

**SHORT TERM HAEMODIALYSIS CATHETERS**

**Guides & Instruction For Use**

Contents

<b>Guides &amp; Instruction For Use</b> .....	1
Contents .....	1
Intended Use:.....	2
How Supplied .....	2
Storage .....	2
Contraindication: .....	2
The devices are contraindicated as follows:.....	2
Device Description .....	2
Which vein to cannulate? .....	2
Patient Evaluation Prior to Access Placement .....	3
Method of insertion .....	3
General preparation to obtain haemodialysis access.....	3
Equipment required for venous Access .....	3
General technique for all routes .....	4
Placement of soft catheters .....	4
Fixation with fixation adhesive .....	5
Fixation by suturin.....	6
Fixation by suturing .....	6
Checks before using the catheter .....	6
Practical problems common to most techniques of insertion .....	6
Complications.....	7
Connection to dialysis machine: .....	7
Disconnection from dialysis machine: .....	7
Precaution against misuse .....	7
Care of catheter between dialysis. ....	7
Prevention and Treatment of Catheter dysfunction.....	7
Signs of Catheter Dysfunction: Assessment Phase .....	8
Causes of Early Catheter Dysfunction.....	8
Methods that should be used to treat a dysfunctional or nonfunctional catheter include: .....	8

Care of catheter between dialysis. ....	8
Catheter removal .....	8
Catheter disposal .....	9
Description of marking system .....	9
Symbols Used in Labeling .....	9

### **Intended Use:**

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

### **Usage Suggestion**

This user manual contains the usage features and surgical technique procedures of the products manufactured by DLR Medikal.

### **How Supplied**

The device is sterilized by Ethylene Oxide. Contents are sterile and non pyrogenic in unopened undamaged package. Do not use catheter if package has been damaged or has been opened.

### **Storage**

Store at room temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet lights, Rotate inventory so that catheter are used prior to expiration date on package label.

### **Contraindication:**

#### **The devices are contraindicated as follows:**

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

#### **WARNING:**

- ⚠ 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 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.

### **Device Description**

The short term haemodialysis catheters are radiopaque and made from polyurethane catheter. The catheters are semi rigid but become softer at body temperature. Catheters tube profile can be single, dual or triple lumen. The catheter is tapered tipped with softer material. Catheter shape can be with both straight tube and extension, straight tube and J shape extension or pre-curved tube and straight extension. In "soft type", annular groove at the side holes preventing their stick to the vessel wall. Moreover equipped with haemostatic female luer Valves.

### **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 veins and femoral veins. Subclavian access

should be used only when no other upper-extremity or chest-wall options are available.

### 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
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	Morbidity associated with placement and maintenance of certain accesses may not justify
History of vascular access	Previously failed vascular accesses will limit available sites for access; the cause of a previous
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.

### Method of insertion

#### General preparation to obtain haemodialysis access

The basic preparation and equipment those are required for venous cannulation are the same regardless of the route or technique cho-sen. 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.

#### PRECAUTION:

- ✚ 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.
- ✚ Sterile pack and antiseptic solution

#### Equipment required for venous Access

- Local anaesthetic - 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 breathless patients.
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.

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### PRECAUTION:

- ✚ 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.

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### PRECAUTION:

- ✚ Over advancement of guide wire can result in serious injuries or arrhythmias.

- 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. 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.

## Placement of soft catheters

### a) 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 as shown in figure 1.

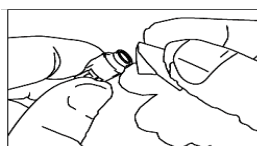
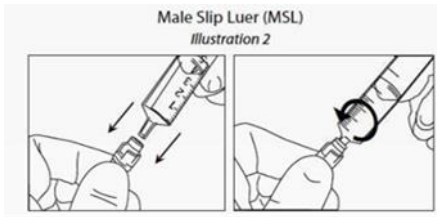


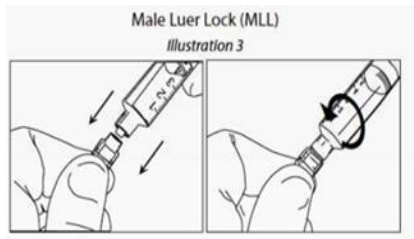
Illustration 1

Secure the male luer valve of the stiffener to the female luer valve of the catheter as shown in figure 2.

