers users a choice of snare loop in three diameters.

The snare loop can be rotated by rotating the handle assembly.



CONTRAINDICATIONS

Contraindications for these devices are those specific to endoscopic polypectomy and tissue resection, which may include:

- 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 polypoid cancer which has infiltrated a tissue or organ and has deteriorated.
- 4) Any other conditions the physician judges unsuitable for use.

POTENTIAL COMPLICATIONS

Potential complications include:

Perforation;

Immediate or delayed hemorrhage;

Infection;

Complications which are not currently known or observed may be present.

CAUTIONS

1. A thorough understanding of the technical principles, clinical applications, and associated risks is expected before usage.
2. Patient should be informed and expressed his/her acceptance for the details of the operation and all the potential risks and complications, which may lead to injury, illness or death of the patients.
3. Please read this instruction manual entirely before use.
4. Serious incident relation to the device should be reported to the manufacturer and the competent authority of the Member State.

NOTES

1. The LesionHunter™ Rotatable Nitinol Cold Snare is a single use device only. Do not re-use or cross use it. **DO NOT REUSE, REPROCESS OR RESTERILIZE.**
2. If polyps cannot be removed, and don't force operation. Please change cold snare or use other methods.
3. For multiple polyps patients, after repeated procedures, please observe whether loop is distorted or not, if distortion, please use another one.
4. A single copy of the instructions for use is provided in a case box (10 devices). If further copies are requested, please contact Micro-Tech, we will provide free of charge.

HOW SUPPLIED

The device is supplied sterile.

STORAGE

Rotate inventory so that products are used prior to the sterilization expiration date on the package label.

Store the device in a cool, dark and dry place, and do not expose the package to organic solvents, ionizing radiation or ultraviolet light. The sterilization is valid for 5 years.

COMPATIBILITY

【Applicable Endoscopes】

Endoscope that are legal listed in EUROPE are recommended such as Olympus.

【Compatible Working Channel】

≥Φ2.8mm

DIRECTIONS FOR USE

【PREPARATIVE CHECK AND PREPARATION】

1. Before using, inspect the pouch for any breach of the package. Do not use if package is damaged.
2. After verifying the sterilization expiry date, open the package carefully, take out the product.
3. Operate the slider back and forth to observe whether the Snare loop extends and retracts smoothly, whether there are distortion and deformation, unraveled wires, disconnections, sharp protrusions in the Snare loop, and whether there are scratches or broken areas, etc. on the surface of the outer tube; do not use the device if any above flaw is found.
4. Before using the device, inspect the endoscope and its accessories to be inserted into human body, to ensure there are no rough surfaces, sharp edges or protrusions which may cause safety hazard.

【INSTRUCTIONS FOR USE】

1. Retract the handle of the LesionHunter™ Rotatable Nitinol Cold Snare and confirm that the Snare loop is fully retracted into the outer tube prior to inserting the outer tube into the endoscope.
2. Slowly advance the outer tube 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 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 Snare loop prior to removing the device from the endoscope



PRODUCT DISPOSAL

After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.

POST-PROCEDURE

Any serious incident that occurs in relation to this device should be reported to the manufacturer and relevant local regulatory authority.