Reusable Needle Guides

User Manual

Models: JEM-001, JEM-002, …, JEM-100
JSM-001, JSM-002, …, JSM-500

Thank you for purchasing our product. Please read this manual carefully before using it, and use it strictly in accordance with the requirements of the product manual. After reading, keep it in a safe place for future reference.

This manual describes the operation of a reusable needle guide, matching with the transducer to guide the needle / instrument to the target position of the human body under the guidance of ultrasound system. Specific applicable ultrasound brand, transducer model, needle size are marked in product label. For the operating procedures of transducer and other devices, please refer to the relevant manuals.

Ⅰ Structure

This product consists of two parts:

- The fixed part matching with the transducer.
- The guiding structure of the biopsy needle.

Ⅱ Prior to use

a) Symbol Description: "⚠WARNING" in this manual is used to identify safety and other important matters. Please carefully understand and remember the meaning of these symbols before reading this manual.

> **⚠WARNING: Description of the precautions necessary to prevent injury or loss of life.**

b) Before using the ultrasound system and needle guide, you should have training.

c) If the ultrasound system has the guideline, verify the relation between the guideline and the actual needle image displayed on the ultrasound system in water before using the needle guide.

d) Disposable parts that need to be used must be packaged sterile and be single-use only. Do not use if package is damaged or if expiration date has passed.

e) Period of validity: 5 years. The date of manufacture is marked on the product label.

Ⅲ Needle path verification

Before using for the first time, perform needle path verification to verify system and needle guide relations. To avoid any injury to the patient, please observe the following.

⚠WARNING：

- Refer to system manual for proper procedure.
- Before verifying, ensure all parts are in good condition.
- Ensure the needle guide and the needle have been installed correctly.
- Use a needle suitable for the biopsy and the needle guide.
- Use proper needle length to reach target area.
- Carefully insert the needle to avoid bending.
- Use a straight, new, sterile needle for each verification procedure to help predict the needle's orientation accurately.
- The guidelines are only used to indicate the expected path of the needle.
- Do not use the needle guide if the needle does not follow the intended path.
- The needle used for this needle path verification must not be used for the actual procedure, and needle guide must be sterilized after needle path verification.

a) Set up the tank, and attach the needle guide to the transducer, then insert the needle into needle guide according to part IV.

b) Immerse the transducer and needle into a tank of test fluid or distilled water.

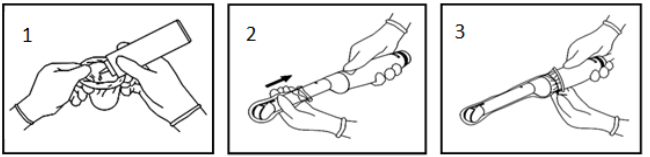
c) Connect the transducer, and turn on the ultrasound system and the guideline. When the needle’s ultrasound image is visible on the system display, adjust the guideline, and make sure that the relation among the system, transducer, and needle guide is correct.

Ⅳ Device assembly and use

1. Covering the transducer

⚠WARNING：

- Transducer covers containing natural rubber latex may cause allergic reactions.
- Use only water-soluble agents or gels. Petroleum or mineral oil based materials might do harm to transducer covers.



a) Place an appropriate amount of gel inside cover and/or on transducer surface. Poor imaging may result if no gel is used.
b) Insert transducer into cover. Pull cover tightly over transducer surface to remove wrinkles and air bubbles, taking care to avoid puncturing cover.
c) Secure cover with enclosed bands.
d) Inspect cover to ensure there are no holes or tears.

