

Expect™ Endoscopic Ultrasound Aspiration Needle

Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

Intended Use/Indications for Use

The Expect™ Needle 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 Expect Endoscopic Ultrasound Aspiration Needle 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.

Potential Adverse Events

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

- Bleeding
- Infection
- Aspiration
- Hypotension
- Tumor seeding
- Perforation
- Peritonitis
- Fever
- Respiratory depression or arrest
- Pancreatitis
- Inflammation
- Allergic reaction to medication
- Cardiac arrhythmia or arrest

Cautions

Read the entire directions for use before using the Expect Needle. The Expect Needle should only be used by or under the supervision of physicians trained in Endoscopic Ultrasound and Fine Needle Aspiration. A thorough understanding of the technical principles, clinical applications and risks associated with Endoscopic Ultrasound and Fine Needle Aspiration 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.

Federal Law (USA) restricts this device to sale by or on the order of a physician.