Midline Venous Catheter kit

Device Description:

AMECATH **Midline Venous Catheters** are Radiopaque Peripherally Inserted venous catheters of single or dual lumens.

AMECATH **Midline Venous Catheters** are made from polyurethane.

AMECATH **Midline Venous Catheters** are longer than peripheral IV catheters and shorter than peripherally inserted central catheters (PICC) which extend into the vena cava.
For Midline Venous Catheters: Catheters size ranges between 3 Fr to 5 Fr and lengths ranges between 10 Cm to 25 Cm.
For Pressure Resistant Midline Venous Catheters: Catheters size ranges between 3 Fr to 5 Fr and lengths ranges between 10 Cm to 25 Cm.

This device provides an alternative to short peripheral IVs for certain treatments
* The tip of the midline catheter should rest in the upper extremity of the insertion arm, not in the midclavicular region as this may be associated with complications due to catheter whip and deep vein thrombosis.
* Pressure resistant catheters (identified by purple color) and indicated also for high pressure injection.

AMECATH **Midline Venous Catheters** to be cannulated in Cephalic, Basilic or the median Cubital veins. Basilic is the preferred insertion site for peripherally inserted venous catheters. Placement above anticubital fossa is recommended.
***Warning:** Placement at or below anticubital fossa may result in phlebitis

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

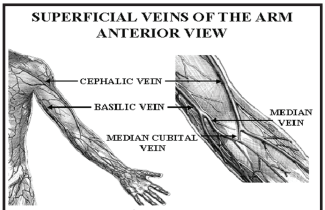


Figure 1

AMECATH **Midline Venous Catheters** are available in different designs and Kit configurations to cover all customer needs.

Device construction:

Catheter Types:

- Non pressure Resistant Midline Venous Catheters
- Pressure Resistant Midline Venous Catheters

List of Accessories:

The Catheter Kit for Seldinger Technique (using IV cath cannula) has the following accessories:

- IV Cannula
- Straight End Stainless Steel Guide Wire

The Catheter Kit for Seldinger Technique (using over needle peel away introducer) has the following accessories:

- Straight End Stainless Steel Wire Stiffener

- Over the Needle Peel Away Sheath Introducer
- Syringe
- Safety Scalpel
- Cap(s)
- Catheter Hub Securement Adhesive (Unifix Lock)
- Transparent Catheter Adhesive

The Catheter Kit for Modified Seldinger Technique (using Over Dilator peel away introducer) has the following accessories;

- Straight End Stainless Steel Wire Stiffener
- Introducer Needle with Echogenic Tip
- Syringe
- Straight End Nitinol Guide Wire
- Over the Dilator Peel Away Sheath Introducer
- Safety Scalpel
- Cap(s)
- Catheter Hub Securement Adhesive (Unifix lock)

Intended Use:

AMECATH **Midline Venous Catheters** is a sterile single use device indicated for use in attaining access to a peripheral vein.

Indications:

AMECATH **Midline Venous Catheters** is indicated for:

- The Infusion of:
  - ☐ All intravenous fluids that are appropriate for short peripheral IV infusion
  - ☐ Infusates that are Less than 10% Dextrose
  - ☐ Infusates that are Less than 5% Protein
  - ☐ Infusates that are between pH 5 and 9 have an osmolarity less than 500 mOsm
- Frequent blood sampling
- Injection of contrast media in pressure resistant type ONLY

N.B:

To ensure that Midline Catheter is performing well in order to achieve its intended use, please:

- Ensure to check pulsatile flow after the insertion of introducer needle into as pulsatile flow is usually an indicator of inadvertent arterial puncture.
- Guide wire should not be stiff to avoid vessel damage.
- While inserting the Catheter, user should be cautious of not to apply excessive force in placing or removing the catheter to avoid catheter breakage and vessel damage.
- If resistance was met while advancing the catheter, user should retract or gently flush while advancing the catheter.
- For pressure resistance Catheters, user should not exceed the maximum flow rate indicated on the catheter extension. As exceeding the maximum flow rate of the flow rate ML/SEC printed on the extension line may result in catheter failure and/or catheter tip displacement.

