HAEMODIALYSIS CATHETER KIT DESCRIPTION

Haemodialysis Catheter is made of soft radiopaque polyurethane. It is available in variety of sizes. The catheter shaft is divided internally into two separate lumens (Double Lumen) and into three separate lumens (Triple Lumen) by a septum.

CONTENTS:

1. Single/ Double/ Triple Lumen (Straight type/ Curved type), Radiopaque Polyurethane Indwelling Catheter (with marking to verify position) with soft tip.
2. Guide wire with length markings & flexible "J" tip with dispenser
3. Y-type Introducer Needle or Seldinger Needle.
4. Vessel Dilator -10Fr.
5. Vessel Dilator -12Fr
6. Luer Lock Syringe or Guiding Syringe 5ml
7. Long Handle Scalpel
8. Injection Caps

Product is provided sterile & non pyrogenic. Do not use if package has been previously opened or damaged. Sterilized by Ethylene Oxide. For single use only. Do not re-sterilize or reuse. The Temporary Access Catheters are intended to be used less than 30 days. Contains no medication.

MATERIALS USED:

ABS, HDPE, PUR, PP, PC, Poly-Isoprene, SS.

INDICATIONS FOR USE:

The Large-Bore Two-Lumen Catheter are designed for haemodialysis, apheresis and are percutaneously inserted into the jugular, subclavian or femoral veins.

CONTRA-INDICATIONS:

These Catheters are not designed for long-term haemodialysis or for use in patients with thrombosed vessels.

POTENTIAL COMPLICATIONS:

The use of an indwelling haemodialysis catheter provides an important means of venous access for critically ill patients. However, before attempting the insertion, the physician should be familiar with the following potential complications and their emergency treatment should they occur:

- Air embolism
- Bacteremia
- Bleeding at site
- Cardiac arrhythmia
- Catheter-related sepsis (septicemia)
- Exit site infection
- Hematoma

These and other complications are well documented in medical literature and should be carefully considered before placing the catheter. Placement and care of haemodialysis catheters should be performed by persons knowledgeable of the risks involved and qualified in the procedures.

RECOMMENDED INSERTION PROCEDURE:

Follow aseptic technique and employ universal precautions & procedure per institutional protocols.

- Position patient in a slight Trendelenburg (head-down) position to improve venous perfusion.
- Prepare the puncture site by thoroughly cleaning and disinfecting the skin and cover with a sterile drape, as required.
- Prepare the indwelling catheter for insertion by flushing catheter lumen with sterile solution to confirm patency and priming. Clamp extension lines or attach injection caps to the appropriate extension line.
- Locate and puncture the vein using the Y introducer needle mounted on syringe.
- Remove the protective cap from the guide wire dispenser. Retract the guide wire into guide wire dispenser to straighten its J-tip. Gently advance guide wire through introducer needle into vein or place through guiding syringe itself incase of guiding syringe. Use the length markings to check the insertion depth. First band indicates 10cm, second band 20cm and third band 30cm.
- Hold guide wire in the desired position and now remove guide wire dispenser and introducer needle.
- By rotating slightly, insert vessel dilator over the guide wire into the blood vessel to enlarge the puncture site. Retaining the position of guide wire, remove the vessel dilator in order to insert the indwelling catheter.
  Insert tip of indwelling catheter over the guide wire. Holding catheter near skin, advance the catheter up to the desired position with slightly twisting movement.
- Irrigate catheter with saline, then clamp catheter extensions to assure that saline is not inadvertently drained from catheter. Use clamps provided.
- Open venous extension clamp. Thread the catheter over proximal end of the guide wire.
- Centimeter marks on indwelling catheter can be taken as reference points to finalize indwelling catheter position.
- Hold indwelling catheter in the desired position and remove the guide wire.
- Verify that the entire guide wire is intact upon removal.
  Check lumen placement by attaching a syringe to each Extension line and aspirating until free flow of blood is observed. Connect extension lines to appropriate luer lock lines as required. Extension line clamps are provided on extension lines to occlude flw through each lumen during line and injection cap changes.
- Secure and dress catheter temporarily.
- Verify catheter tip position by chest x-ray immediately after placement.
- Secure catheter to the skin with movable catheter holder integrated with junction hub.

