LONG TERM HAEMODIALYSIS CATHETER KITS

TWINCATH DUAL LUMEN LONG TERM HAEMODIALYSIS CATHETER (P2) KIT
X SPLIT DUAL LUMEN LONG TERM HAEMODIALYSIS CATHETER (PX) KIT

Device Description:

AMECATH **Long Term Haemodialysis Catheters (P2 & PX)** are Cuffed hemodialysis catheters which are chronic, dual lumen, radiopaque, polyurethane catheters with a polyester cuff, consisting of catheter tube shaft end distally with split (X split catheter) or stepped tip (TwinCath catheter). The cuff promotes tissue in-growth for fixation of the catheter in a subcutaneous tunnel. The catheter tube shaft proximally bifurcates into two catheter extensions. These catheters are suitable for retrograde tunneling they are equipped with arterial and venous extension line to be connected to the catheter after tunneling.

AMECATH **Long Term Haemodialysis Catheters (P2 & PX)** are indicated for long-term use (up to 90 days).

AMECATH **Long Term Haemodialysis Catheters (P2 & PX)** are available in straight tube shape and pre-curved tub shape. The Pre-curved tube shape lies nicely over the clavicle to avoid possible kinking of the catheter during tunneling.
P2 catheters are Available in 08-16 Fr diameter and many lengths from 9-50 Cm that determine the suitability of blood flow and patient age
PX catheters are Available in 12-16 Fr diameter and many lengths from 16-50 Cm that determine the suitability of blood flow and patient age.

AMECATH **Long Term Haemodialysis Catheters (P2)** are for paediatrics and adult use.

AMECATH **Long Term Haemodialysis Catheters (PX)** are for adult use.

AMECATH **Long Term Haemodialysis Catheters (P2 & PX)** to be inserted percutaneously and are ideally cannulated in the internal jugular vein. The other options are the subclavian, femoral vein, translumbar or transhepatic access to the inferior vena cava (IVC). But the internal jugular is the preferred site.
Subclavian access should be used only when no other upper-extremity or chest-wall options are available.
The pre-curved shape is intended for lower internal jugular vein placement.

Target patient populations:
Px: Adults
P2: Adults and paediatrics
Intended user: Health Care Professionals

* The Long-term hemodialysis Catheter material is safe to be used as an implantable long term use device. And it was tested and evaluated for that purpose.

AMECATH **Long Term Haemodialysis Catheters (P2 & PX)** are available in different designs and Kit configurations to cover all customer needs .

Device construction:

Catheter Types:

- Twincath Dual Lumen Long Term Haemodialysis Catheter (P2)
- X split Dual Lumen Long Term Haemodialysis Catheter (PX)

List of Accessories:

- Introducer Needle, Echogenic
- Syringe
- J End Nitinol Core Guide Wire
- Vessel Dilators

- Scalpel
- Blunt Curved Tunneling Stylet
- Grip-lock Peelable introducer sheath
- Valved peelable introducer sheath
- Repair valves
- Guiding Y Connector
- Movable Fixation Wing
- Catheter Tube Fixation Adhesive (unifix)
- Transparent Catheter Fixation Adhesive
- Injection cap
- Flushing Connector
- Slide Clamps
- Free Female luer Line for retrograde (Red for Arterial + Blue for Venous)

Intended Use:

AMECATH **Long Term Haemodialysis Catheters (P2 & PX)** is sterile single use device indicated for use in attaining long term access for Haemodialysis, or apheresis.

N.B:

To ensure that Long term hemodialysis catheter is performing well in order to achieve its intended use, please

- Ensure that while flushing before use, there is no leakage from any place on the catheter. Also, in order to avoid arrythmia, placement of the guide wire should be performed under fluoroscopy.
- To avoid catheter dysfunction, extracorporeal blood flow should attain and be maintained at 300 mL/min (for adult size catheter) or greater at a pre pump arterial pressure more negative than - 250 mm Hg.
- Connection of catheter via it's end to the extension line or the stopcock. And Extension line or stopcock to be connected to the Haemodialysis Machine should be ensured.

Clinical Benefits:

The capability of Long Term Hemodialysis Catheters to attain long term access for Hemodialysis, or apheresis via central venous veins "preferably the internal jugular vein".

Contraindications:

This device should not be used for any intended use other than indicated.

- This device should not be used on a patient diagnosed with a known bleeding disorder.
- The device should not be placed at a site where a previous venous thrombosis or vascular surgical procedure has occurred, or at any site experiencing tissue scars, cellulite, or inflammation which may complicate the use of the device.
- This device should not be used on a patient diagnosed with emphysema or hypercapnia (excessive deep breathing) due to possible injury during placement.
- This device should not be used on a patient suspected of having a device related infection, bacteremia or septicemia in order to help prevent catheter cross contamination.

Warnings and Precautions:

- For single product and patient use only. Do not re-use, reprocess or re-sterilize. Do not use catheter or accessories if any sign of product damage is visible.
- Reprocessing or Re-sterilization may damage the catheter and affect its integrity which may when re-used lead to sever deterioration in health and safety of patients.
- Product expiration date is identified on product label.
- The catheter has metallic part that may produce some MRI imaging artifact at the area of the device.
- The insertion technique has a significant influence on the complications and outcome of the catheter.

