



Brief Summary Document

Overview

Product CoreDX™ Pulmonary Mini-Forceps – IFU 52009098-01A

Rx Statement

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

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.

Read the entire Instructions for Use before using the CoreDx Mini-Forceps. The forceps should only be used by or under the supervision of physicians trained in bronchoscopy and biopsy. A thorough understanding of the technical principles, clinical applications and risks associated with bronchoscopy and biopsy is 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. If CoreDx Mini-Forceps is used in conjunction with Endobronchial Ultrasound Transbronchial Needle Aspiration (EBUS-TBNA), they should only be used by or under the supervision of physicians trained in EBUS-TBNA. A thorough understanding of the technical principles, clinical applications and risks associated with EBUS-TBNA is necessary before using this device.

Content

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

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.

GENERAL 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 patient injuries such as tissue damage/laceration and/or damage to the device.

PRECAUTIONS

- DO NOT force the forceps through the bronchoscope channel to prevent scope and/or device damage.
- 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.
- If for any reason the biopsy jaws fail to close properly or completely, DO NOT try to withdraw a partially opened forceps through the scope. Pull the forceps back into the working channel of the scope and then withdraw the scope and forceps together.

POTENTIAL ADVERSE EVENTS

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

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| • Allergic Reaction | • Laryngospasm |
| • Bronchospasm | • Perforation |
| • Embolism | • Pneumomediastinum |
| • Hemomediastinum | • Pneumothorax |
| • Hemorrhage | • Respiratory Distress/Insufficiency |
| • Infection | • Respiratory Failure |
| • Inflammation/Edema (eg. laryngeal, subglottic, tracheal, etc) | • Tissue Damage |
| • Laceration | • Tumor Cell Seeding |