1 DEVICE DESCRIPTION

The Pinpoint™ GT Introducer Needle is designed for percutaneous access to introduce a guidewire.

The Pinpoint™ GT Introducer Needle contains a magnet which emits a passive magnetic field that can be detected by Ultrasound Systems equipped with Pinpoint™ GT Technology.

The Pinpoint™ GT Introducer Needle, when used with the Pinpoint™ GT System, creates a virtual image of the needle on the Ultrasound display, providing clinicians with a visual representation of the needle throughout the insertion process.

2 INDICATIONS FOR USE

The Pinpoint™ GT Introducer Needle is intended for patients requiring percutaneous access to place a guidewire for subsequent placement of catheters or other medical procedures requiring introducer needle access.

The Pinpoint™ GT Introducer Needle may be used in any appropriate patient population.

3 CONTRAINDICATIONS

No known contraindications.

4 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.

Do not re-sterilize.

Do not use the Pinpoint™ GT Introducer Needle if the package is opened or damaged.

5 CAUTIONS

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

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

Pinpoint™ GT Introducer Needle Kits are not made with natural rubber latex.
CAUTIONS continued

Only qualified healthcare practitioners should use or handle the Pinpoint™ GT Introducer Needle.

Follow standard infection control practices as specified by the CDC (USA) or local equivalent.

When using a guidewire with this needle: If the guidewire must be withdrawn while the needle is inserted, remove both the needle and the wire as a unit to prevent the needle from damaging or shearing the guidewire.

Caution should be used when using the Pinpoint™ GT Introducer Needle around equipment/devices sensitive to magnetics.

SET-UP continued

Warning: Do not use the Pinpoint™ GT Introducer Needle if the package is opened or damaged.

3. Inspect the kit for inclusion of all components.

4. Complete the pre-procedure patient assessment according to clinical protocol, with or without ultrasound.

5. Prepare sterile field according to hospital protocol. If using ultrasound, drape probe with sterile probe cover according to the probe cover IFU, Ultrasound System IFU or hospital protocol.


Note: The Pinpoint™ GT Needle can be used:
- as a stand alone introducer needle
- with the aid of ultrasound
- with the aid of ultrasound equipped with Pinpoint™ GT Technology.

7. Perform the procedure with or without ultrasound per hospital protocol.

SET-UP

1. If using the Pinpoint™ GT Introducer Needle with an Ultrasound System equipped with or without Pinpoint™ GT Technology, refer to the appropriate Ultrasound System Instructions for Use (IFU) and the Pinpoint™ GT System IFU.

2. Examine the package carefully before opening to confirm integrity and that the expiration date has not passed. The device is supplied in a sterile package and is non-pyrogenic; do not use if package is damaged, opened or the expiration date has passed.
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<thead>
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<th>Symbol</th>
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<tr>
<td>i</td>
<td>Consult instructions for use</td>
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<td>2</td>
<td>Do not resterilize</td>
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<td>2</td>
<td>Do not reuse</td>
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<td>Do not use if package is damaged</td>
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- **STERILE EO**: Sterilized using ethylene oxide
- **REF**: Reorder Number
- **Rx Only**: Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- **Quantity**

- **XG (Ymm)**: Gauge
- **X in (Ymm)**: Inner Diameter
- **X in (Ymm)**: Length
- **X in (Ymm)**: Non-pyrogenic
- **Use by**
- **Needle**
- **Lot Number**
- **The Green Dot**
- **Introducer Needle**

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