Product
Acquire™ Pulmonary Endobronchial Ultrasound Fine Needle Biopsy (FNB) Device - IFU 51207145
Expect™ Pulmonary Adaptor Needle Adaptor for use with Expect™/Acquire™ Pulmonary Needle – Symbol Insert 51207144

Rx Statement

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.*

REUSE 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.*

Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE
The Acquire Pulmonary Endobronchial Ultrasound Fine Needle Biopsy (FNB) Device 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.

WARNINGS
- The Acquire 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.
- Acquire Pulmonary Needles and Adaptors should only be used with compatible scope identified on the label.
- Prior to advancing the needle confirm the target area on the ultrasound image to avoid the blood vessels and the pleura. Otherwise, bleeding and/or pneumothorax may occur.
- The stylet tip is sharp. Take precautions to ensure that the stylet is handled properly. After it has been removed from the needle, the stylet should be treated as infectious material and could create an infection risk.
- Ensure that the needle is fully retracted into the sheath. Failure to secure the needle could result in damage to the scope or injury to user.
- Take precautions to ensure that the sample does not spray when it is expelled from the needle. The sample should be treated as infectious material and could create an infection risk.

PRECAUTIONS
- The packaging and the device should be inspected prior to use. Do not use the device if the product or packaging is damaged.
- Visually inspect the stopcock when removed from the package to confirm it is in the open position; otherwise, DO NOT USE IT. Call Boston Scientific Customer Service and return the product.
- Visually inspect the device for loose, bent or broken parts, cracks, or other abnormalities. Inspect the sheath for any kinks or other damage. If an abnormality is detected, DO NOT USE. Broken parts, cracks, or kinks will hinder the mechanical operation

of the Acquire Pulmonary Needle. If the device fails to operate properly in any way or shows any signs of damage, DO NOT USE IT. Call Boston Scientific Customer Service and return the product.

- If the stopcock is not set properly, adequate suction may not be achieved.
- Do not tighten the luer connection too tightly to the scope as it may cause damage to the scope or adaptor.Prior to advancing the needle, ensure that the device is securely fastened to the scope and both the needle length adjustment lock and sheath length adjustment lock are secure. Failure to do so could result in damage to the scope. Sheath must be visible or damage may occur to scope.
- Failure to properly handle the stylet could result in damage to the device.
- Methods of providing suction other than the supplied syringe are not recommended with this device.
- Take precautions to ensure that the sample does not spray when it is expelled from the needle. The sample should be treated as infectious material and could create an infection risk.
- Failure to flush the needle and wipe the stylet prior to reinserting the stylet into the needle could make the stylet difficult to pass or result in damage to the device

POTENTIAL ADVERSE EVENTS

- Hemomediastinum
- Hemorrhage
- Infection
- Inflammation
- Laceration
- Perforation
- Pneumothorax
- Tumor Seeding