



## **Expect™**

### **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 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 as patient injury, such as hemorrhage, can occur.

#### **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 Needle may include:

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