Tear Away Introducer Instructions for Use

Do not reuse

Do not resterilize

Rx only

Consult instructions for use

Store at room temperature in a dark, dry place

Manufacturer

Non-pyrogenic Fluid path

STERILE EO
Sterilized using ethylene oxide

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

DEHP
Not made with DEHP

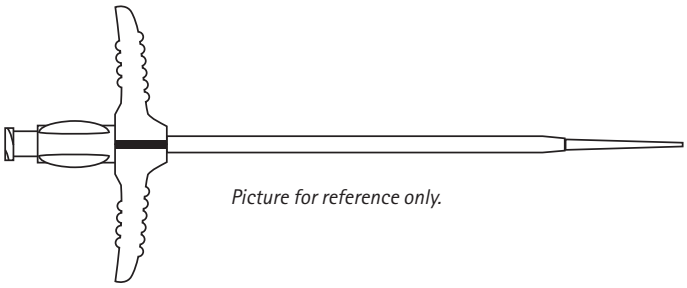
LATEX
Not made with natural rubber latex

LOT
Batch code

REF
Catalog number

MODEL NUMBER
Model number

Use by



Picture for reference only.

LAB-306-00 REV. B 10/16

Refer to Tear Away Assembly for French Size Color Identification:

4F	5F	6F	7F	8F	9F	10F
Red	*Lt. Grey*	*Green*	*Orange*	*Blue*	*Black*	*Lt. Pink*
10.5F	**11F**	**12F**	**13F**	**14F**	**15F**	**16F**
Lt. Green	*Lt. Blue*	*Brown*	*Purple*	*Red*	*Lt. Grey*	*Green*

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.

DEVICE DESCRIPTION:
The Tear Away Introducer system consist of a dilator, sheath and optional kit contents such as syringes, introducer needle and guidewire. Refer to unit labeling for package content. The Tear-Away introducers are available in 4F thru 16F with various useable lengths. Introducer assembly consists of an inner plastic dilator and an outer plastic tear-away sheath. The dilator is locked to the sheath with a locking mechanism. The tear-away sheath handles are color identified by French size.

INDICATIONS FOR USE:
These introducers are used for the percutaneous introduction of diagnostic or therapeutic devices, such as catheters and pacing leads 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, wound infection, intimal tear, subclavian artery puncture, pneumothorax, subclavian vein thrombosis.

PRECAUTIONS:
Store at room temperature in a dark, dry place. Do not use if package is open or damaged. Inspect all components prior to use.

CAUTIONS:
1. This procedure should only be performed by physicians thoroughly trained in this procedure.
2. 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.
3. Because of the delicate and fragile nature of guidewires, extra care in handling must be taken.
4. Do not use forceps to break the handle and/or to peel the sheath as this may damage the sheath and cause premature withdrawal of the sheath from the patient.
5. Do not attempt to use a guidewire over the maximum diameter specified on the package label.
6. Individual patient anatomy and physician technique may require procedural variations.
7. Insertion into artery may cause excessive bleeding and/or other complications.
8. Symmetrical peeling of the sheath is critical.

WARNINGS:

1. Do not alter this device in any way.
2. 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.
3. Do not withdraw guidewire through metal needles; guidewire may shear or unravel.

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 venipuncture as desired.
3. Distend the vessel of choice following standard hospital practice for venipuncture.
   NOTE: If the subclavian vein is selected on the entry site, it is difficult to locate unless it is distended by raising the patient's legs to a 45° angle or by using the Trendelenburg position. The vein will be much easier to locate if the patient is well hydrated.
4. Insert needle into vessel. The needle position should be verified under fluoroscopy and/or 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 guidewire through the introducer needle into the vessel. If inserting a J-tip, use J-tip straightener. 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 entrance into the superior vena cava and right atrium is suggested.
8. Hold guidewire in place and remove introducer needle. Minimize blood loss by applying pressure over the puncture site. Do not withdraw the guidewire back into the cannula as this may result in separation of the guidewire. The cannula should be removed first.
9. Thread the dilator/sheath assembly over the guidewire.
10. 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.
11. Remove the vessel dilator and guidewire, leaving the sheath as a conduit into the vessel. Immediately place a finger over the remaining sheath orifice to prevent excessive bleeding or possible air aspiration.
12. Advance the transvenous lead, catheter or device through the sheath and into the vessel.
    NOTE: If desired, lubricate the lead with a light coating of appropriate sterile lubricant to facilitate passage through the introducer sheath. Apply moderate pressure until the lead tip pushes through the distal end of the sheath. Some resistance may be felt when advancing a lead having tines or a flange tip.
13. When the lead, catheter or other device is properly located, peel the sheath away from the device by using the ends of the sheath as handles and pulling them so that the sheath separates longitudinally and breaks at the distal end.

CAUTION: Do not attempt to withdraw a tined or flanged lead through the introducer sheath. If the lead must be withdrawn, remove the sheath first and then gently pull the lead out of the vessel. Repeat the insertion procedure with a new introducer.

Interventional Systems
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