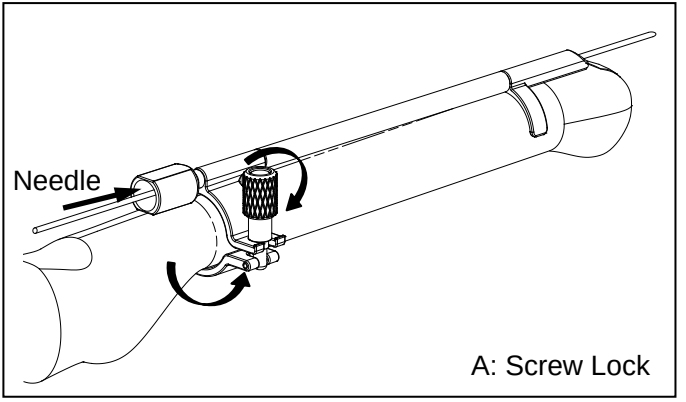
2. Attaching needle guide to transducer

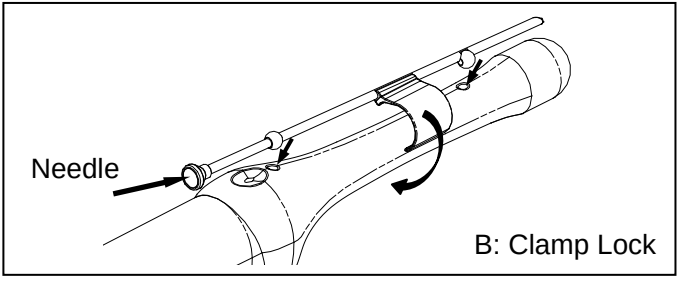
⚠WARNING：

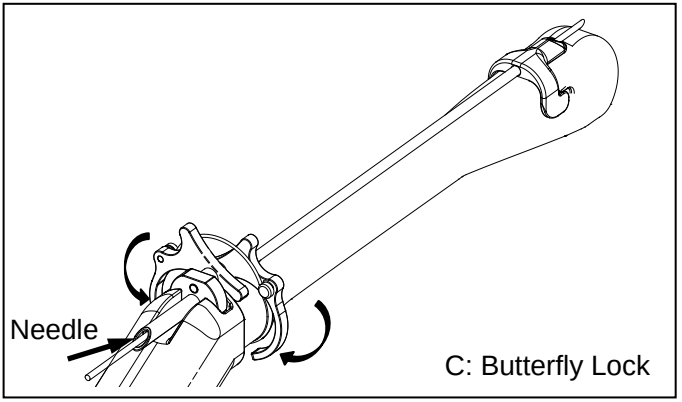
- The device is reusable, but it is packaged non-sterile. To avoid possible infection, ensure the needle guide is properly cleaned, sterilized or disinfected before each use.
- For the convenience of illustration, the transducer may be shown without a transducer cover. Make sure to cover the transducer all the time to avoid cross-infection.
- The installation must be firmly locked, without significant shaking. Do not use the needle guide if it does not fit the transducer properly or it appears damaged.

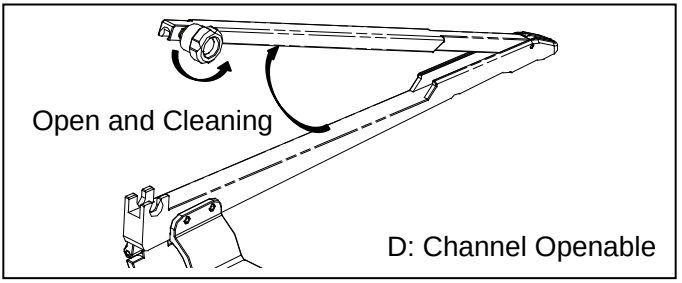
2.1 The assembly and use of endocavity needle guides (for JEM series)

Open the clamp, align the locating features of the needle guide and the transducer, and press it to rest on the transducer, locking the upper and lower clamps (or the natural spring tightness). Confirming the needle guide has been firmly installed, you can then insert the needle into the needle guide tube for biopsy. The following is showing how to install different types of needle guides.









