1 DEVICE DESCRIPTION

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

The Pinpoint™ GT Safety 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 Safety 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 Safety 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 Safety 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 Safety Introducer Needle if the package is opened or damaged.

Failure to advance the safety mechanism until it locks at the tip of the needle may result in an exposed needle tip, potentially resulting in a needlestick injury with a contaminated device. A needlestick with a contaminated needle may result in an infectious disease.

Do not attempt to bypass or defeat the safety mechanism of the Pinpoint™ GT Safety Introducer Needle. A needlestick injury may occur.
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 Safety Introducer Needle Kits do not contain natural rubber latex.

Only qualified healthcare practitioners should use or handle the Pinpoint™ GT Safety 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When using a guidewire with this needle: If the guidewire must be withdrawn while the needle is inserted, remove both the needle and the wire as a unit to prevent the needle from damaging or shearing the guidewire.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 Safety Introducer Needle around equipment/devices sensitive to magnetics.

SET-UP continued

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.

Warning: Do not use the Pinpoint™ GT Safety 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.


SET-UP

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

PINPOINT™ GT SAFETY INTRODUCER NEEDLE USE AND SAFETY ACTIVATION

Note: The Pinpoint™ GT Safety Introducer 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.

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

2. Once the introducer needle is removed from the patient, activate the safety mechanism by:

   A. Holding the hub of the introducer needle in one hand.

   B. With the thumb and finger of the other hand, grasp the safety tab and advance it away from the needle hub.

   C. Holding the hub steady, advance the green safety tab to the end of the needle until it stops completely, covering the tip of the needle.

2. Dispose of the introducer needle per hospital policy.

   Warning: Failure to advance the safety mechanism until it locks at the tip of the needle may result in an exposed needle tip, potentially resulting in a needlestick injury with a contaminated device. A needlestick with a contaminated needle may result in an infectious disease.

   Warning: Do not attempt to bypass or defeat the safety mechanism of the Pinpoint™ GT Safety Introducer Needle. A needlestick injury may occur.

   Caution: After use, this product may be a potential biohazard. Handle and dispose in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.
Consult instructions for use
Do not resterilize
Do not reuse
Do not use if package is damaged

Not made with natural rubber latex.

STERILE EO Sterilized using ethylene oxide

Catalog Number

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

Quantity

Guage

Inner Diameter

Length

Non-pyrogenic

Use by

Needle

Storage Conditions

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