Instructions for Use
ACCEL® Access 3-Piece Introducer System

Do not reuse

Do not resterilize

Consult instructions for use

Store at room temperature

Use by

Non-pyrogenic

Keep dry

Keep away from sunlight

STERILE EO Sterilized using ethylene oxide

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

LATEX Not made with natural rubber latex

DEHP Not made with DEHP

PVC Not made with PVC

LOT Batch code

REF Catalog number

Rx only

Picture for reference only.

LAB-960-00 Original (08/18)

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:

The ACCEL® Access 3-Pc Introducer System is indicated for use in percutaneous introduction and placement of catheters and guidewires.

Device Description:

The Introducer consists of an inner stiffening cannula, 4F dilator, and a 6F outer sheath. The stiffening cannula accepts a 0.018" guidewire, and is designed to be inserted into the inner dilator (as assembled inside the package). The Introducer System allows for the introduction of a 0.018" guidewire and 0.035" or 0.038" working guidewire in percutaneous procedures. The Introducer contains the TrueGlide® Hydrophilic Coating.

Kit configurations may include the following devices:
Guidewire: There are two configurations; Mandrel or Fully Coiled.
The Mandrel guidewire construction uses a tapered core wire which is soldered or welded to a coil at the distal end. The Fully Coiled guidewire construction uses a tightly wound coil which surrounds a tapered core and a safety ribbon. Needle: 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 Introducer is contraindicated if the patient has a known or suspected obstruction in the vessel or target anatomy. There is increased risk of pneumothorax for the patient who has severe chronic lung disease.

Potential Complications:

The potential complications related to the use of the Introducer System include, but are not limited to the following:
Air embolism, device embolism, device dislodgement, pneumothorax, vein thrombosis hematoma formation, hemothorax, vessel erosion, trauma to vessels, inadvertent arterial or venous puncture, local or systemic infection/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 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 or the Introducer, 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.
- Do not expose to organic solvents, eg. alcohol. These solutions may affect the properties of the plastic components resulting in degradation of the device.
- 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 reuse this device. Reuse will result in increased biocontamination risk for the patient resulting in infection or pyrogenic response.
- Do not attempt to straighten a wire that has been kinked or bent.
- Do not advance a guidewire that is kinked or becomes kinked or bent.
- Do not rotate the guidewire if significant resistance is felt.
- Do not withdraw guidewire through metal needles; guidewire may shear or unravel.
- Do not resterilize.
- Do not soak the in hydrophilic coated Introducer System in alcohol.
- To ensure lubricity, do not leave the hydrophilic coated Introducer System hydrated for long periods of time.
- Avoid abrasion of the coating of the hydrophilic coated Introducer System.
- During insertion avoid contact with bone, cartilage and scar tissue, which can damage the needle, guidewire, or introducer.

USE STERILE TECHNIQUE, A Suggested Procedure:

1. Peel open package and place contents on sterile field. Inspect introducer and accessories for defects. Do not use any defective devices.
2. To remove air, flush the introducer with normal saline. For hydrophilic coated Introducer System only: soak the introducer with saline for 15 to 20 sec. in order to completely wet and hydrate the surface. When hydrated (wetted with saline or blood), the introducer is very lubricious. Use sterile gauze soaked with saline to help with keeping the guidewire hydrated and to aid in its handling.
3. Prep skin and drape in area of anticipated puncture site as desired.
4. Insert trocar or chiba introducer needle using sterile technique. The needle position should be verified.
5. The angle of the needle should be adjusted depending on the patient's build.
6. Remove stylet leaving introducer needle cannula in place.
7. Advance the 0.018" guidewire through the introducer needle. Advance guidewire to required depth using ultrasound guidance, CT or fluoroscopy. Leave an appropriate amount of guidewire exposed. At no time should the guidewire be advanced or withdrawn when resistance is met. Determine the cause of resistance before proceeding. Fluoroscopic verification of the guidewire location is suggested.
8. Hold guidewire in place and remove needle. Do not withdraw the guidewire back into the cannula as this may result in separation of the guidewire. The cannula should be removed first.

CAUTION: Do not allow Guidewire to advance totally into patient.

9. Advance the Introducer over the 0.018" guidewire into the desired position.
10. Release and remove the stiffening cannula and the inner dilator, leaving the outer sheath and 0.018" guidewire in position.
11. Advance the 0.038" or 0.035" guidewire through the outer sheath (alongside the 0.018" guidewire) into the desired position.
12. Remove the 0.018" guidewire.
13. Remove the outer sheath leaving the 0.038" or 0.035" guidewire in place.
14. Utilize guidewire for placement of further diagnostic or interventional devices.

Interventional Systems

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