Clinical Benefits:

The capability to have access to the peripheral circulation system through a single puncture site for applications that include IV fluid infusion infusates administration as well as blood sampling.

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 prevents proper devices stabilization and/or access.
- History of mastectomy at the insertion site.
- Fever of unknown origin.
  *This catheter is not intended for any use other than that which is indicated. Do not implant catheter in thrombosed vessels.

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 catheters should not be placed in patient for more than 4 weeks.
- 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.
- Since upper arm veins run deeper than veins used for insertion and likely targets for short peripheral IV catheters, complications from the infusion may not be recognized until a severe reaction has occurred. Therefore, certain medications that are likely to be damaging to the vein generally should not be infused through Midline catheters. These medications include vancomycin, nafcillin, Primaxin, Phenergan (promethazine), and Dilantin (phenytoin) as well as any agent that is hyperosmolar (> 500 mOsm) or very acidic of basic
- Ultrasound could 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 antimicrobial ointments on catheters as it may cause its degradation.
- The proper size selection for the catheter size and length is the responsibility of the physician considering the patient's anatomy.

Specific:

- 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.
- Do not use scissors to remove dressing to minimize the risk of cutting catheter.
- 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

Complications:

Common Complications:

- Sepsis
- Thrombosis
- Catheter occlusion
- Malposition/Migration
- Damage/Fracture of catheter
- Aseptic mechanical phlebitis
- Drainage from insertion site
- Pinch-off syndrome
- Cellulitis

Potential Complications:

- Air Embolism
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Exit site infection
- Extravasation
- Hematoma
- Perforation of the vessel
- Subcutaneous hematoma
- Thromboembolism
- Vascular thrombosis

*** Before attempting the insertion, ensure that you are familiar with the common and potential complications and their emergency treatment should any of them occur.**

How Supplied:

- AMECATH **Midline Venous Catheter** is a sterile, single-use Medical device.
- Each AMECATH **Midline 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 **Midline Venous Catheter Kits.**

AMECATH Midline 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

***Precaution:** Clinicians should use sterile techniques and dress in protective clothing

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.

Warning: Do not cut placement wire when trimming catheter to minimize the risk of foreign embolism

Precautions:

- 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 he used.

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 huh 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 he 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.

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 either guide wire 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

a. To access the valve connector: Swab silicone seal in accordance with facility protocol. (illustration 1)

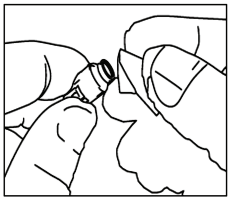
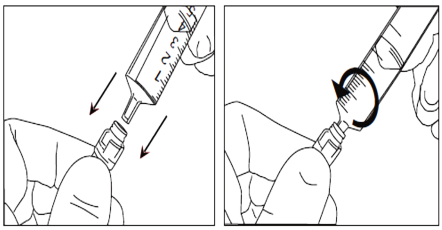


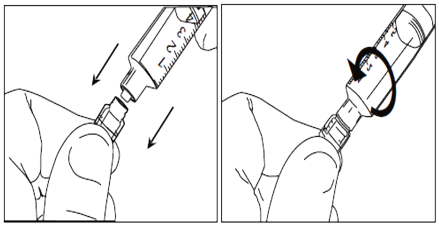
illustration 1

b. 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 preopen the slit in the valve (illustration2)



Male Slip Luer (MSL)
illustration 2

c. 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).



Male Luer Lock (MLL)
illustration 3

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.

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

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

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

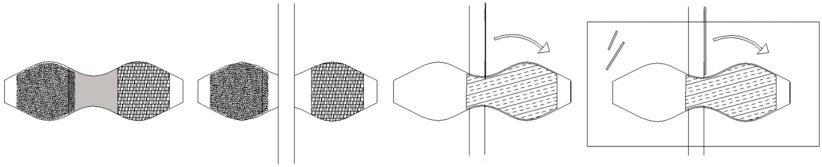
16. Cleanse insertion site per hospital protocol.

