INSTRUCTION FOR USE

Invaducer

INTRODUCER SET

1. **PRODUCT NAME**
   INVADUCER INTRODUCER SET

2. **DEVICE DESCRIPTION**
   The INVADUCER is designed to perform as an introducer sheath. The Introducer Sheath Set is a hemostasis valve introducer system that consists of a dilator, guidewire, syringe, and sheath with a hemostasis valve and a sideport on the most proximal end of the sheath assembly. The Introducer Sheath Set is designed to facilitate percutaneous introduction of catheters into the vascular system while minimizing blood loss.

3. **HOW SUPPLIED**
   Sterile: Invaducer Introducer Set is sterile with EtO. Non pirogenite. Do not use if the package is opened or damaged. It is for one use only. Do not sterilize again.
   Storage: Avoid exposure to water, direct sunlight, extreme temperature, or high humidity during storage.

4. **INDICATIONS**
   Invaducer Introducer Set is indicated for use in percutaneous procedures to introduce catheters and other intravascular devices into the vasculature.

5. **CONTRAINDICATIONS**
   Use of the introducer is contraindicated if the patient has a known or suspected obstruction in the vessel. There is increased risk of pneumothorax for the patient who has severe chronic lung disease. The potential complications related to the use of the introducer include, but are not limited to the following: Air embolism, wound infection, intimal tear, perforation of the vessel wall, pneumothorax and subclavian vein thrombosis. Insertion into artery may cause excessive bleeding and/or other complications.

6. **WARNINGS**
   It is for single use only. Do not reuse or resterilize. Reuse or re-sterilization processes may cause structural changes, biological and chemical residues on the device, the device does not work or the device does not work properly and may cause harm to the patient. Reuse or resterilization procedures may result in infection, permanent illness / disability, or death. Do not use after the "expiry date" on the package.

7. **PRECAUTION**

   - Before use, inspect the packaging and device carefully and make sure no damage has occurred during shipping and handling. If packaging is compromised do not use the device.
   - This device must only be used by a trained physician.
   - This product has been sterilized by ethylene oxide gas. For single use only. Do not reuse. Do not resterilize. Do not reprocess. Reprocessing may compromise the sterility, biocompatibility and functional integrity of the device.
   - All components are sterile, non-toxic and non-pyrogenic in an unopened, undamaged package.
   - Do not use if the package or product is stained or damaged.
   - Before use, make sure the sheath size (Fr.) is appropriate for the access vessel and the interventional/diagnostic device to be used.
   - Use the device immediately after opening the package and dispose of the device after use.
   - The entire procedure, from skin incision to sheath removal, must be carried out aseptically.
   - When applying torque to the sheath, a guide wire or the dilator should be inserted.
   - Do not use agents containing organic solvent or oleosus contrast medium directly on this product.
   - Do not wipe off the surface of the device with chemical solution such as alcohol.
   - Do not rapidly and/or forcibly advance or insert the dilator, guide wire and other devices for co-use if the sheath of this product is folded, bended or distorted.
   - Do not heat or bend the sheath tip. Do not apply a boring machine to bore side holes.
   - Damage to the sheath may result.

8. **SIDE EFFECTS**
   - Puncture site hematoma
   - Vessel spasm
   - Vascular thrombosis
   - Bleeding from the vessel

9. **DIRECTIONS FOR USE**
   1) Peel open package and place contents on sterile field. Inspect catheter introducer sheath and accessories for defects To remove air, flush the dilator, catheter introducer sheath and sideport with normal saline solution. Prep skin and drape in area of anticipated puncture site as desired. Insert needle cannula into vessel. The needle position should be verified by observing blood return. The angle of the needle should be adjusted depending on the patient's build: shallow in a thin person, deeper in a heavyset person. Aspirate the puncture needle using a syringe.
   2) Remove the syringe and insert the soft tip of the guidewire through the introducer needle into the vessel. Advance guidewire to required depth. Leave an appropriate amount of guidewire exposed. At no time should the guidewire be advanced or withdrawn when resistance is met. Determine the cause of resistance before proceeding. Fluoroscopic verification of the guidewire location is suggested.
   3) Hold guidewire in place and remove introducer needle. Do not withdraw the guidewire back into the cannula as this may result in separation of the guidewire. The cannula should be removed first. Do not allow guidewire to advance totally into patient.
   4) Assemble the introducer system by carefully inserting the dilator completely into the sheath introducer. Firmly push the snap fit ring on the dilator into the sheath valve cap. When using an introducer with a sideport, follow standard hospital practice for using a continuous drip of normal saline solution through the sideport while the hemostasis introducer is in the vessel.
   5) While holding the catheter introducer system close to the skin, advance the dilator and sheath together with a twisting motion over the guidewire and into the vessel. Fluoroscopic observation maybe advisable. Attaching a clamp or hemostat to the proximal end of the guidewire will prevent inadvertently advancing the guidewire entirely into the patient.
   6) To detach the dilator from the sheath cap, push the dilator hub to one side until it becomes detached. Remove the vessel dilator and guidewire, leaving the sheath as a conduit into the vessel. Introduce the selected catheter or other device into the sheath using the instructions provided by the manufacturer of the catheter or other device, and standard hospital practice.
   7) To change catheters, slowly withdraw the catheter from the vessel and repeat the insertion procedure. When removing the catheter, aspirate via the sideport extension to collect fibrin that may have been deposited at the tip of the sheath.
   8) This procedure should only be performed by physicians thoroughly trained in this procedure.

10. **SHELF LIFE**
    When preserved under specified conditions, the product has a shelf life of 36 months after the date of manufacture. It is not used after the expiry date.

11. **DESTRUCTION**
    Dispose of the Invaducer Introducer Set according to standard institutional procedures for medical waste, including single use, blood contact devices.

12. **WARRANTY DISCLAIMER AND LIMITATION OF SOLUTION**
    There are no express or implied warranties for the INVAMED product (s) described in this publication, including without limitation the implied warranty of merchantability or fitness for a particular purpose. Under no circumstances will INVAMED be liable for any direct, incidental or consequential damages other than those expressly stated in the specific law. Nobody has the authority to represent or guarantee INVAMED other than the one specifically stated here. With this publication, the definitions or specifications in the INVAMED printed material are only for the general introduction of the product at the time of manufacture and do not constitute any express warranty.
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13. DESCRIPTION OF LABEL / MARKING

MANUFACTURER:
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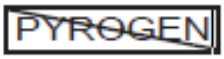
	Etilenoxide
	Read instruction before use
	Do not use if the product is damaged or package is already.
	Fragile
	One usage
	Pat attention to label warnings
	Production Date
	Cannot Sterile Second Time.
	Keep away from sunlight.
	Keep at the temperature of 5- 24c°
	May create potential biological waste after use.
	Reference Number
	Expiration Date
	Keep in dry place
	Lot Number
	Manufacturer
	Non Pyrogen
	Dispose according to medical waste regulations