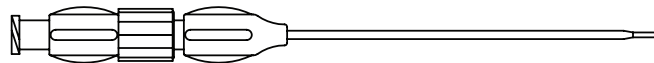
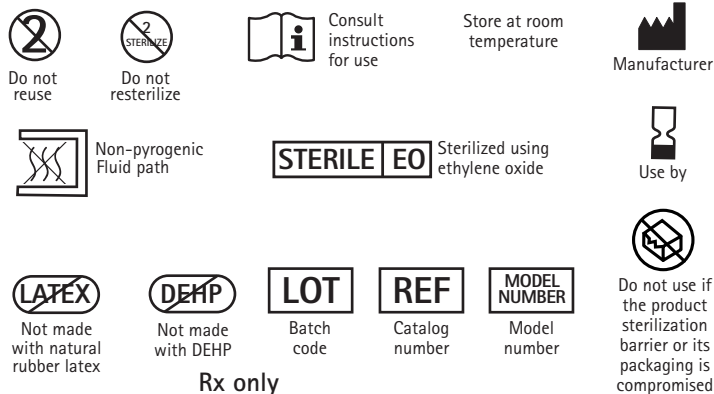


Instructions for Use

Micro-Introducer Kit and SeamLess Micro-Introducer Kit

Package Contents: •One-Micro-Introducer Set •One-Introducer Needle •One-Guidewire



Picture for reference only.

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French Sizes:

Refer to Micro-Introducer Kit Assembly for French size color identification.



Red



Light Grey

Instructions for Use:

Contents of unopened, undamaged package are:
STERILE • NONPYROGENIC FLUID PATH

Disposable - This device is intended for one use only.
Do not reuse or resterilize.
Sterilized with Ethylene Oxide.

Device Description:

The Micro-Introducer Kit includes a micro-introducer set that is designed for vessel entry during placement of up to 0.038" guidewires. The micro-introducer set is available in 4F or 5F with a useable length of 10 cm and consists of an inner plastic dilator contained in an outer plastic sheath. The dilator is locked to the sheath with a rotating lock mechanism. To facilitate entry into the vasculature system, the kit also includes a 21 gauge introducer needle and a 0.018" guidewire.

Indications for Use:

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

Contraindications:

Use of the introducer is contraindicated if the patient has a known or suspected obstruction in the subclavian vein. 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, wound infection, intimal tear, subclavian artery puncture, pneumothorax, subclavian vein thrombosis, bleeding, cardiac arrhythmia, hematoma formation, hemothorax, hydrothorax, thoracic duct injury, vessel erosion.

Precautions:

Store at room temperature. Do not use if package is open or damaged. Inspect all components prior to use.

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.

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.
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 sheath and accessories for defects. Do not use any defective devices.
2. To remove air, flush the dilator and catheter introducer sheath with normal saline solution.
3. Prep skin and drape in area of anticipated veni-puncture site as desired.

4. Distend the subclavian vein or internal jugular vein. The subclavian vein is difficult to locate unless it is distended by raising the patient's legs to a 45-degree angle or by using the Trendelenburg position. The vein will be much easier to locate if the patient is well hydrated.
5. Insert 21 gauge introducer needle into vessel. The needle position should be verified by observing venous blood return. (Puncture the vein as medially as possible by entering just lateral to the ligament which joins the clavicle and the first rib).
6. The angle of the Introducer needle should be adjusted depending on the patient's build: shallow in a thin person, deeper in a heavyset person.
7. Aspirate the Introducer needle using a syringe.
8. Remove the syringe and insert the soft tip of the .018 in. 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.
9. Hold guidewire in place and remove introducer needle. Do not withdraw the guidewire back into the Introducer cannula as this may result in separation of the guidewire. The Introducer 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.

10. Thread the Micro-Introducer assembly over the guidewire.
11. 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.
12. Remove the vessel dilator and guidewire, leaving the sheath in place. Immediately place a finger over the remaining sheath orifice to prevent excessive bleeding or possible air aspiration.
13. If inserting a catheter smaller than the inside diameter of the 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 sheath. Advance the guidewire through the sheath as far as appropriate. Verify correct positioning using fluoroscopy or ultrasound.
14. Slowly withdraw and remove the sheath, while holding the guidewire in position.
15. Proceed with insertion of the standard introducer system following normal technique.

Interventional Systems

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