



CoreDX™
Pulmonary Mini-Forceps
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.

Warning

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.

Intended Use/Indications for Use

The CoreDx Pulmonary Mini-Forceps are specifically designed to collect tissue endoscopically for histologic examination. These forceps can be used with endobronchial ultrasound endoscopes for ultrasound guided mini-forceps biopsy (MFB) of submucosal and extramural lesions of the tracheobronchial tree. These forceps should not be used for any purpose other than their intended function.

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 biopsy include, but are not limited to coagulopathy.

Warnings

These single use biopsy forceps should only be used to biopsy tissue where possible hemorrhage will not present a danger for patients. Adequate plans for management of potential bleeding and appropriate airway management should be in place.

DO NOT use the forceps to create the access hole because doing so may cause tissue laceration or damage to the device.

Precautions

Application of excessive force to the forceps may damage the device. The forceps should be held with the index finger and middle finger comfortably resting on the spool ledge and the thumb in the loop. When other methods of operation are used, such as pushing on the thumb loop with the palm of one's hand, excessive force may damage the device.

Potential Adverse Events

Complications associated with the use of the CoreDx Mini-Forceps forceps may include:

- Embolism
- Hemomediastinum
- Hemorrhage
- Infection
- Inflammation
- Laceration
- Perforation
- Pneumomediastinum
- Pneumothorax
- Tumor Cell Seeding