

Trocar and Chiba Introducer Needle

Instructions for Use:

Contents of unopened, undamaged package are:

STERILE • NONPYROGENIC

Disposable - This device is intended for one use only.

Do not reuse or resterilize.

Sterilized with Ethylene Oxide.

Indications for Use:

These needles are used for the percutaneous introduction of guidewires.

Device Description:

Introducer Needles are composed of three components: a needle cannula, stylet, and depth stop. The introducer needle provides an access path into the target anatomy for placement of a 0.018" guidewire.

Contraindications:

Use of the needle is contraindicated if the patient has a known or suspected obstruction in the vessel or target anatomy.

Potential Complications:

The potential complications related to the use of the needle include, but are not limited to the following: Air embolism, device dislodgement, needle cannula breakage, hematoma, hemothorax, pneumothorax, thrombosis, trauma to vessels, sepsis.

Precautions:

Store at room temperature. Do not use if package is open or damaged. Inspect all components prior to use.

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

Cautions:

- This procedure should only be performed by professionals thoroughly trained in this procedure.
- If resistance is met when advancing or withdrawing the guidewire through the needle, determine the cause by fluoroscopy and correct before continuing with the procedure.
- Do not attempt to use a guidewire over the maximum diameter specified on the package label.
- Individual patient anatomy and physician technique may require procedural variations.
- Insertion into artery may cause excessive bleeding and/or other complications.

Warnings:

- Do not alter this device in any way.
- Do not use alcohol, acetone or solutions containing these agents. These solutions may affect the properties of the plastic components resulting in degradation of the device.
- Do not reuse this device. Reuse will result in increased biocontamination risk for the patient resulting in infection or pyrogenic response.
- Do not withdraw guidewire through metal needles; guidewire may shear or unravel.
- Do not resterilize.

USE STERILE TECHNIQUE, A Suggested Procedure:

1. Peel open package and place contents on sterile field.
2. Prep skin and drape in area of anticipated puncture site as desired.
3. Insert appropriate size Needle into vessel or target anatomy - observe for flash back.
4. Follow standard clinical practice for placement of guidewire.

Needle Disposal: The needle should be disposed of in accordance with policies and procedures for contaminated sharps disposal. Single use only.



Picture for reference only.

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Do not reuse



Do not resterilize



Consult instructions for use

Store at room temperature



Non-pyrogenic

STERILE EO

Sterilized using ethylene oxide



Use by



Not made with DEHP



Not made with natural rubber latex



Not made with PVC



Batch code



Catalog number



Keep dry



Keep away from sunlight



Do not use if the product sterilization barrier or its packaging is compromised

Rx only

Interventional Systems

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