**WARNING:** To avoid severing or damaging wire, do not cut guidewire to alter length, nor withdraw guidewire against needle bevel.

3. Hold guidewire in place and remove Raulerson syringe.

**PRECAUTION:** Maintain a firm grip on guidewire at all times.

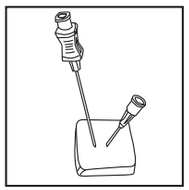
4. If making skin-nick, enlarge cutaneous puncture site with cutting edge of scalpel positioned away from guidewire.
5. If using dilator, pass it over guidewire to enlarge site as needed.

**WARNING:** To avoid possible vessel wall perforation, do not leave dilator in place as an indwelling catheter.

6. Thread tip of catheter into vessel using guidewire. Grasping catheter near skin, advance into vein with a slight twisting motion.
7. Advance catheter into final indwelling position. Hold catheter and remove guidewire. Check lumen placement by aspirating through pigtails. Apply dressing per hospital protocol. Verify catheter tip position by X-ray (or other method in compliance with hospital protocol).

## NEEDLE STOPPER

A needle stopper is included to temporarily shield the sharpened tips of bevelled needles before they are disposed of in accordance with local, state, and federal regulations.



**CAUTION:** Federal Law (USA) restricts this device to sale by or on the order of a physician or licensed practitioner.

## WARRANTY

BIOPTIMAL warrants all its products free from defect in workmanship and materials under proper use and handling. This warranty is in lieu of all other warranties, whether expressed or implied, including any warranty of merchantability, suitability or fitness for a particular purpose since handling, storage as well as factors relating to the patient, his diagnosis, treatment, surgical procedures, and other matters beyond BIOPTIMAL'S control, directly affect BIOPTIMAL'S products and the results obtained from their use. BIOPTIMAL shall not be liable for any incidental or consequential loss, damage, or expense directly arising from the use of its products. BIOPTIMAL neither assumes, nor authorizes any other person to assume for it, any other additional liability or responsibility in connection with its products.

## PRODUCT INFORMATION

For further information or assistance relating to the BIOPTIMAL products, please contact:

***Legal Manufacturer:***

**BIOPTIMAL INTERNATIONAL PTE. LTD.**

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CE 0344



Bioptimal™

## INSTRUCTIONS FOR USE OF SINGLE-LUMEN AND MULTIPLE-LUMEN CENTRAL VENOUS CATHETERS

| | | | |
|---|---|---|---|
| | Read Instruction Manual Before Use | | Keep Dry |
| STERILE EO | Sterile And Non-Pyrogenic | | Do Not Use If Package Is Damaged |
| | For Single Use Only | | Keep From Direct Sunlight |
| | Do Not Re-sterilize | | Non-Pyrogenic |

**READ ALL INSTRUCTIONS, WARNINGS AND PRECAUTIONS CAREFULLY PRIOR TO USE.**

## DEVICE DESCRIPTION

BIOPTIMAL Central Venous Catheters (CVC) are constructed with a flexible tubing with a blue flex tip and is available in single or multi-lumen. Each catheter is provided in a sterile package in a complete procedural tray or in a basic insertion tray.

Catheter Body is marked for identification of depth of insertion. Every 10$^{th}$ cm distance from distal tip has a single, double and triple line marking indicating respective distance. The 15$^{th}$ and 25$^{th}$ cm are marked with the respective number. Starting from the 16$^{th}$ cm distance, every 1 cm distance is marked with a dot.

## INDICATIONS AND INTENDED USE

BIOPTIMAL Central Venous Catheters are designed for use in critical care patients to monitor central venous pressures; sample venous blood; and administer drugs and solutions intravenously. Multiple lumen catheters provide multiple access channels to the central venous circulation through a single insertion site, permitting several functions to be performed simultaneously.

## PRECAUTIONS

- RX only
- Do not use catheter after indicated expiration date on the packaging.
- This product is designed for single use only. Do not reuse or resterilize the catheter or kit components.
- Do not use catheter or components if package is opened or damaged as contents may lose sterility.
- Do not alter catheter, guidewire, or any other kit components during insertion, use, or removal.
- To minimize potential for catheter rupture, infusion pressures should not exceed 40 PSI.
- To minimize pressures generated during flushing procedures, use a 10-ml or larger syringe.
- For short term use of less than 7 days.
- Central venous catheterization must be performed by trained personnel well versed in anatomical landmarks, safe technique and potential complications.
- Used catheter must be properly disposed as biohazard material and processed accordingly to facility protocol.
- Risks associated with general and local anesthesia, surgery and post-op recovery.

