

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.

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

For Radial Jaw 4 Forceps: None known.

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.

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.

Precautions

The single-use biopsy forceps must be used in conjunction with a Type F 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

Reuse Warning

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.