

Short Term Haemodialysis Catheter Kit

Device Description:

AMECATH Short Term Haemodialysis Catheter is a soft radiopaque biocompatible polyurethane sterile catheter.

AMECATH Short Term Haemodialysis Catheters are single, dual and triple lumen catheters for adult and pediatric use.

The catheters are placed centrally or through femoral vein.

AMECATH catheters are semi rigid but become softer at body temperature.

Catheter tube profile is single, dual or triple lumen. The catheter has a tapered tip with softer material. Catheter shape can be with straight tube and extension lines, straight tube and J shape extension lines or pre-curved tube and straight extension lines.

AMECATH short term SMART Catheter has annular grooves at the side holes preventing their stuck to the vessel wall.

AMECATH short term Haemodialysis Catheter are indicated for Short term <30 days

The nominal size of Short Term Haemodialysis catheters ranges from 6 to 20 Fr and from 80 to 200 mm (8 to 20 CM)

Which vein to cannulate?

The preferred insertion site for dialysis catheters is the right internal jugular vein. Other options include the right external jugular vein, left internal and external jugular veins, subclavian and femoral veins. Subclavian access should be used only when no other upper- extremity or chest-wall options are available.

Target patient populations: Adults and children (paediatrics)

Intended user: Health Care Professionals

AMECATH Short Term Haemodialysis Catheters are available in different designs and Kit configurations to cover all customer needs

Device construction:

Catheter Types:

- Single lumen catheter :10 Fr, 130 -200 mm (13-20 Cm)
- Dual Lumen Catheter: 06-16 Fr, 80-240 mm (8-24 Cm)
- Triple lumen Catheter: 12-14 Fr, 150 -250 mm (15-25 Cm)
- SMART Dual lumen Short Term Haemodialysis catheter: 12-14 Fr, 120-200 mm (12-20 Cm)
- SMART Triple lumen Central venous haemodialysis catheter: 13-14 Fr, 150-200 mm (15-20 Cm)

List of Accessories:

- J End Nitinol Guide Wire with Scaled Dispenser
- Vessel Dilators
- Syringe
- Guiding Y Connector
- Guiding syringe (instead of Syringe and Guiding Y connector)
- Scalpel
- Introducer Needle, Echogenic
- Injection Cap

- Movable Fixation Wings (with Pre-curved catheter only).
- Towel

Intended Use:

Sterile single use device indicated for use in attaining short term access for Haemodialysis or aphaeresis.

N.B:

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

- 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.
- Do not over tighten the luers as Over tightening of catheter luers may lead to its failure.
- 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 use sharp instruments near the extension line or tubing. Do not use scissors to remove dressing, as this could possibly cut or damage catheter.

Clinical Benefits:

The capability of Short -Term Hemodialysis Catheters to attain Short term access for Hemodialysis, or apheresis via central venous veins “preferably the internal jugular vein”.

Contraindications:

- The device is intended for short term vascular access only and shouldn't be used for any purpose other than indicated in this Document.
- The catheter should not be placed in patient with bleeding disorders.
- The catheter should not be placed at the site where previous venous thrombosis or vascular surgical procedure has occurred.
- Local tissue factors will prevent proper devices stabilization and/or access.
- The catheter should not be used if severe chronic obstructive lung disease exists.
- When infection or bacteremia exists or is suspected due to the use other device.
- Post irradiation of prospective insertion site.

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.
- The Short term hemodialysis catheter should not be placed in patient for more than 30 days.
- Do not trim.
- Product expiration date is identified on product label.
- 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 catheter. 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.
- Be sure that you are familiar with the possible complications and emergency measures to be taken if any occur.

- 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 this 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.
- The catheters should not be placed in patient for more than 4 weeks.
- Catheter Occlusion is a risk, to clear an occlusion please follow this clearing procedure:
 - For an occluded catheter, assess further to rule out a non-thrombotic occlusion.
 - For thrombotic occlusions, consider treatment with a thrombolytic (IA).
 - For a suspected precipitate occlusion, consider treatment with a clearing agent (IC).
- 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 tear when subjected to excessive force or rough edges.
- Use only 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 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 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.
- The position of the tip of any central catheter should be verified by a radiological means.
- The proper size selection for the catheter size and length is the responsibility of the physician considering the patient's anatomy.
- 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.

Misuse can be due to:

- Improper positioning of the catheter tip which may lead to diminished flow rate.

