AMECATH

10.5. Short Term Haemodialysis Catheter Kit "Soft Step Tip" Instructions for Use

Short Term Haemodialysis Catheter KIT "Soft Step Tip Catheter"

Device Description:

AMECATH Short Term Haemodialysis Catheter "Soft Step Tip Catheter" is a soft with no side holes and the tip shape is different than the dual lumen Short term Haemodialysis catheters

AMECATH Short Term Haemodialysis Catheter "Soft Step Tip Catheter" shape can be with straight extensions, J shape extension or one side double J shape extension.

AMECATH Short Term Haemodialysis Catheters "Soft Step Tip Catheter" 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 Soft Step Tip catheters ranges from12 to 14 Fr and from 12 to 35 CM (120 mm to 350 mm)

AMECATH Short Term Haemodialysis Catheter "Soft Step Tip Catheter" is to be inserted preferably in 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 "Soft Step Tip Catheter" and its accessories:
Device construction:
List of Accessories

- Stiffener with Haemostatic Valve
- J End Nitinol Guide Wire with Scaled Dispenser
- Vessel Dilators
- Syringe
- Introducer Needle, Echogenic
- Scalpel
- Injection Cap
- Unifix Catheter Tube Fixation Adhesive
- Transparent Catheter Fixation Adhesive
- Movable Fixation Wings
- Guiding Y Connector

Intended Use:

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

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.
- 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.

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 valve.

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 "Soft Step Tip Catheter"** is a sterile, single-use Medical device
- Each **AMECATH Short Term Haemodialysis Catheter "Soft Step Tip Catheter" kit** is packed in a PETG hard blister covered with window bag.
- Each carton box includes 10 **AMECATH Short Term Haemodialysis Catheter "Soft Step Tip Catheter" kits**

AMECATH Short Term Haemodialysis Catheter "Soft Step Tip Catheter" method of application

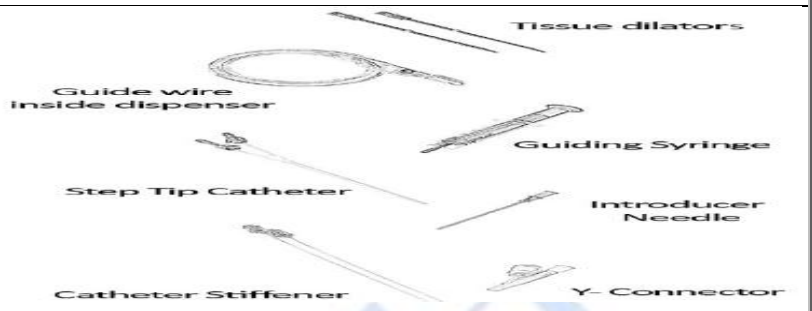
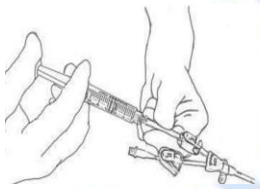
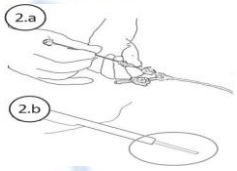
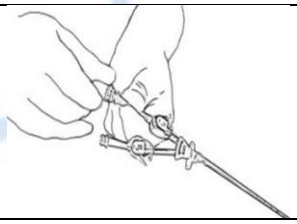
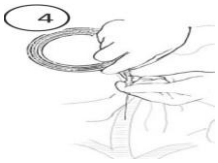
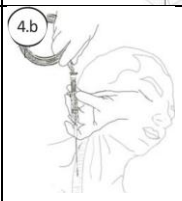
Before cannulation, you should consider the following

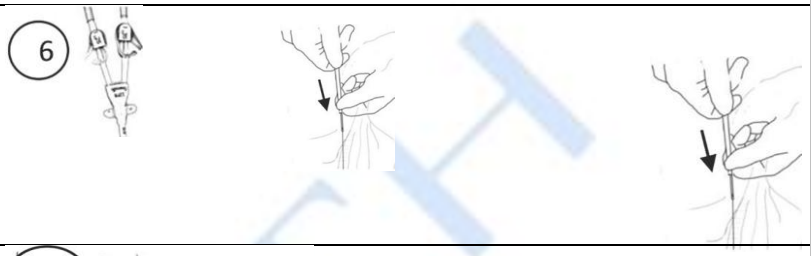
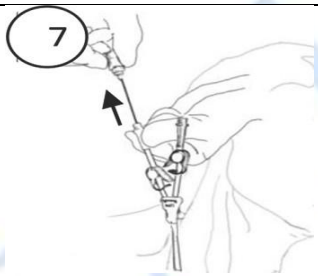
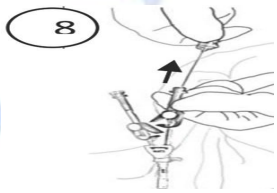
Patient Evaluation Prior to Access Placement

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.

Methods of Application:

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

Soft Step Tip catheter **placement- quick illustrations**	
1. Prepare the catheter by flushing each catheter lumen using saline or according to hospital protocol	
2. Strengthen the catheter by inserting the catheter stiffener in the venous lumen (2a) until it protrudes (2b) from the venous tip and lock the stiffener end to the catheter venous (blue) female luer end.	
3. If stiffener for the arterial lumen is provided, to more strengthen the catheter, insert it into catheter arterial lumen and lock its end to the catheter arterial (red) female luer end	
4. Use Seldinger technique to access the vein by accessing the vein by the introducer needle followed by guide wire advancement through the needle then remove the needle. At this point you have the option to use the guiding Y connector (4a) or the guiding syringe (4b) to advance the guide wire	
4. a) If Guiding Y connector is used connect it between the introducer needle and the syringe and advance the guide wire, once vein is accessed, through its side valve.	
4. b) If Guiding syringe is available advance the guide wire, once vein is accessed, through its piston back.	

5. Dilate the catheter passage by advancing the vessel dilator over the guidewire. Proper dilatation is required as the catheter does not have a tapered tip.	
6. Advance the tip of the stiffener of the venous lumen over the guide wire	
7. Advance the catheter to the vessel for approximate 7 cm then unlock the stiffener end and withdraw it for app 5 cm and continue catheter advancement and simultaneously pull back the guidewire.	
8. When the catheter tip reaches the desired level, pull out the stiffener with the guide wire and also the arterial lumen stiffener if used	
9. Aspirate each catheter lumen to verify free flow of blood and flush according to hospital protocol, then fix the catheter to the skin	

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

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.

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.

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 not everyone centimeter however the first 5 centimeters is not marked.

5 • • • • 10 • • • • 15 • • • • 20 • • • •

Product Variants:

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

Step Tip Soft Dual Lumen Short Term Haemodialysis Catheter Kits

Code Structure: SDLC-xxll-K00

Xx: for Catheter size in Fr.

Ll: for Catheter Length in cm.

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

K: Subclavian Kit **KJ:** Jugular Kit. **KPC:** Pre-Curved Kit.

Reference	Contents
SDLC-XXLL-K00	• Step Tip Soft Dual Lumen Short Term Haemodialysis Catheter • Stiffener with Haemostatic Valve • J End Nitinol Guide Wire with Scaled Dispenser • 2 Vessel Dilators • 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 (SDLC-xxll –K00-GS).	

Storage and Product Safe Disposal

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