

Site~Rite*

Needle Guide Kits and Ultrasound Probe Cover Kits Instructions For Use

Intended Use

The **Site~Rite*** Needle Guides and Probe Cover Kits are intended to be used with **Site~Rite*** Ultrasound System probes.

Indications for Use

- **Site~Rite*** Needle Guide Kits 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*** Needle Guide Kits and Probe Cover Kits provide a protective covering to sheath an ultrasound probe and isolate a site of surgical penetration from microbial and other contamination.

Warnings

- Use only sterile, legally marketed plastic probe covers that are 1 mil (0.001 inch or 0.0254 mm) thick.
- Never use probes that are out of alignment for needle guidance.

Precautions

- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- Only apply commercially available ultrasonic couplant, 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.
- Some commercially available probe covers contain latex. Natural rubber latex may cause allergic reactions. Refer to the US FDA alert titled: "Medical Alert: Allergic Reactions to Latex-Containing Medical Devices". **Site~Rite*** Needle Guide Kits and Ultrasound Probe Cover Kits do not contain natural rubber latex.
- 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.

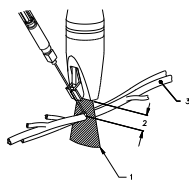
Site~Rite* Needle Guides

Site~Rite* Needle Guides attach to the needle guide hook located on the probe. **Site~Rite*** 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

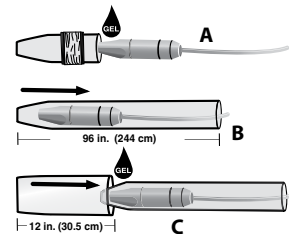
When using **Site~Rite*** Ultrasound System probe in a sterile environment, the probe and part of the probe cable must be covered with a sterile, acoustically transparent plastic sheath.

Warning: Use only sterile, legally marketed plastic probe covers that are 1 mil (0.001 inch or 0.0254 mm) thick.

Caution: Some commercially available probe covers contain latex. Natural rubber latex may cause allergic reactions. Refer to the US FDA alert titled: "Medical Alert: Allergic Reactions to Latex-Containing Medical Devices", issued March 29, 1991. **Site~Rite*** Needle Guide Kits and Ultrasound Probe Cover Kits do not contain natural rubber latex.

To drape the probe for sterile use:

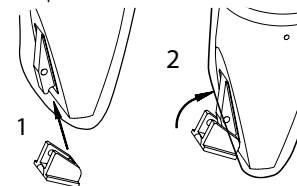
1. Clean and disinfect probe. Refer to **Site~Rite*** Ultrasound System Instructions for Use.
2. Place the probe in the side arm probe holder on the roll stand.
3. Apply a layer of non-sterile ultrasonic coupling gel on the acoustic window of the probe head.
4. Ensure the probe cover is fully rolled up.
5. Place the probe cover over the probe head, being careful not to wipe off the coupling gel.
6. Cover the probe and cable with the probe cover.
7. Smooth the probe cover over the acoustic window of the probe to remove any air bubbles or folds in the probe cover.
8. Secure probe cover with provided fasteners.
9. 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 a layer of sterile coupling gel to the covered acoustic window.
11. Discard probe covers after use, following hospital procedures.



Attaching the Needle Guide to the Probe

To attach the needle guide to the probe:

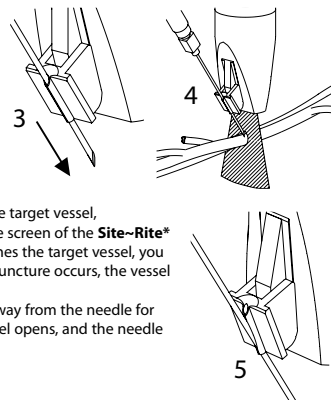
1. Choose the appropriate needle guide based on the needle gauge and the depth of the target structure.
2. Ensure that a sterile probe cover has been placed over the probe. See *Draping the Probe for Sterile Use*.
3. Clip the short end of the needle guide to the end of the needle guide hook closest to the top of the probe.
4. 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

1. Slide the appropriately sized needle, beveled edge facing the probe, into the channel on the guide.
2. Place the probe against the skin, perpendicular to the target structure.
3. Hold the probe so that the needle guide points away from the heart.
4. Center the dot markers on the target vessel. The dot markers are displayed on the **Site~Rite*** Ultrasound System screen.
5. While keeping the dot markers centered on the target vessel, slowly advance the needle while looking at the screen of the **Site~Rite*** Ultrasound System. When the needle approaches the target vessel, you should see the anterior wall indenting. Once puncture occurs, the vessel returns to normal shape.
6. Hold the needle, then gently rock the probe away from the needle for a smooth separation. The needle guide channel opens, and the needle smoothly disengages from the guide.



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Attention, see instructions for use



Contents



Conductive Gel



Do not resterilize



Do not reuse



Do not use if package is damaged

Rx Only

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



Manufacturer



Needle guide gauge size



Non-pyrogenic

PE

Polyethylene

PU

Polyurethane



Probe cover length. Probe cover with 2 elastic bands.



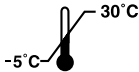
Site~Rite® Needle Guide Set, depth(s)



Sterilized by Ethylene Oxide



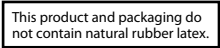
Sterilized by Irradiation



Storage Conditions



The Greendot



This product and packaging do not contain natural rubber latex.