

## Long-Term Hemodialysis Catheters

### **OPTIMA** DUAL LUMEN LONG TERM (PERMANENT) HEMODIALYSIS CATHETER

### **HIGHSTREAM** Y SPLIT DOUBLE LUMEN LONG TERM (PERMANENT) HEMODIALYSIS CATHETER

#### User Manuals & Instructions

#### **MEDICAL / INDICATIONS FOR USE:**

Sterile single use device indicated for use in attaining long term access for Haemodialysis.

They 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. Te pre -curved shape is intended for lower internal jugular vein placement.

#### **Usage Suggestion**

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

#### **HOW TO SUPPLIED:**

The devices are sterilized by ethylene oxide. Contents are sterile and non-pyrogenic in unopened and undamaged package. Do not use catheter if package has been damaged or has been opened.

#### **STORAGE:**

Store at room controlled temperature. 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.

#### **Contraindications:**

This product should not be used for any purpose other than those specified. • This product should not be used on a patient with a diagnosis of a known bleeding disorder.

- The placement of this Medical Device may be difficult in the presence of a history of previous vein thrombosis or vascular surgery entry. It should not be in the area that arouses suspicion.
- This catheter should not be used in patients with emphysema or hypercapnia (extremely deep breathing) who may experience respiratory distress due to possible pleural or parenchymal injuries that may occur during insertion.
- It should not be used in patients with emphysema and HYPERCOPNIS who may experience respiratory distress due to possible pleural membrane or parenchyma that may occur during the placement of this product.
- This product should not be used in patients who suspect that they have bacteremia or septicemia due to foreign body or graft infection in order to prevent catheter cross-contamination.

#### **WARNING**

- A single product is for one patient use only. Do not reuse, (re-sterilize) or resterilize. Do not use the catheter or accessories if the product shows signs of damage.
- Do not use the product outside the declared area of use.
- The products cannot be used for drug administration.
- Our company is not responsible for the use of the products other than their intended use.
- Re-sterilization (re-serilization) damages the catheter and can affect its integrity, which can seriously compromise health and patient safety when reused.

- The expiry date of the product is defined on the product label.
- The catheter has no metal components, so it is MRI compatible.
- Implantation technique has a significant impact on catheter complications and outcomes. Implantation should be performed by competent and experienced persons. Insertion of a catheter by an inexperienced person without an experienced person can have serious consequences.
- It should be applied in centers that can offer a solution when possible complications develop.
- Do not separate the arterial and vein lumens of split catheters as this may cause catheter perforation.
- Since the risk of pneumothorax is relatively high in subclavian interventions, it should be applied in conditions with ventilation support. (Intubation, Oxygen ... etc.)
- Excessive advancement of the guidewire may result in major vessel injuries or arrhythmias.
- It is recommended to use the distance and measuring marks on the guide wire.
- If unusual resistance is encountered while advancing the catheter, do not handle with the guide wire or other medical supplies. The wire may break or unravel. In this case, both the catheter and guide wire should be removed together.
- After the catheter is placed or after each use, the pathways should be closed by means of latches or caps on the catheter. In this way, the possibility of bleeding and air embolism should be avoided.

## WARNING

- Whether the product is used or not, the faulty products encountered should be sent to the manufacturer specified on the label, without being disposed of.

## Measures:

- To avoid damaging the catheter, do not use sharp instruments close to its lumens. Do not cut the dressing of the catheter with scissors. Do not suture by accidentally passing any part of the catheter. The catheter tube may be ruptured by applying excessive force or possible pressure-applying materials.
- To clamp the lumens of the catheter, use the clips included in the kit or use flat-bladed forceps in hospitals. If the catheter is clamped from the same point each time, the lumens may weaken. At the end of each treatment, examine the catheter for possible damage.
- Tape the injection caps between treatments to protect them from accidental removal. (or other types used).
- It is recommended that only luer lock (threaded) connections (including syringes, bloodlines, IV tubing and injection caps) be used with the catheter. Repeated tightening of bloodlines, syringes, and caps will reduce connector life and may result in potential connector failure. Check the catheter frequently for nicks, scrapes, cuts, etc. that may impair performance.
- Ultrasound or fluoroscopy is recommended for catheter placement.
- Do not use pure alcohol or acetone-based products for catheter cleaning. A 2% chlorhexidine or iodine-based solution is recommended as an antiseptic solution.
- It is not recommended to use creams or ointments that may cause the catheters to fail.
- Over tightening of the catheter lumens can lead to malfunctions.
- If any resistance is felt while inserting the catheter, the needle should be pulled out while the wire is still in. And the procedure should be repeated. This reduces the risk of guidewire entanglement and needle cut.
- The valve of the guide connector must be opened by the guide wires end. Do not thread the guide wire before opening the valve with the feed tip, otherwise the wire may be bent or damaged.
- The valve should not be closed and the Catheter should not be pushed until the guidewire is seen at the valve level before it leaves the tip of the catheter.
- tighten the luer lock.
- There is a risk of pneumothorax in subclavian interventions. Therefore, ventilation support and other concomitant medical interventions may be required at the same time. (Ex: intubation, oxygen)
- Long-term use of the subclavian vein may be associated with subclavian stenosis.
- Do not overexpand the subcutaneous tissue during tunneling. Overexpansion may delay or inhibit cuff growth.
- Tearaway introducer valve will prevent air passage. At a vacuum pressure of 12 mmHg, the valve can allow air passage close to 4 cc/sec.