- 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 %20 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 crack catheter's female luer.

Note: 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 the thoracic duct
- Injury to surrounding nerves
- Air embolism
- Catheter embolus
- Pneumothorax

Late Potential Complications:

- Venous thrombosis
- Cardiac perforation
- Tamponade Infection
- Hydrothorax

How Supplied:

- **AMECATH Short Term Haemodialysis Catheter** is a sterile, single-use Medical device
- Each **AMECATH Short Term Haemodialysis Catheter Kit** is packed in a PETG hard blister covered with Tyvek
- Each carton box includes 10 **AMECATH Short Term Haemodialysis Catheter Kits**

AMECATH Short Term Haemodialysis Catheter 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 disorder	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.

General preparation to obtain haemodialysis access

The basic preparation and equipment that is required for venous cannulation is the same regardless of the route or technique chosen. Clinicians who insert dialysis catheter should be taught the technique by an experienced colleague. If this is not possible then the access routes associated with the fewest complications are the femoral vein

Equipment required for venous access

- Sterile pack and antiseptic solution
- Local anesthetic; e.g. 5ml lignocaine %1 solution
- Appropriate catheter for age/purpose
- Syringes and needles
- Saline or heparinized saline to prime and flush the line after insertion
- Suture in case of fixation by suturing e.g. 0/2 silk on a straight needle
- Sterile dressing
- Shaving equipment for the area if massive hairs (especially the femoral)

General technique for all routes

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 very hairy.
3. Using a strict aseptic technique, prepare and check all the equipment for use. Read instructions with the catheter.
4. Disinfect the skin and drape the area.
5. Infiltrate the skin and deeper tissues with local anesthetic. In cases where difficulty is anticipated use the small local anesthetic needle to locate the vein before using the larger needle. This reduces the risk of trauma to other structures.
6. Position the patient as for the specific route described - avoid long periods of head down, particularly in patients with difficulty in breathing.
7. Identify the anatomical landmarks for the chosen route and insert the needle at the recommended point. After the needle has penetrated 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.
8. Advance a guidewire (Seldinger technique), into the vein, flexible J-shape end first, then remove the needle.
 - 8.1. 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.

9. Advance the guide wire equivalent length to the desired position of the catheter tip
10. It is necessary to dilate up the hole in the vein. Make a small incision in the skin and fascia where the wire enters the patient. Thread the dilator over the wire into the vein with a twisting motion. Excessive force should not be needed. Remove the dilator taking care not to dislodge the guidewire.
11. Thread the catheter over the guide wire until the end of the wire protrudes from the end of the catheter and whilst holding the wire still advance the catheter into the vein.
N.B. Take care not to allow the wire to be pushed further into the vein whilst advancing the catheter.
12. Check that blood can be aspirated freely from all lumens of the catheter and flush with saline.
13. Secure the catheter in place with the suture and cover with a sterile dressing. Tape any redundant tubing carefully avoiding any kinking or loops which may snag and pull out the catheter.
14. Connect catheter to a bag of intravenous fluid or flush both lumen with appropriate anti thrombotic.

Checks before using the catheter

- Ensure fluid runs in freely and that blood flows freely back.
- If available, take a chest X-ray (ideally erect) to check the position of the catheter tip and to exclude a pneumo, hydro or haemothorax. An early radiograph may not show up abnormalities and it may be best to wait 3-4 hours unless symptoms develop. The tip of the catheter should lie in within the right atrium.
- Ensure that the patient will be nursed and their access can be supervised. Give appropriate written instructions regarding how, and what it is to be used for, and who to contact if there is a problem between dialysis sessions.

Practical problems common to most techniques of insertion

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 pneumothoraxes 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 hypovolemic 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
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Connection to dialysis machine:

- Catheter is to be connected to the blood line of the dialysis machine. The blood line is a set of arterial and venous lines. After swabbing the female luer end, push straight with twisting the male luer of the blood tube inside the respectable catheter female luer end. Open the pinch clamp.
- Ensure that the patient will be nursed during dialysis. Give appropriate written instructions regarding how, and what it is to be used for, and who to contact if there is a problem.
- The catheter should allow a free flow of fluids. The free flow is usually indicated by flow of blood within the accepted venous and arterial pressure in the extracorporeal circuit of the dialysis machine.

