Introducer Set

INDICATIONS FOR USE

The introducer set is intended for percutaneous introduction of guide wire or catheter into the vascular system through introducer needle. The introducer set should be used only by physicians trained in percutaneous, intravascular techniques and procedures.

CONTRAINDICATIONS

Use of introducer set is contraindicated if the patient has a known or suspected obstruction in the subclavian vein. There is increased risk of pneumothorax for the patient who has severe chronic lung disease. Poor healing may result in the patient who has had irradiation to the anterior chest.

Potential adverse events that may occur during or after a procedure using balloon inflation device

Including but are not limited to:

1. Air embolism
2. Wound infection
3. Intimal tear
4. Subclavian artery puncture
5. Pneumothorax
6. Subclavian vein thrombosis
7. Bleeding
8. Cardiac arrhythmia
9. Hematoma formation
10. Hemothorax/hydrothorax
11. Thoracic duct injury
12. Vessel erosion/occlusion
13. Laceration or perforation of a vessel
14. Guidewire shearing, fracture or embolization
15. Hematoma formation
16. Inflammation, necrosis or scarring
17. Skin jnfection
18. Pain in region

Digitally signed by Jighili Tatiana
Date: 2022.10.08 14:17:31 EEST
Reason: MoldSign Signature
Location: Moldova

STORAGE AND TRANSPORT

Store in a dry, dark, cool place.

PRECAUTIONS AND WARNINGS

READ INSTRUCTIONS PRIOR TO USE.
DO NOT USE IF THE UNIT PACKAGING OR THE PRODUCT HAVE BEEN DAMAGED OR SOILED.

1. For single patient use only. Don't reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

2. Do not use alcohol, acetone or solutions containing these agents.
3. These solutions may affect the properties of the plastic components resulting in degradation of the device.
4. Do not reuse this device.
5. Do not withdraw guide wires through introducer needles; guide wires may shear or unravel.
6. Do not alter this device.
7. Do not advance or withdraw a guide wire against resistance until the cause of the resistance has been determined. Excessive force against resistance may result in guide wire damage or vessel perforation.
8. Do not attempt to disengage the locking mechanism.
9. The device has not been evaluated for use in the neuro vasculature.
10. This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.
11. Use the device prior to the “Use By” date specified on the package
12. Movement of the device against resistance may result in damage to the device or vessel perforation.
13. Do not use a guide wire larger than the maximum diameter specified on the package label.
14. Individual patient anatomy and physician technique may require procedural variations.
15. Insertion into artery may cause excessive bleeding and/or other complications.
16. Do not advance or withdraw the guide wire against resistance. Determine the cause of resistance before proceeding.
17. Do not withdraw the guide wire into the cannula of the needle, as this may result in separation of the guide wire. If the guide wire must be withdrawn while threaded through the introducer needle, remove both the introducer needle and guide wire as a unit to prevent from damaging or shearing the guide wire.

INSTRUCTIONS FOR USE

Preparation for USE

1. Open package using sterile technique and place contents onto sterile filed.
2. Prepare the skin and drape the area of the anticipated puncture.

Deployment Procedure

1. Insert the introducer needle into the vein or artery and verify position by observing blood return. Adjust the angle of the needle to accommodate the patient’s build: shallow angle in a thin person, deeper angle in a heavyset person.
2. Aspirate the introducer needle using a syringe.
3. Remove syringe and insert soft, floppy tip of the guide wire through the introducer needle and into the vessel. Advance guide wire to required depth while leaving enough of the guide wire outside the body.
4. While holding the guide wire in place, slowly remove the needle by threading back over the guide wire.
5. Thread the dilator or introducer sheath over the guide wire.
6. Advance the dilator set or introducer sheath using a twisting motion over the guide wire and into the vessel. Use fluoroscopy or ultrasound to confirm position.
7. Remove the inner dilator and guide wire together.

MAINTENANCE

1. To keep the clear of the introducer set.
2. The operation should according to the principle of aseptic strictly.
3. To observe whether there is abnormal situation or not.

GRAPHIC SYMBOLS CONTAINED IN DEVICE LABELING


Keep dry


Do not use if package is damaged


Consult operating instructions


Keep away from sunlight


Date of Manufacture

Sterilized using ethylene oxide

Lot number


Do not reuse

Do not resterilize


Attention, see instructions for use

Catalog number


Use by

CE Mark


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