## WARNINGS

- Do not place the catheter into or allow it to remain in the right atrium or right ventricle. Failure to heed this warning may result in severe patient injury or death.
- Due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, health care workers should routinely use universal blood and body-fluid precautions in the care of all patients. Sterile technique must be strictly adhered to during any handling of the device.
- This device is intended for single patient use only.
- **DO NOT** resterilize and/ or reuse this device, as this can compromise its performance and can lead to device failure and procedure complications with severe injury or patient death. Reuse and resterilisation bear the risk of cross contamination and patient infection and may also cause transmission of infectious diseases from patient to patient.

## CONTRA-INDICATIONS

The device is contraindicated whenever:

- The presence of other device related infection, bacteremia, or septicemia is known or suspected.
- Severe chronic obstructive lung disease exists.
- Past irradiation of prospective insertion site has occurred.
- Previous episodes of venous thrombosis or vascular surgical procedures at the prospective placement site had occurred.

## COMPLICATIONS

| | |
|---|---|
| Allergic Reaction | Fibrin Formation |
| Bleeding | Hematoma |
| Brachial Plexus Injury | Hemothorax |
| Cardiac Arrhythmia | Hydrothorax |
| Cardiac Tamponade | Myocardial Damage |
| Catheter Damage | Nerve Damage |
| Catheter Embolism | Perforation or Laceration of Vessels or Viscus |
| Catheter Occlusion | Pneumothorax |
| Catheter or Cuff Erosion through the skin | Thoracic Duct Injury |
| Catheter-Related Blood Stream Infection | Thromboembolism |
| Catheter Sepsis | Tissue Necrosis |
| Catheter Tip Migration | Deep Vein Thrombosis |
| Death | Vessel Erosion |
| Endocarditis | Phlebitis |
| Extravasation | |

## INSTRUCTIONS FOR USE

### RECOMMENDED INSERTION PROCEDURE:

**CAUTION:** Follow aseptic technique and employ Universal Precautions and procedures per institutional protocols.

1. Prepare and drape puncture site as required.

**CAUTION:** To lessen the risk of air embolism during catheter insertion, the patient should be positioned in a slight Trendelenburg position as tolerated.

2. Prepare the catheter for insertion by flushing the catheter lumen with sterile solution to prime and ensure patency. Clamp extension lines or attach injection ports to the appropriate lumen extensions. Leave the distal lumen extension uncapped for guidewire passage.
3. Infiltrate the insertion site with local anesthetic per institutional protocol.

**INSTRUCTIONS FOR INTRODUCER NEEDLE**

4. Place the introducer needle on the syringe.
5. Locate the vein, insert the needle, and aspirate. Assure a good flow of venous blood is established.
6. Remove the syringe. Pulsatile flow exiting the introducer needle usually indicates inadvertent arterial puncture.
7. Retract the guidewire into guidewire dispenser to straighten its J-tip. Gently insert guidewire tip through the needle into the vessel. Advance the guidewire to required depth.

**PRECAUTIONS:**

- Exercise care while inserting or withdrawing guidewire.
- Do not withdraw guidewire against needle bevel to avoid possible severing of guidewire.
- If resistance to advancement of guidewire is encountered, withdraw guidewire and try to reintroduce gently.
- Advancement of guidewire into the right heart can cause arrhythmias, right bundle branch block, and vessel wall, arterial or ventricular perforation.
- While holding guidewire in place, remove introducer needle. Use centimeter markings on guidewire as a reference to adjust indwelling length to achieve desired depth of indwelling catheter placement.

**CAUTION:** Maintain firm grip on guidewire at all times.

8. Insert vessel dilator over the guidewire into the blood vessel to enlarge the puncture site. Remove the vessel dilator.

**WARNING:** Do not leave vessel dilator in place as an indwelling catheter as this may cause vessel wall perforation.

**CAUTION:** The physician must be aware of potential air embolism complications associated with leaving open needles or catheter in central venous puncture sites, or as a consequence of inadvertent disconnection.