- Insertion must be performed by a competent and experienced catheter insertion team. Inexperienced personnel should not be permitted to perform the implantation except under the direct supervision of an experienced physician or surgeon.
- Be sure that you are familiar with the possible complications and emergency measures are known and available if any occur.
- Do not over split the arterial and venous lumen of the split catheters as they may lead to catheter perforation.
- Patient requiring ventilation support is at great risk of pneumothorax during subclavian vein cannulation.
- Over advancement of guide wire can result in serious injuries or arrhythmias.
- Use the marking over the guide wire or over the dispenser to determine the advanced length.
- Do not advance the guide wire or catheter if unusual elastic resistance is encountered. Do not insert or withdraw the guide wire forcibly from any component.
- The wire could break or unravel, in which case both the catheter and guide wire must be removed simultaneously.
- In the rare event that a hub or connector separates from any component during the insertion or use, take all necessary steps and Precautions to prevent blood loss or air embolism and remove the catheter immediately.
- Patients requiring ventilator support are at increased risk of pneumothorax during subclavian vein cannulation, which may cause complications.
- Do not use sharp instruments near the extension line or tubing. Do not use scissors to remove dressing, as this could possibly cut or damage catheter. Do not suture through any part of the catheter.
- Catheter tubing can be torn when subjected to excessive force or rough edges.
- Use only clamp provided with the kit or smooth jawed forceps for clamping. Clamping the catheter repeatedly in the same spot could weaken the tubing.
- Change the position of the clamp regularly to prolong the life of the tubing.
- Avoid clamping near the adapter and hub of the catheter.
- Do not clamp the lumen portion of the catheter.
- Clamp only the extensions.
- Examine tubing for damage at the end of each treatment.
- Tape injection caps (or other types used) between treatments to safeguard them against accidental removal.
- It is recommended that only luer lock (threaded) connections be used with the catheter (including syringes, bloodlines, IV tubing, and injection caps).
- Repeated over tightening of bloodlines, syringes, and caps will reduce connector life and could lead to potential connector failure.
- Inspect the catheter frequently for nicks, scrapes, cuts, etc. which could impair its performance.
- Ultrasound or fluoroscopy should be used in the placement of catheters.
- Do not use absolute alcohol or acetone-based product on the catheter, 2% chlorhexidine or Iodine based solution is recommended as antiseptic solution.
- It is not recommended to use ointments on catheters as it may cause its degradation.
- Over tightening of catheter luers may lead to its failure.
- If any resistance is felt, then the needle should be pulled out with the wire still inside and the procedure repeated.
- This reduces the risk of entangling of the guide wire, or its end being cut off by the needle tip.
- The valve of the guiding syringe connector should be opened by the guide wire advancer tip.
- Do not attempt passing the guide wire before opening the valve by the advancer tip otherwise the wire may be kinked or destroyed.
- Do not over tighten the luer lock.
- Extended use of the subclavian vein may be associated with subclavian vein stenosis.
- Do not over-expand subcutaneous tissue during tunneling. Over-expansion may delay/ prevent cuff in-growth.
- Catheter will be damaged if clamps other than what is provided with this kit are used.

- In the event a clamp breaks, replace the catheter at the earliest opportunity.
- Clamping of the tubing repeatedly in the same location may weaken tubing.
- Avoid clamping near the luers and hub of the catheter.
- Examine catheter lumen and extensions before and after each treatment for damage.
- To prevent accidents, assure the security of all caps and bloodline connections prior to and between treatments.
- The selection of the appropriate catheter length is at the sole discretion of the physician.
- To achieve proper tip placement, proper catheter length selection is important.
- Routine x-ray should always follow the initial insertion of this catheter to confirm proper placement prior to use.
- The position of the tip of any central catheter should be verified by a radiological means
- Avoid repeated clamping on the same point. Avoid clamping near catheter hub or connectors as it may lead to cracks.

MISUSE CAN BE DUE TO:

- Improper positioning of the catheter tip.
- Selecting wrong size or length of catheter has a reflection on catheter permit flow rate capacity.
- Avoid kinking of the catheter at tunnel area otherwise flow rate could be diminished.
- Use only recommended antiseptics otherwise catheter material will be affected.
- Aggressive Insertion of male luer may cracks catheter female luer.
- Misconnection of catheter extension line(s) by connecting the venous line of the dialysis blood line to catheter extension line that is dedicated to the arterial line and marked red. This can lead to high recirculation rate of up to 37% that may lead to inefficient dialysis.
- Improper heparinization during the dialysis may result in blood clotting and obstruction of the catheter.
- Improper heparinization of the catheter between dialysis may result in thrombus formation.
- Inserting male luer aggressively may cracks catheter female luer.

*Trend analysis of changes in access flow is the best predictor of access patency and risk for thrombosis.

Complications:

Early Potential Complications:

- Arterial puncture
- Bleeding
- Cardiac arrhythmias
- Injury to thoracic duct
- Injury to surrounding nerves
- Air embolism
- Catheter embolus
- Pneumothorax

Late Potential Complications:

- Venous thrombosis
- Cardiac perforation and tamponade
- Infection
- Hydrothorax

How Supplied:

AMECATH **Long Term Haemodialysis Catheter (P2 & PX)**) is a sterile, single use medical device.

- Each AMECATH **Long Term Haemodialysis Catheter (P2 & PX)** Kit is packed a PETG hard blister covered with PETG hard blister cover and wrapped together into one soft window bag.
- Each AMECATH **Long Term Haemodialysis Catheter (P2 pediatrics)**, Each catheter kit is packed in a PETG hard blister covered with Tyvek
- Each carton box includes 10 AMECATH **Long Term Haemodialysis Catheters (P2 & PX)** Kits.

