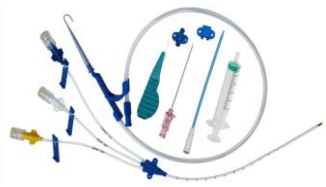
Instruction for Use

Central Venous Catheter Kit



Variant	**:** Single/Double/Triple/Quadruple Lumen
Product Class as REGULATION (EU) 2017/745	: III
Product Class as per Medical Device Rule 2017	: C
Duration of use	: Short Term

DESCRIPTION

CVC is designed with a soft & conical tip that ensures, Atraumatic, safe & easy insertion. Radiopaque catheter & Length marking ensures accurate placement. Kink-resistant Nickel-Titanium Guidewire with soft & flexible J tip offers better torque which helps in easy insertion & Prevents vessel perforation.
The major components of the Central Venous Catheter Kit are;
Catheter- PU, Dilator-HDPE/PP, Syringe-PP/Silicon, Introducer Needle-SS 304, Scalpel- SS 304, Guidewire- SS 304 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

CVC is used for catheterization of Superior Vena cava using seldinger technique in infusion therapy or parenteral nutrition, application of vein irritating solutions, for intermittent or continuous monitoring of central venous pressure & for blood sampling.

MODE OF ACTION

The central venous catheter placement procedure begins with administering local anesthesia to numb the selected area for catheter insertion. The seldinger technique is most common method to use while placing the central venous catheter. Central Lines are used on the following veins:

- Internal Jugal Vein
- Subclavian Vein
- Femoral vein

Central venous Catheter Kit is a combination of a Catheter, dilator, Introducer Needle, scalpel & other accessories assembled together in a tray to form a functional unit. This functional unit is sterilized by Ethylene Oxide, as a "single unit sterile pack".

Central Venous Catheters are placed in chosen vein cannulated with a needle, a guidewire is inserted to maintain a tract through the skin in to the vein, and the catheter is then inserted over the wire in to vein before the guidewire is removed in the patient with multiple, incompatible intravenous (IV) medications with limited peripheral access.

Ultrasound may be used to determine the exact site on the body where the catheter will be placed. The catheter is advanced in to the central vein until the tip of the CVC reaches the right atrium.

INDICATION FOR USE

Pre-application

- Ensure fluid runs freely, through the lumens and there is no blockage.
- If possible, take a chest X-ray (ideally erect) to check the position of the catheter tip and to exclude a pneumo, hydro or haemothorax. An early radiograph may not show up the abnormalities and it may be best to wait 3-4 hours unless symptoms develop.
- Ensure that the patient will be nursed and their catheter can be supervised. Give appropriate written instructions regarding how and what it is to be used for.

Application

- Position patient as clinically indicated to reduce risk of potential air embolus.
- Prepare and drape Puncture site as required.
- Prepare the catheter for insertion by flushing each lumen.
- Clamp extension lines or attach injection caps to the appropriate lumen extension. Leave the distal lumen extension uncapped for guidewire passage.
- Insert introducer needle supplied with attached syringe into vein and aspirate. Assure a good flow of venous blood is established.
- The color of the blood aspirated is not always a reliable indicator of venous access because of the potential for inadvertent arterial placement. Verify venous access via a wave from obtained by calibrated pressure transducer. If hemodynamic monitoring equipment is not available to permit transducing a central venous wave from, disconnect the syringe and check for pulsatile flow. Pulsatile flow is usually an indicator of inadvertent dispenser.