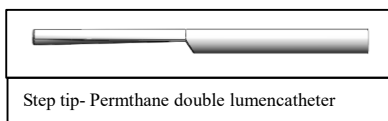
- Do not twist the sheath dilator during insertion as bending may cause sheath tearing. Initially hold the introducer close to its tip (approximately 3 cm from the tip) before penetrating the skin surface. To advance the introducer into the vein, grab a few centimeters above the original grip position and push down on the introducer. Advance and retract the Introducer several times to the vein according to the patient's anatomy, then retract and release the introducer.
- Never separate the Sheath from the catheter by indwelling.
- Do not tear off the sheath that remains in the container. To avoid vessel damage, pull the sheath back as far as possible and separate the sheath only a few centimeters at a time.
- The catheter will be damaged if clamps other than those provided with this kit are used.
- In case of breakage of the clamp, replace the catheter as soon as possible.
- Continuously tightening the tubes in the same direction can weaken tubing. Avoid squeezing the catheter near the luer and hubs.
- Compression of tubing in the same location at all times weakens tubing. Avoid tightening the catheter near the luer and hubs.
- Inspect the catheter lumen and extensions for damage before and after each treatment.
- Make sure all caps and bloodline connections are secure before and between treatments to avoid accidents.
- The selection of the appropriate catheter length is at the physician's discretion. Selection of the appropriate catheter length is important to achieve proper tip placement. Routine X-rays should always be taken following interception.
- Misuse can be mentioned in the following cases:
  - Incorrect positioning of the catheter tip,
  - Incorrect connection in the catheter extension line(s) by connecting the venous line of the dialysis blood line of the arterial line with the special and red marked extension line to the catheter extension line. This can lead to a high circulation rate of up to 37%, which can cause inefficient dialysis.
  - Incorrect connection of the catheter line (such as connecting the venous line to the dialysis line of the arterial extension line marked with a red barker) leads to a 37% higher re-circulation rate, which leads to in-effective dialysis.
  - Inadequate heparinization during dialysis can cause blood clots and blockage of the catheter. Inadequate heparinization of the catheter during dialysis may result in thrombus formation.
  - Being aggressive when tying luers together can cause cracks in male and female luers.

**MEDICAL MATERIAL DESCRIPTION :**

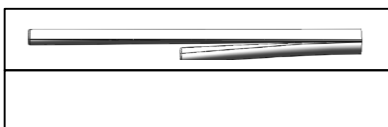
Cuffed hemodialysis catheters are chronic , double-lumen , radiopaque , polyester-cuffed polyurethane catheters consisting of a split distal catheter tube shaft tip ( Y split catheter ) or a stepped tip ( Permthane double lumen catheter ) . The cuff provides tissue ingrowth to fix the catheter in a subcutaneous tunnel. The catheter tubeshaft bifurcates proximally into two catheter extension legs. The catheter extension legs terminate at the female luer hubs.

It is available in the form of a catheteric tube and a precurved tube. The precurved tube shape is above the clavicle to prevent possible bending of the catheter during tunneling.

Catheters come in many sizes and lengths. Catheters are intended for adult use .



