UniQath Short Term Haemodialysis Catheter KIT

Device Description:

AMECATH **Short Term Haemodialysis Catheter "UniQath"** is a soft radiopaque biocompatible tecoflex polyurethane sterile catheter. Catheter has two lumens.

AMECATH **Short Term Haemodialysis Catheter "UniQath"** is soft short term dual lumen catheter, radiopaque, polyurethane catheter. The catheter is soft to offer patient comfort and be easily shaped to fit various insertion locations. The catheter is tapered tipped with softer material and have annular groove at the side holes preventing their stick to the vessel wall. The catheter extension lines end with swabable female luer valve. A stiffener made from polycarbonate tube and swabable valve male luer is supplied to be inserted into the catheter to stiffening it for easy advancement into the vessel. The swabable valves permit passage of the guide wire and offer mechanical seal of the catheter ends. Catheter is without fixation connection (Hub) and to be fixed (anchored) to patient skin either by the supplied adhesive fixation or by suturing of the movable fixation wing to the skin.

AMECATH **Short Term Haemodialysis Catheters "UniQath"** are indicated for Short term <30 days

AMECATH **Short Term Haemodialysis Catheters "UniQath"** may be inserted percutaneously and are ideally placed in the internal jugular vein. Although these catheters may be inserted into the subclavian or femoral vein, the internal jugular is the preferred site. The pre-curved shape is intended for internal jugular vein placement.

The nominal size of Uniqath catheters ranges from 12 to 14 Fr and from 15 to 25 CM (150 mm to 250 mm)

AMECATH **Short Term Haemodialysis Catheter "UniQath"** is to be cannulated preferably is the right internal jugular vein. Other options include the right external jugular vein, left internal and external jugular veins, subclavian veins and femoral veins. Subclavian access should be used only when no other upper-extremity or chest-wall options are available.

Target patient populations: Adults Only
Intended user: Health Care Professionals

AMECATH Short Term Haemodialysis Catheter "UniQath" and its accessories:

Device construction:

List of Accessories

- Dual Lumen Haemodialysis Catheter
- Stiffener with Haemostatic Valve
- J End Nitinol Guide Wire with Scaled Dispenser
- (I) Vessel Dilator
- (I) Vessel Dilator with hydrophilic coating
- Syringe
- Guiding Y Connector
- Guiding syringe (instead of Syringe and Guiding Y connector)
- Introducer Needle, Echogenic
- Scalpel
- Injection Cap
- Unifix Catheter Tube Fixation Adhesive
- Transparent Catheter Fixation Adhesive
- Movable Fixation Wings

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 "UniQath" 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 over tighten the luer lock.
- Over advancement of guide wire can result in serious injuries or arrhythmias.
- 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 "UniQath" 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 (Instructions for use).
- 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 suspected due to the use other device.

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 severe deterioration in health and safety of patients.
- The Short term hemodialysis catheter "UniQath" should not be placed in patient for more than 30 days.
- Adult use only, not pediatric or neonatal.
- 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.
- The position of the tip of any central catheter should be verified by a 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 ointments on catheters as it may cause its degradation.
- Over tightening of catheter luers may lead to its failure.
- Do not over tighten the luer lock.
- Do not attempt to insert the luer at an angle. There is no need to pry open the slit in the valve.
- 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 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.

- 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 cracks catheter female luer.
- Improper connection of the valve with the bloodlines leads to decrease the flow rate as the valve has to be fully opened to give the required flow rate.
- Inserting male luer at angel may destroy the swabable valves.

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

AMECATH Short Term Haemodialysis Catheter "UniQath" 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 are 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.

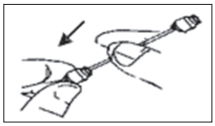
Equipment required for venous access

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

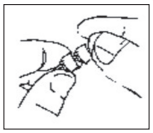
General technique for all routes

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. Sterilize 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 guide wire (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. 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.
    10.1. Inserting the stiffener with no angle because angle leads to its kinking, breaking and sticking of the guide wire (as given in the below figure)

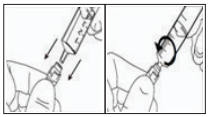


11. Stiffing the catheter:
    - In some instance and for easier advancement of the catheter into the vein over the guide wire, the stiffener which is included with the catheter is to be used.
    - Insert the stiffener tip into the slit of the valve at the venous extension line marked with the blue ring.
    - Gently advance the stiffener inside the lumen of the catheter till it reaches the catheter tip, do not insert the stiffener (with an angle) because inserting with an angle leads to kinking, broken and sticking of the guide wire and the Stiffener but insert it with the same line of the catheter (as given in the below figure).



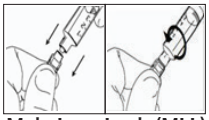
    - Secure the male luer valve of the stiffener to the female luer valve of the catheter.
12. Advance the catheter over the wire till the guide wire comes out of the female luer valve.
13. Continue advancing the catheter while holding the guide wire preventing it to be advanced with the catheter. Advance the catheter till the desirable length is reached.
14. Unlock the male valve of the stiffener from the catheter female luer valve and withdraw it together with the guide wire leaving the catheter in place.
15. Check that blood can be aspirated freely from all lumens of the catheter and flush with saline.
16. To access the valve connector: Swab silicone seal in accordance with facility protocol. (illustration 1)

17. 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)



«Male Slip Luer (MSL)»

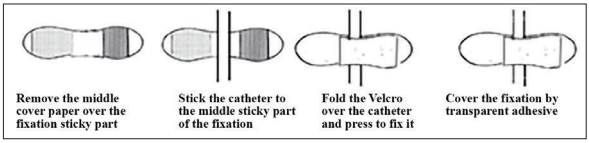
18. To attach Male Luer Lock to valve connector: Grasp the valve connector and position the luer so that the luer will be pushed straight into the valve using a twisting motion, as shown (illustration 3).



