



Expect™ Slimline Endoscopic Ultrasound Aspiration Needle

Prescriptive Information

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. Rx Only

Warning

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.

Intended Use/Indications for Use

The Expect Slimline (SL) Needle is designed to sample targeted submucosal and extramural gastrointestinal lesions through the accessory channel of a curvilinear echoendoscope. It can also be used for delivery of injectable materials (fluids) or fiducials into tissue or for passage of accessory devices.

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

Precautions

The packaging and the device should be inspected prior to use. Do not use the device if the product or packaging is damaged.

Potential Adverse Events

Complications associated with the use of the Expect Slimline (SL) Needle may include:

- Allergic Reaction
- Aspiration
- Bleeding
- Cardiac Arrhythmia or Arrest
- Fiducial Migration
- Hypotension
- Infection
- Inflammation
- Pain
- Pancreatitis
- Perforation
- Peritonitis
- Respiratory Depression or Arrest
- Tumor Seeding