Step tip- Permthane double lumencatheter



Split tip-Y split double lumencatheter

## Pre-implantation Patient Evaluation

Factor	Suitability
Previous CVC history	Previous CVC placement is associated with central venous stenosis.
Dominant arm	The use of the non-dominant arm is preferred to minimize its negative impact on quality of life.
History of pacemaker use	There is a relationship between pacemaker use and central venous stenosis.
severeCHF history	Catheter insertion can alter hemodynamic and cardiac output.
Arterial or venous peripheral catheter history	Prior placement of an arterial or venous peripheral catheter may have caused target vascular damage.
Diabetes mellitus history	Diabetes mellitus is associated with damage to the vascular system necessary for internal accesses.
Anticoagulant therapy or any history of coagulation disorders	Abnormal coagulation can cause coagulation in the access area or problems with hemostasis.
Presence of co-morbid conditions such as malignancy or coronary artery disease that limit the patient's life expectancy,	The morbidity associated with insertion and obtaining some access disapproves its use in some patients.
Vascular access history	Previous failed vessel accesses may limit areas available for access, a previous failure may affect planned access if the cause is still present.
History of heart valve disease or prosthesis	The infection rate associated with certain types of access should also be taken into account.
Previousarm , neck, or chest surgery/traumatic history	Vascular damage associated with previous surgery or trauma may limit viable areas of access.

## Possible Complications

Table 3. Possible Complications	
Early	Late
Arter puncture-Bleeding-Cardiac arrhythmias- Thoracic canal injury-Peripheral nerve injury-Air embolism-Catheterembolism-Pneumothorax	Venous thrombosis Cardiac perforation and tamponade Infection – Hydrothorax



### Warnings

- **Implantation technique has a significant impact on catheter complications and outcomes. Implantation should be performed by a competent and experienced catheter placement team. Inexperienced personnel should not be allowed to perform implantation without the direct supervision of an experienced physician or surgeon.**
- **Make sure you are familiar with and are familiar with known potential complications and emergency measures if they occur.**

### Which vein?

The preferred site of placement for tunneled-cuffed venous dialysis catheters is the right internal jugular vein. Other options are transhepatic access to the right external jugular vein, left and outer jugular veins, subclavian veins, femoral veins, and translumbar and inferior vena cava(IVC). Subclavian access should be used only when no other upper

extremity or chest wall options are available.

#### A. General technique for all catheters

Ideally, catheter insertion should be performed in the sterile conditions of the operating room .

#### ⚠ Precautions:

- ⚠ **Ultrasound or fluoroscopy should be used for catheter insertion.**
- ⚠ **The position of any central catheter tip should be controlled by radiological means.**
- ⚠ **On the catheter 2% chlorhexidine or iodine-based solution is recommended as an antiseptic solution .**
- ⚠ **It is not recommended to use ointments that may cause the catheters to fail.**
- ⚠ **Continuously squeezing the catheter in the same spot can weaken the tubing. Avoid squeezing the catheter near the adapter and hub as this can cause breakage.**
- ⚠ **Over tightening of the catheterluer's can lead to malfunctions.**

**Table 1. Equipment required for venous access.**

- Sterile kit package with appropriate catheter design / size / length
- Local anesthetic
- Sterile dressing and antiseptic solution
- Injectors and needles
- Saline or heparinized serum for setting up and flushing the post-insertion line
- Sewing supplies
- Shaving equipment for the area (especially femoral) if needed
- Chest X-ray, ultrasonography, fluoroscopy facility

### INSERTION AREA

#### Subclavian Vein

Although a high success rate can be achieved in its placement, serious complications occur more frequently than with other routes. Subclavian puncture should be avoided in patients with abnormal coagulation, as it is difficult to apply pressure to the subclavian artery following accidental puncture. Anteriorly, the vessel is completely covered by the clavicle. It is located under the subclavian artery. Behind the artery is the cervical pleura, which rises at the sternal end of the clavicle.

**Preparation and positioning.** The patient should be in the supine position, with the arms at the sides, with the head on a tilted table to prevent stretching of the central veins and air embolism. Turn the head forward from the side to be cannulated unless there is cervical vertebral injury. Normally, the right SCV is cannulated as the thoracic duct is on the left and can sometimes be damaged during cannulation.

**Technique.** Stand on the patient's side to be cannulated. Identify the midclavicular point and sternum notch. The needle should be inserted 1 cm below the skin and laterally to the midclavicular point. Keeping the needle horizontal, advance posterior to the clavicle, targeting the sternal notch. If the needle touches the clavicle, pull back and guide it to pass under it. Do not insert the needle beyond the sternal head of the clavicle.