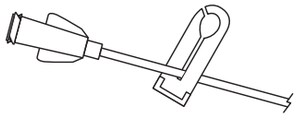
9. Thread tip of catheter over guidewire. Grasping catheter near skin, advance catheter into vein with slight twisting motion. Sufficient guidewire length must remain exposed at hub end of catheter to permit a firm grip on guidewire.
10. Using centimeter marks on catheter as positioning reference points, advance catheter to final indwelling position.
11. Hold catheter at depth desired and remove the guidewire.

**CAUTION:** If resistance is encountered when attempting to remove the guidewire after the catheter placement, withdraw the catheter 2 or 3 cm and attempt to remove the guidewire. Applying an undue force during guidewire withdrawal increases the potential for guidewire breakage. If resistance is again encountered, remove the guidewire and catheter simultaneously.

12. Verify that the entire guidewire is intact upon removal.
13. Check lumen placement by attaching a syringe to each lumen extension and aspirate until free flow of blood is observed. Connect all lumen extensions to appropriate Luer lock line(s) as required. Unused ports may be "locked" through injection cap(s) following standard institutional protocols. Slide clamps are provided on lumen extensions to occlude flow through each lumen during line and injection port changes.

**PRECAUTIONS:**

- Use only Luer lock connectors on catheters and accessories to avoid disconnect problems.
- To avoid damage to lumen extensions from excessive pressure, each clamp must be opened prior to infusion.
- For total occlusion of flow through each lumen, please ensure that the extension line clamps are pressed completely to the opposite end (As shown in diagram below).



14. Secure and dress catheter temporarily.
15. Verify catheter tip position by chest x-ray immediately after placement.

**CAUTION:** Catheter should be positioned so that its distal tip is advanced as far as possible in the superior vena cava and as close as possible to the right atrium without touching it. Physicians must be aware of possible complications caused by a right atrium perforation in the case of the catheter being advanced too deeply.

16. Secure catheter to patient by suturing the integral suture hub to patient skin. If necessary, clamp a suture wing over the catheter. Snap a clamp fastener onto the suture wing to secure the catheter before suturing the suture wing and its cover together on patient's skin.

**CAUTION:** Do not suture directly to the outside diameter of the catheter to avoid cutting or damaging the catheter or impeding catheter flow.

17. Dress puncture site per hospital protocol.

**CAUTION:** Complications associated with central venous catheters include air embolism, catheter embolism, cardiac tamponade secondary to vessel wall, atrial, or ventricular, septicemia, and thrombosis. See Section under COMPLICATIONS.

**CAUTION:** Ensure that sampling/distribution devices are connected to the right extension of the catheter.

**RECOMMENDED MAINTENANCE:**

**CAUTION:** Due to the risks of exposure to blood-borne pathogens or HIV (Human Immunodeficiency Virus), health care workers should routinely use "universal blood and body-fluid precautions" in the care of all patients.

1. Indwelling catheters should be routinely inspected for desired flow rate, security of dressing, correct catheter position and secure Luer-lock connections. Use centimeter markings to determine if catheter position has changed.
2. Only x-ray examination of catheter placement can ensure that catheter tip has not entered the heart or no longer lies parallel to the vessel wall. If catheter position change is suspected, immediately perform chest x-ray examination to confirm catheter tip position and relocate as necessary.
3. Maintain the insertion site with regular meticulous dressing changes using aseptic technique in accordance with institutional protocols.
4. To minimize pressures generated during flushing procedures, use 10-ml or larger syringe.

**CAUTION:** Do not contact the indwelling catheter with solutions containing acetone or alcohol, which could weaken the catheter and can cause it to leak or break.

5. The physician should evaluate the length of time the catheter is to be left in place to reduce risk of contamination at femoral access sites.
6. To sample blood, temporarily shut off port(s) through which solutions are being infused.

**CAUTION:** Compression or kinking of catheter or extension tubing may cause sudden increases, decreases, or small boluses of vasoactive drugs to be injected into the patient, which could result in sudden changes in cardiac output.

**CATHETER REMOVAL:**

1. To prevent air embolism after removal of central venous catheter, cover wound with dressing impermeable to air.
2. Avoid removing dressing with scissors or other sharp instruments that may cut the catheter.
3. Inspect the catheter upon removal to make sure that the entire catheter length has been removed.

