

INTRODUCER SHEATH USER GUIDE

Manufacturer :
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Product Name :
Introducer Sheath

Description :
The Gemed intravenous set consists of an introducer sheath, dilator, guide wire, puncture needle and syringe. It is used to facilitate percutaneous access of the device.

Sheath:



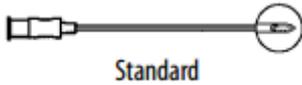
Dilator:



Guide Wire:



Seldinger needle:



Syringe:



Purple Red Grey Green Orange Blue Black

Purpose of Use :

The Introducer System is indicated for use in percutaneous procedures to introduce catheters and other intravenous devices into the vascular system.

Indications :

To facilitate placement of the first angioma during angiography and intervention and the advancement of all other materials through it.

Contraindications :

- The use of Introducer is contraindicated if the patient has a known or suspected obstruction in the vein.
- Patients with severe chronic lung disease have an increased risk of pneumothorax

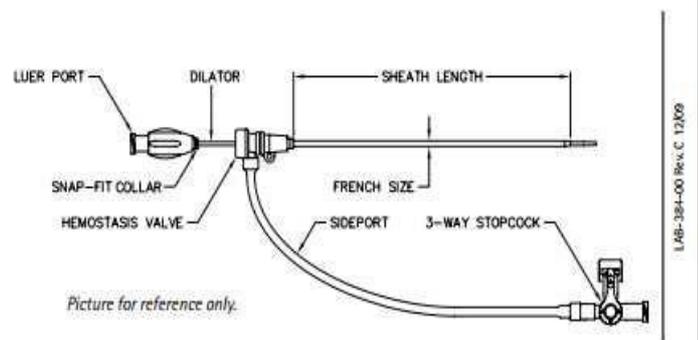
Instructions for Use :

Preparation of sheath:

1. Make sure that the correct size (diameter and length) is selected.
2. Remove the Introducer Sheath from its packaging and examine it for possible damage or malfunction. Do not use any damaged or defective product.
3. Pass intravenous fluid through the dilator, introducer sheath and side port to heparin.
4. Consider using an intravenous fluid flow with a continuous heparin under pressure applied through the side port connection at a time when the sheath will stay in a vein for a long time.

Use Case:

1. Fully insert the dilator end cap into the sheath until the dilator hub contacts the hemostasis valve.



In this way, be sure that the cone portion of the dilator goes beyond the end of the sheath.

NOTE: When advancing the sheath, make sure the dilator is fully inserted into the sheath and that the dilator hub is in contact with the hemostasis valve.

2. Follow normal accepted practice for vascular puncture or incision and guidewire entry.
3. Guide the dilator / sheath as a unit over the guidewire in the guideline of fluoroscopy; do not allow the dilator to come back out of the sheath. If resistance is encountered, stop driving ahead. Investigate the cause of resistance before continuing. Carefully proceed as far as possible to the desired position. To avoid damage to the sheath or vessel, proceed by gently turning the dilator / sheath assembly.
4. Keep the case stationary and protect the position of the guide wire until it is fully retracted from the guide bar when retracting the dilator from the guide over the guide wire.
5. While maintaining the guidewire position, push the selected catheter or other interventional medical device through the guidewire into the sheath, taking care to keep the sheath assembly as straight as possible out of the body and avoid twisting.
6. Care should be taken to keep the position of the guiding wire and sheath in the vascular system correct while replacing the different catheters and devices by means of the introducer sheath.
7. Carefully support all wires, catheters, and devices when pushing across the hemostasis valve.
8. Precautions should be taken to prevent bleeding, damage to the vagina or other serious injuries after removal of the sheath.

Pre-Use Control and Precautions :

- Check the expiry date of the product.
- Check that the product package is not torn / punctured.
- Do not expose to organic solvents.
- When advancing the dilator and introducer sheath, do not pull suddenly to avoid damage to the vein or sheath.
- Check that the cutter and drill bit parts in the package damage other product parts or do not tear or tear the package.

Packaging:

Products are placed on a specially designed blister tray and packaged in a non-breathable manner.

Storage :

Store the product in the original package at temperatures between 15 oC and 30 oC, protected from direct sunlight and moisture.

WARNINGS

- Introduser sheath is sold sterile only for single use. Do not use it again and do not sterilize it. Re-use of a single-use device can put the structural integrity of the device in jeopardy and can pose a risk of disease-causing infection or cause serious patient injury.
- Do not pull the introducer sheath, which may occur when moving the device through the vein. It may cause damage to the device or vascular perforation.
- Introduser sheath guide wire is not intended to be used, may cause vascular injury.
- Check the expiry date of the product before unpacking, we do not use products with expiration date is not guaranteed.

EXPLANATION OF SAMPLES

Manufacture Name and Information



Production Date



Expire Date



Lot Number



Disposable Product



Do Not Sterile Twice



Sterilized by Ethylene Oxide



Read User's Guide



Warning



Protect form humidity



Protect form sunlight



Do not use packing damaged product.



Temperature Lower-Upper Limit

93/42/EC Medical Device Directive
Compliance Mark and CE Approved
Identification Number