

PERIPHERAL INSERTED CENTRAL VENOUS CATHETER KIT

Device Description:

AMECATH Peripheral Inserted Central Venous Catheters are Radiopaque and made from polyurethane.

AMECATH Peripheral Inserted Central Venous Catheters are single, dual or multilumen catheters for adult and pediatric use.

For Non pressure resistant peripheral inserted central venous catheters: Catheters size ranges between 3 Fr to 6 Fr and length ranges between 40 Cm to 60 Cm.

For pressure resistant peripheral inserted central venous catheters: Catheters size ranges between 3 Fr to 6 Fr and length ranges is 55 Cm.

AMECATH Peripheral Inserted Central Venous Catheters are placed peripherally in the cubital area. Peripheral placement avoids possible risk of central placement.

* Pressure resistant catheters (identified by purple color) and indicated also for high pressure injection.

*Catheters are supplied with two kit types for direct puncture following Seldinger technique (using over needle peel away) or its modified technique (using over dilator peel away).

AMECATH Peripheral Inserted Central Venous Catheters to be cannulated Cephalic, Basilic or the median Cubital veins. Basilic is the preferred insertion site for peripherally inserted central venous catheters. Placement above antecubital fossa is recommended.

***Warning:** Placement at or below antecubital fossa may result in phlebitis

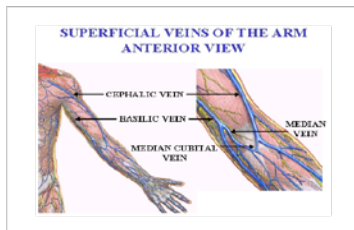


Figure 1

Device construction:

Catheter Types

- Non pressure Resistant Peripheral Inserted Central Venous Catheters
- Pressure Resistant Peripheral Inserted Central Venous Catheters

List of Accessories:

The Catheter Kit for Seldinger Technique (Direct Puncture) has the following accessories:

- Tohy-burst T connector with side valve.
- Straight end Nitinol core wires with stainless steel tip or gold coated tip.
- Over the needle peel away sheath introducer.
- Mini scalpel.
- Syringe.
- Additional Valves.
- Catheter securement.
- Measuring tape.

The Catheter Kit for Modified Seldinger Technique has the following accessories:

- Tohy-burst T connector with side valve.
- Straight end Nitinol core wires with stainless steel tip or gold coated tip.
- Straight end Nitinol guide wires.
- Echogenic Introducer needle.
- Short over dilator peel away sheath introducer.
- Measuring tape.
- Mini scalpel.
- Syringe.
- Additional Valves.
- Catheter securement.

Intended Use:

The Peripheral Inserted Central Venous Catheter is a sterile single use device indicated to be placed peripherally for use in attaining access to the central venous system for the purpose of:

- Administration of vasoactive/inotropic drugs which can be given peripherally
- Administration of incompatible medications
- Administration of hypertonic solutions including total parenteral nutrition
- Frequent blood sampling
- Blood transfusion
- Channel for measurement of central venous pressure (extra equipment is required)
- Power Injection of contrast media in pressure resistant (identified by purple color) ONLY

Contraindications:

- The catheter should not be placed in patient with bleeding disorders
- In the presence of another device related infection, bacteraemia or septicemia is known or suspected.
- If severe chronic obstructive lung disease exists
- Previous episodes of venous thrombosis or vascular surgical procedure at the prospective placement site have occurred.
- Local tissue factors which may prevent proper devices stabilization and/or access.
- History of mastectomy at the insertion site.

Warnings and Precautions

General

- For single 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 severe deterioration in health and safety of patients.
- The catheter does not have any metallic components and can be exposed to various environmental conditions including thermal ignition source (during MRI) as long as no metal component is attached to it.
- The insertion technique has a significant influence on the complications and outcome of the patient. Insertion must be performed by a competent and experienced catheter insertion team. Inexperienced personnel should not be permitted to perform the insertion except under the direct supervision of an experienced physician or surgeon