AMECATH Long Term Haemodialysis Catheters (P2 & PX) method of application:

Before cannulation, you should consider the following:

Patient Evaluation Prior to Access Placement

Consideration	Relevance
History of previous CVC	Previous placement of a CVC is associated with central venous stenosis.
Dominant arm	To minimize negative impact on quality of life, use of the non dominant arm is preferred.
History of pacemaker use	There is a correlation between pacemaker use and central venous stenosis.
History of severe CHF	Placement of catheter may alter haemodynamics and cardiac output.
History of arterial or venous peripheral catheter	Previous placement of an arterial or venous peripheral catheter may have damaged target vasculature.
History of diabetes mellitus	Diabetes mellitus is associated with damage to vasculature necessary for internal accesses.
History of anticoagulant therapy or any coagulation	Abnormal coagulation may cause clotting or problems with haemostasis of access site.
Presence of co-morbid conditions, such as malignancy or coronary artery disease, that limit patient's life expectancy	Morbidity associated with placement and maintenance of certain accesses may not justify their use in some patients.
History of vascular access	Previously failed vascular accesses will limit available sites for access. The cause of a previous failure may influence planned access if the cause is still present.
History of heart valve disease or prosthesis	Rate of infection associated with specific access types should be considered.
History of previous arm, neck, or chest surgery/trauma	Vascular damage associated with previous surgery or trauma may limit viable access sites.

***Be sure that you are familiar with the above possible complications and emergency measures are known and available if any occur.**

General Steps:

*Ideally, catheter insertion should be undertaken under operating room sterile conditions.

1. Catheterize the patient in the usual manner.
2. Long Term Haemodialysis Catheter to be connected via it's end to the extension line or the stopcock.
3. Extension line or stopcock to be connected to the Haemodialysis Machine.

Equipment required for venous access:

Sterile kit pack of appropriate catheter design/ size/length
Local anesthetic
Sterile dressings and antiseptic solution
Syringes and needles
Saline or heparinized saline to prime and flush the line after insertion
Suture material
Shaving equipment for the area if required (especially the femoral)
Facility for chest X-ray, ultrasound, fluoroscopy

INSERTION SITE:
The Subclavian Vein.

- Whilst a high success rate for placement can be achieved, serious complications occur more commonly than with the other routes. Subclavian puncture should be avoided in patients with abnormal clotting since it is difficult to apply pressure to the subclavian artery following accidental puncture.
- Anteriorly, the vein is covered throughout its entire course by the clavicle.
- It lies anterior to, and below the subclavian artery as it crosses the first rib.
- Behind the artery lies the cervical pleura which rises above the sternal end of the clavicle.

Preparation and positioning.

- The patient should be supine, both arms by the sides, with the table tilted head down to distend the central veins and prevent air embolism.
- Turn the head away from the side to be cannulated unless there is cervical spine injury.
- Normally the right SCV is cannulated since the thoracic duct is on the left and may occasionally be damaged during cannulation.

Technique.

- Stand beside the patient on the side to be cannulated.
- Identify the midclavicular point and the sternal notch.
- The needle should be inserted into the skin 1cm below and lateral to the midclavicular point.
- Keeping the needle horizontal, advance posterior to the clavicle aiming for the sternal notch.
- If the needle hits the clavicle withdraw and redirect slightly deeper to pass beneath it.
- Do not pass the needle further than the sternal head of the clavicle.

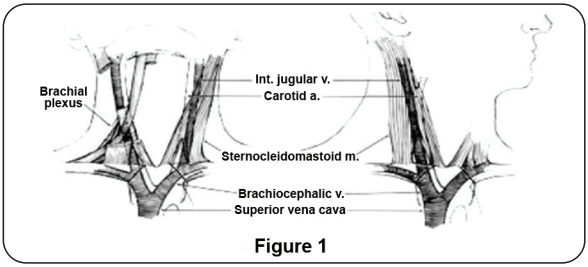


Figure 1

- Complications: Any of the described complications can occur but pneumothorax (2-5%) or rarely haemothorax or chylothorax (fatty white fluid in the pleural cavity due to leakage of lymph from thoracic duct) are more common with this route than the others.
- Occasionally the catheter may pass up into either jugular or the opposite SCV rather than into the chest which should be verified by radiological means.

The Internal Jugular Vein.

- The internal jugular vein (IJV) is a potentially large vein commonly used for central venous access which drains blood from the brain and deep facial structures.
- Cannulation is associated with a lower incidence of complications than the subclavian approach.

Preparation and positioning.

- The patient should be supine, both arms by the sides, with the table tilted head down to distend the central veins and prevent air embolism.
- Slightly turn the head away from the side to be cannulated for better access (turning it too far increases the risk of arterial puncture).

Technique.

- Stand at the head of the patient.
- Locate the cricoid cartilage and palpate the carotid artery lateral to it at this level.
- Keeping a finger gently over the artery, insert the needle at an angle of 30-40o to the skin and advance it downward towards the nipple on the same side (in a woman guess where the nipple would be as if she is a man). Always direct the needle away from the artery under your finger.
- The vein is usually within 2-3cm of the skin.
- If the vein is not found, redirect the needle more laterally.

