



**Product** Captivator™ Cold Single-Use Polypectomy Snares – IFU 51102758

**Rx Statement** **CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

*Prior to use, please refer to all applicable “Instructions for Use” for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator’s Instructions.*

### REUSE WARNING

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.

### 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

- No modification of this equipment is allowed.
- Markings on handle, if present, are intended only to assist in determining the approximate retraction of the snare loop. (Confirm if markings are on handle). Polypectomy and tissue resection should be performed under direct endoscopic vision at all times to avoid injury to the patient.
- 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.
- Before removing the snare from the endoscope, fully retract the loop into the sheath. Remove the snare from the endoscope slowly and deliberately to prevent inadvertent damage to the endoscope and or patient injury.

### 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.
- 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.
- To avoid damage, uncoil the snare before proceeding with preparation.
- Advance the snare through the endoscope using short, deliberate 2-3 cm (20-30 mm) movements to prevent inadvertent damage to the snare or endoscope.

## **POTENTIAL ADVERSE EVENTS**

Adverse events include, but are not limited to:

- Hemorrhage
- Infection
- Pain
- Perforation
- Stricture Formation
- Tissue Damage

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