Guidewire 0.018in. Diameter Instructions for Use

Do not reuse

Do not resterilize

Consult instructions for use

STERILE EO
Sterilized using ethylene oxide

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

Rx only

Manufacturer

DEHP
Not made with DEHP

LATEX
Not made with natural rubber latex

LOT
Batch code

REF
Catalog number

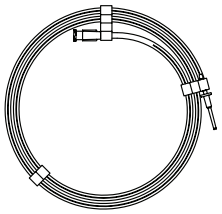
MODEL NUMBER
Model number

CORE/TIP:
Tip Configuration

Use by

Store at room temperature in a dry place

Non-pyrogenic Fluid path



Picture for reference only.

LAB-274-00 REV. B 10/16

Instructions for Use:

Contents of unopened, undamaged package are:
STERILE • NON-PYROGENIC FLUID PATH
Disposable - This device is intended for one use only.
Do not reuse or resterilize. Sterilized with Ethylene Oxide.

Device Description:

These guidewires are constructed of one or more of the following materials: stainless steel, nitinol, and/or platinum and may have lubricious coating. Specific guidewire materials, configuration (length, diameter, tip description) and coating material (optional) are indicated on the product pouch label.

Indications for Use:

Guidewires are intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and peripheral vasculature.

Contraindications:

Use of the guidewire is contraindicated if the patient has a known or suspected obstruction in the vasculature.

Potential Complications:

The potential complications related to the use of the guidewire include, but are not limited to, the following: Air embolism, wound infection, hematoma at the puncture site, and/or perforation of the vessel wall.

Precautions:

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

Cautions:

This procedure should be performed only by physicians thoroughly trained in this procedure.

Guidewires should be routinely inspected prior to use and discarded should any deformities be present in the guidewire.

If resistance is met when advancing or withdrawing the guidewire, determine the cause by fluoroscopy and correct before continuing with the procedure.

Because of the delicate and fragile nature of guidewires, extra care in handling must be taken.

Warnings:

Do not alter this device in any way.
Do not reuse this device
Do not withdraw guidewire through metal needles as guidewire may shear, unravel, and/or PTFE coating may scrape off.
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 venipuncture as desired.
3. Perform skin wheel using 25 gauge needle (not supplied).
4. Locate vessel using a small gauge needle and syringe (not supplied).
5. Insert appropriate gauge Introducer Needle into vessel - observe for flash back.
6. Flush the guidewire with sterile heparinized normal saline or a similar isotonic solution. Insert desired flexible tip of the guidewire through the introducer needle into vessel. Slowly advance guidewire to required depth. Advancement of "J" tip may require a gentle rotating motion. **Caution:** At no time should guidewire be advanced or withdrawn when resistance is met. Determine cause of resistance before proceeding.
7. Hold guidewire in place and remove Introducer Needle. **Caution:** Do not withdraw the guidewire back into the cannula as this may result in separation of the guidewire. The cannula should be removed first.
8. With the guidewire in place, follow the instructions for use provided by the manufacturer of the introducer, catheter or other device, as well as the medical facility's standard procedure for these types of devices.
9. To lengthen the flexible segment of a movable core guidewire, gently withdraw the core. To shorten the flexible segment, push the core forward carefully. **Caution:** When the guidewire is in a vessel, do not advance the movable core if the tip is in a curved shape. Never twist or force the movable core because excessive force may cause it to penetrate the coil and damage the vessel.

Interventional Systems
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