- Ultrasound could be used in the placement of catheters.
- The position of the tip of any central catheter should be verified by radiological means.
- 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 antimicrobial ointments on catheters as it may cause its degradation
- Do not place central venous catheter (CVC) or peripherally inserted central catheter (PICC) into or allow them to remain in the right atrium or right ventricle. X-ray exam or other method in compliance with hospital protocol must show catheter tip located in right side of mediastinum in the superior vena cava above its junction with right atrium and parallel to vessel wall and its distal tip positioned at a level above either azygos vein or carina of the trachea, whichever is better visualized.
- Although cardiac tamponade secondary to pericardial effusion is uncommon, there is a high mortality rate associated with it.
- Practitioners must be aware of the potential for entrapment of guidewire by any implanted device in circulatory system (i.e., vena cava filters, stents). Review patient's history before catheterization procedure to assess for possible implants. Care should be taken regarding length of guidewire inserted. It is recommended that if patient has a circulatory system implant, catheter procedure be done under direct visualization to minimize the risk of guidewire entrapment.
- Catheter tip must be located in central circulation when administering > 10% glucose solution, total parenteral nutrition, continuous vesicant therapy, infusates with pH less than 5 or greater than 9, and infusates with an osmolality above 600 mOsmol, or any medication known to be irritating to vessels proximal to the vena cava.
- Be aware of the risk of chemically induced thrombophlebitis when catheter is placed with distal end located in a vessel proximal to the Superior Vena Cava (SVC).
- Do not leave open needles or uncapped, unclamped catheters in central venous puncture site. Air embolism can occur with these practices.
- The methods of application are variable, and could be modified by the Physician according to his own experience.

Specific

- For high pressure injection applications, only utilize lumen indicated for such applications. Lumen not indicated for high pressure applications can result in inter-lumen crossover or rupture with potential for injury.
- Do not apply excessive force in placing or removing catheter. Failure to do so can result in catheter breakage. If placement or withdrawal cannot be easily accomplished, an x-ray should be obtained and further consultation requested.
- Do not secure, staple, and for suture directly to outside diameter of catheter body or extension lines to minimize the risk of cutting or damaging the catheter or impeding catheter flow. Secure only at indicated stabilization locations.
- Do not cut catheter to alter catheter length unless procedure requires it.
- Catheter clamp must not be attached to catheter until either guidewire or placement wire is removed.
- Do not use scissors to remove dressing to minimize the risk of cutting catheter.
- Catheter clamp must be opened prior to infusion to minimize risk of damage to extension lines from excessive pressure.
- If supportive wire has been removed prior to catheter insertion. Attempting supportive wire advancement or reinsertion increases the risk of damaging catheter or wire.
- Do not clamp extension lines when placement wire is in catheter to minimize the risk of wire kinking.

- Check ingredients of prep sprays and swabs before using. Some disinfectants used at catheter insertion site contain solvents which can attack the catheter material. Alcohol and acetone can weaken the structure of polyurethane materials. These agents may also weaken the adhesive bond between catheter stabilization device and skin.
- Take care when instilling drugs containing high concentration of alcohol.
- Allow insertion site to dry completely prior to applying dressing.
- Do not use syringes smaller than 10 ml to minimize the risk of pressure induced damage to catheter.
- Do not exert excessive force while removing the catheter to minimize the risk of catheter breakage.
- Continuously monitor catheters for:
 - desired flow rate
 - security of dressing
 - adherence of stabilization device to skin and connection to catheter
 - correct catheter position; use centimeter markings to identify if catheter position has changed
 - secure connections
- Inject a small amount of radiopaque dye to locate catheter tip if difficulty is encountered in visualizing the catheter tip

Complications

Early Potential Complications:

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

Late Potential Complications:

- Venous thrombosis
- Cardiac perforation and tamponade
- Infection

How Supplied:

- AMECATH Peripheral Inserted Central Venous Catheter is a sterile, single-use Medical device
- Each AMECATH Peripheral Inserted Central Venous Catheter Kit is packed in a PETG hard blister covered with PETG hard blister cover and wrapped together into one soft window bag
- Each carton box includes 10 AMECATH Peripheral Inserted Central Venous Catheter Kits

AMECATH Peripheral Inserted Central Venous Catheter method of application

Before Insertion

Identify insertion vein:

- Apply tourniquet above anticipated insertion vein.
- Identify appropriate vein for insertion and access vein suitability.
- Temporarily release the tourniquet.

Measure patient to assure placement of catheter in the SVC.

- Extend arm laterally 45° to 90° from trunk.
- Use the measuring tape to measure distance from insertion site along presumed anatomical course of vessel to be catheterized.

