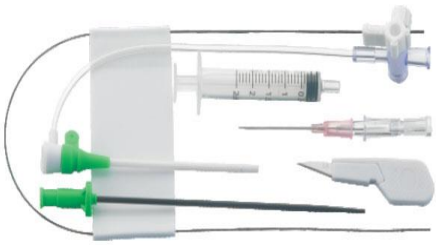
Instruction for Use



Introducer Set

Variant	: Radial/Femoral
Product Class as REGULATION(EU)2017/745	: IIa
Product Class as per Medical Device Rule 2017	: C
Duration of use	: Short Term

DESCRIPTION

It is a combination of sheath, dilator & other accessories. It is available in different sizes as per the requirement. it is used to facilitate the catheter to enter through a haemostatic valve which does not allow the blood to flow in the reversed direction.

The major components of the Introducer Set are;
Introducer Sheath-HDPE, Dilator-PAPS, Introducer Needle-SS 304, Guidewire SS 304 NT/Hydrophilic Guidewire etc..

The device does not contain;

- DEHP
- medicinal substance, including a human blood or plasma derivative,
- tissues or cells, or their derivatives, of human origin
- tissues or cells of animal origin, or their derivatives.

Patient Target Group: All Age groups.

Product Packaging

- The product is available in non-toxic, medical-grade, sterile packing, that allows for maintaining product sterility to the point of use and to maintaining aseptic presentation.
- The product is a single-use device.

INTENDED USE

Introducer sheaths are used, when there is need for larger catheters, such as for rapid volume administration or for the insertion of pulmonary artery catheter.

MODE OF ACTION:

Introducer Set, is a combination of Introducer sheath & dilator along with other accessories assembled together in a tray to form a functional unit.
Introducer sheath is placed using a seldinger technique in to a femoral & central vein; the internal jugular, subclavian & radial veins are most commonly used.
It is encasing device used in vein or artery, during different cardiac procedures. They assist the catheter to be advanced towards the heart through the vein or the artery.

INDICATION FOR USE

Pre-application

- Examine the extremities of the patient thoroughly.
- Make the site aseptic and anesthetize as clinically required.
- Take out all the components of the product from its packaging under sterile conditions.
- Use saline for flushing. After having flushed the side port extension tube with its stopcock, turn off the stopcock to prevent blood from flowing out when inserting into the blood vessel.
- Leak test or other necessary testing are advised prior to use.

Application

- To be pre-decided by the end user to use 4 Fr (violet), 5 Fr (grey), 6 Fr (green), 7 Fr (orange), 8 Fr (blue) or 9 Fr (black) depending upon vessel size.
- Prepare and drape puncture site with Puncture needle.
- Advance the guide wire spring through guide wire introducer needle into vein.
- Advance guide wire to required depth. Advancement of J" tip may require a gentle rotating motion. Straighten the" J" tip by retracting the guide wire into the dispenser tip straightened. When the tip is straightened, the guide wire is ready for insertion. Centimeter marks are referenced from "J "end. One band indicates 10 cm, two bands 20 cm, and three bands for 30 cms.
- Hold guide wire in place and remove introducer needle for the catheter.
- Maintain firm grip on guide wire at all time. Use centimeter markings on guide wire to adjust indwelling length.
- Product must not be re-sterilized. The re-sterilization of the device will alter mechanical and chemical properties, inappropriate of intended use and also increase the EO residue on device.

INTENDED USERS:

- Product is recommended to use by qualified medical/paramedic staff.

CONTRAINDICATION

- This device is not designed, sold, or intended for use except as indicated.
- 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.
- Previous radiation therapy.
- The Patient is known or is suspected to be allergic to materials contained in the device.

