

Refer to the device directions for use for complete instructions on device use.

Intended Use/Indications for Use

The Single-Use Polypectomy Snares are indicated for use in the removal and cauterization of: Diminutive Polyps, Sessile Polyps, Pedunculated Polyps

Contraindications

Contraindications for these devices are those specific to endoscopic polypectomy.

Warnings

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.

It is suggested that the operator and the assistant wear protective gloves to prevent accidental burns. Universal precautions should be used in all cases. While operating the device avoid contact with the patient.

Warning: It is highly recommended that the user consult the current medical literature on recommended monopolar settings and techniques.

- No modification of this equipment is allowed.

Fluids or flammable agents that may pool under the patient or in body depressions or cavities should be mopped prior to electro-surgery.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy. Precautions may be found in the complete instructions for use.

Potential Adverse Events

Potential adverse effects include, but are not limited to:

- Perforation
- Fulguration
- Immediate or delayed hemorrhages
- Transmural burns, characterized by abdominal pain, fever, and transient ileus

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

Please be aware that potential complications may arise even with the proper use of medical devices. Accordingly, this device should only be used by persons qualified in the procedures for which it is indicated.

Cautions

Cautions can be found in the product labeling supplied with each device. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.