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 fixation adhesive.



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.

Direct puncture - Seldinger technique. (Used with catheter type with tapper tip):

1. Insert the IV Cath into vein and be sure that the flow is not pulsatile. Pulsatile flow is usually an indicator of inadvertent arterial puncture.

2. Remove the inside needle of the IV Cath.

3. Insert soft tip of guide wire through the IV Cath into vein. Advance guide wire to desired depth.

3.1 Do not insert stiff end of guidewire into vessel as this may result in vessel damage.

4. Hold guidewire in place while removing the IV Cath and maintain firm grip on guide wire at all times.

5. Advance the catheter over the guide wire.

6. Advance catheter to final position then withdraw the guide wire.

   6.1 Caution should be taken that catheter clamp must not to be clamped until guidewire is removed.

7. Verify Catheter tip placement by checking catheter placement with syringe and aspirating through distal lumen until free flow of venous blood is observed.

   7.1 Caution should be taken that the color of blood observed is not always a reliable indicator of venous access

8. Secure catheter in place by using adhesives. The hub is suitable to work with many commercial hub fixation adhesives (Statlok, Griplok, unifix lok,...)

Checks before using the pressure resistant MIDLINE 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 indicated on the catheter extension.

   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.

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 malposition 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 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 venous catheter for intermittent infusion therapy, proper flushing using a positive-pressure flushing technique will help prevent occlusion.
- ❒ All valves, if used, need are 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 1 centimeter and dot every 5 centimeters however the first 5 cm is not marked. The marking start and ascend from catheter hub.

Example for 25 cm long:

Tip 25 • • • • • • 20 • • • • • 15 • • • • • • • 10 • • • • 5 • • • Hub

Product Variants:

For variants of AMECATH **Short Term Haemodialysis Catheters**, Kindly refer to the catalogue, visit our website on: " **www.amecathgroup.com** ", or contact your nearest AMECATH representative."

Midline Venous Catheter Kit:

Code Structure: MLnLC-xxll-K 00:

ML : Midline.
N: number of Lumens **S:** for Single Lumen Catheter **D:** for Dual Lumen Catheter
Xx: for Catheter size in Fr.
Ll: for Catheter Length in cm.
00: Variable Kit Configurations with Different Contents as per below table.

Reference	Contents
MLnLC-xxll -K	● Single/Dual Lumen Midline Venous Catheter ● Catheter Over Needle ● Straight end Nitinol Guide Wire ● Needless Connector (one for single lumen and two for dual lumen)
● Pressure resistant catheters are available. Please add PR before the code (PRMLnLC-xxll-K)	
MLnLC- xxll-K ON	● Single/Dual Lumen Midline Venous Catheter 0.018" Nitinol Stiffener with Flexible end ● Touhy Burst Adapter ● T-Connector with Side Arm with Needless Connector ● Over the Needle Peel Away Sheath Introducer ● 10cc Syringe ● Safety Scalpel ● Needless Connector (with dual lumen catheters only) ● Catheter Hub Securement Adhesive (Unifix Lock) ● Transparent Catheter Adhesive
● Pressure resistant catheters are available. Please add PR before the code (PRMLnLC-xxll-KON)	
MLnLC- xxll -KOD	● Single/Dual Lumen Midline Venous Catheter 0.018" Nitinol Stiffener with Flexible Tip ● Introducer Needle with Echogenic Tip ● Touhy Burst Adapter ● T-Connector with Side Arm with Needless Connector ● 10cc Syringe ● Straight end 0.018"x 50 cm Nitinol Guidewire. ● Over the Dilator Peel Away Sheath Introducer ● Safety Scalpel ● Needless Connector ● Catheter Hub Securement Adhesive (Unifix lock) ● Transparent Catheter Adhesive
● Pressure resistant catheters are available. Please add PR before the code (PRMLnLC-xxll-KOD)	

Storage and Product Safe Disposal

- Store between °5C to °30C.
- 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 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.

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