

## Ultrasound Biopsy Guide Instructions



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technique. Cover the transducer as far as possible.

- Make sure no air between transducer lens and cover.
  - Pull the cover tightly over transducer. Tie the bands.
  - Inspect the cover, make sure no holes or leakage of gels.
2. Attaching the ultrasound guide to transducer
- Make sure guide fit properly, if not, don't use.
  - If the guide does not fit the ultrasound transducer and system guide line properly, do not use.
  - The guide is just single use only.
  - Attach guide to transducer by probe locating features. Make sure the lock is tightly locked.
  - Choose the right tube refer to the needle size.
  - Insert the right needle-guide tube, rotating the needle-guide tube positioning point to the needle-guide tube positioning. Insert the needle.
  - Choose the right angle refer to the ultrasound system.
  - Use the right needle to reach the target.

### 3. Cleaning, disinfecting and warning

- The biopsy guide is packaged non-sterile and is reusable.
- To avoid possible patient contamination, ensure the biopsy

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### A. General Information and Description:

1. The **Leapmed Ultrasound Biopsy Guide** is a non-sterile and **reusable device**. It can provide a tool for performing needle-guided procedures with ultrasound diagnostic.

### 2. Classification for ultrasound biopsy guide:

General Biopsy Guide and Endocavity Biopsy Guide.

### B. How supplied:

The Leapmed Ultrasound Biopsy Guide is sold non-sterile for reusable use and available in various ultrasound systems.

### C. Warnings:

1. The biopsy the biopsy guide or device should be used by or on order of a physician. Before use, physician should be trained in ultrasonography, have the right the biopsy guide operation and use of the knowledge.

Note: Choose the right guide for the exact ultrasound transducer and system. Perform the training guide with needles to check the ultrasound guide line diagnostic.

Note: Restored the guide line in the ultrasound system when needed. Contact Leapmed or ultrasound system service when needed.

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guide is properly cleaned, sterilized or disinfected before each use.

- Users of this product have an obligation and responsibility to provide the highest degree of infection control to patients and themselves.

- After each use, remove the biopsy guide from transducer probe, discarding single-use, disposable components such as needles and transducer covers. For other reusable components, follow infection control policies established by your facility.

- Clean, disinfect and sterilizing the biopsy guide and the needle-guide tubes respectively.

- Disinfection method reference: First use flow water to wash or soak. Use instrument brush to remove trapped contaminants from surfaces and features. Repeat soaking and washing, and finally dipped in paraffin and medical devices dedicated oil, dry cloth to wipe the equipment, packaging, into the high-temperature, high pressure sterilizer for disinfection.

- Disinfection program is in accordance with the relevant provisions of the facility.

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2. Always place a cover over transducer to protect patients and users from cross-contamination. Ultrasound transducer covers are packaged sterile and are single-use only. Do not use if integrity of packaging is violated or if expiration date has passed.

Note: (Users of this product have an obligation and responsibility to provide the ultrasound transducer covers.)

3. Place an appropriate amount of gel inside cover and/or transducer face. Poor imaging may result if no gel is used.

4. Well fixed the biopsy the biopsy guide with the transducers. If the biopsy guide does not fit properly, do not use.

5. Use appropriate the biopsy guide tube.

6. According to the demand of clinical diagnosis. Use appropriate needle length to reach target area.

7. The ultrasound biopsy guide has been designed for non-sterile and is reusable. To avoid possible patient contamination, ensure biopsy guide is properly cleaned, sterilized or disinfected before each use. Reusing this medical device without sterilize bears the risk of cross-patient contamination as medical devices particularly those with long and small lumina, joints, and/or crevices between

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- High-level disinfect for sterilize biopsy guide using CIDE-X® Activated Dialdehyde Solution (Johnson & Johnson) or equivalent 2% glutaraldehyde-based solution, or a hydrogen peroxide-based solutions. Follow manufacturer's instructions and recommendations for concentration, time of contact and post-process procedure.

- Biopsy Guide and tubes must be sterilized using steam (autoclave) at 132-138°C for 15 to 30 minutes.

### E. Contraindications

Coagulation disorders.  
Other contraindications unclear.

### F. Adaptive Disease

Ultrasound guided biopsy.  
Ultrasound guided therapy.

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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.

8. Do NOT disassemble the device. Disassembling the device without right instructions bears the risk of personal injury.

### D. Instructions

#### 1. Covering the ultrasound transducer

- Transducer cover containing natural rubber latex may cause allergic reactions.
- Use only water-soluble gels. Petroleum or mineral oil based materials may harm cover and transducer lens.
- Ultrasound covers are single-use only. Don't use if package is broken or if expiration date has passed.
- Place an appropriate amount of gel inside cover or no transducer lens. Lack of gels may result a poor imaging.
- Insert transducer into cover, and make sure use sterile

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