PRODUCT NAME: Dextra™ CruX Central Venous Catheter (CVC)

This document, supplied separately from the package, is an essential component for using the product manufactured by Blueneem Medical Devices Pvt. Ltd., Bangalore, India. It should be referenced before using the product, as it contains crucial information regarding its safe use .

DEVICE DESCRIPTION:
The Dextra CruX CVC is a flexible tube made of polyurethane. It is intended to be inserted into the internal jugular, common femoral, and subclavian veins to gain access to the central venous axis. The tip of the device is radiopaque, ensuring easy removal and visibility. The device is available in various sizes and lengths.

Product Name	Size (Fr)	Length (cm)
Dextra™ CruX	7	13, 16

Set includes:
- 7 Fr Triple lumen indwelling polyurethane catheter with clamps
- Guidewire with J tip 0.035''× 60cm advancer
- Introducer needle 18G × 7cm
- Scalpel blade #11
- Tissue dilator 8.5 Fr × 10 cm
- 5 ml Luer slip syringe
- 22G Needle 1.5 inches
- Additional site catheter fixing disc & cap
- Dust caps-3, non-vented
- Occlusion Dressing

INTENDED USE:
The Dextra™ CruX CVC is intended to provide short-term (< 30 days) central venous access for the treatment of diseases or conditions requiring central venous access. This includes, but is not limited to, the following:
- Total parenteral nutrition (TPN)
- Lack of usable peripheral IV sites
- Central venous pressure monitoring
- Infusions of fluids, medications, or chemotherapy
- Frequent blood sampling or receiving blood
- transfusions/blood products
- Volume resuscitation.
- Administration of vasopressors

Indwelling period: Safe for Up to 30 Days.

CONTRAINDICATIONS (To be mindful of)
• Infection or cut wound around the puncture site.
• Disturbance/abnormal blood coagulation.
• Abnormal or unclear anatomical situation at the puncture area, such as severe emphysema, obvious inadaptability from previous operation
• 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

POTENTIAL COMPLICATIONS:
Bleeding and hematoma formation, vessel perforation, infection, Thrombosis or Blood clot formation, Air embolism, Delayed healing and scar tissue formation

WARNINGS:
1. Sterile, Single-use: Do not reuse, reprocess or resterilize. Reuse of the device creates a potential risk of serious injury and/or infection which may lead to death.
2. Read all package insert warnings, precautions, and instructions prior to use. Failure to do so may result in severe patient injury or death.
3. Do not place catheter into or allow it to remain in the right atrium or right ventricle. X-ray examination or other methods in compliance with institutional policies and procedures must show catheter tip located in the lower 1/3 of the Superior Vena Cava (SVC), in accordance with institutional guidelines.
4. Clinicians must be aware of potential entrapment of the guidewire by any implanted device in the circulatory system. It is recommended that if the patient has a circulatory system implant, catheter procedure be done under direct visualization to reduce the risk of guidewire entrapment.
5. Do not use excessive force when introducing the guidewire or tissue dilator as this can lead to vessel perforation, bleeding, or component damage.
6. Passage of the guidewire into the right heart can cause dysrhythmias, right bundle branch block, and perforation of the vessel, atrial, or ventricular wall.
7. Do not apply excessive force in placing or removing the catheter or guidewire. Excessive force can cause component damage or breakage. If damage is suspected or withdrawal cannot be easily accomplished, radiographic visualization should be obtained and further consultation requested.
8. Using catheters not indicated for high-pressure injection for such applications can result in inter-lumen crossover or rupture with the potential for injury.
9. Do not secure, staple, and/or suture directly to the outside diameter of the catheter body or extension lines to reduce the risk of cutting or damaging the catheter or impeding catheter flow. Secure only at indicated stabilization locations.
10. Air embolism can occur if air is allowed to enter a central venous access device or vein. Do not leave open needles or uncapped, unclamped catheters in the central venous puncture site. Use only securely tightened connections with any central venous access device to guard against inadvertent disconnection.
11. Clinicians should be aware that slide clamps may be inadvertently removed.
12. Clinicians must be aware of complications associated with central venous catheters including, but not limited to cardiac tamponade secondary to vessel, atrial, or ventricular perforation, pleural (i.e., pneumothorax) and mediastinal injuries, air embolism, catheter embolism, catheter occlusion, thoracic duct laceration, bacteremia, septicemia, thrombosis, inadvertent arterial puncture, nerve injury, hematoma, hemorrhage, fibrin sheath formation, exit site infection, vessel erosion, catheter tip malposition, dysrhythmias.*
13. Do not cut the catheter to alter length.