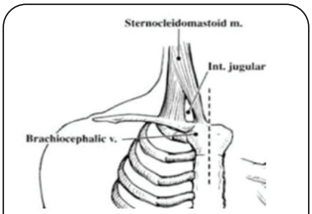
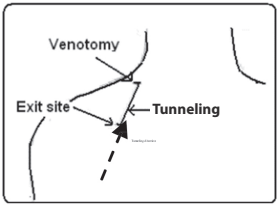


Figure 2

PLACEMENT PROCEDURE FOR TWINCATH, X SPLIT CATHETERS

The Twin Cath, X split Cath have no connector hub and their extensions legs end proximally without female luers connected to them. The catheters are suitable for retrograde tunnelling.
In retrograde tunnelling, inserting the catheter first to properly place its tip in the vessel, then perform the tunnelling of the proximal part of the catheters including its two legs The catheter extension sets are then re-assembled to the catheter legs.



INSERTION TECHNIQUES:

A. Direction for Seldinger insertion (venipuncture)

1. Confirm that central venous access is needed and select the most appropriate route. Explain the procedure to the patient.

2. Shave the needle insertion area if required.

3. While using a strict aseptic technique, prepare and check all the equipment for use. Sterilize the skin and drape the area.

4. Infiltrate the skin and deeper tissues with local anesthetic. In cases where difficulty is anticipated, you may use the small local anesthetic needle to locate the vein. This reduces the risk of trauma to other structures while using the larger introducer needle to locate the vein.

5. Position the patient for the selected route and better to avoid long periods of head down, particularly in breathless patients.

6. Identify the anatomical landmarks for the chosen route. Attach the guide wire introducing needle to a syringe then insert the needle at the recommended point of the selected route.

7. After penetrating the skin, aspirate gently whilst advancing the needle as directed until the vein is entered. If the vein is not found, slowly withdraw the needle whilst gently aspirating; often the vein has been collapsed and transfixed by the entry of the needle. Redirect the needle until gush of dark blood obtained.

8. A J-shaped guide wire is to be passed through the needle, with the wire tip positioned as far as the tip of the catheter should be better with fluoroscopic guidance. The length of the guide wire depends on patient size. Arrhythmia may take place if the guide wire is over advanced. The patient should be placed on Cardiac monitor all through the procedure.

9. The needle is then withdrawn, maintaining the guide wire in place.

B. Placing the catheter into the vein

10. By using a tip of a small scalpel, enlarge the skin puncture hole around the guide wire by 2 or 3 mm.

11. Use tissue dilators to dilate the entry of the guide wire. Use the 12 Fr dilator followed by the 14 Fr. Advance the dilator over the guide wire. A twisting motion while advancement of the dilator may facilitate dilatation. Remove the dilator and leave the guide wire in place.

12. Remove the dilator of the sheath and reinsert it into the opposite end. Lock the dilator in place by rotating it ninety degrees clockwise.

13. Advance a tearaway sheath introducer with its dilator over the guide wire straight end. Make sure that the sheath tip lies inside the vein. Do not bend the sheath dilator as this may cause permanent sheath tear. While advancing the sheath dilator, grasp it a few Centimeters from the skin entry. Advance, then re-grasp at the other location until complete advancement inside the vein.

*Precautions:

- The valve of the tear away introducer will substantially reduce air intake- At -12 mmHg vacuum pressure the valve may allow up to 4 cc/sec of air to pass through.

- Do not bend the sheath dilator during insertion as bending will cause the sheath to prematurely tear. Hold the introducer close to the tip (approximately 3 cm from the tip) when initially inserting through the skin surface.
- To progress the introducer towards the vein, re-grasp the introducer few centimeters above the original grasp location and push down on the introducer.
- Repeat procedure until introducer is inserted to appropriate depth based on patient anatomy.
- Never leave the sheath as indwelling catheter as this may injure the vein.
- Do not tear apart the portion of the sheath that remain in the vessel.
- To avoid vessel damage, pull back the sheath as far as possible and tear the sheath only few centimeters at a time.

14. Remove the guide wire and the dilator of the tearaway sheath and leave the sheath in place, if non valved tearaway is used, secure against possible air entry or blood loss through the sheath by closing its end by the thumb finger.

15. Use the clamp provided in the kit to clamp the catheter opened extension end marked with red print. This to prevent possible air embolism or blood loss. Do not use metal clamp as it will destroy the catheter.

16. Introduce the catheter tips (or both tips in X split catheter) into the sheath and advance it, while sharply snap the tabs of valve housing in a plane perpendicular to the long axis of the sheath to split the valve and tear the sheath apart while withdrawing from the vessel. tearing apart the sheath, until it is completely in the vein. Do not tear the part of the sheath inside the vessel. Pull the sheath and peel only a few centimeters at a time.

17. Further adjustment of the tip position should be done under fluoroscopy.

    17.1 Failure to verify catheter position may result in serious injuries or fatalities.

    17.2 Proper tip position will enhance flow rate and reduce possible recirculation.

C. CONSTRUCTING THE SUBCUTANEOUS TUNNEL.

18. Determine the tunnel position and its appropriate length so as to have the cuff lies inside it approximately 2 Cm from its exit site. Mark the exit site.

19. Once the exit site is determined, local anesthetic (lidocaine) is administered. The tunnel tract should also be anesthetized with 1% Lidocaine with epinephrine. The addition of epinephrine will keep bleeding to a minimum.

20. Initially a small dermatotomy (number 11 blade) is made at the exit site. Keeping the exit site small will help retain the cuff and decrease the opportunity for bacterial migration.

21. The tunnel length itself can vary. Original articles suggested a tunnel of at least 6 cm. However, this is not necessary depending on the patient's anatomy.

22. Using the supplied curved tunneling stylet with covering guard, create and widen a tunnel from the venotomy site in the direction of the exit site in a subcutaneous plane in a gentle dissection. Do not tunnel through muscle. Tunnel gently to avoid damaging the surrounding vessels.