- Catheter tip should lie in distal one-third of SVC above right atrium and parallel to SVC wall.
- If catheter stabilization device will be used, add 2 cm to catheter measurement

General Steps:

1. Drape puncture site.
2. Perform a local anesthetic as needed.
3. Prepare Catheter with supportive wire in place.
4. Trim Catheter as needed by retracting the supportive wire and cut the catheter straight across (90° to catheter cross section) to maintain a blunt tip. If greater resistance is felt, it is likely to be caused by the supportive wire which has not been sufficiently retracted. If so, do not use catheter.

*Warnings and Precautions:

- Clinicians should use sterile techniques and dress in protective clothing.
- Review catheter marking pattern as catheter is marked so clinician can easily identify desired length of catheter to be trimmed.
- Inspect cut edge for clean cut and no loose material.
- Check that there is no wire in cut catheter segment.
- If any evidence that placement wire has been cut or damaged, catheter should not be used.
- Do not cut placement wire when trimming catheter to minimize the risk of foreign embolism

Insertion with Modified Seldinger - Using over dilator peel away sheath.

1. Reapply tourniquet and replace sterile gloves.
2. Locate vein for insertion and use image guidance if available.
3. Insert introducer needle into vein and check for pulsatile flow. Pulsatile flow is usually an indicator of inadvertent arterial puncture.
 - 3.1. Caution should be taken that the color of blood observed is not always a reliable indicator of venous access.
4. Insert soft tip of guide wire through introducer needle into vein. Advance guide wire to desired depth.
 - 4.1. Do not insert stiff end of guidewire into vessel as this may result in vessel damage.
 - 4.2. Do not cut guide wire to alter length.
 - 4.3. Do not withdraw guidewire against needle bevel to minimize the risk of possible severing or damaging of guidewire
 - 4.4. 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
5. Hold guidewire in place while removing introducer needle and maintain firm grip on guidewire at all times.
6. Enlarge puncture site if necessary by using scalpel positioned away from the guidewire to enlarge the puncture site.
7. Thread tapered tip of peel-away sheath dilator assembly over guidewire. Advance assembly with slight twisting motion to a depth sufficient to enter vessel. Dilator may be partially withdrawn to further facilitate advancement of sheath into the vessel. A slight twisting motion of the peel-away might help sheath advancement.
 - 7.1. Caution should be taken Not to withdraw tissue dilator until the sheath is well within the vessel to minimize the risk of damage to sheath tip.

- 7.2. Caution should be taken that Sufficient guide wire length must remain exposed at hub end of sheath to maintain the firm grip on guide wire
8. Hold the sheath in place; withdraw guide wire and dilator as one unit.
 - 8.1. Do not leave the dilator in place to minimize the risk of possible vessel wall perforation.
 - 8.2. Do not apply undue force on guidewire to minimize the risk of possible breakage.
9. Insert Catheter through peel-away sheath.
 - 9.1. Do not apply excessive force in placing or removing catheter. Failure to do so can result in catheter breakage.
 - 9.2. If placement or withdrawal cannot be easily accomplished, an X-ray should be obtained and further consultation requested.
10. If resistance is met while advancing catheter, retract and/or gently flush while advancing.
11. Before reaching pre-established insertion length, withdraw peel-away sheath over catheter until free from puncture site.
12. Grasp tabs of peel-away sheath and pull apart away from catheter until sheath splits down entire length.
13. Advance catheter to final position and remove catheter supportive wire.
 - 13.1. Remove placement wire and luer-lock sidearm assembly, if used, as one unit. Failure to do so may result in wire breakage.
 - 13.2. Caution should be taken that Catheter clamp must not be clamped until guidewire is removed.
14. Verify Catheter tip placement by checking catheter placement with syringe and aspirating through distal lumen until free flow of venous blood is observed.
 - 14.1. Caution should be taken that the color of blood is not always a reliable indicator of venous access.
15. Flush lumen(s) to completely clear blood from catheter. Use catheter clamps, if provided, to occlude lumen(s). If catheter is equipped with female luer valve follow the following instructions
 - 15.1. To access the valve connector: Swab silicone seal in accordance with facility protocol. (illustration 1)
 - 15.2. To attach Male Slip Luer to valve connector: Grasp the valve connector and position the luer/syringe so that the luer/syringe will be pushed straight into the Valve using a twisting motion, as shown. Do not attempt to insert the luer/syringe at an angle. There is no need to pry open the slit in the valve (illustration 2)
 - 15.3. To attach Male Luer Lock to valve connector: Grasp the valve connector and position the luer so that the luer will be pushed straight into the valve using a twisting motion, as shown (illustration 3).