«Male Luer Lock (MLL)»

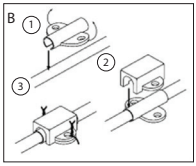
N.B for further information on luer connections, please refer to latest version of BS EN ISO 7-80369

Fixation with fixation adhesive



Fixation by suturing

1. Take the flexible part of the moveable wing and spread the wings until the internal slit is opening. Fix 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.



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 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

Caution:

- Improper connection of the valve with the bloodlines leads to decrease the flow rate as the valve is partially opened but it has to be fully opened to give the required flow rate.
- Some blood lines are shorter than others so make sure that the valve is fully opened by enough pushing of luer slip inside the female valve.

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 valve, push straight with twisting the male luer of the blood tube inside the respectable swabable valve. This will open the valve that allows accessing the patient venous system.
- 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.

***Warning:**

- The valve works properly when it is fully opened. Full opening is only achieved by pushing the valve by full advancement of male slip of a luer (as shown in Figure 1).

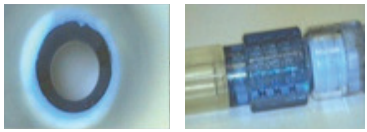


Fig. 1: Fully open valve

- In blood lines with short slip luer, the screwing of the male luer lock may prevent full advancement of the slip inside the female valve and as a result the valve is not fully opened and creates a sort of resistance to flow rate and hence low flow and high pressure are noted (as shown in Figure 2). , to solve the problem the male slip should be advanced and fully pushed inside the female valve before screwing the lock (as shown in Figure 1).

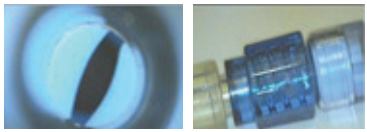


Fig. 2: Partially open valve

Disconnection from dialysis machine:

- Pull out with twisting the male luer of the blood tube from the valve. The valve will be closed and mechanically seals the catheter end. Flush the catheter according to hospital protocol.
- Prepare two syringes containing amount of heparin corresponding to the amount printed on the catheter extensions or located at below table:

Kit Code	Lumen Side	Priming Volume CC
UNDLC-12-K	Venous	1.10
	Arterial	1.00
UNDLC-14-K	Venous	1.20
	Arterial	1.10

- 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.

Care of catheter between dialysis.

- Insertion side should be inspected for possible bleeding. Anti-thrombotic should be regularly injected to the catheter to prevent catheter thrombus and obstruction.
- No further heparin is necessary for 48-72 hrs if the catheter have not been used.

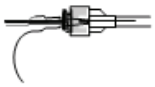
Prevention and Treatment of Catheter dysfunction

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 CVC 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 prepump pressure.
- Unable to aspirate blood freely (late manifestation).
- Frequent pressure alarms - not responsive to patient repositioning or catheter flushing.

*Exchange the catheter over guide wire

1. Push the guide wire advancer tip inside the valve slit at the female luer connected to the catheter venous side (marked blue). Advance the guide wire into the catheter till its end comes out of the catheter tip (usually 35 Cm in 20 Cm catheter long)	
2. Gently withdraw the catheter over the guide wire. Do not allow the guide wire to be pulled back with the catheter.	
3. Once the catheter completely withdrawn, make sure that the quite length of guide wire is in the vessel.	
4. Advance the new catheter over the guide wire and follow the same steps (10-24) mentioned above.	

*Valve repair

1. Repair valve assembly is composed of swabable valve connected to short tube.
2. Insert the repair valve assembly tube inside the slit of the damaged valve.
3. Twist and lock the repair valve assembly to the female luer with the damaged valve.
4. The repair valve assembly will work exactly as the original valve.

Catheter removal

- Only physician familiar with the technique should attempt the removal.
- Always review hospital protocols, possible complications and their treatments, precautions and warning. 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 breath holding 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.

Description of marking system

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

Product Variants:

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

Uniqath Dual Lumen Short Term Haemodialysis Catheter Kits

Code Structure: UN-DLC-xxll-K

Xx: for Catheter size in Fr.

Ll: for Catheter Length in cm.

Reference	Contents
UN-DLC-XXLL-K	• Dual Lumen Haemodialysis Catheter • Stiffener with Haemostatic Valve • J End Nitinol Guide Wire with Scaled Dispenser • (1) Vessel Dilator • (1) Vessel Dilator with hydrophilic coating • Syringe • Guiding Y Connector • Introducer Needle, Echogenic • Scalpel • Injection Cap • Unifix Catheter Tube Fixation Adhesive • Transparent Catheter Fixation Adhesive • Movable Fixation Wings
• **Guiding syringe is available Please add GS after the code (UN-DLC-xxll -K-GS).** • **Guiding syringe instead of Syringe and Guiding Y connector**	

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 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 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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