

Radial Jaw™ 4 Multibite™

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

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

Rx ONLY

Caution: 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.

DEVICE DESCRIPTION:

Radial Jaw 4 (RJ4)

All RJ4 Biopsy Forceps are designed to collect tissue endoscopically for histologic examination. The devices consist of a handle, lumen connector, and jaws. The handle of the RJ4 forceps consists of a thumb ring and a spool. Sliding the spool backward and forward will open and close the forceps jaws. The lumen connector attaches to the handle and jaws, which provides columnar support.

RJ4 Biopsy Forceps

RJ4 Large Capacity (LC), Jumbo and Standard Capacity (SC) Biopsy Forceps are available in 160 cm and 240 cm lengths. This design incorporates two sizes of jaws, one requiring a 2.8 mm working channel and one requiring a 3.2 mm working channel. All sizes and lengths are available with or without needle.

The RJ4 Pediatric Biopsy Forceps have a Pediatric jaw size requiring a 2.0 mm or larger working channel endoscope and are available with or without a needle, with a 160 cm or 240 cm working length.

The RJ4 Pulmonary Biopsy Forceps are available in two jaw sizes: Pulmonary Standard Capacity (Pulmonary SC) requiring a 2.0 mm or larger working channel endoscope and Pulmonary Large Capacity (Pulmonary LC) requiring a 2.8 mm or larger working channel endoscope. Pulmonary SC is available with or without a needle, whereas the Pulmonary LC is available without a needle only. Both forceps have a 100 cm working length.

RJ4 Hot Biopsy Forceps

The RJ4 Hot Biopsy Forceps have a standard capacity (2.2mm) jaw size compatible with a 2.8mm or larger working channel endoscope and are available with a 240cm working length. Using the RJ4 Hot Biopsy Forceps the user can cauterize and remove polyps and/or tissue by opening the jaws, pressing the jaws against the tissue site, closing the jaws, applying an electrical current through the connector and pulling the jaws away from the tissue site.

The RJ4 Hot Biopsy Forceps require an active cord in order to operate as intended.

Multibite

The Multibite Multiple Sample Biopsy Forceps are designed to collect tissue endoscopically for histological examination. A total of four biopsy samples may be taken without removing the forceps from the scope. The Multibite Biopsy Forceps are available in both 160 cm and 240 cm working lengths and require a scope with a minimum working channel of 2.8 mm.

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.

For Multibite Forceps

The Multibite Multiple Sample Biopsy Forceps are designed specifically to collect tissue endoscopically for histologic examinations. These instruments are intended for endoscopic gastrointestinal biopsy and should not be used for any purpose other than their intended function.

CONTRAINDICATIONS

For Radial Jaw 4 Forceps

None known.

For Multibite Forceps

When gastrointestinal endoscopy or biopsy is otherwise contraindicated.

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 a danger for patients. Adequate plans for management of potential bleeding and appropriate airway management should be in place.

PRECAUTIONS

The single-use biopsy forceps 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 forceps 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. Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the procedure.

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 single-use biopsy forceps in these patients.

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 biopsy forceps, are additive. Consult the endoscope manufacturer about the proper grounding of the endoscope.

- Please review the operations and service manuals of the electrosurgical generator for proper set and operation prior to using the single-use Hot biopsy forceps.
- 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.
- 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.
- Application of excessive force to the instrument may damage it. 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, the resulting force may be so excessive as to cause jaw damage.

ADVERSE EVENTS

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

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

HOW SUPPLIED

Handling and Storage

Store in a cool, dry, dark place. Do not use if package is opened or damaged. Use the device prior to the "Use by" date noted on the product label. Do not use if labeling is incomplete or illegible.

FOR HOT BIOPSY FORCEPS

The single-use Hot biopsy forceps adapt to a variety of monopolar generators using the appropriate active cord as indicated below.

The single-use biopsy forceps are available with the following active cord configuration:

Active Cord Order Number	Generator Compatibility
M00561250	Olympus® Brand Generator
M00561270	Bovie®, Valleylab®, Aspen Labs, ERBE® Brand Generators, EndoStat™ and EndoStat™ II, EndoStat™ III

OPERATIONAL INSTRUCTIONS

Set-Up

1. Remove the package from the carton.
2. Peel the package open and carefully remove the biopsy forceps.
3. Remove the protective sleeve from the forceps jaws.
4. Visually inspect the forceps for loose, bent or broken parts, cracks or other abnormalities. Inspect the shaft for any kinks or other damage.
5. Operate the handle of the forceps several times, by inserting a thumb through the thumb ring and sliding the spool forward and backward, to ensure the jaws open and close smoothly and the jaws close completely with no gaps in the mating surfaces.

Note: 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.

Procedure

1. Maintaining the forceps in a closed position, insert the forceps through the biopsy valve and into the working channel of the endoscope with short deliberate strokes.

Note: If difficulty is experienced while inserting the forceps through the scope, it may be necessary to reposition the scope to allow the smooth passage of the forceps. DO NOT force the forceps through the endoscope channel.

2. Using short deliberate strokes, advance the forceps to the location of the planned biopsy.
3. To perform a biopsy, open the jaws carefully while visualizing the operation on a video monitor. Move the forceps forward against the tissue to be sampled and close the jaws. Carefully pull the forceps back from the tissue being sampled.

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.

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

Apply cautery. For recommendations on current settings for hot biopsy, refer to the instructions provided by the manufacturer of the electrosurgical generator. Other references are as follows:

“30 to 40 Watts” MAw-Soon MD et al, Monopolar Coagulation Versus Conventional Endoscopic Treatment for High Risk Peptic Ulcer Bleeding: A Prospective Randomized Study. *Gastrointestinal Endoscopy* Volume 58 No 3 Pages 323-329.

“30 Watts” K.E. Monkemueller et al, Histological Quality of Polyps Resected Using the Cold Versus Hot Biopsy Technique, *Endoscopy* 2004; 36: 432-436

Precautions: It is recommended that the operator not use the device with any generator setting which may output a voltage exceeding the Maximum Voltage Rating. Single-use Hot biopsy forceps Maximum Voltage Rating: 1600 V peak (3200 V peak-to-peak). Active accessories (such as active cord) should be selected that have an Accessory Voltage Rating equal to or greater than 1600 V peak.

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.

4. Maintaining the forceps in a closed position, slowly withdraw the forceps through the endoscope.

Prior to removal of the single-use Hot biopsy forceps from the endoscope, ensure the electrosurgical generator is turned OFF.

Note: For all biopsy forceps, if for any reason the biopsy jaws fail to close properly or completely, DO NOT try to withdraw a partially open forceps through a scope. Pull the forceps back to the channel opening and then withdraw the scope and forceps together.

For Multibite Forceps

5. To obtain subsequent samples, it is not necessary to remove the forceps from the endoscope. With the forceps closed, relocate the distal end to a biopsy site. Open the forceps while moving forward against the tissue to be sampled. A total of four biopsy samples may be taken without removing the forceps from the scope. Carefully pull the forceps back from the area and withdraw slowly through the scope.
6. For all biopsy forceps, remove the tissue samples from the forceps jaws.
7. For additional samples return to procedure step 1.

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 resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

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