2.2 The assembly and use of general purpose needle guides (for JSM series)

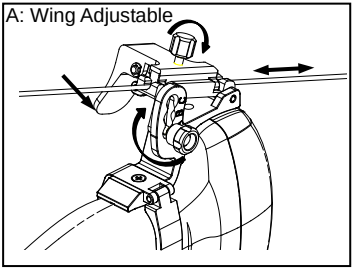
a) Installation of needle guide and transducer:
Open the clamp, align locating features of needle guide and transducer. Lock the clamp of the needle guide with the knob.

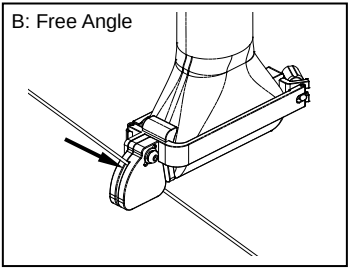
b) Installation of needle guide and biopsy needle, then perform biopsy operation (Install and use according to the type of the needle guides):

Style A. Wing adjustable: select the desired angle according to the biopsy target position and tighten angle thumbscrew securely (this

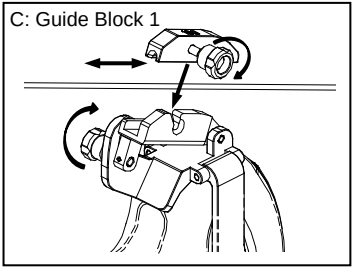
step is unnecessary if the angle is fixed). Open the rotor of the needle guide, put the needle into the needle track and press it, turn the knob to slightly lift the rotor. Perform biopsy through the gap. After finishing biopsy, press the rotor to release the biopsy needle.

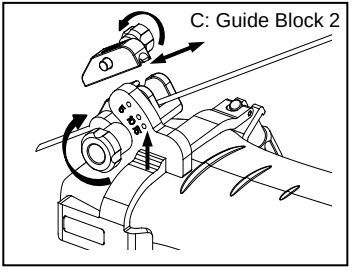
Style B. Free angle: insert the biopsy needle into the side biopsy guide groove for biopsy. The movement of the biopsy needle is limited to the ultrasound beam plane but the angle is free. The biopsy needle is also easy to detach from the needle guide after the biopsy needle is in place.





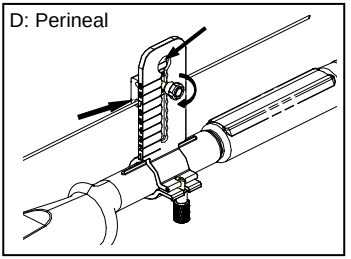
Style C. Guide block: select the desired angle according to the biopsy target position and tighten angle thumbscrew securely (this step is unnecessary if the angle is fixed). Install the guide block corresponding to the required needle and lock, insert the needle into the hole for biopsy. Unscrew the guide block to release the needle once the biopsy needle is in place.

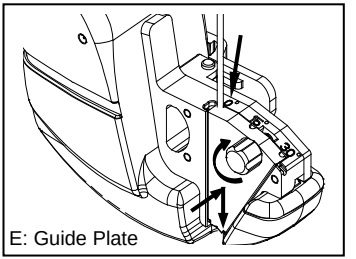




Style D. Perineal: bring the guide block through the hole on needle guide after needle guide is installed firmly with transducer. Slide the guide block to the appropriate gear according to the target position of the biopsy. Lock firmly the knob in the locating taper hole and then insert the biopsy needle into the corresponding biopsy hole to perform the operation. After the biopsy is in place, unscrew the guide block to release the biopsy needle.

Style E. Guide plate: insert the guide plate into alignment needle guide and lock it. Select the appropriate gear according to the biopsy target position and insert the biopsy needle into the corresponding biopsy hole of the guide piece to perform the operation. After the biopsy is in place, unscrew the guide to release the biopsy needle.





3. Notice for biopsy

Ultrasound systems produce tomographic plane images with information of a certain thickness in the thickness direction of the transducer. Even though the biopsy needle appears to have penetrated the target object in the image, it may not actually have done so. When the target for biopsy is small, dispersion of the ultrasound beam may lead to image deviation from the actual position. Please note the following.

