
MICRO-INTRODUCER KIT

Indications for Use:

These Micro-Introducer Kits are intended to introduce up to a .038 inch guidewire or catheter into the peripheral vascular system following a small gauge needle stick.

Device Description:

The Micro-Introducer device consists of an inner dilator within a slightly shorter outer sheath which are connect using a spin-lock type connector. The inner and outer dilators are made from radiopaque material so they are visible under fluoroscopy.

Kit include the following devices:

Guidewire: There are two configurations; Mandrel or Fully Coiled. Mandrel guidewire construction uses a tapered core wire which is soldered or welded to a coil at the distal end. Fully Coiled guidewire construction uses a tightly wound coil which surrounds a tapered core and a safety ribbon.

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.

Contraindications:

Use of the introducer is contraindicated if the patient has a known or suspected obstruction in the vessel . There is 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 introducer 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.
- When locking dilator into the outer sheath, Do Not over-tighten dilator. Damage to the locking feature in the sheath will occur if dilator is rotated more than 1/8 turn in the sheath.

MICRO-INTRODUCER KIT

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.












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 veni-puncture as desired.
3. Distend the vessel following standard hospital practice for venipuncture. The vein will be much easier to locate if the patient is well hydrated.
4. Insert 21 gauge introducer needle into vessel. The needle position should be verified by observing venous blood return.
5. 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 assembly over the guidewire.
10. Advance the micro-introducer assembly 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 dilator 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 dilator, 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 dilator as far as appropriate. Verify correct positioning using fluoroscopy or ultrasound.
13. Slowly withdraw and remove the dilator, while holding the guidewire in position.
14. Proceed with insertion of the standard introducer system following normal technique.

MICRO-INTRODUCER KIT

REF	LOT				
Part Number	Lot Number	Use By Date	Manufacturer	Non-Pyrogenic	Consult Instructions for Use
	STERILE EO				
Store in Dry Place	Ethylene Oxide Sterilized	Single Use Only	Distributor	Do Not Re-Sterilize	Damaged Package – Do Not Use
		Rx ONLY			
Store In A Dark Place	Not Made With Natural Rubber Latex	Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner)			

Manufactured for:
Typenex Medical, LLC
303 E. Wacker Drive, Suite 1030
Chicago, IL 60601, USA
www.typenexmedical.com
For customer feedback
or to report a problem call
866-897-3639

AN-1808-136.1
 LAB-903-00, Rev. D