TYPENEX MEDICAL

Typenex Introducer Set

Indications for Use:
The Typenex Introducer Set is indicated for use in percutaneous procedures to introduce catheters and other intravascular devices into the peripheral vasculature.

Device Description:
The Typenex Introducer Set assembly consists of a sheath introducer with an integrated hemostasis valve, with an optional side port, and a dilator.
Kit configurations may 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.

Potential Complications:
The potential complications related to the use of the introducer include, but are not limited to the following: Air embolism, device dislodgement, hematoma, hemothorax, trauma to major vessels, sepsis, pneumothorax, vein thrombosis.

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.
- 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.
- Do not leave a catheter introducer in place for extended periods of time without a catheter or an obturator to support the cannula wall.
- Damage to the valve assembly may occur under the following circumstances:
  - Obturator/Dilator is not centered in the valve or parallel with the sheath when inserted in the valve

- Obturator or catheter in valve system for extended periods.
- Inner catheter is withdrawn to rapidly.

Warnings:

- The safety and effectiveness of this device has not been established in the coronary vasculature or neurovasculature.
- 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.

USE STERILE TECHNIQUE, A suggested procedure:

1. Peel open package and place contents on sterile field. Inspect catheter introducer and accessories for defects. Do not use any defective devices.
2. To remove air, flush the dilator, catheter introducer and sideport with normal saline solution.
3. Prep skin and drape in area of anticipated puncture site as desired.
4. Insert needle cannula into vessel. The needle position should be verified by observing 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 heavy set person.
6. Aspirate the puncture needle using a syringe.
7. Remove the syringe and insert soft tip of the 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. Fluoroscopic verification of the guidewire location is suggested.
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: Do not allow Guidewire to advance totally into patient
9. Assemble the introducer set by carefully inserting the dilator completely into sheath introducer. Firmly push the snap fit ring on the dilator into the sheath valve cap.
10. When using an introducer with a sideport, follow standard hospital practice for using a continuous drip of normal saline solution through the sideport while the hemostasis introducer is in the vessel.
11. While holding the catheter introducer set close to the skin, advance the dilator and sheath together with 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.
12. To detach the dilator from the sheath cap, push the dilator hub to one side until it becomes detached. Remove the vessel dilator and guidewire, leaving the sheath as a conduit into the vessel.
13. Introduce the selected catheter or other device into the sheath using the instructions provided by the manufacturer of the catheter or other device, and standard hospital practice.
14. To change catheters, slowly withdraw the catheter from the vessel and repeat the insertion procedure.
    CAUTION: When removing the catheter, aspirate via the sideport extension to collect fibrin that may have been deposited at the tip of the sheath.

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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 core because excessive force may cause it to penetrate the coil and damage the vessel.

OBTURATOR, insertion and withdrawal:

1. For occlusion of sheath, use obturator of same size as sheath.
2. For flushing and infusion, use an obturator one french size smaller than the designated sheath size.

					
Part Number	Lot Number	Use By Date	Manufacturer	Non-Pyrogenic	Consult Instructions for Use
					
Store in Dry Place	Ethylene Oxide Sterilized	Single Use Only	Distributor	Do Not Re-Sterilize	Damaged Package – Do Not Use
					
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:
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