PINPOINT
Gel Cap With Needle Guide

BARD
ACCESS SYSTEMS
GEL CAP DEVICE DESCRIPTION

The Pinpoint® Gel Cap is a sterile, single use accessory for use with the Site–Rite Prevue® Ultrasound System. The device is intended for use as an ultrasound coupling medium. This device attaches to the ultrasound probe and contains a hydrogel pad that interfaces directly with the transducer face and the patient’s skin to provide an acoustic coupling pathway. The device contains a feature that accommodates attachment of a needle guide. The packaging tray protects the hydrogel pad during transit and while the clinician is attaching the device on the ultrasound probe.

NEEDLE GUIDE DEVICE DESCRIPTION

The Pinpoint® Needle Guide is a sterile, single use accessory for use with ultrasound. The device is intended to 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 the needle in a specific structure. The Pinpoint® Needle Guide attaches to the Pinpoint® Gel Cap which attaches to the ultrasound probe. Each needle guide accommodates multiple vein depths.

GEL CAP INDICATIONS FOR USE

- The gel cap is intended for use as an ultrasound coupling medium for use with the Site–Rite Prevue® Ultrasound System. The device is intended for use with pediatrics and adults.

NEEDLE GUIDE INDICATIONS FOR USE

- The needle guides are intended to 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. This device is intended for use with pediatrics and adults.

CONTRAINDICATIONS

- None known

WARNINGS

- 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.
- The Pinpoint® Gel Cap contains potassium metabisulfite and carrageenan which may cause allergic reactions in certain patient populations. Patients with known sensitivity to these ingredients should avoid contact with the gel.
- Do not pierce the hydrogel with the needle. This may cause patient injury.
CAUTION

- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- Do not remove Gel Cap from the tray until you are ready to scan, this may prematurely dry out the hydrogel.
- Gel Cap may fall off if not attached properly.
- Poor image may result if the Gel Cap is not attached properly.
- Only use the following approved skin prep agents with the Gel Cap and guides: isopropyl alcohol, Chlorhexidine, and povidone iodine.
- 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 patient or clinician.
- After use, this product maybe a potential biohazard. Handle and dispose of in accordance with accepted medical practice and local, state, and federal laws and regulations.
- If resistance is encountered while inserting a Vascular Access Device (VAD) into the needle guide, remove VAD and replace the Pinpoint® Gel Cap with a new one.
PROCEDURE

Assessment Scan

1) Open the Pinpoint* Assessment Cap package.

Note: Shipping may cause gel to shift inside the gel cap. If gel is out of position, but can still be used aseptically, continue use of gel cap.

2) Orient and snap the Pinpoint* Assessment Cap onto the probe.

3) Place the Pinpoint* Assessment Cap onto the patient’s skin and slide to image and to identify the target vessel.

(Refer to Ultrasound System IFU)
4) Align vessel center with available guide depth by scanning along the length of the vessel. Make note of vessel depth and anatomical location.

Caution: After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable local, state, and federal laws and regulations.

Vascular Access Procedure

5) Select appropriate Pinpoint® Gel Cap with Guide for appropriate depth and gauge size.

6) Clean insertion area per institutional protocol.
7) Open the Pinpoint\textsuperscript{®} Gel Cap using aseptic technique.

**Note:** A minimum of a 1\" needle must be used in guide.

See Minimum needle length vs. depth table on page 8.

**Note:** Shipping may cause gel to shift inside the gel cap. If gel is out of position, but can still be used aseptically, continue use of gel cap.

8) Orient and snap the Gel Cap onto the probe.

9) Adjust Guide by sliding it to the appropriate depth until arrows on probe and Guide align. (Example shows a depth of 0.25 cm set)

10) Remove pin from selected Guide Channel. (If applicable)
11) Scan to relocate the vessel identified during the assessment scan.

12) Align vessel with selected needle guide depth.

   Center the vessel in the image.

   **Note:** Pressure applied near the insertion site can cause vessel movement.

13) Load an appropriately sized vascular access device (VAD) with the beveled edge facing the probe into the pre-determined guide channel. Verify needle is in channel prior to advancing into vessel.

**Caution:** If resistance is encountered while inserting Vascular Access Device (VAD) into the needle guide, remove VAD and replace the Pinpoint* Gel Cap with a new one.

**Caution:** 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 patient or clinician.
14) While stabilizing the probe with one hand, advance needle to target vessel with other hand until access has been identified by the anterior vessel wall indenting. Once the puncture occurs the vessel wall returns to normal shape.

**Warning:** Do not pierce the hydrogel with the needle. This may cause patient injury.

15) Hold the needle, then gently rock the probe away to disengage the needle from the guide.

**Caution:** After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and local, state, and federal laws and regulations.

16) Complete procedure per institutional protocol.
# TABLE OF DEPTH VS. COMPATIBLE NEEDLE LENGTH

<table>
<thead>
<tr>
<th>Needle Guide Depth (cm)</th>
<th>1.0 in</th>
<th>1.16 in</th>
<th>1.25 in</th>
<th>1.75 in</th>
<th>1.88 in</th>
<th>2.0 in</th>
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An issued or revision date for these instructions is included for the user’s information. In the event two years elapsed between this date and product use, the user should contact Bard Access Systems, Inc. to see if additional product information is available.

Revision date: July, 2012

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