SUPER SHEATH INTRODUCER
INSTRUCTIONS FOR USE

INTENDED USE:

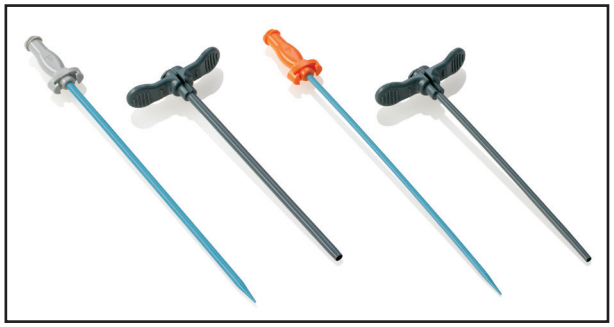
The Super Sheath Introducer is intended to obtain central venous access to facilitate catheter insertion or placing pacing leads into the central venous system. The Super Sheath is compatible with a 0.018" or smaller guidewire.

CONTRAINDICATIONS:

The Super Sheath Introducer is not designed for use in the arterial system or as a hemostatic device.

DESCRIPTION:

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



POTENTIAL COMPLICATIONS:

Potential risks exist for serious complications to include:

- Perforation/Trauma of a vessel or viscus
- Laceration of a vessel or viscus
- Bleeding
- Wire or catheter embolism
- Extravasation
- Hematoma
- Hemothorax
- Hydrothorax
- Inflammation, necrosis or scarring
- Risks normally associated with percutaneous interventional procedures
- Pain in region
- Skin infection
- Edema

WARNINGS AND PRECAUTIONS:

- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Single use only. DO NOT RE-USE. Re-Use may lead to infection or illness/injury.
- Do not advance the guidewire against resistance until the cause of the resistance has been determined.
- Discard biohazard according to facility protocol.
- Product is sterile in unopened, undamaged package. STERILIZED BY ETHYLENE OXIDE STERILE EO
- Do not use if package is damaged.
- Do not resterilize.
- 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.

INSTRUCTIONS FOR USE:

1. Gain percutaneous access with entry needle.
2. Draw the flexible end of the .018" guidewire back into the advancer so that only the end of the guidewire is visible. Insert the advancer's distal end into the needle hub. Advance the guidewire with forward motion into and past the needle hub.
3. Remove the needle, leaving the guidewire in place.
4. Thread the Sheath Dilator over the guidewire. Once the Sheath Dilator is in place, remove the guidewire leaving the sheath and dilator in position.

Caution: DO NOT bend the sheath/dilator during insertion as bending will cause the sheath to prematurely tear. Hold sheath/dilator close to the tip (approximately 3cm from the tip) when initially inserting through the skin surface. To progress the sheath/dilator towards the vein, regrasp the sheath/dilator a few centimeters (approximately 5cm) above the original grasp location and push down on the sheath/dilator. Repeat procedure until sheath/dilator is inserted to appropriate depth based on patient anatomy and physician's discretion.

Caution: Never leave sheath in place as an indwelling catheter. Damage to the vein will occur.

5. Continue performing desired interventional radiology procedure.

REMOVAL:

1. Remove the dilator from the sheath.
2. 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 (a slight twisting motion may be helpful).

Caution: Do not pull apart the portion of the 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.

Caution: If unable to tear sheath, stop the procedure.

Examine the device after it is removed from the patient to ensure no foreign material remains inside the patient.

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.

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 in accordance with all relevant regulatory requirements.

SYMBOL TABLE

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 *		
5.4.4	Caution, consult Accompanying Documents *		

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

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

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