Thin-Wall Introducer Needle

Package Contents: •One - 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.

Contraindications:

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

Description of Device:

The Introducer Needle consists of a standards needle cannula with a luer taper hub. The needle cannula can be offered in various diameter and length sizes. The needle can be made with an echogenic tip. An echogenic tip allows the tip of the needle to be located using Ultrasound techniques. Refer to unit labeling for Introducer needle specifications.

Indications for Use:

These needles are used for the percutaneous introduction of guidewires.

Potential Complications:

The potential complications related to the use of the needle include, but are not limited to the following: Air embolism, wound infection, intimal tear, subclavian artery puncture, pneumothorax, subclavian vein thrombosis.

Precautions:

Do not use if package is open or damaged. Inspect all components prior to use. Store in a dry, dark, cool place.

Cautions:

This procedure should only be performed by physicians thoroughly trained in this procedure. If resistance is met when advancing or withdrawing the guidewire, determine the cause by fluoroscopy and correct before continuing with the procedure.

Individual patient anatomy and physician technique may require procedural variations. Insertion into artery may cause excessive bleeding and/or other complications.

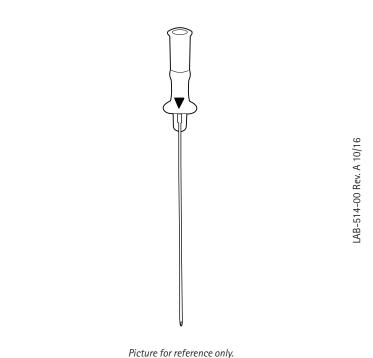
Do not attempt to use a guidewire over the maximum diameter specified on the package label.

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. 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 observe for flash back.
- 4. Follow standard hospital 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.









Consult instructions for use Store in a dry, dark, cool place





Sterilized using ethylene oxide in unopened, undamaged inner package













Model number

MODEL

Interventional Systems

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