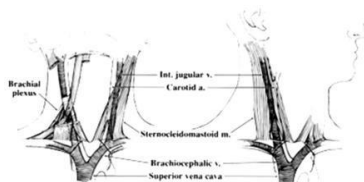


Figure 1

**Complications.** Any of the complications described may occur, but pneumothorax (2-5%) or rarely hemothorax or chylothorax (oily white fluid in the pleural space due to lymph leakage from the thoracic tube) is more common than others. Sometimes the catheter may enter the neck or reverse SCV instead of the chest, this should be confirmed by radiological methods.

**Internal Jugular Vein.** The internal jugular vein (IJV) is a potentially large vessel widely used for central venous access that drains blood from the brain and deep facial structures. Cannulation is associated with a lower incidence of complications than the subclavian approach.

**Preparation and positioning.** The patient should be in the supine position, with the arms at the sides, on a tilted table upside down to avoid stretching of the central veins and air embolism. For better access, turn the head forward from the side to be cannulated. (turning too far increases the risk of arterial puncture).

**Technical.** Stand on the patient's side to be cannulated. Locate the cricoid cartilage and palpate the carotid artery lateral at this level. Keeping your finger lightly on the artery, insert the needle into the skin at an angle of 30-40 ° and move down towards the nipple on the same side (guess the nipple as if it were a male in female). Always guide the needle under your finger away from the artery. The vein is usually within 2-3 cm of the skin. If no vein is found, guide the needle laterally.

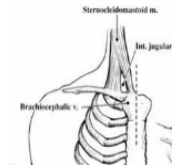


Figure 2

## INSERTION PROCESS FOR SPLITCATHETERS

Proximal to any connector hub and end of the split catheter

As a result, female luers do not have extension legs without being attached to them.

Catheters are suitable for retrograde tunneling.

In retrograde tunneling, the tip of the catheter is first placed in place in accordance with the containi this way, tunneling of the proximal part of the catheters, including both legs, takes place.

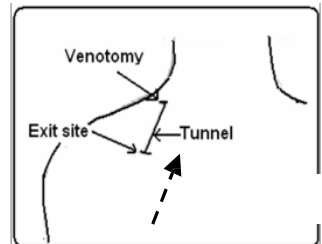


Figure 3

### A. Seldingerinsertion direction

- 1) Confirm that central venous access is required and choose the most appropriate route. Explain the procedure to the patient.
- 2) Shave the needle insertion area if necessary.
- 3) When using strict aseptic technique, prepare and inspect all equipment. Sterilize the skin and cover the area.
- 4) Infiltrate the skin and deep tissues with local anesthetic. In situations where difficulty is expected, you can use a small local anesthetic needle to locate the vein. When using a larger introducer needle to locate the vein, this reduces the risk of trauma to other structures.
- 5) Especially in respiratory patients, position the patient according to the chosen route to avoid prolonged standing upside down.
- 6) Identify the anatomical landmarks of the selected route. Insert the needle guidewire into a syringe, then insert the needle at the recommended point of the chosen route.
- 7) After penetrating the skin, aspirate gently, while advancing the needle in the same direction until the vein is entered.
- 8) If the vein is not found, slowly remove the needle, aspirate at the same time, usually with needle

- insertion, the vein collapses and is punctured. Guide the needle until dark blood gushes out.
- 9) J-shaped guide wire runs along the needle, the wire tip is positioned until the catheter is better with the fluoroscopic guide. The length of the guide wire depends on the size of the patient. If the guide wire goes too far, arrhythmia may occur. The patient should be placed on the cardiac monitor throughout the entire procedure.
  - 10) The needle is then withdrawn, the guidewire held in place.

### **B. Insertion of the catheter into the vein**

- 11) Enlarge the guide wire perimeter by piercing with a scalpel to allow the dilator to enter easily.
- 12) Advance the dilator over the guide wire. Use a 12 Fr dilator followed by a 14 Fr. The twisting movement facilitates the dilatation during the progress of the dilator. Remove the dilator and leave the guidewire in place.
- 13) Remove the dilator from its sheath and reinsert it in the opposite direction. Lock the dilator by turning it clockwise ninety degrees.
- 14) Advance the tearaway sheath introducer with the dilator on the flat end of the guidewire. Make sure the sheath is in the vein. Do not twist the sheath dilator as this may cause permanent sheath tear. Do not grasp the sheath dilator a few centimeters from the skin entrance as it advances. Advance, then re-grasp in the other position until the vein stops moving.



