TRANSCAROTID/PERIPHERAL ACCESS KIT

Indications for Use:
These access kits are intended to introduce up to a .038 inch guidewire or catheter into the peripheral vascular system, including the carotid artery, following a small gauge needle stick.

Device Description:
The access kit includes the following 5 components:
Micro-introducer: The micro-introducer consists of an inner dilator within a slightly shorter outer sheath which are connected using a spin-lock type connector. The inner dilator and outer sheath are made from radiopaque material so they are visible under fluoroscopy.
Stiffen Inner Dilator: A stiffen inner dilator is an optional component of the access kit to be used in place of the standard inner dilator if desired. The stiffen inner dilator is composed of three components; stainless steel hypo-tubing inserted into a Polyamide tubing with a over molded hub.
Guidewire: Mandrel guidewire construction uses a tapered core wire which is soldered or welded to a coil at the distal end.
Needle: Introducer needles are composed of two components: a stainless steel cannula with an over molded hub. The introducer needle provides an access path into the vasculature.
Extension Tube with Stopcock: The extension tube is an optional accessory that consists of 20cm poly tube with a male luer connector at one end and a 3-way stopcock at the other.

Contraindications:
Use of the access kit is contraindicated if the patient has a known or suspected obstruction in the vessel. There is an increased risk of pneumothorax for the patient who has severe chronic lung disease. Poor healing may result in the patient who has had irradiation to the anterior chest.

Potential Complications:
The potential complications related to the use of the access kit 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, sepsis.

Precautions:
Store in a dry, dark, cool place. Do not use if package is open or damaged. Inspect all components prior to use.
USA CAUTION: 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.
- If resistance is met when advancing or withdrawing the guidewire or the micro-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.
- Guidewires should be routinely inspected prior to use and discarded should any deformities be present in the guidewire.
- 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 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 resterilize.

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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 vessel access as desired.
3. Distend the vessel following standard hospital practice for vessel access.
4. Insert 21 gauge introducer needle into vessel. The needle position should be verified by observing blood return.
5. For percutaneous access the angle of the needle should be adjusted depending on the patient's build: shallow in a thin person, deeper in a heavyset person.
6. Aspirate the puncture needle using the syringe.
7. Remove the syringe and insert soft tip of the .018 in. outside diameter guidewire through the introducer needle into the vessel. Advance guidewire to required depth. 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.
8. Hold guidewire in place and remove introducer 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: If the guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to prevent the needle from damaging or shearing the guidewire.
9. Thread the micro-introducer over the guidewire.
10. Advance the micro-introducer together using a twisting motion over the guidewire and into the vessel. Fluoroscopic observation may be advisable. Attaching a clamp or hemostat to the proximal end of the guidewire will prevent inadvertently advancing the guidewire entirely into the patient.
11. Remove the inner vessel dilator and guidewire, leaving the outer sheath in place. Immediately place a finger over the remaining dilator orifice to prevent excessive bleeding or possible air aspiration.
12. If inserting a catheter smaller than the inside diameter of the outer sheath, the catheter may be inserted directly. Otherwise, using a standard guidewire, straighten the J-tip of the guidewire with the tip straightener and insert the tapered end of the tip straightener into the dilator. Advance the guidewire through the outer sheath as far as appropriate. Verify correct positioning using fluoroscopy or ultrasound.
13. Slowly withdraw and remove the outer sheath, while holding the guidewire in position.
14. Proceed with insertion of the standard introducer system following normal technique.

Rx ONLY **Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner)**

REF **Catalog Number**	LOT **Lot Number**	**Use By Date**	**Inner Diameter**	**Length**	**Outer Diameter**	**Consult Instructions for Use**	**Non-Pyrogenic**	**Manufacturer**
STERILE EO **Sterilized Using Ethylene Oxide**	**Single Use**	**Do Not Re-Sterilize**	**Do Not Use If Package Is Damaged**		**Keep Dry**	**Keep Away from Sunlight**	**Not Made With Natural Rubber Latex**	**Distributor**

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