  Detail of colour use – Blue – Proximal end
  Yellow – Medial end
  White – Distal end
- Using the guidewire advancer, guidewire spring through guidewire introducer needle into vein. Advance guidewire to the required depth. Advancement of J" tip may require a gentle rotating motion.
- Do not cut guidewire to alter length. Do not withdraw guidewire against needle level to avoid possible damaging of guidewire.
- Straighten the" J" by retracting the guidewire into the dispenser tip straightener. When the tip is straightened, the guidewire is ready for insertion. Centimeter marks are referenced from "J "end. One band indicated 10 cm, two bands 20 cm, and three bands 30 cm.
- Hold guidewire in place and remove introducer needle for catheter.
- Maintain firm grip on guidewire at all time. Use centimeter markings on guidewire to adjust indwelling length according to desired depth of indwelling catheter placement.
- Enlarge cutaneous puncture site with cutting edge of scalpel positioned away from the guidewire.
- Do not cut guidewire. 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.
- Thread tip of catheter over guidewire. (Sufficient guidewire length must remain exposed at hub end of catheter to maintain firm grip on guidewire) Grasping near skin, advance catheter into vein with slight twisting motion. PRECAUTIONS: Suture wing and clamp must not be attached to catheter until guidewire is removed.
- Using cm marks on catheter as positioning reference points, advance catheter to final indwelling position. Record indwelling catheter length on patients' chart and check position routinely.

- Hold catheter at desired depth and remove guidewire.
  Although the incidence of guidewire failure is extremely low, practitioner should be aware of the potential for breakage if undue force is applied to the wire. The catheter included in this product has been designed to freely pass over the guidewire. If resistance is encountered when attempting to remove the guidewire after catheter placement the guidewire may be kinked about the tip of the catheter within the vessel. In this circumstance, pulling back on the guidewire may results in undue force being applied resulting in guidewire breakage. If resistance is encountered, withdraw the catheter relative to the guidewire about 2- 3 cm and attempt to remove the guidewire. If resistance is again encountered remove the guidewire and catheter simultaneously.
- Verify that the entire guidewire is intact upon removal.
- Check lumen placement by attaching a syringe to each lumen extension and aspirate until free flow of blood is observed. Connect all lumen extension to appropriate Luer Lock lines (s) as required. Unused port(s) may be "locked" through injection cap(s) using standard hospital protocol. Slide clamps are provided on lumen extensions to occlude flow through each lumen during line and injection cap change.
  To avoid damage to lumen extension verifies venous access via a wave from obtained by a calibrated pressure transducer. If hemodynamic monitoring equipment is not available to permit.
- Secure and dress catheter temporarily.
- Verify catheter tip position by chest x-ray immediately after placement.
  For central venous placement, x-ray exam must show the catheter located in the right side of the mediastinum in the SVC with the distal end of the catheter parallel to the vena cava wall and its distal tip positioned at a level above either the azygos vein or the carina of the trachea, whichever is better visualized. If catheter tip malposition, reposition and re-verify.
- Secure catheter to patient using integral hub suture holes or movable suture wings and clamp.
  Do not suture directly against the catheter tubing to avoid cutting or damaging the catheter or impending catheter flow.
- Suture wing and suture wing clamp Instructions:
- After guidewire has been removed and the necessary lines have bee connected or locked, spread wings of rubber clamp and position on catheter as required to ensure proper tip location. Snap rigid fastener on to catheter clamp. Secure catheter to patient by suturing the suture wing to the skin, using side wings to prevent catheter migration.
- Dress puncture site as per hospital protocol.
  Maintain the insertion site with regular meticulous redressing using aseptic technique.
- Record on the patient's chart the indwelling catheter length as to centimeter markings on catheter where it enters the skin. Frequent visual reassessment should be made to ensure that the catheter has not moved.

SUGGESTED INSERTION DIRECTIONS

The medical techniques and procedures described in these instructions do not represent all medically acceptable protocols, nor are their intended as a substitute for the physician's experience and judgement in treating any specific patient.

