PERCUTANEOUS INTRODUCER SET
INSTRUCTIONS FOR USE

DESCRIPTION:
The Percutaneous Introducer Set is comprised of a guidewire with radiopaque tip, introducer needle, syringe, and a sheath/dilator.

INTENDED USE:
The Percutaneous Introducer Set is used for percutaneous introduction and placement of guidewire or catheter for interventional radiology procedures.

POTENTIAL COMPLICATIONS:

Potential risks exist for serious complications to include:

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

INSTRUCTIONS FOR USE:

1. Gain percutaneous access with entry needle.
2. Insert the guidewire into needle and advance to target site.
3. Remove needle, leaving guidewire in place.
4. Thread the sheath dilator over guidewire into target site.
5. Continue performing desired interventional radiology procedure.
6. Examine the device after it is removed from the patient to ensure no foreign material remains inside the patient.

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

WARNINGS AND PRECAUTIONS:

- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Product is sterile in unopened, undamaged package. STERILIZED BY ETHYLENE OXIDE STERILE EO
- 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.
- Do not use if package is damaged.
- Do not resterilize.
- Discard biohazard according to facility protocol.
- 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.

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 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*		
5.1.2 EC REP	Authorized Representative in the European Community		
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.**