

Expect™ Pulmonary Endobronchial Ultrasound Transbronchial Aspiration Needle

Prescriptive Information

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.

Expect Pulmonary Needles and Adaptors should only be used with compatible scope identified on the label.

The Expect Pulmonary 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.

Intended Use/Indications for Use

The Expect Pulmonary Endobronchial Ultrasound Transbronchial Aspiration Needle is designed to be used with endobronchial ultrasound endoscopes for ultrasound guided fine needle aspiration (FNA) of the submucosal and extramural lesions of the tracheobronchial tree and the gastrointestinal tract. Do not use this instrument for any purpose other than its intended use.

Contraindications

- This procedure should not be attempted in any patient whose general medical condition and degree of respiratory failure would not allow the patient to tolerate bronchoscopy (rigid or flexible) and/or the manipulation required to perform the procedure.
- Relative contraindications to submucosal and extramural aspiration include, but are not limited to: coagulopathy.
- Uncooperative patient.

Precautions

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

Adverse Events

Infection	Pneumothorax	Hemomediastinum
Hemorrhage	Inflammation	Laceration
Perforation		