

Radial Jaw™ 4 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.

Warning:

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.

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.

Warnings for Hot Biopsy Forceps:

It is suggested that the operator and the assistant wear protective gloves to prevent accidental burns. Universal precautions should be used in all cases.

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 electrosurgery.

Warnings:

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

For Hot Biopsy Forceps:

Warning: The electrosurgical generator should be placed in the OFF position prior to inserting the single-use Hot biopsy forceps through the endoscope to avoid injury to patient or equipment resulting from improper electrical circuit grounding.

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Warning: Ensure that the patient is properly grounded prior to use of the monopolar electro-surgical generator and single-use Hot biopsy forceps to avoid patient injury.

Caution: Application of excessive force to the forceps may damage the device. The forceps should be held with the index finger and middle finger comfortably resting on the spool ledge and the thumb in the loop. When other methods of operation are used, such as pushing on the thumb loop with the palm of one's hand, excessive force may damage the device.

Warranty:

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or reesterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**