Catheter Size (Fr)	Compatible Guidewire (inches)
7	0.038

PRECAUTIONS:
1. Do not alter (Sharp or acute bending) the catheter, guidewire, or any other kit/set component during insertion, use, or removal.
2. Procedure must be performed by trained personnel well versed in anatomical landmarks, safe technique, and potential complications.
3. Use standard precautions and follow established institutional policies and procedures.
4. Some disinfectants used at the catheter insertion site contain solvents which can weaken the catheter material. Alcohol, acetone, and polyethylene glycol can weaken the structure of polyurethane materials. These agents may also weaken the adhesive bond between the catheter stabilization device and the skin.
   - Do not use acetone on the catheter surface.

- Do not use alcohol to soak the catheter surface or allow alcohol to dwell in a catheter lumen to restore catheter patency or as an infection prevention measure.
- Do not use polyethylene glycol
- containing ointments at the insertion site.
- Take care when infusing drugs with a high concentration of alcohol.
- Allow the insertion site to dry completely prior to applying dressing.

5. Minimize catheter manipulation throughout the procedure to maintain proper catheter tip position.
6. clamp extension lines when catheter not in use

INSTRUCTION FOR USE:

1. Kits/Sets may not contain all accessory components detailed in these instructions for use. Become familiar with instructions for individual component(s) before beginning A Suggested Procedure: Use sterile technique. Prep Puncture Site:1. Position the patient appropriately for the insertion site.
   - For Subclavian or Jugular approach: Place the patient in a slight Trendelenburg position as tolerated to reduce the risk of air embolism and enhance venous filling.
   - For Femoral approach: Place the patient in a supine position.
2. Begin by applying an appropriate antiseptic solution to prepare the access site, followed by draping in a standard manner.
3. Administer local Anaesthesia. generously to the surrounding soft tissue of the access site.
4. Prepare catheter and flush each lumen with sterile normal saline. clamp or attach syringe connector(s) to extension line(s) to contain saline within lumen(s). Leave the distal extension line uncapped for the guidewire passage.
5. Palpate the surface, Insert the introducer needle /needle with the attached syringe (where provided) into the vein and aspirate.
   - Warning: Do not leave open needles or uncapped, in the central venous puncture site. Air embolism can occur with these practices. *
   - Caution: Do not reinsert the needle into the introducer catheter to reduce the risk of catheter embolus.
6. Use the Seldinger technique: Create a small incision in the skin, slightly larger than the diameter of the drainage catheter.
7. Utilizing fluoroscopic, CT scan, or ultrasound guidance, proceed to advance the 18-gauge introducer needle into the vein.
8. Advance guidewire into needle approximately 10 cm until it passes through into the introducer needle.
   • Advancement of guidewire through needle may require a gentle rotating motion.
9. Use centimetre markings on the guidewire as a reference to assist in determining how much guidewire has been inserted.
   NOTE: For every 10 cm, a marking band is provided. For example, from the 10 cm mark (one band) to the 30 cm mark (three bands), after which there are two bands, then one band respectively. The total length of our guidewire is 60 cm.
10. Remove introducer needle while holding guidewire in place.
11. If necessary, enlarge the cutaneous puncture site with the cutting edge of a scalpel, positioned away from the guidewire.
12. Use a tissue dilator(8.5Fr×10cm) to enlarge tissue tract to the vein as required. Follow the angle of the guidewire slowly through the skin.
13. **Advance Catheter**: Thread tip of the catheter over the guidewire. Sufficient guidewire length must remain exposed at hub end of the catheter to maintain a firm grip on guidewire.
14. Grasping near skin, advance the catheter into vein with slight twisting motion.
    Warning: Do not attach the catheter clamp and fastener until guidewire is removed.
15. Using centimetre marks on the catheter as positioning reference points, advance catheter to a final indwelling position.
    NOTE: Centimetre marking symbology is referenced from catheter tip.
16. If resistance is again encountered, remove the guidewire and catheter simultaneously.
17. **Complete Catheter Insertion:** Check lumen patency by attaching a syringe to each extension line and aspirate until free flow of venous blood is observed.
18. Flush lumen(s) to completely clear blood from the catheter.
19. Connect all extension line(s) to the appropriate connector(s) as required. Unused port(s) may be locked through connector(s) using standard institutional policies and procedures.
    - Slide clamp(s) are provided on extension lines to occlude flow through each lumen during line and connector changes.
    - Secure Catheter: Use a catheter stabilization device, catheter
    - clamp and fastener, staples, or sutures (where provided).
    - Use the triangular juncture hub with side wings as the primary suture site.
    - Use the catheter clamp and fastener as a secondary suture site as necessary.