Preparation

- The selection of the insertion site and the appropriate catheter type and length is at the sole discretion of the physician.
- Flush each of the catheter lumens with saline expelling all the air then clamp the catheter extensions to ensure that the saline does not inadvertently drain from the catheter. Use the integral clamps provided.
- Insertion
- Administer sufficient local anaesthetic to completely anaesthetise the insertion site.
- Insert the introducer needle into target vein. Aspirate to ensure proper placement.
- Insert the flexible end of the guide wire into the introducer needle and advance the guide wire with forward motion into the target vein. Use ultrasonic to ensure a correct insertion, if necessary.
- Remove the needle leaving the guide wire in the vessel and enlarge the cutaneous puncture site with a scalpel.
- Thread the vessel dilators over the proximal end of the guide wire and dilate the subcutaneous tissue and vein wall to facilitate the insertion of the catheter.
- Remove the vessel dilator leaving the guide wire in place.
- Open the distal extensions clamp and thread the catheter over the proximal end of the guide wire.
- Ease the catheter through the subcutaneous tissue and into the target vein.
- Once proper placement is confirmed, remove the guidewire and close the clamp.
- Attach a syringe to each of the extensions in turn. Open the clamp and blood should aspirate easily. If the lumens exhibit excessive resistance to blood aspiration, the catheter may need to be rotated or repositioned to obtain adequate blood flows.
- Once adequate aspiration has been established, each lumen should be locked according to standard hospital protocols.
- Close the clamp and attached the injection cap(s) onto the extension line female luer(s).

Infusion

- The locking solution should be removed from each lumen prior to instigating infusion and aspiration should be based on standard hospital protocol.
- Check all connections carefully before initiating any infusion. Infusion protocols should be determined by physician prescription.
- Blood Sampling
- When taking blood samples through the catheter temporarily shut off other limes(s) through which solutions are being infused.

Daily Care

Daily care of the puncture site should be undertaken according to standard hospital protocols.

Catheter Removal

- Carefully remove all securement devices and dressing, and then slowly withdraw the catheter.
- Apply pressure to the exit site for approximately 10-15 minutes or until bleeding stops.
- Apply dressing in accordance with standard hospital protocols
- Dispose of the devices as contaminated medical device and in accordance with hospital protocols.

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.
- Infection or cut wound around the puncture site.
- Disturbance/abnormal of blood coagulation.
- Conducting the anticoagulated treatment.
- Symptoms of inadaptability of puncture operation.
- Abnormal or unclear anatomical situation at the puncture area, such as severe emphysema, obvious inadaptability from previous operation
- Coagulopathy.
- Previous radiation therapy.
- Suspected proximal vascular injury.
- Inexperience, Unsupervised Operators.
- The Patient is known or is suspected to be allergic to materials contained in the device.

CLINICAL BENEFITS

- It makes it easier to draw blood, which are frequently necessary due to the patient's condition
- Long-term antibiotics
- Long-term pain medications
- Chemotherapy drugs
- Drugs that may cause phlebitis when placed in the peripheral veins (these include calcium chloride, hypertonic saline, potassium chloride, and vasopressors such as dopamine and epinephrine.)

- Continuous rehydration (administration of fluids)
- Collecting peripheral blood stem cell
- Peripheral venous access is not possible

CAUTION /WARNING

- Do not use the product if the package is damaged or open.
- The product is designed for single use only.
- Do not re-sterilize.
- If reuse it may lead to cross contamination
- Do not alter the catheter or guide wire or any other component during insertion, use or removal.
- It is strongly recommended that you do not place the catheter into or allow it to remain in the right atrium or right ventricle. Failure to follow these instructions can result in serve patient injury.
  Troubleshooting**:** User Paramedic staff should be aware & able to troubleshoot the certain complications may occur during the application of the product such as; hemothorax, pneumothorax, and hematoma, Dysrhythmias, etc. related to the device. He should be qualified to address the related troubleshooting.
- Do not clamp the multi-lumen body of the catheter. Clamp only the extension lines and use only the clamps provided. Never use serrated forceps to clamp the extension lines.
- The device should be open in control environment (complying in the requirement of OT for cardiac surgery) the manufacturer does not hold any responsibility in case any syringe used during the use of device after opening the pack, other than syringe available in the pack.
- Catheter should not be forcibly removed, doing so may result in catheter breakage and embolization. Follow institutional policies and procedures for difficult to remove catheter.

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.
- If re-used it may lead, but not limited to cross-infection.

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

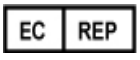
Dispose off/Discard the used Device, in accordance with your country's health care and safety regulations.

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			
Meaning	Medical device	Unique Device Identifier	

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