**CAUTION:** Do not reuse or resterilize the catheter.

**PACKAGING AND STERILITY**

Product is supplied sterile and non-pyrogenic if package is undamaged or unopened. Do not use if package is opened or damaged. Catheters are for single use only. Do not clean or resterilized a used catheter.

**STORAGE**

Bioptimal CVC and kits should be stored unopened in its original packaging in dark, cool dry places.

**SHELF-LIFE**

The recommended shelf-life is indicated on each package.

**OPTIONAL ACCESSORIES**

**TRANSPARENT DRESSING**

**Instructions for Use:**

1. Prep site and allow skin to dry.

   After completing the skin prep required by your institution's protocol, make certain that the site to be dressed by Transparent Dressing is completely dry.
2. Place foam pad under catheter or hub.

   Attach required tubing or other Luer lock components as required. Place one of the foam accessory tape strips under the catheter or hub.
3. Apply main Transparent Dressing.

   Peel the main dressing from the liner. Handling of the Transparent Dressing may be easier if you handle the "no-stick tab" portion as the tab will prevent the Transparent Dressing from sticking to your gloves. The tab may be removed to expose the adhesive surface after applying the dressing.

   Apply the Transparent Dressing so that the catheter site is visible through the transparent window. In addition, the bottom of the crossbar should partially overlap the foam strip, which was placed under the catheter or hub. Make certain that the edges of the dressing adhere properly.

   Grip the wings on the liner between your thumb and fingers, break open the liner, and peel the wings and liner apart while applying the dressing.

   Apply the Transparent Dressing so that the catheter site is visible through the transparent window.

   Make certain that the edges of the dressing adhere properly.
4. Pinch the main Transparent Dressing around the catheter or hub to occlude and to stabilize.

   Pinch the main dressing about the catheter (or hub) so that the dressing seals around the catheter and down onto the accessory tape strip placed earlier underneath the catheter. This pinching not only occludes the area about the catheter or hub; it also stabilizes by adhering to the catheter or hub, controlling catheter movement.
5. Secure tubing set with stretchable foam accessory tape strips.

   Strategically place the remaining foam strips about the tubing set for stability employing techniques (including stress loops) dictated by your institution's protocol.

   Note: Foam strips can be stretched to accommodate different positioning requirements.
6. Removal. Alcohol or adhesive removal wipes will facilitate Transparent Dressing removal.

   Stabilize the catheter. Peel up small portion of one of the dressing's edges. Take an alcohol or adhesive removal wipe and rub it under the exposed adhesive surface. Slowly remove the dressing while rubbing the alcohol or adhesive removal wipe on the adhesive surface where it meets the skin. Use this same technique to remove the dressing where it adheres to either the catheter or the hub, being very careful to minimize manipulation of the catheter. Do not contact alcohol wipes or acetone with the catheter tubing. Do not use scissors to remove the dressing.

**NEEDLES (25G and 22G)**

Needle (25G) is included for administering local anesthetic. Needle (22G) can be used for the pre-location of vein.

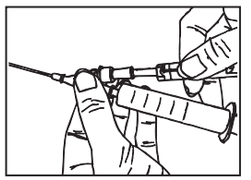
**Y-VALVE NEEDLE**

**Instructions for Use:**

The Y-Valve Needle is designed to prevent back flow of blood during guidewire insertion when using the Seldinger technique.

**Guidewire Insertion Procedure:**

1. Attach the syringe to the straight-through connector on the Y-Valve Needle. Locate the vein, insert the needle, and aspirate. Assure a good flow of venous blood is established. Keep the syringe attached to the needle.
2. Stretch the flexible J-tip of the guidewire by pulling it into the guidewire dispenser. Attach the dispenser tip to the side connector of the Y-Valve Needle, then advance the guidewire into the vein.



3. After the guidewire has reached the desired depth, remove the guidewire dispenser. Then remove the needle while keeping the guidewire in place.
4. Insert the dilator and catheter as recommended in the Instruction For Use.

**RAULERSON SYRINGE**

**Instructions for Use:**

1. After administering local anesthetic, locate vein using thin-wall introducer needle attached to Raulerson syringe. The vessel may be prelocated with a smaller needle.
2. Using Guidewire Advancer, straighten J tip of guidwire, if used, and advance through rear of syringe plunger.