Sensation™ Short Throw Snare

Prescriptive Information

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

Intended Use/Indications for Use

Indicated for use in the removal and cauterization of diminutive, sessile, and pedunculated polyps.

Contraindications

Contraindicated for 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 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. 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.

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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 body depressions or cavities should be mopped prior to electrosurgery.

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

Potential Adverse Events

Potential adverse events include perforation, fulguration, immediate or delayed hemorrhages, and transmural burns, characterized by adominal pain, fever, and transient ileus.

Please be aware that potential adverse events 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.

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.

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Cautions

A thorough understanding of the technical principles, clinical applications, and risks associated with Monopolar Polypectomy is necessary before using this product.

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.