Advance the catheter over the wire till the guide wire comes out of the female luer valve.



- b) 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.
- c) 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.
- d) Check that blood can be aspirated freely from all lumens of the catheter and flush with saline
- e) To access the valve connector: Swab silicone seal in accordance with facility protocol (**illustration 1**)
- f) 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**)
- g) 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**).

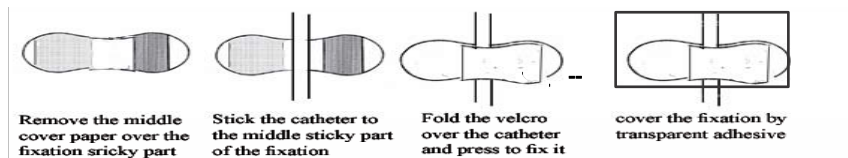


**PRECAUTION:**

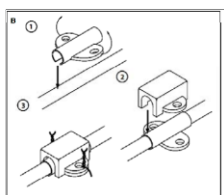
- ⚠ Do not attempt to insert the luer at an angle. There is no need to pry open the slit in the valve.
- ⚠ Do not over tighten the luer lock.

- h) To disconnect from valve: Grasp valve and twist syringe or blood tubing set connector clockwise until loose, then pull away from valve connector.
- i) Flush the valve connector after each use, in accordance with facility protocol.
- j) The valve closes and seals once a connector is removed from the valve connector therefore capping is optional.
- k) Fix the catheter in place with the either suture or the fixation adhesive supplied with the catheter.

**Fixation with fixation adhesive**



### Fixation by suturin



### Fixation by suturing

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

Table 2 lists some problems that may occur with any of the routes for central venous access.

Table 2. Problems during haemodialysis cannulation	
<b>Arterial puncture</b>	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.
<b>Suspected pneumothorax</b>	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.
<b>Arrhythmias during the procedure</b>	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.
<b>Air embolus</b>	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.
<b>The wire will not thread down the needle</b>	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.

<b>Persistent bleed-ing at the entry side</b>	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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## Complications

<b>Table 4. Potential complications.</b>	
<b>Early</b>	<b>Late</b>
Arterial puncture- Bleeding- Cardiac arrhythmias Injury to the thoracic duct- Injury to surrounding nerves- Air embolism- Catheter embolus- Pneumothorax	Venous thrombosis Cardiac perforation and tamponade Infection- Hydrothorax

## 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.

## Precaution against 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 and 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.
- Agressive Insertion of male luer may cracks catheter female luer.

## Care of catheter between dialysis.

Insertion side should be inspected for possible bleeding.

## Prevention and Treatment of Catheter dysfunction

Catheters should be evaluated when they become dysfunctional. Dysfunction is defined as failure to attain and maintain an extracorpo-real 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 prepump pressure
- Unable to aspirate blood freely (late manifestation)
- Frequent pressure alarms - not responsive to patient repositioning or catheter flushing

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#### PRECAUTION:

- Trend analysis of changes in access flow is the best predictor of access patency and risk for thrombosis.

### 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 thrombolytics, 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 heparine 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 side 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 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. If this still fails, cover it with a sterile dressing and ask an experienced person for advice.



### Catheter disposal




















Used Catheter should be disposed as hospital protocol or in sanitary container to prevent possible contamination and cross infection.

### 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 • • • •

### Symbols Used in Labeling

SYMBOL	SYMBOL NAME	SYMBOL	SYMBOL NAME
	Notified Body		EO Sterilized
	Lot Number		Production Date
	Disposable		Expiration Date
	See operating instructions		Keep away from sunlight
	Do not use if package is damaged		Keep Dry
	Manufacturer		Barcode
	Product Code		Do not resterilize
	Temperature storage conditions		DataMatrix Code
	Attention		Should only be used by an expert
	Does not contain latex.		