    Catheter Stabilization Device (occlusion dressing) (where provided):
    - A catheter stabilization device should be used in accordance with the manufacturer's instructions for use.
      Catheter Clamp and Fastener (where provided):
    - A catheter clamp and fastener are used to secure the catheter when an additional securement site other than the catheter hub is required for catheter stabilization.
    - After the guidewire has been removed and necessary lines have been connected or locked, spread wings of rubber clamp and position on catheter making sure the catheter is not moist, as required, to maintain proper tip location.
    - Snap rigid fastener onto catheter clamp.
    - Secure catheter clamp and fastener as a unit to the patient by using either catheter stabilization device, stapling, or suturing. Both catheter clamp and fastener need to be secured to reduce the risk of catheter migration
20. Ensure the insertion site is dry before applying dressing per the manufacturer's instructions.
21. Assess catheter tip placement in compliance with institutional policies and procedures.
22. **Care and Maintenance:** Dressing: Dress according to institutional policies, procedures, and practice guidelines. Change immediately if the integrity becomes compromised (e.g. dressing becomes damp, soiled, loosened, or no longer occlusive).
23. **Catheter Patency:** Maintain catheter patency according to institutional policies, procedures, and practice guidelines. All personnel who care for patients with central venous catheters must be knowledgeable about effective management to prolong the catheter's dwell time and prevent injury.

Verify Venous Access:

Utilize one of the following techniques to verify venous access because of the potential for inadvertent arterial placement: Verify catheter tip position by *chest x-ray* immediately after placement. For central venous placement, an 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.

Central Venous Waveform:

The procedure involves inserting a catheter using techniques like the Seldinger technique, as mentioned earlier. Once the catheter is in place, it can be connected to a pressure transducer, which converts pressure changes into an electronic signal displayed on a monitor.

Caution: Do not rely on blood aspirate color to indicate venous access.

PROCEDURE: CATHETER REMOVAL INSTRUCTIONS:

- Position the patient as clinically indicated to reduce the risk of potential air embolus.
- Remove dressing.
- Release the catheter and remove it from the catheter securement device(s).
- Ask the patient to take a breath and hold it if removing an internal jugular or subclavian catheter.
- Remove the catheter by slowly pulling it parallel to the skin. If there is resistance, STOP removing the catheter.
  Caution: The catheter should not be forcibly removed, doing so may result in catheter breakage and embolization. Follow institutional policies and procedures for difficult-to-remove catheters.
- Apply direct pressure to the site until haemostasis is achieved followed by an ointment-based occlusive dressing.
  Warning: The residual catheter track remains an air entry point until the site is epithelialized. Occlusive dressing should remain in place for at least 24 hours or until the site appears epithelialized.
- Document the catheter removal procedure including confirmation that the entire catheter length and tip have been removed per institutional policies and procedures. For reference literature concerning patient assessment, clinician education, insertion technique, and potential complications associated with this procedure, consult standard textbooks and medical literature.

Hazard event:

- Using the device by an untrained or unauthorized person
- Using a damaged device on a patient
- Insufficient flow due to occluded arterial hole resulting from a clot
- Sharp or acute bending of the catheter during insertion
- Failure to clamp extension lines when catheter not in use Catheter mispositioning
- Pulling back the guidewire when the needle is in place
- Clinical risks (air embolism, bleeding, cardiac arrhythmia, brachial plexus injury, catheter-related sepsis, hemothorax, pneumothorax)
- Failure of the pouch to maintain sterility of the product
- Using the device when the package is damaged or opened Re-sterilization of the device by the user
- Not storing the device in prescribed conditions
- Using the device in non-prescribed conditions
- Using the device after the shelf-life period

HOW SUPPLIED:

The device is packed in a medical-grade peel-open pouch, supplied sterilized by Ethylene Oxide gas. It is intended for one-time use and remains sterile if the package is unopened or undamaged. Do not use the product if there is any doubt about its sterility. Store it in a dark, dry, cool place, and avoid extended exposure to light. Upon removal from the package, inspect the product to ensure no damage has occurred.

STORAGE:

- Store the central venous kit in a clean, dry, and dark place to avoid extended exposure to light and moisture.
- Storage environment should be rat-proof and moth-proof in order to maintain the integrity of the package.
- Keep it from contacting corrosion gas.
- Storage temperature: 20°C to 40°C.

REFERENCES:

These instructions for use are based on experience from physicians and (or) their published literature. Refer to your local Blueneem sales representative for information on available literature.

SYMBOLS USED IN LABELING:

Symbols used on the label are as per EN ISO 15223-1-2021

BLUE NEEM MEDICAL DEVICES PVT. LTD.
Plot Nos 270 & 271, Road No 5, Harohalli Industrial Area,
II Phase, Kanakapura Taluk, Ramanagara - 562112, India.
Phone: +91 80 29761336
E-Mail: contact@blueneem.com
Website: www.blueneem.com