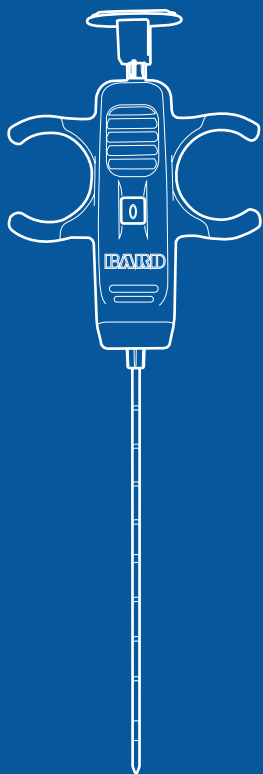


Lung Biopsy

Complex Case Review with
the Mission™ Disposable
Core Biopsy Instrument



Cases by:

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Disclaimer: The opinions and techniques presented herein are for informational purposes only. The decision of which technique to use in a particular procedural or surgical application should be made by the physician based upon individual facts and circumstances of the patient and previous surgical experience.

Please consult product inserts and labels for any indications, contraindications, hazards, warnings, cautions and directions for use. Procedural or surgical techniques should follow the directions for use section of the IFU.

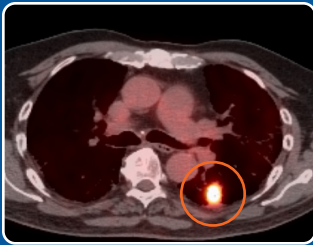
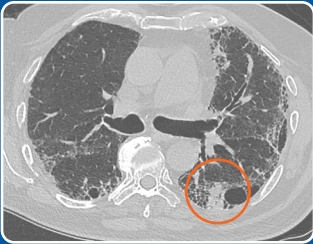
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Content based on personal experience in lung cancer treatment/protocol in local treatment center.

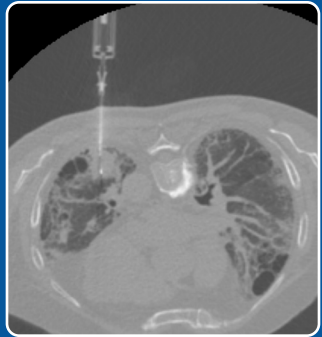
This Pocket Guide is on behalf of BD. Dr. Mammarappallil has been compensated by BD for the time to develop and present this information.

Indications for Use: The Mission™ Disposable Core Biopsy Instrument and Kit is intended for use in obtaining biopsy samples from soft tissues such as from the lung, liver, spleen, kidney, prostate, lymph nodes, breast, thyroid, and various soft tissue tumors.

Growing Lung Lesion in a Patient with Fibrosis



Computed Tomography (CT) Scan and Positron Emission Tomography (PET)-CT of Left Lower Lobe Peripheral Lesion



Transthoracic Needle Biopsy (TTNB) of Left Lower Lobe Lesion



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Growing Lung Lesion in a Patient with Fibrosis

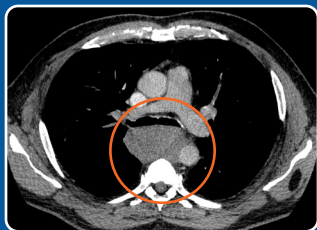
Transthoracic Needle Biopsy Diagnostic of Malignancy Squamous Cell Carcinoma

Case Considerations

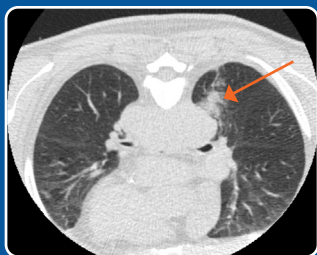
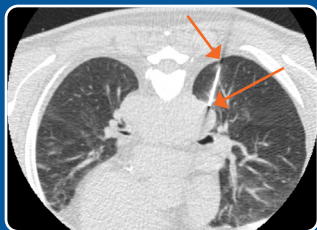
- High risk patient, chest tube and air leak
- 19G introducer, data in non-small-cell lung carcinoma suggest good yield with 20G core system¹
- Tangential to the pleura
- Engage the lesion on one pass
- Core time with needle in place ~3 min