⚠WARNING：

- Please evaluate the size of the object and confirm if the biopsy can be carried out before you perform the biopsy.
- Do not rely only on the needle tip on the image. Pay attention to that, when the biopsy needle comes into the target object or contacts with it, the object should shift slightly.

When performing biopsy using a needle guide to guide an ablation needle (e.g. radiofrequency ablation, microwave ablation, etc.), please carefully operate the ablation needle.

⚠WARNING：

- Do not damage the insulation coating of needle tube, because the destruction of insulation coating may cause burning to the tissue around the damaged site.

Ⅴ Disposal

⚠WARNING：

- Dispose the disposable parts such as cover as contaminated waste.
- Clean, disinfect or sterilize reusable parts after each use.
- Refer to the ultrasonic system manual on how to handle used transducers.

Ⅵ Cleaning, disinfecting and sterilizing needle guide

⚠WARNING：

- Users of this product have an obligation and responsibility to provide the highest degree of infection control to patients, co-workers and themselves. Follow your hospital's infection control policies to avoid cross-infection.
- Only use the disinfection and sterilization methods recommended in this manual, otherwise the consequences of product damage shall be borne by the user. **In particular, it is forbidden to use the disinfectant containing Chloride ions (Cl^-) or Fluoride ions (F^-).**

1. Cleaning the needle guide

a) Remove the needle guide from the transducer after each use. Use a small, soft brush to remove visible contaminants from the surface. Keep parts from drying out until complete cleaning can be accomplished.

b) Soak the needle guide for at least five minutes in a neutral pH, low foaming enzymatic detergent. While immersed, use instrument brush to remove trapped contaminants from surfaces and features. If visible contaminants are not easy to remove, repeat the soaking procedure for another five minutes. Remove the needle guide from cleaning solution and remove any remaining residue with dry wipe. Observe cleaning solution manufacturer’s directions for use and recommendations for concentration.

2. Disinfecting and sterilizing needle guide

⚠WARNING：

- When selecting and using sterilant or sterilization equipment, please follow local regulations and refer to the manufacturer's instructions for detailed information and parameter settings to achieve the level of disinfection or sterilization.
- When using soaking sterilization methods, make sure to rinse the needle guide thoroughly with sterile water to remove all chemical residues on it after sterilization.

a) High-level disinfect or sterilize the needle guide using 2% glutaraldehyde-based solution.

b) The needle guide could be disinfected or sterilized with a high temperature and high pressure steam sterilizer (autoclave) .

Ⅶ Storage and transportation

⚠WARNING：

- Dry the needle guide after sterilization and store it in a sterile environment.
- Make sure to sterilize the needle guide for subsequent handling if needle guide will be scraped or returned to the manufacturer for repair.

a) Take care and avoid the crash, drop etc.

b) Please store and transport the device in the following environment:

- Store in non-corrosive gas and well-ventilated room
- Ambient temperature: -35℃∽55℃
- Relative humidity: 15%∽95%（no condensation）
- Atmospheric pressure: 700hPa∽1060hPa

Ⅷ Record information and contact information

Manufacturer：
JingFang Precision Medical Device (Shenzhen) Co., Ltd.
After-sale services supplier：
JingFang Precision Medical Device (Shenzhen) Co., Ltd.
Address：3/F, Bldg C, Jinwei Yuan, Crossing at Qingsong West Road and Qinglan 2nd Road, Julongshan, Grand Industrial Zone, Longtian Street, Pingshan District, Shenzhen 518118, China
Tel：+86-755-2759 7952
E-mail: sales@innofine.cn / **Website:** www.innofine.cn

EC REP **EC Representative**

CE

Shanghai International Holding Corp. GmbH (Europe)
Address：Eiffestrasse 80, 20537 Hamburg, Germany

℞ Only **Caution:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

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InnoFine

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