CATHETER REMOVAL

As with all invasive procedures, the physician will assess the anatomical and physiological needs of the patient to determine the most appropriate catheter removal technique.

CAUTION STATEMENTS REGARDING haemodialysis TREATMENT

- Before dialysis begins, all connections to the catheter and extracorporeal circuits should be examined carefully.

- If a leak in the catheter tubing or hub occurs, or if a connector separates from any component during insertion or use, clamp the catheter and take all necessary steps and precautions to prevent blood lossor air embolism.
- To minimize the risk of air embolism, keep the catheter clamped at all times when not attached to a syringe, IV tubing, or bloodlines.

WARNING:

- 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 severe patient injury or death.
- If a resistance is encountered when attempting to remove the guide wire after placement, withdraw the catheter 2 or 3 cm and attempt to remove the guide wire. If resistance is again encountered, remove the guide wire and catheter simultaneously.
- Do not suture directly to the outside diameter of the catheter to avoid cutting or damaging the catheter or restricting flow through catheter lumen.

  Do not bring catheter into contact with acetone or similar solvents, which can weaken the catheter and can cause it to leak or break.
- Do not connect the catheter to pressure of more than 3 bars.
- Use different sites for blood sampling and administration of medication or infusions to reduce the risk of infection.

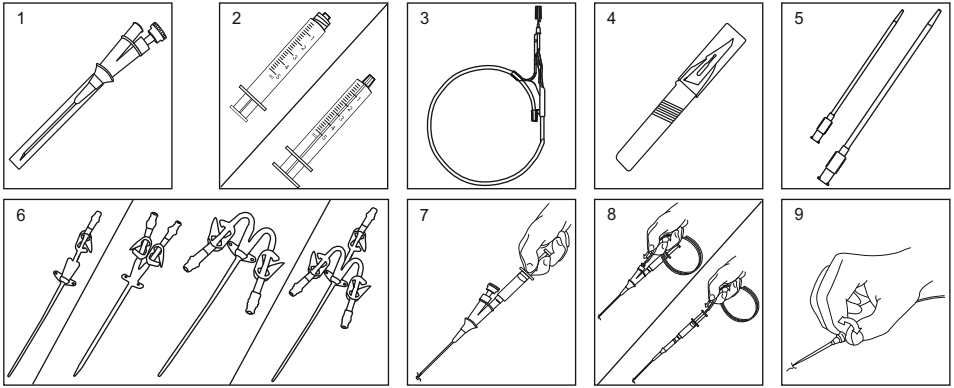
WARRANTY:

Manufacturer warrants its products free from defects in workmanship and material under proper handling and use. This warranty voids if failure or defect is due to handling, storage as well as factors relating to the patient, his / her diagnosis, treatment, surgical procedures, and other matters beyond manufacturers, control, directly affect manufacturer's products and the results obtained from their use.

POLYMED

POLY MEDICURE LTD.
Plot No.115-117, Sector -59, HSIIDC Industrial Area, Ballabhgarh, Faridabad, Haryana- 121004, India.
Web : www.polymedicure.com
Contact customer care executive:
+91-129-4287053,
Email: customercare@polymedicure.com
Address: Same as above

Rev. 00-25/08



Cautions

See Instructions for use

REF — Product reference/Art. No.

For single use only

Do not Resterilize

Do not use if packaging or product has been damaged or contaminated

LOT — Batch Number

Date of Manufacturing

Use by / Expiry date

STERILE EO — Sterilised by Ethylene Oxide

Single Sterile Barrier System

Manufactured by

Non Pyrogenic

5°C – 35°C — Storage Condition

Keep Away from direct Sunlight

Keep Dry

MD — Medical Device