23. Attach the opened end of catheter extension to the barbed end of the tunneling stylet and make sure it is securely connected.

24. Remove the clamp over the extension line.

25. Advance both catheter extensions inside the catheter guard tube, while pulling it onto them, to a reliable distance.

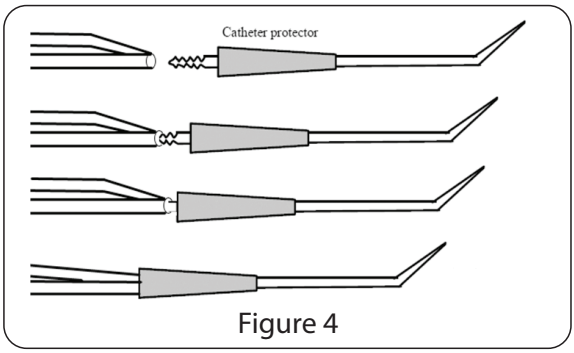


Figure 4

26. Pull the Tunneling stylet through the subcutaneous tunnel plane dragging the catheter with until the guard tube comes out the exit site with the catheter extension(s) inside it. If you feel resistance try simple dissection.

27. Clamp both catheter extension lines using the provided clamps.

28. Free the catheter extension ends by sliding the guard tube over the stylet and disconnect them.

29. Cut the catheter extension at the line marked for priming volume.

29.1 Cut the catheter at the priming volume line otherwise priming volume will not be correct

30. Secure the cuff in place and suture the tunnel exit site. Palpate the tunnel until proper cuff placement is achieved.

31. Assemble the catheter extension line (Figure 5 Step 1) by placing tighter cover of the catheter extension.
***N.B:** lumen distention is color identified on catheter extension.

31.1 Use only catheter extension assembly supplied in the kit. Extension line supplied by other manufacture might be not suitable with the catheters.

32. Connect the catheter extension assembly to the catheter (Step 2) by inserting the tube of the catheter extension assembly inside catheter extension. Screw the tighten cover to the female luer (Step 3) to tighten the assembly in its place.

33. Remove clamps over the catheter extensions.

33.1 Caution should betaken while assembling the red extension line to the catheter extension marked with red printing. Assemble the blue extension set to the catheter extension and marked with blue printing.

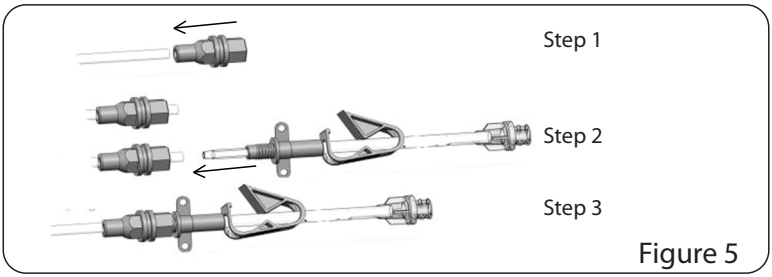


Figure 5

34. Attach syringe to the assembled catheter luer hub. Remove the pinch clamp on the catheter and aspirate. Good blood flow should be obtained from both the arterial and venous sides of the catheter otherwise catheter may need repositioning.

35. Once good blood flow is verified, flush catheter lumen with saline. Clamp catheter extension set.

36. Connect Catheter extension set and again open clamp on the catheter and aspirate to be sure that there is no air in the extension sets then flushed with saline. Close clamp of the extension set and cover its female luer end with the injection cap.

37. To keep patency heparin or other anti-coagulant lock should be used according to hospital protocol. It is imperative that catheters be flushed appropriately to avoid intraluminal thrombus. Each catheter will differ, and it is important to read priming volume printed on the catheter. Use positive intermittent flushing ("turbulent flow technique") and remove the flushing syringe while under pressure to reduce backflow of blood into the catheter.

38. Record Catheter Lot number, size, length and priming volume at patient file.

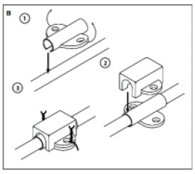
D. Securing the Device

39. Any exposed part of the catheter at the venotomy site should be implanted under the skin. Simply cut the skin for a suitable length, implant this part then suture the venotomy closed.

40. It is imperative that the device be secured. Using the tunneling method above there is less chance for catheter mobility and inadvertent removal. The addition of a 3 - 0 non-absorbable suture (not silk) may assist in stability. Place it approximately 1- 2 cm from the exit site to reduce infection from suture. Do not suture catheter tube. Use catheter fixation wing, a movable fixation wing or other fixation devices.

Fixation by suturing:

1. Take the flexible part of the moveable wing and spread the wings until the internal slit is opening position it on the catheter at the desirable place.
2. Snap the rigid part of the moveable wing over the flexible wings.
3. Suture the wings through the holes to the skin of the patient.



