iNod Ultrasound Guided Biopsy Needle (iNod Single-Use-Device "SUD")

Prescriptive Information

Boston Scientific
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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.

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.

Intended Use/ Indications For Use

The iNod Ultrasound Guided Biopsy Needle is intended for use through a flexible bronchoscope for intraluminal sonographic imaging in the tracheobronchial tree and retrieval of specimens from patients with endobronchial lesions, peripheral lung nodules, or lung masses.

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 and/or the manipulation required to perform the procedure.
- Patients with an uncorrectable coagulopathy.

Adverse Events

- Bleeding/HemorrhageLoreum
- Bronchospasm
- Infection
- Inflammation
- Laceration
- Perforation
- Pneumothorax
- Respiratory distress
- Tissue Damage

Precautions

- Read the entire instructions for use before using the iNod SUD. The packaging and the iNod SUD should be inspected prior to use. Do not use the iNod SUD if the product or packaging is damaged.
- Never attempt to attach or detach the iNod SUD while the motor is running. To do so may damage the connector.
- Always turn the iNod MDU "OFF" before withdrawing the iNod SUD because it could cause the iNod MDU to overload.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the iNod Ultrasound Guidance System, including cables specified by the manufacturer. Otherwise, degradation of the performances of this equipment could result.
- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take migration measures, such as relocating or re-orienting the equipment.
- Electromagnetic Interreference (EMI) may occur on this instrument near equipment marked with the following symbol  EMI may occur on this instrument near other portable and mobile radio frequency (RF) communication equipment, for example, cellular phones. To check for EMI, verify the system's operation in which it will be used. Should EMI occur, employ mitigation measures like reorienting or repositioning the instrument, or shielding its location. Placing this instrument near other medical electrical equipment or mobile RF communications equipment may result in EMI, which may degrade the video image.