Introducer Set

Intended Use

The INT Introducer set is intended to provide access and facilitate the introduction of guide wire and catheters through the skin into femoral or radial artery while minimize blood loss during interventional procedures.

Device Description

The Introducer Set is supplied with an introducer sheath, a dilator, a guidewire and an access needle. These devices will be manufactured in 5.0, 6.0, 7.0, and 8.0 French and in lengths of 5, 7 and 11 centimeters. The sets are compatible with the supplied 0.018", 0.021'' guidewire and 21G needle in length of 7cm. The sets are supplied sterile and intended for single use.

The sheath shaft and hub are manufactured of Fluorinated ethylene propylene and copolyester; one-piece construction of the sheath shaft and hub allows smooth passage of medical devices. The hub, color-coded by French size, contains a hemostatic valve to prevent blood leakage during a procedure. A side tube equipped with a three-way stopcock is attached to the sheath hub. The side tube extension may be used for fluid and medication administration, as well as blood sampling.

The dilator is an open, tapered plastic tube with an integral luer hub for guidewire insertion.

The guidewire is inserted into the introducer sheath to facilitate and support entry of the sheath into the patient's vasculature. The dilator is longer than the sheath with a rounded tapered distal tip. The dilator tubes are manufactured of polypropylene. Dilator tubes are press-fit into the dilator hub with a bushing. The sheath hub and dilator hub lock using a rotating motion.

Introducer Set is designed specifically to introduce therapeutic or diagnostic devices into the vasculature. Using the Seldinger technique, the physician gains percutaneous access to the vascular system and then employs the introducer sheath as a conduit for inserting diagnostic and/or interventional devices into the patient.

Contraindication

Radial access is contraindicated if there is an abnormal Allen's Test, radial pulse, or insufficient dual arterial supply.

Warnings

- The Introducer Set is provided sterile for single use only. Reuse of a single -use device creates a potential risk of patient or user infections and may compromise device functionality, which may lead to illness or serious patient injury.
- Prior to beginning radial artery access, an assessment such as the Allen's test should be performed to access the presence/adequacy of dual arterial circulation to the hand.

- Do not leave the introducer in place for extended periods of time without a catheter or obturator to support the cannula wall.
- The device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.
- Don’t repackage and sterilization more than once.
- After use,dispose of product and packaging in accordance with hospital,administrative,and/or local government policy.

Precautions for use

- Do not use the Introducer Set if the package is damaged.
- Before use, make sure the sheath (Fr.) and dilator size are appropriate for the access vessel and the system to be used.
- Apply appropriate anticoagulant therapy to the patient.
- This product is intended for use by physicians trained and experienced in proper vascular access techniques.
- Do not advance and withdraw an intravascular device against resistance until the cause of the resistance has been determined.
- Use the device prior to the “Use By” date specified on the package.
- Federal Law restricts this device to sale by or on the order of a physician Device
- Compatible device and Recommend size

Introducer set	Guiding catheter	Angiography catheter	Guidewire
5F	5F	5F	≤0.038"
6F	6F	6F	≤0.038"
7F	7F	7F	≤0.038"
8F	8F	8F	≤0.038"

Potential complication

- Vessel perforation or injury
- Vascular variation, passing difficulties
- Vascular tortuosity, passing difficulties
- Puncture site hematoma
- Artery occlusion
- Febrile reaction
- Hemorrhage
- Infection
- Intimal tear,
- Thrombus formation,

- Cardiac arrhythmia,
- Cardiac tamponade.
- Myocardial ischemia and/or infarction
- Vascular thrombosis

Preparations for use

- Prior to use, carefully inspect the Introducer Set packaging and components for damage.
- Utilizing sterile technique, remove the Introducer set from its packaging and transfer to the sterile field.
- Prior to insertion, flush the needle with saline heparinized/saline.
- Inset the dilator through the sheath, and observe that the distal tip of the dilator is exposed beyond the distal tip of the introducer sheath.

Instruction for use

- Prepare the skin, disinfect, spread towel, and place gauze at the puncture site.
- Insert the puncture needle into the blood vessel at an angle of 30-45 degrees until bright red blood flows from the tail of the needle to ensure that it enters the correct blood vessel site.
- Insert the guide wire into the needle and advance it to the desired depth.
- Hold the guide wire firmly and remove the puncture needle.
- Insert the dilator into the introducer sheath.
- Pass the head of the dilator through the guide wire, hold the dilator close to the skin, and gently turn it to push it into the blood vessel.
- Grasp the introducer sheath and pull out the guide wire and dilator.
- The catheter is introduced into the blood vessel through the catheter sheath and placed in the appropriate position. Secure the introducer sheath with sutures if necessary.
- After the operation, remove the catheter sheath, and then stop the bleeding at the puncture site.

Storage Conditions

The product should be prevented from sun and rain, and should be saved in the environment with shade, dryness and cleanness.

Shelf-life

Three years

Manufacturer

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	Use by date	2607	ISO 15223-1	Medical devices Symbols to be used with medical devices labels, labeling, and information to be supplied -Part 1:General requirements	To indicate that the device should not be used after the date accompanying the symbol, for example on amedical device or its packaging.
	Batch code	2492	ISO 15223-1	Medical devices Symbols to be used with medical devices labels, labeling, and information to be supplied -Part 1:General requirements	To identify the manufacturer's batch or lot code, for example on a medical device or the corresponding packaging. The code shall be placed adjacent to the symbol.