

2F/3F INTRODUCER INSTRUCTIONS FOR USE

INTENDED USE:

- Introducer is intended to obtain peripheral venous access to facilitate catheter insertion into the central venous system.

CONTRAINDICATIONS:

- Introducer is not designed for use in the arterial system.





DESCRIPTION:

- Introducer is a sheath and dilator assembly that facilitates vascular access for placement of intravascular catheters.

POTENTIAL COMPLICATIONS:

- Embolism
- Perforation/Trauma of vessel or viscus
- Laceration of vessel or viscus
- Bleeding
- Hematoma
- Pain in region
- Infection
- Edema

WARNINGS:

- Federal Law (USA) restricts the device to sale by or on the order of a physician.
- This device is for Single Use Only. 
- Do not resterilize by any method. 
- Re-Use may lead to infection or illness/injury.
- The manufacturer shall not be liable for any damages caused by re-use or resterilization of the device.
- Contents sterile and non-pyrogenic in unopened, undamaged package.
- Caution when using this device. Be aware of sharps.
- Do not use if components are damaged, deformed or missing.
- Do not overtighten. Do not proceed if resistance is felt or interaction between components is failing.
- STERILIZED BY ETHYLENE OXIDE 
- Do not use if package is opened or damaged. 
- Do not use if any sign of product damage is visible.

INSTRUCTIONS FOR USE:

- Gain percutaneous access with entry needle.
- Insert .010" guidewire into the needle hub and advance wire into the vessel.
- Remove the needle, leaving the guidewire in place.
- Thread the introducer over the guidewire.
- Once the introducer is in place, remove the guidewire leaving the sheath and dilator in position.
- Remove the inner dilator from the sheath.
- Insert distal tip of the catheter into and through the introducer sheath until the catheter tip is correctly positioned.
- Remove the tear-away sheath by slowly pulling it out of the tissue while simultaneously splitting the sheath by grasping the tabs and pulling them apart.
- Examine the device after it is removed from the patient to ensure no foreign material remains inside the patient.
- Discard biohazard according to facility protocol.

CAUTIONS:

- Do not pull apart the portion of sheath that remain in the vessel. To avoid vessel damage, pull back the sheath as far as possible and tear the sheath only a few centimeters at a time.
- Never leave sheath in place as an indwelling catheter. Damage to the vein will occur.
- If unable to tear sheath, stop the procedure.

Medcomp® does not recommend a particular technique for the use of this device. The physician should evaluate the appropriateness of the device according to individual patient conditions and his or her medical training and experience.


WARRANTY

Medcomp® WARRANTS THAT THIS PRODUCT WAS MANUFACTURED ACCORDING TO APPLICABLE STANDARDS AND SPECIFICATIONS. PATIENT CONDITION, CLINICAL TREATMENT, AND PRODUCT MAINTENANCE MAY EFFECT THE PERFORMANCE OF THIS PRODUCT. USE OF THIS PRODUCT SHOULD BE IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED AND AS DIRECTED BY THE PRESCRIBING PHYSICIAN.












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5.1.1 	Manufacturer *	5.6.3 	Non-pyrogenic *
5.1.4 	Use-by Date *	5.3.2 	Keep Away from Sunlight *
5.4.2 	Do Not Re-use *	5.2.6 	Do Not Resterilize *
5.3.4 	Keep Dry *	Rx Only	Prescription Use Only ***
5.1.5 	Batch/Lot Number *	5.1.6 REF	Catalogue Number *
5.2.8 	Do Not Use if Package is Damaged *		
5.1.2 	Authorized Representative in the European Community *		
5.2.3 	Sterilized Using Ethylene Oxide *		

* This symbol is in accordance with ISO 15223-1.

*** FDA guidance Use of Symbols in Labeling.

PN 40664BSI

Rev. 11/18 B