

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 an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single 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

The Acquire Fine Needle Biopsy Device is designed to sample targeted submucosal and extramural gastrointestinal lesions through the accessory channel of a curvilinear echoendoscope.

Contraindications

Contraindications for this device are those specific to the primary endoscopic procedure to be performed in gaining access to the desired site. Relative contraindications to submucosal and extramural aspiration include, but are not limited to: coagulopathy.

Warnings

The Acquire™ Endoscopic Ultrasound Fine Needle Biopsy Device should only be used to sample tissue where possible hemorrhage will not present a danger to patients. The device should be used with caution and only after careful consideration in patients with elevated bleeding times or coagulopathies.

Precautions

Read the entire directions for use before using the Acquire Needle. The Acquire Needle should only be used by or under the supervision of physicians trained in Endoscopic Ultrasound and Fine Needle Aspiration/Biopsy. A thorough understanding of the technical principles, clinical applications and risks associated with Endoscopic Ultrasound and Fine Needle Aspiration/Biopsy are necessary before using this device. The packaging and the device should be inspected prior to use. Do not use the device if the product or packaging is damaged.

Adverse Events

Complications associated with the use of the Acquire Needle may include:

- Bleeding
- Perforation
- Pancreatitis
- Infection
- Peritonitis
- Inflammation
- Aspiration
- Fever
- Allergic Reaction to Medication
- Hypotension
- Tumor Seeding
- Respiratory Depression or Arrest
- Cardiac Arrhythmia or Arrest