

Captivator™ COLD Single-Use Snare

REFER TO THE DEVICE DIRECTIONS FOR USE FOR COMPLETE INSTRUCTIONS ON DEVICE USE. RX ONLY.
CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Warning

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization 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. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

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

User Information

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

Intended Use/Indications for Use

The Captivator COLD Single-Use 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.

Warnings

- Universal precautions should be used in all cases.
- No modification of this equipment is allowed.

Precautions

- Captivator COLD Single-Use Snares are packaged sterile in a sealed pouch.
- Before using, inspect the pouch for any breach of the package to ensure sterility. If the package is opened or damaged, do not use.
- A thorough understanding of the technical principles, clinical applications, and risks associated with cold snaring (non-electrical) Polypectomy and tissue resection is necessary before using this product.
- Captivator COLD Single-Use Snares should only be used by or under the supervision of physicians thoroughly trained in endoscopic polypectomy and tissue resection.
- The 2.4 mm OD snares require an endoscope with a minimum working channel of 2.8 mm.

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- Any use of these devices, other than those indicated in the instructions, is not recommended.
- This device is intended for cold snaring only. Do not attempt to connect to a generator.
- Should be used with caution and only after careful consideration in patients who are at risk for bleeding complications.

Adverse Events

Adverse events include, but are not limited to:

- Perforation
- Immediate or delayed hemorrhages

Check for the proper position of the snare loop using direct vision. Positioning the snare loop in an improper location may lead to patient injury.