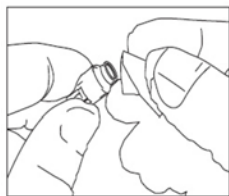


Illustration 1



Precaution:

- Do not attempt to insert the luer at an angle. There is no need to pry open the slit in the valve.
- Do not over tighten the luer lock.

15.4. To disconnect from valve: Grasp valve and twist syringe or blood tubing set connector clockwise until loose, then pull away from valve connector.

15.5. Flush the valve connector after each use, in accordance with facility protocol.

15.6. The valve closes and seals once a connector is removed from the valve connector therefore capping is optional

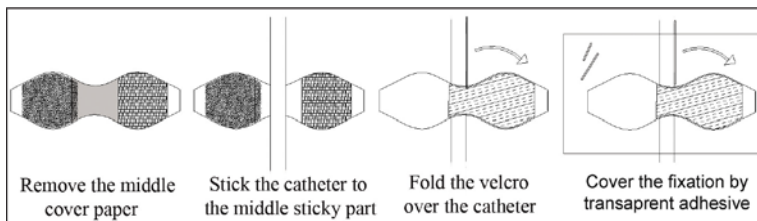
16. Cleanse insertion site per hospital protocol.

17. Ensure insertion site is dry before applying dressing.

17.1. Caution should be taken not to apply prophylactic topical antimicrobial or antiseptic ointment or cream to the insertion site of peripheral venous catheters because of the potential risk to promote fungal infections and antimicrobial resistance.

18. Secure catheter in place by suture fixation or using adhesives.

- Fixation with tube fixation adhesive



- Fixation with hub fixation adhesive

The hub is suitable to work with many commercial hub fixation adhesives

19. Assess placement of catheter tip in compliance with hospital protocol.

Insertion by Direct Puncture - Using over needle peel away sheath.

1. Reapply tourniquet and replace sterile gloves.
2. Locate vein for insertion and use image guidance if available.
3. Insert the over needle peelaway sheath into vein and be sure that the flow is not pulsatile. Pulsatile flow is usually an indicator of inadvertent arterial puncture.
4. Hold the sheath in place, withdraw its needle.
5. Continue with step (9.) mentioned above

Checks before using the pressure PICC Catheter (identified by purple color) for contrast media injection.

1. Attach a 10 ml or larger syringe filled with sterile normal saline.
2. Aspirate for adequate blood return and vigorously flush the catheter with the full 10 ml of sterile normal saline.
 - 2.1. Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
3. Detach the syringe
4. Attach the power injection device to the catheter pressure tube marked "pressure"

- 4.1. The lumen indicating “pressure” is the only lumen to be used for high pressure injection. Do not attempt to use the other lumen(S) in this procedure as it may result in catheter rupture and high risk to the patient.
5. Contrast media should be warmed to body temperature prior to power injection.
 - 5.1. Failure to warm contrast media to body temperature prior to power injection may result in catheter failure.
6. Use only lumens marked “Pressure” for power injection of contrast media.
 - 6.1. Use of lumens not marked “Pressure” for power injection of contrast media may cause failure of the catheter.
7. Complete power injection study taking care not to exceed the flow rate limits. Do not exceed the maximum flow rate of 5 ml/sec.
 - 7.1. Power injector machine pressure limiting feature may not prevent over-pressurization of an occluded catheter, which may lead to catheter failure.
 - 7.2. Exceeding the maximum flow rate of the flow rate ML/SEC printed on the extension line or the maximum pressure of power injectors of 300 psi may result in catheter failure and/or catheter tip displacement.
8. Disconnect the power injection device.
9. Flush the catheter with 10 ml of sterile normal saline, using a 10 ml or larger syringe. In addition, lock each lumen of the catheter with heparinized saline. Usually one ml per lumen is adequate.

Causes of Early Catheter Dysfunction

- Mechanical compression (pinch off syndrome in subclavian catheter)
- Malposition of catheter tip
- Kinks
- Catheter migration
- Drug precipitation (some antibody locks or IV IgG)
- Loss of catheter integrity by infection

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

- Repositioning of a malpositioned catheter.
- Use of thrombolytic, as per hospital protocol.
- 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 Care and Maintenance

Dressing

- Replace dressing according to organizational policies, procedures, and practice guidelines. Change immediately if the integrity becomes compromised e.g. dressing becomes damp, soiled, loosened, or no longer occlusive.
- Transparent semipermeable membrane dressing should be changed every week.