¹ Tam AL, Kim ES, Lee JJ, et al. Feasibility of image-guided transthoracic core-needle biopsy in the BATTLE lung trial. *J Thorac Oncol.* 2013;8(4):436-442. doi:10.1097/JTO.0b013e318287c91e

New Mediastinal Mass in a Patient with Prior History of Genitourinary (GU) Malignancy



CT of New Mediastinal
Lesion



TTNB of Mediastinal
Lesion



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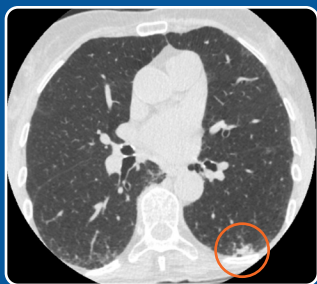
New Mediastinal Mass in a Patient with Prior History of GU Malignancy

Transthoracic Needle Biopsy
Diagnostic of Malignancy
Metastatic Germ Cell Tumor

Case Considerations

- Central lesion
- Interventional pulmonology –
Safer, but non-diagnostic in this case
- Higher risk – Crossing the pleura 2x
- Tangential to the pleura
- Engage the lesion on one pass
- Core time with needle in place ~3 min

Growing Nodule on a Lung Cancer Screening Study



Growth of a Left Lower Lobe (LLL) Lesion on Lung Cancer Screening



Follow-up TTNB



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Growing Nodule on a Lung Cancer Screening Study

Transthoracic Needle Biopsy

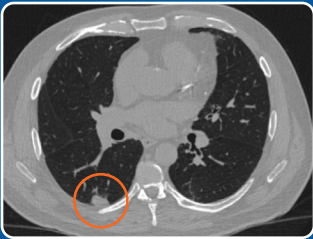
Diagnostic of Malignancy

Squamous Cell Carcinoma

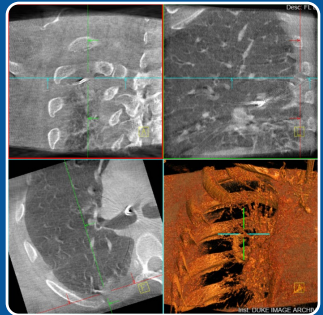
Case Considerations

- Proximity of rib to lesion location

Suspicious Nodule Seen on CT: Similar Case Done by Interventional Pulmonology



Growing Right Lower Lobe Nodule



Follow-up Transbronchial Biopsy



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Suspicious Nodule Seen on CT: Similar Case Done by Interventional Pulmonology

Transbronchial Needle Biopsy

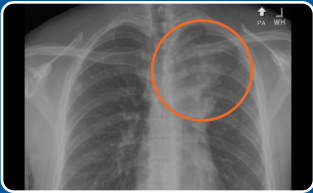
Diagnostic of Malignancy

Adenocarcinoma

Case Considerations

- Sedation
- Procedural time

New Onset Night Sweats and Itching



Initial Chest Radiograph



Confirmatory CT Imaging



Follow-up PET/CT



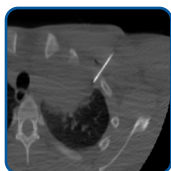
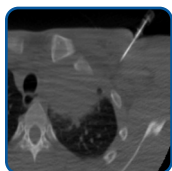
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New Onset Night Sweats and Itching

Thoracoscopic Surgical Biopsy

Dense Fibrosis with Markedly Crushed
Cellular Infiltrate Non-Diagnostic



Follow-Up
CT-Guided 18G
Core Biopsy

Transthoracic Needle Biopsy

Diagnostic of Malignancy – Classic Hodgkin
Lymphoma, Nodular Sclerosis Variant

Case Considerations

- Mediastinal lesion = Larger core sizes, not traversing lung, decreased pneumothorax risk
- Surgeons need diagnosis
- PET/CT to target lesion



Indications for Use: The Mission™ Disposable Core Biopsy Instrument and Kit is intended for use in obtaining biopsy samples from soft tissues such as from the lung, liver, spleen, kidney, prostate, lymph nodes, breast, thyroid, and various soft tissue tumors.