CLINICAL BENEFITS:

- Flexible hub minimizes potential for kinking of introducers
- Suture point facilitates skin fixation
- Profiled sheath tip and matched dilator is designed to facilitate a smooth atraumatic insertion
- Dilator luer locking collar secures dilator to sheath hub during insertion
- Latex free, self-sealing hemostasis valve is designed to minimize the risk of blood loss
- Short and strong dilator for optimal insertion performance.
- Smooth tapers and tip transitions allow consistent and controlled vascular access
- Robust hemostatic valves minimize back bleeding and air aspiration

CAUTION/WARNING

- Do not use the product if the package is damaged or open.
- Do not cut guide wire. Use vessel dilator in place to enlarge site as required. Do not leave vessel dilator in place as an indwelling catheter to avoid possible vessel wall perforation.
  Although the incidence of guide wire failure is extremely low, the practitioner should be aware of the potential for breakage if undue force is applied to the wire. The sheath included in this kit has been designed to freely pass over the guide wire. If resistance is encountered when attempting to remove the guide wire after sheath placement, the guide wire may be kinked around the tip of the catheter within the vessel. In such a circumstance, pulling back the guide wire may result in guide wire breakage due to undue force being applied. If resistance encountered, withdraw the sheath relative to the guide wire about 2-3 cm and remove the guide wire.
- Verify that the entire guide wire is intact upon removal.
- After guide wire has been removed and the necessary lines have been connected or locked, spread wings of rubber clamp and position on catheter as required to ensure proper tip location. Snap rigid fastener onto catheter clamp. Secure catheter to the patient by suturing the suture wing to the skin, using side wings to prevent catheter migration.
- Dress the puncture site after the procedure.
- Troubleshooting: User Paramedic staff should be aware & able to troubleshoot the certain complications may occur during the application of the product such as;
  - Kinked introducer
  - Leak/ splash
  - Difficult to Remove unraveled material

RISKS OF RE-USE

- A device designated, as 'single-use' must not be reused. It should only be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient.
- The reuse of single-use devices can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risk.
- The reuse of single-use devices has legal implications:
  - Anyone who reprocesses or reuses a device intended by the manufacturer for use on a single occasion, bears full responsibility for its safety and effectiveness.
  - Anyone who reprocesses a single-use device and passes it to a separate legal entity for use, has the same legal obligations under the Medical Devices Regulations as the original manufacturer of the device.
- Reprocessing a single-use device may alter its characteristics so that it no longer complies with the original manufacturer's specifications and, therefore, the performance may be compromised.

STORAGE

Based on the stability study report as per ICH guidelines the recommended storage condition in between Temp 15˚C to 40˚C and maintaining the relative humidity condition 50 to 75%. In case of any tempering in the packaging, the product condition may be affected even incase store at above defined condition.
Product Sterility is valid for three years, from the manufacturing of the product.

DISCLAIMER

The condition of the device must be verified prior to use. BL is not responsible for any damage to person, property, etc. from any inappropriate or recommended use of the device, including reuse. Reuse could cause infection or serious health issues.

DISPOSITION

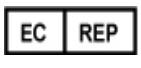
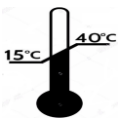
Dispose off/Discard the used Device, in accordance with your country's health care and safety regulations.

GOODS RETURN POLICY

Refer to the company's return goods policy.
Please contact the branch office or customer service at blls@bllifesciences.com or call +91 11 45100100.

Company Website Link to product IFU: https://www.bllifesciences.com

SYMBOLS USED ON PRODUCT LABEL

Symbol			
Meaning	Caution	2460 Conformity of European Norm with Notified Body Number	Manufacturer
Symbol			
Meaning	Do not re-use	Use-by date	Date of Manufacture
Symbol			
Meaning	Batch/Lot Number	Authorized representative in the European Community	Sterilized using ethylene oxide Single sterile barrier system
Symbol			
Meaning	Do not resterilize	Consult Instruction for use	Non-pyrogenic
Symbol			
Meaning	Do not use if package is damaged	Catalogue number	Temperature Limit

Symbol			
Meaning	Fragile, handle with care	Keep dry	This way up
Symbol			
Meaning	Keep away from sunlight	Stacking limit by number	
Symbol	MD	UDI	
Meaning	Medical device	Unique Device Identifier	

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