Product Description

Pinpoint™ GT Needle Guide Kits consist of the following single use sterile disposables: a set of Pinpoint™ GT Needle Guides, conductive gel, a Site~Rite® Probe Cover, and elastic bands to secure the probe cover to the ultrasound probe.

Indications for Use

Pinpoint™ GT Needle Guide Kits are intended to be used with Site~Rite® Ultrasound Systems.

Pinpoint™ GT Needle Guides provide guidance for a needle to intersect an ultrasound beam at a fixed distance below the skin to assist the medical practitioner in placing the tip of a needle in a specific structure.

Site~Rite® Probe Covers sheathe the transducer and isolate a site of surgical penetration from microbial and other contamination.

WARNING

- Use the sterile, legally marketed plastic probe cover(s) included in the kit.
- Never use probes that are out of alignment for needle guidance.
- Intended for single use. Do not reuse. Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of the patient.
- Do not re-sterilize.
- Do not use if the sterile packaging is damaged.

Cautions

- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and all applicable laws and regulations.
- If the needle is advanced further than the channel end of the needle guide when preparing for a procedure, there is the possibility of a premature needle stick to the patient or clinician.
- Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- Only apply commercially available ultrasonic coupling gel, which has been specifically formulated for use in medical applications, to the acoustic window (or face) of the probe.
- Use water or rubbing alcohol and a soft cloth to remove couplant from the acoustic window (or face) of the probe. Failure to do so may scratch the acoustic window.
- Do not allow ultrasonic couplant to dry on the acoustic window (or face) of the probe. If the couplant should dry, use water or rubbing alcohol and a soft cloth to remove it. Never use a tool of any kind to remove dry couplant from the acoustic window (or face) of the probe.
- Always snap the needle guides on to the probe hook. Do not slide the needle guide on to the needle guide hook, as the sterile sheath may tear.

Note: For Site~Rite® Ultrasound System warnings and precautions, refer to the applicable Site~Rite® Ultrasound System instructions for use.

Pinpoint™ GT Needle Guides

Pinpoint™ GT Needle Guides attach to the needle guide hook located on the probe. Pinpoint™ GT Needle Guides provide guidance for a needle to intersect an ultrasound beam at a fixed distance below the skin to assist in placing the tip of the needle in a specific structure.

1 — Ultrasound Plane: The ultrasound imaging area.
2 — Intersection Depth: When placed through a needle guide, the needle will intersect the ultrasound plane at the depth indicated on the needle guide.
3 — Example target structure

Draping the Probe for Sterile Use

When using Site~Rite® Ultrasound System probe in a sterile environment, the probe and part of the probe cable must be covered with a sterile, acoustically transparent plastic sheath.

Warning: Use the sterile, legally marketed plastic probe covers included in the kit.


To drape the probe for sterile use:
1. Clean and disinfect probe. Refer to Site~Rite® Ultrasound System Instructions for Use.
2. Place the probe in a probe holder.
3. (A) Apply a layer of ultrasonic coupling gel on the acoustic window of the probe head.
4. Ensure the probe cover is fully rolled up.
5. Place the probe cover over the probe head, being careful not to wipe off the coupling gel.
6. (B) Cover the probe and cable with the probe cover.
7. Gently smooth the probe cover over the acoustic window of the probe to remove any air bubbles or folds in the probe cover.
8. Secure the probe cover with provided fasteners.
9. (C) If a second probe cover is provided, follow steps 2-6 to apply. Ensure gel is applied between all layers of probe covers to assure good acoustic transmission.
10. Apply sterile coupling gel to the covered acoustic window.
11. Discard the probe covers after use, following hospital procedures.

Attaching the Needle Guide to the Probe

To attach the needle guide to the probe:
1. Choose the appropriate needle guide based on the needle gauge and the depth of the target structure.
2. Ensure that a sterile probe cover has been placed over the probe. See Draping the Probe for Sterile Use.
3. (D) Clip the short end of the needle guide hook to the end of the needle guide hook closest to the top of the probe.
4. (E) Push the larger end of the needle guide toward the probe until the needle guide snaps on to the needle guide hook. Do not slide.

Caution: Always snap the needle guide on to the probe hook. Do not slide the needle guide on to the needle guide hook, as the sterile sheath may tear.

Using the Needle Guides for Vascular Access

Using the Pinpoint™ GT Needle Guides with Pinpoint™ GT Needle Technology

Note: Refer to the Pinpoint™ GT Needle Technology instructions for use included with your Pinpoint™ GT Needle Technology-enabled Site~Rite® Ultrasound System’s Instructions for Use.

1. Place the probe against the skin, perpendicular to the target structure, ensuring that the needle guide hook faces away from the patient’s heart.
2. While imaging the access target, complete calibration of the Pinpoint™ GT Needle Technology. Refer to the Pinpoint™ GT Needle Technology instructions for use.
3. (F) Place the Pinpoint™ GT Safety Introducer Needle, bevel up and facing the probe, into the needle guide channel. The virtual needle image should appear on the Site–Rite® Ultrasound System display. Refer to the Pinpoint™ GT Needle Technology instructions for use.

4. (G) Slowly advance the needle. Continue insertion in one smooth motion using a “light touch” (i.e., minimal stress, force, or pressure on the needle). Confirm final needle placement on the Site–Rite® Ultrasound System display. Refer to the Pinpoint™ GT Needle Technology instructions for use.

5. (H) Once access is complete, hold the needle; then gently rock the probe away from the needle. The needle guide channel should separate, allowing the needle to disengage from the needle guide.

Using the Pinpoint™ GT Needle Guides with Site–Rite® Ultrasound Systems without Pinpoint™ GT Needle Technology

If loading the needle guide on the skin:

1. First place the probe against the skin, perpendicular to the target structure, ensuring that the needle guide hook faces away from the patient's heart.

2. Center the dot markers on the target vessel. The dot markers are displayed on the Site–Rite® Ultrasound System display.

3. (F) Slide the appropriately-sized needle, bevel up and facing the probe, into the channel on the guide.

4. (G) While keeping the dot markers centered on the target vessel, slowly advance the needle while looking at the Site–Rite® Ultrasound System display. When the needle approaches the target vessel, you should see the anterior wall indenting. Once puncture occurs, the vessel returns to normal shape.

5. (H) Once access is complete, hold the needle; then gently rock the probe away from the needle. The needle guide channel should separate, allowing the needle to disengage from the needle guide.

If loading the needle guide off the skin:

1. (F) First slide the appropriately sized needle, bevel up and facing the probe, into the channel on the guide.

2. Place the probe against the skin, perpendicular to the target structure, ensuring that the needle guide hook faces away from the patient's heart.

3. Then center the dot markers on the target vessel. The dot markers are displayed on the Site–Rite® Ultrasound System display.

4. (G) While keeping the dot markers centered on the target vessel, slowly advance the needle while looking at the Site–Rite® Ultrasound System display. When the needle approaches the target vessel, you should see the anterior wall indenting. Once puncture occurs, the vessel returns to normal shape.

5. (H) Once access is complete, hold the needle; then gently rock the probe away from the needle. The needle guide channel should separate, allowing the needle to disengage from the needle guide.

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<th>Minimum Compatible Needle Length</th>
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<tr>
<td>Depth (cm)</td>
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