Contraindications: Good medical judgment should be exercised in considering biopsy on patients who are receiving anticoagulant therapy or who have a bleeding problem. It is not intended for use in bone.

Warnings: **1.** Post-biopsy patient care may vary with the biopsy technique utilized and the individual patient's physiological condition. Observation of vital signs and other precautions should be taken to avoid and/or treat potential complications that may be associated with biopsy procedures. **2.** When used for breast biopsy, the product is for diagnosis only. **3.** The collection of multiple core biopsy samples may help to ensure the detection of any cancer tissue. A "negative" biopsy in the presence of suspicious radiographic findings does not preclude the presence of carcinoma. **4.** The Instrument and Kit have been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints, and/or crevices between components – are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications. Additionally, re-use and/or repackaging may compromise the structural integrity and/or material and design characteristics of the device, which may lead to device failure, and/or lead to patient injury. **5.** Do not resterilize the Instrument or Kit. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing and/or resterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes. **Note:** Inspect the Instrument and Kit needle components for damaged point, bent shaft, or other imperfections prior to use and after each sample is collected. DO NOT USE the device if any imperfection is noted or if product damage is evident. **Note:** After use, the Instrument and Kit may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and local, state and federal laws and regulations. Dispose of sharps in designated sharps disposal containers; the Instrument and Kit are for single-use only and should be disposed of appropriately, not recapped or resterilized.

Precautions: **1.** The Instrument and Kit should be used by a physician who is completely familiar with the indications, contraindications, limitations, typical findings and possible side effects of core needle biopsy, in particular, those relating to the specific tissue being biopsied. **2.** Inspect the packaging to ensure that package integrity has not been compromised. The Instrument and Kit are sterile unless the seal is broken. **3.** The introduction of the needle into the body should be carried out under imaging guidance (e.g. ultrasound, X-Ray, CT, etc.). Note: This product has not been tested for MR Imaging compatibility. **4.** Never test the Instrument by firing into the air. Damage may occur to the needle/cannula tip and could result in patient and/or user injury. **5.** Unusual force applied to the stylet or unusual resistance against the stylet while extended out of the cannula may cause the stylet to bend at the specimen notch. A bent specimen notch may interfere with needle function.

Potential Complications: Potential adverse events associated with use of the device are site-specific and may include bleeding/hematoma/hemorrhage (including site-specific bleeding such as hemoptysis, hemothorax, and hematuria); damage to nearby organs or structures (such as pneumothorax, blood vessel damage, vertebral puncture, organ injury, nerve injuries, and other tissue injuries); infection/bacteremia/sepsis; pain; swelling/edema; vasovagal reaction; and air embolism (Air embolism is a rare but serious potential complication of lung biopsy procedures. Rapid deterioration of neurological status and/or cardiac arrhythmia may be indicative of air embolism. Prompt diagnosis and treatment must be considered if the patient exhibits signs or symptoms of air embolism). Adverse events may lead to other issues such as dysphagia, dysphonia, need for surgical intervention, or loss of organ function. Note: Users and/or patients within the European Union, should report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. User outside of the European Union should report any serious incident that has occurred in relation to the device to the manufacturer and the regulatory authority of the country in which the user and/or patient is established.

Please consult package insert for more detailed safety information and instructions for use.

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Have questions about the Mission™ Disposable Core Biopsy Instrument for lung biopsy?

Schedule a peer-to-peer consultation
with **Dr. Joseph G. Mammarrappallil,
MD, PhD**



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