

Radial Jaw™, Radial Jaw™ 3, Radial Jaw™ 4, Radial Edge™

Single-Use Biopsy Forceps and Single-Use Hot Biopsy Forceps

Prescriptive Information

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

Caution/Rx Only:

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

Warnings:

Contents supplied STERILE using a Radiation process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single patient 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.

These single use biopsy forceps should only be used to biopsy tissue where possible hemorrhage will not present a danger for patients. Adequate plans for management of potential bleeding and appropriate airway management should be in place.

Intended Use / Indications for Use:

These single-use biopsy forceps are specifically designed to collect tissue endoscopically for histologic examination. These forceps should not be used for any purpose other than their intended function.

For Hot Biopsy Forceps: These Single-Use Hot Biopsy Forceps are intended to be used through an endoscope to cauterize and remove polyps and/or tissue specimens throughout the alimentary tract. The alimentary tract to include the esophagus, stomach, duodenum, jejunum, ileum and colon.

Contraindications:

None Known

Precautions:

- Endoscopy should be performed only by persons having adequate experience and training.
- Read these instructions thoroughly. Failure to follow instructions may lead to serious medical consequences.
- The packaging and the device should be inspected prior to use. Do not use the device if the product or packaging is damaged.
- When the forceps are employed with endoscopes, instruments or accessories from other manufacturers in a procedure, verify compatibility in advance.
- If the device fails to operate properly in any way or shows any sign of damage, DO NOT USE IT. Call Boston Scientific Customer Service and return the product. Attempts to repair nonfunctional or damaged instruments may induce dangerous failure modes during use.
- Single Use Hot Biopsy Forceps should not be used in the presence of flammable liquids, in an oxygen enriched atmosphere or in the presence of explosive gases.

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Adverse Events:

Complications associated with the use of the single-use biopsy forceps may include:

- Bleeding
- Perforation
- Infection
- Pneumothorax (Specific to Pulmonary Forceps)