41. Place occlusive dressings on venotomy and exit sites.

Practical problems common to most techniques of insertion
Problems during Venous cannulation

Arterial puncture	Usually obvious but may be missed in a patient who is hypoxic or hypotensive. Withdraw the needle and apply firm direct pressure to the site for at least 10 minutes or longer if there is continuing bleeding. If there is minimal swelling then retry or change to a different route.
Suspected pneumothorax	If air is easily aspirated into the syringe (note that this may also occur if the needle is not firmly attached to the syringe) or the patient starts to become breathless. Abandon the procedure at that site. Obtain a chest radiograph and insert an intercostal drain if confirmed. If access is absolutely necessary then try another route ON THE SAME SIDE or either femoral vein. DO NOT attempt either the subclavian or jugular on the other side as bilateral pneumothoraces are produced.
Arrhythmias during the procedure	Usually from the catheter or wire being inserted too far (into the right ventricle). The average length of catheter needed for an adult internal jugular or subclavian approach is 15cm. Withdraw the wire or catheter if further than this.
Air embolus	This can occur, especially in the hypovolaemic patient, if the needle or cannula is left in the vein whilst open to the air. It is easily prevented by ensuring that the patient is positioned head down (for jugular and subclavian routes) and that the guidewire or catheter is passed down the needle promptly
The wire will not thread down the needle	Check that the needle is still in the vein. Flush it with saline. Try angling the needle so the end of it lies more along the plane of the vessel. Carefully rotate the needle in case the end lies against the vessel wall. Reattach the syringe and aspirate to check that you are still in the vein. If the wire has gone through the needle but will not pass down the vein it should be very gently pulled back. If any resistance is felt then the needle should be pulled out with the wire still inside, and the procedure repeated. This reduces the risk of the end of the wire being cut off by the needle tip.
Persistent bleeding at the entry side	Apply firm direct pressure with a sterile dressing. Bleeding should usually stop unless there is a coagulation abnormality. Persistent severe bleeding may require surgical exploration if there is an arterial or venous tear.

Considerations for Accessing Catheters and Cleansing Catheter Exit Sites:

Infection-control measures that should be used for all HD catheters include the following:

- The catheter exit site should be examined for proper position of the catheter and absence of infection by experienced personnel at each HD session before opening and accessing the catheter/port catheter system.
- Changing the catheter exit-site dressing at each HD treatment, using either a transparent dressing or gauze and tape.
- Use of dry gauze dressing combined with skin disinfection, using either chlorhexidine or povidone iodine solution, followed by povidone iodine ointment or mupirocin ointment at the catheter exit site are recommended after catheter placement and at the end of each dialysis session.
- Using aseptic technique to prevent contamination of the catheter, including the use of a surgical mask for staff and patient and clean gloves for all catheter or port catheter system connect, disconnect, and dressing procedures.
- The catheter hub caps, or bloodline connectors should be soaked for 3 to 5 minutes in povidone iodine and then allowed to dry prior to separation.
- Catheter lumen should never remain open to the air. A cap or syringe should be placed on or within the catheter lumen, while maintaining a clean field under the catheter connectors.

*Precautions:

- Patients must not swim, shower, or soak dressing while bathing.
- If profuse perspiration or accidental wetting compromises adhesion of dressing, the medical or nursing staff must change the dressing under sterile conditions.
- **Skin cleansing should include the following steps:**

1. Apply solution/swab in a circular motion working from catheter exit site outwards.
2. Cover an area 10 cm in diameter.
3. Repeat this step twice. Do not rinse off or blot excess solution from skin.
4. Allow solution to dry completely before applying dressing.

To cleanse the connection between any Dialysis hub and cap use 2 swabs:

1. Grasp connection with 1 swab.
2. Use second swab to clean from catheter connection up catheter for 10 cm.
3. Cleanse hub connection site and cap vigorously with the first swab. Discard swab.
4. Do not drop a connection site once it is cleaned.

To cleanse the section of the catheter that the skin, gently swab the top and undersides of the catheter starting at the exit site and working outwards. lies adjacent to

Connection to dialysis machine:

- The heparin solution must be removed from each lumen prior to treatment to prevent systemic heparinization of the patient. Aspiration should be based on dialysis unit protocol.
- Before dialysis begins all connections to catheter and extracorporeal circuits should be examined carefully.

- Frequent visual inspection should be conducted to detect leaks to prevent blood loss or air embolism.
- If a leak is found, the catheter should be clamped immediately.
  ***Precaution**
  Only clamp catheter with the provided clamps.
- Necessary remedial action must be taken prior to the continuation of the dialysis treatment.
  ***Note:** Excessive blood loss may lead to patient shock.
- Hemodialysis should be performed under physician's instructions.

E. End of Dialysis

At the end of the dialysis session

1. Clamp catheter extension line(s) and cap the catheter with the injection cap. This should be followed by priming the catheter by injecting heparin or equivalent (according to priming volume of catheter and its extension line) in the catheter via the injection caps.

2. Unclamp the catheter, inject heparin then clamp immediately to lock heparin inside the catheter.

3. Use of dry gauze dressing combined with skin disinfection, using either chlorhexidine or povidone iodine solution, followed by povidone iodine ointment or mupirocin ointment at the catheter exit site are recommended at the end of each dialysis session.

Prevention and Treatment of Catheter dysfunction

Catheters should be evaluated when they become dysfunctional. Dysfunction is defined as failure to attain and maintain an extracorporeal blood flow of 300 mL/min (for adult size catheter) or greater at a pre pump arterial pressure more negative than - 250 mm Hg.

Signs of Catheter Dysfunction: Assessment Phase

- Blood pump flow rates <300 mL/min
- Arterial pressure increases (< - 250 mm Hg)
- Venous pressure increases (>250 mm Hg)
- Conductance decreases (<1.2): the ratio of blood pump flow to the absolute value of pre-pump pressure.
- Unable to aspirate blood freely (late manifestation)
- Frequent pressure alarms - not responsive to patient repositioning or catheter flushing

Causes of Early Catheter Dysfunction

- Mechanical compression (pinch off syndrome in subclavian catheter)
- Kinks (angulations in tunnel)
- Misplaced sutures that cause catheter migration
- Side holes occlusion due to clotting or fibrin sheath formation or stuck to vein wall.
- Drug precipitation (some antibody locks or IV IgG)
- Patient position especially in not well fixed and secured catheter
- Loss of catheter integrity by infection
- Catheter extension crushing, tear or crack from repeated clamping

Methods that should be used to treat a dysfunctional or nonfunctional catheter include:

- Repositioning of a malposition catheter using snare.

