MODIFIED SELDINGER TECHNIQUE (MST) KIT
INSTRUCTIONS FOR USE

INDICATIONS FOR USE:

- The 2F and 3F Vascu-Sheath Tearaway Introducer is intended for percutaneous venous access by modified Seldinger Technique in neonates, infants, and children.

DESCRIPTION:

- Tearaway Introducers are available in a variety of lengths and diameters. See product label for specifications. Kit consists of a tear-away introducer, needle, guidewire, and syringe (optional).

CONTRAINDICATIONS:

- This catheter is not intended for any use other than that which is indicated. Do not implant catheter in thrombosed vessels.
- The presence of skin related problems around the insertion site (infection, phlebitis, scars, etc.).
- The presence of device related bacteremia or septicemia.
- Previous history of venous/ subclavian thrombosis or vascular surgical procedures at insertion site.
- Fever of unknown origin.
- The patient's body size is insufficient to accommodate the size of the implanted device.
- The patient is known or is suspected to be allergic to materials contained in the device.
- Past irradiation of prospective insertion site.

Local tissue factors will prevent proper device stabilization and/or access.

POTENTIAL COMPLICATIONS:

- Air Embolism
- Perforation/Trauma of vessel or viscus
- Laceration of vessel or viscus
- Bleeding
- Wire embolism
- Hematoma
- Hemothorax
- Pain in region
- Infection
- Edema
- Pneumothorax

WARNINGS:

- Federal Law (USA) restricts the device to sale by or on the order of a physician.
- 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.
- 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.
- STERILIZED BY ETHYLENE OXIDE STERILE EO
- 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 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
- Remove the dilator and guidewire from the sheath by rotating the dilator ninety degrees counterclockwise to unlock the dilator from the sheath and withdraw the dilator and guidewire 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 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.

*optional to attach syringe to back of needle prior to insertion. Once needle is in vessel, syringe would get removed.

CAUTION:

- Do not pull apart the portion of sheath that remains 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 TREATEMENT, AND PRODUCT MAINTENANCE MAY AFFECT THE PERFORMANCE OF THIS PRODUCT. USE OF THIS PRODUCT SHOULD BE IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED AND AS DIRECTED BY THE PRESCRIBING PHYSICIAN.

Because of continuing product improvement, prices, specifications, and model availability are subject to change without notice. Medcomp® reserves the right to modify its products or contents without notice.

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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 LOT	Batch/Lot Number *	5.1.6 REF	Catalogue Number *
5.2.8 	Do Not Use if Package is Damaged *		
5.2.3 STERILE EO	Sterilized Using Ethylene Oxide *		

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

***** FDA guidance Use of Symbols in Labeling.**

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