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.
- STERNIZE
- 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.

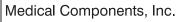
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EC REP

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C E 2797

Keep Dry

Ratch/Lot
Number*

Do Not Use if Package is Damaged

Sterilized Using Ethylene Oxide*

Keep Dry

Ratch/Lot
Number*

Prescription Use Only***

Catalogue Number*

Catalogue Number*

Catalogue Number*

Catalogue Number*

Sterilized Using Ethylene Oxide*

Caution, consult Accompanying Documents*

(K)

Non-pyrogenic

Do Not Resterilize*

Keep Away from Sunlight*

Manufacturer

Use-by Date

Do Not Re-use

(2)

PN 40418BSI Rev. 11/18 B

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

^{***} FDA guidance Use of Symbols in Labeling