- Change patient position, ask him to cough or vigorous flush (if no resistance is felt) trying to dislodge side holes a way from vein wall.
- Fibrin sheath stripping using a snare if a fibrin sheath is present.
- Exchanging the thrombosed catheter over a guidewire if a fibrin sheath is present or if the catheter is malpositioned or of inadequate length.
- Use of thrombolytics, as per hospital protocol.
- Treatment of an infected HD catheter should be based on the type and extent of infection.
- All catheter-related infections, except for catheter exit-site infections, should be addressed by initiating parenteral treatment with an antibiotic(s) appropriate for the organism(s) suspected.
- Definitive antibiotic therapy should be based on the organism(s) isolated.
- Catheters should be exchanged as soon as possible and within 72 hours of initiating antibiotic therapy in most instances, and such exchange does not require a negative blood culture result before the exchange. Follow-up cultures are needed 1 week after cessation of antibiotic therapy.
- Catheter extension crushing can be solved by exchanging the damaged part. The extension tube is to be clamped between catheter and the damaged part. Cut the catheter tube at the damaged part and reassembled a female luer as illustrated in Figure 5.

Treatment of Infection of Tunneled Cuffed Catheters

Tunneled cuffed catheter infection is a serious problem. Appropriate treatment is dependent upon the nature of the infection:

i. Catheter exit site infections

Characterized by redness, crusting, and exudates at the exit site in the absence of systemic symptoms and negative blood cultures should be treated as follows:

1. Apply topical antibiotics, ensuring proper local exit site care; do not remove the catheter.

2. If there is tunnel drainage, treat with parenteral antibiotics (anti-staphylococcal, anti-streptococcal therapy pending exit site cultures) in addition to following appropriate local measures. Definitive therapy should be based on culture results. Do not remove the catheter unless the infection fails to respond to therapy. If the infection fails to respond to therapy, remove the catheter and replace it using a different tunnel and exit site.

ii. Catheter-related bacteremia

Should be treated by initiating parenteral treatment with an antibiotic(s) appropriate for the suspected organism(s), usually Staphylococcus and Streptococcus. Definitive therapy should be based on the organism(s) isolated. The catheter should be removed in all instances if the patient remains symptomatic more than 36 hours. The catheter should also be removed in any clinically unstable patient. A new permanent access should not be placed until blood cultures, performed after cessation of antibiotic treatment, have been negative for at least 48 hours.

F. Catheter removal

*** Only a physician familiar with the appropriate techniques should attempt the following procedures.**

*** Always review hospital or unit protocol, potential complications and their treatment, warnings, and precautions prior to catheter removal.**

*Precautions

1. Remove any dressing and suture material.

2. Ask the patient to take a breath and fully exhale.
3. Removal of the catheters required infiltration of local anesthesia at the exit site and cuff area.
4. Cut sutures if present.
5. Palpate the cuff at the tunnel make 2 Cm cut over the cuff and parallel to catheter.
6. Perform careful dissection around the Dacron cuff to free it from the subcutaneous tissues and fibrous sheath.
7. Grasp the cuff with clamp and cut the catheter between cuff and insertion site.
8. Remove catheter remaining through the cut made over the cuff.
9. Pull the proximal part of the catheter from the exit site and not from the incision over the cuff.
10. Apply pressure at the tunnel area for 10-15 minutes or until any bleeding stops.
11. Ask the patient to remain in an upright position for a minimum of 2 hours.

N.B for further information on luer connections, please refer to latest version of BS EN ISO 80369-7

Product Variants:

For variants of AMECATH **Long Term Haemodialysis Catheters (P2 & PX) ,** Kindly refer to the catalogue, visit our website on **"www.amecathgroup.com"** , or contact your nearest AMECATH representative.

1. Code Structure: P2TC -xxll-K00

Xx: for Catheter size in Fr.

Ll: for Catheter Length in cm.

K00: Variable Kit Configurations with Different Contents as per below table

Reference	Contents
Pediatric Range	
P2TC-XXLL-KV	• Permthane Long Term Pediatric Twin Lumen Haemodialysis Catheter with Integrated Female Luer Valve • J End Nitinol Core Guide Wire • (2) Vessel Dilator • 5cc Syringe • G18 x 5 cm Introducer Needle, Echogenic • Scalpel #11 • Movable Fixation Wing • Valved Peelable Introducer Sheath • Blunt Curved Tunneling Stylet • (2) Repair Valves