Disconnection from dialysis machine:

Clamp the catheter extension line. Pull out with twisting the male luer of the blood tube from catheter female luer end. Connect the flushing device to the catheter female luer end then re-open the clamp. Flush the catheter according to hospital protocol. Clamp again the catheter and remove the flushing device. 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.

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

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)
- Malposition of catheter tip
- Kinks
- 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

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

- Repositioning of a malpositioned catheter.

- 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 thrombolytic, 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.

At the end of the dialysis session, clamp catheter extension line(s) and cap the catheter with the injection cap. This should be followed by injecting heparin or other anti-thrombotic at each lumen (according to lumen priming volume) in the catheter via the injection caps.

Care of catheter between dialysis.

- Insertion site should be inspected for possible bleeding.
- Anti-thrombotic should be regularly injected to the catheter to prevent catheter thrombus and obstruction.

Catheter removal

Remove any dressing and suture material. Ask the patient to take a breath and fully exhale. Remove the catheter with a steady pull while the patient is holding his breath and apply firm pressure to the puncture site for at least 5 minutes to stop the bleeding. Excessive force should not be needed to remove the catheter. If it does not come out, try rotating it whilst pulling gently. If this still fails, cover it with a sterile dressing and ask an experienced person for advice.

Description of marking system

The catheter tube is marked for effective length in numerical number every 5 centimeters and dot every one centimeter however the first 5 cm is not marked.

5 10 15 20

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.”

Short Term Haemodialysis Catheter Kits:

1. Adult Tapered Tip Short Term Haemodialysis Catheter Kits:

a) Single Lumen Tapered Tip Short Term Haemodialysis Catheter Kits:

Code Structure: SLC-xxII-DK

xx: for Catheter size in Fr.

LI: for Catheter Length in cm.

Reference	Contents
SLC-XXLL-DK	<ul style="list-style-type: none"> ● Single Lumen Haemodialysis Desilet Catheter ● J End Nitinol Guide wire in scaled dispenser ● Vessel Dilator ● Syringe ● Introducer Needle, Echogenic ● Scalpel ● Injection Cap ● Towel

b) Multi Lumen Tapered Tip Short Term Haemodialysis Catheter Kits:

Code Structure: nLC-xxII-K000

N: number of Lumens

D: for Dual Lumen Catheter

T: for Triple Lumen Catheter

xx: for Catheter size in Fr.

LI: for Catheter Length in cm.

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

K: Subclavian Kit

KJ: Jugular Kit.

KPC: Pre-Curved Kit.

Reference	Contents
nLC-XXLL-K000	<ul style="list-style-type: none"> ● Tapered Tip Short term Haemodialysis Catheter ● J End Nitinol Guide Wire with Scaled Dispenser ● 2 Vessel Dilators ● Syringe ● Guiding Y Connector ● Introducer Needle, Echogenic ● Scalpel ● (2) Injection Cap for Double lumen, (3) injection cap for triple lumen ● Movable Fixation Wings (with Pre-curved catheter only).
	<ul style="list-style-type: none"> ● Guiding syringe is available Please add GS after the code (nLC-xxII -K000-GS). ● Smart haemodialysis catheter is available Please add SM after the code (nLC-xxII -K000SM), if with Guiding syringe (nLC-xxII -K000SM-GS) ● Guiding syringe instead of Syringe and Guiding Y connector

2. Pediatric Tapered Tip Dual Lumen Short Term Haemodialysis Catheter Kits:

Code Structure: DLC-xxII-KP00

xx: for Catheter size in Fr.

LI: for Catheter Length in cm.

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

KP: Subclavian Kit

KJP: Jugular Kit.

Reference	Contents
DLC-XXLL-K000	<ul style="list-style-type: none"> ● Pediatric Tapered Tip Dual Lumen Short term Haemodialysis Catheter ● J End Nitinol Guide Wire with Scaled Dispenser ● 2 Vessel Dilators ● Syringe ● Guiding Y Connector ● Introducer Needle, Echogenic ● Scalpel ● (2) Injection Cap ● Movable Fixation Wing (with Pre-curved catheter only)

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.

N.B. please provide patients by the instructions of home care attached to this document.

In case of any questions or queries, kindly contact the local Authorised Representative or visit [AMECATH](http://www.amecathgroup.com) website on : “ www.amecathgroup.com ”

In case of any Adverse event, Contact your local Health Authority immediately.



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