Rotatable Snare Single-Use

Prescriptive Information

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

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Cautions can be found in the product labeling supplied with each device

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 governmental policy.

Intended Use/Indications For Use

The Rotatable Snare is indicated for use endoscopically for the removal and or cauterization 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

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: This device is not intended to be used in the presence of flammable liquid, in an oxygen enriched atmosphere or in the presence of explosive gases.

Any electrosurgical device constitutes a potential electrical hazard to the patient and/or the operator.

- 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 electrosurgery.

Precautions

Precautions: The Rotatable Snare must be used in conjunction with a Type BF or CF generator, see Generator Compatibility section. The active cord (sold separately) is connected to the snare handle by a plug pushed onto the connector as far as possible so that none of the connecting pin is visible. The other end of the active cord is inserted into the generator. Always follow the manufacturer's suggestions for the operation of the unit to prevent unnecessary hazard to the operator and/or the patient. Consult the neutral electrode manufacturer about the proper grounding of the patient. It is recommended that a monitoring neutral electrode be used, if a contact quality monitor is available, or built into the generator. The entire area of the neutral electrode should be attached reliably to the patient's body, and as close to the operating field as possible. The patient should not come into contact with metal parts or objects that may be grounded to earth. The use of antistatic sheeting is recommended for this purpose.

Skin-to-skin contact should be avoided (for example between the patient's arms and body) by way of dry cloth or gauze. Monitoring electrodes should be placed as far from the surgical area as possible. Needle monitoring electrodes are not recommended. Avoid incidental contact between Active Cords and the patient's body, or any other electrodes. The output power setting selected should remain under 50 Watts, yet be as low as possible for the intended purpose.

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Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the procedure. **It is very important that if the proper setting of the generator is not known, one should set the unit at a power setting lower than the recommended range and cautiously increase the power until the desired effect is achieved**. Based on the medical literature, a power setting of 40 to 50 watts is typically achieved.

Possible safety hazards may result from gas embolism caused by over-insufflation of air, inert gas prior to high frequency surgery, etc. Endogenous gases should be sucked away if possible prior to procedure. Patient leakage currents from endoscope, as well as energized polypectomy snare, are additive. Consult the endoscope manufacturer about the proper grounding of the endoscope.

- Rotatable 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 Monopolar and/or cold snaring (non-electrical) Polypectomy and tissue resection is necessary before using this product.
- Rotatable 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.
- Please review the operations and service manuals of the electrosurgical generator for proper set and operation prior to using the Rotatable Snare.
- Monopolar diathermy or electrosurgical cautery in patients with pacemakers or implantable cardiac defibrillators can result in electrical reset of the cardiac device, inappropriate sensing and/or therapy, tissue damage around the implanted electrodes, or permanent damage to the pulse generator. A cardiologist should be consulted prior to using Rotatable Snares in these patients.
- Should be used with caution and only after careful consideration in patients who are at risk for bleeding complications.

Adverse Events

Complications include, but may not be limited to:

- Perforation
- Fulgurations
- Immediate or delayed hemorrhages
- Transmural burn characterized by abdominal pain, fever and transient ileus.

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.