

VENOUS INTRODUCERS

Medical Devices class: IIa
CE marking : 2000

Products references:

- 4010xx: standards venous introducers
- 4320xx peel away venous introducers

Product sterilized by ethylene oxide

Sterile product as long as the packaging hasn't been opened, or broken.

Single use product

WARNING: Don't resterilise

WARNING: Store in a cool and dry place with ambient temperature. Avoid extreme temperatures and humidity.

Conserve in the original packaging.

WARNING: Read carefully instructions before using.

WARNING: Shelf life. Use this device before the expiration date indicated on the package.

VENOUS INTRODUCER DESCRIPTION AND USE:

The venous introducer is made to permit to introduce a catheter in the venous blood flow. It is composed of a dilatator and a sheath (standard or peel away) in polyethylene tube.

The standard venous introducer is used to introduce temporarily using catheters which will be taken off of the patient body before the introducer itself.

The peel away sheath venous introducer is used to introduce short or long term using catheters (implantable device).

The introducer sheath is striped and its hub is divisible.

So it can peel this sheath after broken his hub which allows its extraction without take off the catheter putted in place.

It is provided in standard with a puncture needle and a spiral guide wire.

WARNING: Do not use in other than venous system.

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. Poor healing may result in the patient who has had irradiation to the anterior chest.

CAUTIONS:

1. This procedure should only be performed by physicians thoroughly trained in this procedure.
2. If resistance is met when advancing or withdrawing the guidewire or the introducer, determine the cause by fluoroscopy and correct before continuing with the procedure.

3. Because of the delicate and fragile nature of guidewires, extra care in handling must be taken.

4. Do not use forceps to break the handle and/or to peel the sheath as this may damage the sheath and cause premature withdrawal of the sheath from the patient.

5. Do not attempt to use a guidewire over the maximum diameter specified on the package label.

6. Individual patient anatomy and physician technique may require procedural variations.

7. Insertion into artery may cause excessive bleeding and/or other complications.

8. Symmetrical peeling of the sheath is critical.

THE VENOUS INTRODUCER PLACING: SELDINGER METHOD

WARNING: The biggest careful has to be brought on the manipulation's ASEPSIS.

WARNING: Check the integrity of the sterility protector primary packaging. Never use a device which primary packaging is damaged.

WARNING: Check that the introduction area doesn't present any infection sign (red blotches, local inflammation or pain at the palpation).

Fluoroscopic observation is advisable during all the procedure.

1. Vascular puncture

Assemble the supplied puncture needle on a Luer Lock syringe.

Fill it on half with sterile physiological serum.

By a continuous movement, introduce the needle in a sufficient depth to reach the vessel to puncture.

Exercise a weak traction on the syringe piston to maintain this one in depression.

As soon as the needle bevelled edge reach the vascular lumen, a blood rush appears in the syringe.

WARNING: Check the vessel type punctured (arterial or venous), checking the blood reflux colour and the pressure.

2. Putting into place of the spiral guide wire

After disconnecting the syringe, introduce by his soft tip the spiral guide wire corresponding to the needle in the lumen of this needle, on some cm.

3. Needle removal

Take off the needle, immobilising the spiral guide wire.

At this effect, it can retain its endovascular distal extremity compressing it with the finger through the tissues if the vessel is superficial; otherwise it maintains the proximal extremity free.

Do not withdraw the guidewire back into the cannula as this may result in separation of the guidewire. The cannula should be removed first.

Immediately after the needle withdrawal, exercise compression at the level of the vascular puncture point in order to realise the homeostasis.

Then, at the cutaneous emergency point of the guide wire, it practices a short skin incision on 2 to 3 mm, to make easier later the venous introducer penetration.

4. Introducer placing

The introducer is inserted over the guide wire until it comes in stop on the skin.

WARNING: From this moment and during the moves that will follow, check that the guide wire passes always of some centimetres of the proximal hub.

The dilatator taken in hand at some cm of the skin is pushed progressively across the tissues in a spiral movement around the guide wire.

Then the sheath is pushed in a spiral movement around the dilatator to come catheterise the vessel.

While holding back the sheath, the guide wire and then the dilatator are taken off.

Immediately place a finger over the remaining sheath orifice to prevent excessive bleeding or possible air aspiration.

The vascular access is from now free to accept the planned catheters.

5. Sheath withdrawal

For the normal venous introducer, take off the sheath as soon as the catheter is taken off.

For the peel away sheath introducer, break the sheath divisible hub and take out slowly stage by stage the sheath peeling it as one goes along.

WARNING: Check during the sheath peeling that it is well peeled following its stripes.

WARNING: Do not peel the sheath while it is still inside the vessel.

POTENTIAL COMPLICATIONS:

The potential complications related to the use of the introducer include, but are not limited to the following: Air embolism, wound infection, intimal tear, subclavian artery puncture, pneumothorax, subclavian vein thrombosis.

WARNING: Observe regulations for disposal of contaminated instruments

WARNING: Re-use of the device could result in leakage, increased risk of infection or other improper functioning of the device.

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The materials of introducers are:










- dilator = PE+PP,
- sheath = PE,
- needle= SS + SBC,
- guide wire = SS



ZAE Les Pointes
230, rue des Grands Prés
60230 Chambly - FRANCE

Tel : +33 (0)1.30.28.43.07

www.isomedfrance.fr

 <p>EN: Do not use if the packaging is damaged FR: Ne pas utiliser si l'emballage est endommagé DE: Nicht verwenden, wenn die Verpackung beschädigt ist ES: No utilizar si el embalaje está deteriorado</p>		<p>EN: Reference number FR: Numéro de référence DE: Bestellnummer ES: Número de referencia</p>	 <p>EN : Manufacturing date FR : Date de fabrication DE : Herstellungsdatum ES : Fecha de fabricación</p>
 <p>EN: See instruction for use FR: Lire la notice DE: Anleitung lesen ES: Consulte las intrucciones de uso</p>		<p>EN: Single use FR: Usage unique DE: Zum einmaligen Gebrauch ES: De un solo uso</p>	 <p>EN: Use by FR: À utiliser avant la date DE: Verfallsdatum ES: Utilizar antes de</p>
 <p>EN: Sterilized by Ethylene Oxide FR: Stérilisé à l'oxyde d'éthylène DE: Mit Ethylenoxid sterilisiert ES: Esterilizado con óxido de etileno</p>		<p>EN: Manufactured by FR: Fabriqué par DE: Hergestellt von ES: Fabricado por</p>	 <p>EN: Batch code FR: Numéro de lot DE: Chargennummer ES: Número de lote</p>