- Gauze and tape should be changed every 2 days.
- Label dressing with type, size, and length of catheter; date and time.

Maintain Catheter Patency:

Maintaining central venous catheter patency should be done in accordance with hospital policies, procedures, and practice guidelines. The personnel who care for patients with central venous catheters must be knowledgeable about effective management to prolong catheters dwell time and prevent injury.

- Solution and frequency of flushing a venous access catheter should be established in hospital policy.
- Catheter patency is established and maintained by flushing intermittently via syringe with heparinized saline or 0.9% sodium chloride. Continuous drip is preferred.

***Caution:** Assess patient for heparin sensitivity. Heparin-induced thrombocytopenia has been reported with the use of heparin flushing solutions.

- The volume of flush solution should be equal to at least twice the priming catheter.
- When using any central venous catheter for intermittent infusion therapy, proper flushing using a positive-pressure flushing technique will help prevent occlusion.
- All valves, if used, need to be properly swapped with an appropriate antiseptic before being accessed.

Catheter removal

Catheter shall be removed immediately upon patient assessment for:

- suspected contamination
- unresolved complication
- discontinuation of therapy
- Place patient in supine position to minimize the risk of potential air embolism.
- Remove dressing and securements.
- Remove catheter by slowly pulling it parallel to skin. If resistance is met, catheter should not be forcibly removed and the physician should be notified.

Caution should be taken not to exert excessive force while removing the catheter; to minimize the risk of catheter breakage.

- Upon removal of catheter, measure and inspect to ensure entire catheter length has been removed
- Apply direct pressure at site until hemostasis is achieved.
- Dress insertion site with sterile occlusive dressing

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

Description of marking system

The catheter tube is reversely marked for effective length in numerical number every 10 centimeter and dot every 1 centimeter. The marking starts and ascends from catheter hub.

Example for 60 cm long:

Tip 50 40 30 20 10 hub

Product Variants:

For variants of AMECATH Peripheral Inserted Central Venous Catheters, Kindly refer to the catalogue, visit our website on “www.amecathgroup.com”, or contact your nearest AMECATH representative.

Peripheral Central Venous Catheter Kits

Code Structure: nLPICC-xxII-K00

N: number of Lumens

S: for Single Lumen Catheter **D:** for Dual Lumen Catheter **T:** for Triple Lumen Catheter

XX: for Catheter size in Fr.

II: for Catheter Length in cm.

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

Reference	Contents
nLPICC-xxII-KON	<ul style="list-style-type: none"> • Single/Multi Lumen Peripheral Inserted Central Venous Catheter. • Touhy-Burst adaptor • T-connector with sidearm with needless connector • 0.018" Nitinol Stiffener with flexible tip • Over the needle peel away sheath introducer. • Safety scalpel • 10 cc Syringe lock • Needleless connector (valve), 1 for dual lumen and 2 for triple lumen • Catheter hub securement adhesive. (Unifix lock) • Transparent catheter adhesives. • Measuring Tape.
Pressure resistant catheters are available. Please add PR before the code (PRC nLPICC-xxII-KON)	
NCD-SET-H	<ul style="list-style-type: none"> • Single/Multi Lumen Peripheral Inserted Central Venous Catheter. • Touhy-Burst adaptor • T-connector with sidearm with needless connector • 0.018" Nitinol Stiffener with flexible tip • G21x 7 cm introducer needle with echogenic tip. • Straight end 0.018" x 50 cm Nitinol core guidewires • 5 Cm Over the dilator peel away sheath introducer. • Safety scalpel • 10 cc Syringe lock • Needleless connector (valve), 1 for dual lumen and 2 for triple lumen • Catheter hub securement adhesive. (Unifix lock) • Transparent catheter adhesives. • Measuring Tape.
<ul style="list-style-type: none"> • Pressure resistant catheters are available. Please add PR before the code (PRCnLPICC-xxII-KOD) • If we Take Over the Dilator 7 Cm. Please add (*) after the code (PRCnLPICC-xxII-KOD*) 	

Storage and Product Safe Disposal

- Store at room controlled temperature.
 - 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.
 - Used Catheter should be disposed as hospital protocol or in sanitary container to prevent possible contamination and cross infection.
- ◆ In case of any questions or queries, Kindly contact the local Authorised Representative or visit **AMECATH** website on : "www.amecathgroup.com"
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