	• Transparent Catheter Fixation Adhesives • Catheter Tube Fixation Adhesive (Unifix) • Guiding Y Connector
P2TC-XXLL-K	• Permthane Long Term Pediatric Twin Lumen Straight Haemodialysis Catheter. • (1) J End Nitinol Core Guide Wire • (2) Vessel Dilators • (1) 5 cc Syringe • (1) G18 x 5 cm Introducer Needle, Echogenic • (1) Scalpel #11 • (1) Movable Fixation Wing • (1) Valved Peelable Introducer Sheath • (1) Blunt Curved Tunneling Stylet • (2) Injection Caps • (2) Transparent Catheter Fixation Adhesive • (1) Catheter Tube Fixation Adhesive (Unifix) • (1) Guiding Y Connector
P2TC-XXLL-KPC	• Permthane Long Term Pediatric Pre-Curved Haemodialysis Catheter (1) J End Nitinol Core Guide Wire • (2) Vessel Dilators • (1) 5 cc Syringe • (1) G18 x 5 cm Introducer Needle, Echogenic • (1) Scalpel #11 • (1) Movable Fixation Wing • (1) Valved Peelable Introducer Sheath • (1) Blunt Curved Tunneling Stylet • (2) Injection Caps • (2) Transparent Catheter Fixation Adhesive • (1) Catheter Tube Fixation Adhesive (Unifix) • (1) Guiding Y Connector
Adult Range	
P2TC-XXLL-K	• (1) Permthane Long Term Adult Twin Lumen Straight Haemodialysis Catheter. • (1) J End Nitinol Core Guide Wire • (2) Vessel Dilators • (1) 10 cc Syringe • (1) G18 x 7 cm Introducer Needle, Echogenic • (1) Scalpel #11 • (1) Movable Fixation Wing • (1) Valved Peelable Introducer Sheath (Peelable Introducer Sheath for 16Fr Catheter) • (1) Blunt Curved Tunneling Stylet • (2) Free Female Luer Line for Retrograde (Red for Arterial + Blue for Venous) • (1) Flushing Connector • (2) Slide Clamps • (2) Transparent Catheter Fixation Adhesive • (1) Catheter Tube Fixation Adhesive (Unifix) • (1) Guiding Y Connector
P2TC-XXLL-KPC	• (1) Permthane Long Term Adult Twin Lumen Pre-Curved Haemodialysis Catheter. • (1) J End Nitinol Core Guide Wire • (2) Vessel Dilators • (1) 10 cc Syringe • (1) G18 x 7 cm Introducer Needle, Echogenic • (1) Scalpel #11 • (1) Movable Fixation Wing • (1) Valved Peelable Introducer Sheath (Peelable Introducer Sheath for 16Fr Catheter) • (1) Blunt Curved Tunneling Stylet • (2) Free Female Luer Line for Retrograde (Red for Arterial + Blue for Venous) • (1) Flushing Connector • (2) Slide Clamps

	• (2) Transparent Catheter Fixation Adhesive • (1) Catheter Tube Fixation Adhesive (Unifix) • (1) Guiding Y Connector

2. Code Structure: PXDLC -xxll-K00

Xx: for Catheter size in Fr.

Ll: for Catheter Length in cm.

K00: Variable Kit Configurations with Different Contents as per below table

Reference	Contents
PXDLC-XXLL-K	• Permthane Long Term X Split Dual Lumen Straight Haemodialysis Catheter • J End Nitinol Core Guide Wire • (2) Vessel Dilator • 10cc Syringe • G18 x 7 cm Introducer Needle, Echogenic • Scalpel #11 • Movable Fixation Wing • Valved Peelable Introducer Sheath (Peelable Introducer Sheath for 16Fr. Catheter) • Blunt Curved Tunneling Stylet 3mm, Round Tip, Screw End • (2) Free Female Luer Line for Retrograde (Red for Arterial + Blue for Venous) • Flushing Connector • Slide Clamps • Transparent Catheter Fixation Adhesives • Catheter Tube Fixation Adhesive (Unifix) • Guiding Y Connector
PXDLC-XXLL-KPC	• Permthane Long Term X Split Dual Lumen Pre-Curved Haemodialysis Catheter • J End Nitinol Core Guide Wire • (2) Vessel Dilator • 10cc Syringe • G18 x 7 cm Introducer Needle, Echogenic • Scalpel #11 • Movable Fixation Wing • Valved Peelable Introducer Sheath (Peelable Introducer Sheath for 16Fr. Catheter) • Blunt Curved Tunneling Stylet 3mm, Round Tip, Screw End • (2) Free Female Luer Line for Retrograde (Red for Arterial + Blue for Venous) • Flushing Connector • Slide Clamps • Transparent Catheter Fixation Adhesives • Catheter Tube Fixation Adhesive (Unifix) • Guiding Y Connector

Storage and Product Safe Disposal

- Store between 5°C to 30°C.
- Do not expose to organic solvents, ionizing radiation or ultraviolet light.
- Rotate inventory so that catheters are used prior to expiration date on the package label.
- Used product should be disposed in sanitary container to prevent possible contamination and cross infection.

- **N.B. please provide patients by the instructions of home care attached to this document.**
- In case of any questions or quiries, Kindly contact the local Authorised Representative or visit AMECATH website on : " **www.amecathgroup.com** "
- **In case of any Adverse event, Contact your local Health Authority immediately.**
- **Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established**
- For Summary of Safety and Clinical Performance "SSCP" please visit **EUDAMED** website on : **https://ec.europa.eu/tools/eudamed/eudamed** (BASIC UDI-DI: 6221139DIA-LGT-03RX).

AMECO MEDICAL INDUSTRIES
Industrial Zone B4 - Plot 119 East.
10th of Ramadan City - Egypt
Tel: +20 5545 01321/2 - Fax: +20554501224
support@amecathgroup.com | www.amecathgroup.com

EC REP

OBELIS S.A
Bd. Général Wahis, 53
1030 Brussels - BELGIUM
Tel: +32.2.732.59.54 | Fax: +32.2.732.60.03
mail@obelis.net | www.obelis.net