ESS Reusable Biopsy Forceps (QFC/QGR Part/SKU# & "Ratigator" Instruments)

Indications for Use

Biopsy Forceps are designed to collect tissue endoscopically for histological examination.

**NOTE:** E.S.S. Brand biopsy forceps are not designed to be used in conjunction with an electrocautery unit.

Inspection

The following inspection procedure should be followed upon receipt of the forceps and prior to each use after that.

1. Ensure that the biopsy forceps are compatible in size and length with the endoscope.
2. Visually inspect the entire forceps for loose parts, cracks, crushed areas, excessively bent shaft, bent needle, etc.
3. Using the handle and finger grip, open and close the forceps a few times to make sure they are operating smoothly. Always operate the forceps lightly; excessive force on the finger grip is a major cause of deterioration or breakage.

Insertion

1. The forceps should be inserted into the instrument channel of the scope after the area of interest has been visually determined.
2. Always advance the forceps slowly, a little bit at a time. Be sure to keep the proximal (handle) end extending from the channel opening as straight as possible at all times. Do not allow it to hang from the fiberscope, as this could cause damage.
   If your scope is equipped with a forceps elevator, raise the elevator fully before loading. Advance the forceps. The passage of the forceps will be stopped at the tip by the raised forceps elevator. At this point, lower the forceps elevator and continue to advance the forceps slowly. Then use the elevator to bring the forceps into view.

Taking the Biopsy

1. Tissue samples are obtained by grasping the mucosa in the biopsy cups and then gently pulling the forceps back until the specimen is removed. It is not necessary to apply excess pressure to cut cleanly through the tissue; doing so may damage your instrument.
2. Fully lower the forceps elevator and slowly withdraw the forceps from the scope, keeping the jaws of the forceps closed.
   If your forceps should fail to close so that they cannot be withdrawn, attempt to close them by pressing them against the mucosal wall. If they still cannot be closed, try to close them by winding the proximal portion of the shaft around your finger several times. If they still cannot be closed, pull the forceps back up against the channel opening slowly, withdrawing both the forceps and scope together.

Cleaning After Use

1. Cleaning must begin immediately after the use of the forceps. If not cleaned immediately, thorough cleaning of the forceps will be much more difficult, and the instrument will deteriorate due to the presence of dried mucus, blood, etc.
   If, for any reason, the forceps are not able to be cleaned immediately after use, they should be coiled loosely beginning with the distal end and placed in a bowl of warm soap solution or warm water to soak until they can be cleaned. Never allow dirty forceps to dry before cleaning.
2. The following method is recommended for cleaning:
   a. Prepare a bowl of warm (~35°C or 95°F) surgical scrub soap solution.
   b. Wear rubber gloves to protect yourself from infection or skin damage.
   c. Thoroughly wash the forceps with the cleaning solution using a brush. Always begin at the distal end and work back toward the proximal end. Special attention must be taken to remove blood, mucus, and other debris from difficult to clean areas such as the cup hinges, cup interior, needle, etc.
   d. Do not sharply flex the shaft of the forceps.
   e. When cleaning the forceps equipped with a needle, exercise care not to bend the needle.
   f. Rinse the instrument in a large bowl of water and wipe dry using a gauze pad.
Ultrasonic Cleaning

The use of an ultrasonic cleaner is desirable to aid in the removal of particulate matter. Ultrasonic cleaning is mandatory if the forceps will be autoclaved.

1. Clean the forceps as described above before placing in the ultrasonic cleaner.
2. Use only tap water in the ultrasonic cleaner. Some surfactants and other agents may cause the forceps to operate sluggishly.
3. Clean the forceps with an ultrasonic cleaner with 40 kHz or higher output for 5 minutes or longer. Lower output would require a much longer time.
4. Dry the forceps with a gauze pad.

Storage

1. Lubricate the cups with a medical grade silicone spray or liquid lubricant.
2. Do not store the forceps with the shaft sharply coiled. Avoid direct contact with sunlight, high temperature and high humidity.

Disinfection and Sterilization

The biopsy forceps must be cleaned meticulously prior to starting the disinfection or sterilization procedure. The method used to disinfect or sterilize the endoscopic accessories is up to the individual physician or hospital. The following commonly used methods have been utilized without deterioration of instruments.

1. Ethylene oxide gas.
   Ethylene Oxide Gas sterilization can be safely performed, however not commonly used due to the extremely long time required for the cycle and aeration.
   
   The following parameters are recommended:
   Temperature: 57°C (135°F) max.
   Pressure: 1~1.7 kg/cm²
   Humidity: 50% max.
   Gas concentration: 12%
   Time: 4 hours
   Aeration time: & days at room temperature or 12 hours in an aeration chamber between 50°C (122°F) and 57°C (135°F)

2. Autoclave
   a. The forceps must be ultrasonically cleaned prior to autoclaving.
   b. If the forceps is placed in a sterilization package, a 6-inch minimum diameter coil must be maintained.
   c. Autoclave at temperatures not to exceed 134°C (274°F), at any standard autoclave cycle.

3. Disinfectant solution
   Glutaraldehyde solutions that are allowed to be marketed by FDA for high level disinfection are recommended
   a. Forceps must be thoroughly cleaned prior to soak sterilization.
   b. Follow manufacturer’s recommendations for detailed sterilization instructions.
   c. Upon completion, immediately rinse with sterile water to remove residue. Dry thoroughly.

Caution:
Federal law restricts this device to sale by or on the orders of a physician.
Non sterile. Sterilize before use.