#### Measures:

- Tearaway introducer valve will prevent air passage. At a vacuum pressure of 12 mmHg, the valve can allow air passage close to 4 cc/sec.
  - sheath dilator during insertion as bending will cause sheath tearing. Initially hold the introducer close to its tip (approximately 3 cm from the tip) before penetrating the skin surface. To advance the introducer into the vein, grab a few centimeters above the original grasp location and push down towards the introducer. Repeat the procedure until the introducer vein has entered the appropriate depth for the patient's anatomy.
  - Do not leave the sheath as an indwelling catheter as this could become a vein.
  - sheath that remains in the container. To avoid vessel damage, pull the sheath back as far as possible and separate the sheath only a few centimeters at a time.
- 15) Slowly advance the catheter through the Peelway sheath without bending it. After 50% of the catheter is in the peelaway sheath, start the tearing process slowly. Peel off the sheath until the entire catheter is in the vein. Pull and remove the sheath in the vein.
  - 16) Further adjustment of tip position should be done under fluoroscopy.

#### Measures:

- **Failure to verify catheter position can result in serious injury or death.**
- **Proper tip location will increase flow rate and reduce possible recirculation.**

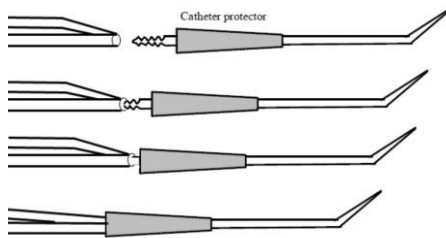
### **C. Creating the Tunnel**

Determine the tunnel position and suitability to place the cuff approximately 2mm or 3 mm from the exit area. Mark the OutputField .

- 17) After the Exit Area is determined , local anesthetic ( lidocaine) is applied. It is recommended that the entire route should be anesthetized with 1% Lidocaine together with epinephrine. Epinephrine injection will cause minimal bleeding.
- 18) Initially, a small dermatotomy (no.11 blade) is performed at the exit site. Keeping the Exit Area

small protects the cuff and helps reduce bacterial migration opportunities.

- 19) Tunnel length may vary . The original articles recommended a tunnel of at least 6 cm. However, it is not necessary depending on the patient's anatomy.
- 20) Using the curved tunnel stylet supplied with the veneer safety , create and widen a tunnel from the venotomy field in the subcutaneous plane in soft dissection in the direction of the exit field (Figure 3) . Build the underground, not the cash . Lightly tunnel to avoid damage to surrounding containers .
- 21) Insert the opened end of the catheter extension to the barbed end of the TunnelStyle and ensure it is securely attached.
- 22) Remove the clamp from the extension line .
- 23) At a safe distance , within the catheter protection tube , advance both catheter extensions while pulling over them (Figure 4).



**Figure 4**

- 24) Pull tunneling through the plane of the subcutaneous tunnel by pulling the catheter until the catheter extension(s) inside emerge from the safety tube exit area of the tunnel stylet. If you feel resistance, try simple dissection.
- 25) Clamp both catheter extension lines using the supplied clamps.
- 26) Release and disconnect the catheter extension end by sliding the safety tube on the stylet.
- 27) Cut both catheter extension ends on the line marked for working volume.



**Warnings:**

- Cut the catheter in the working volume line or the working volume will not be correct .

- 28) Keep the cuff in place and sew up the tunnel exit area. Palpate the tunnel until correct cuff placement is achieved.
- 29) Insert the catheter extension line (Figure 5 Step 1) by firmly positioning the cap of the catheter extension line.  
NB lumen distension is the color defined on the catheter extension.



**Warnings:**

• Use only the catheter extension assembly provided in the kit. May not be compatible with other manufacturer supplied extension line catheters.

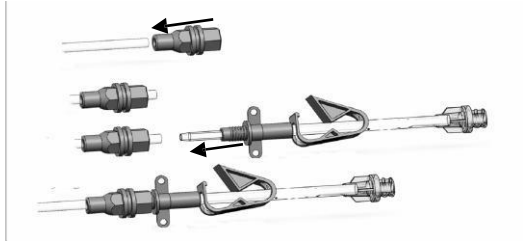
- 30) Attach the catheter extension assembly to the catheter (Step 2) by inserting the tube of the catheter extension assembly within the catheter extension. Screw the cap tightly onto the female luer (Step 3) so that the assembly is clamped in place.
- 31) Remove the clamps on the catheter extensions.





### **Precautions:**

Connect the catheter extension marked with red print to the red extension line. Connect the catheter extension marked with blue print and the blue extension line.



**Figure 5**

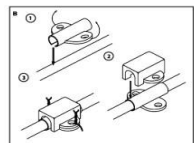
- 32) Attach the syringe to the mounted catheter luer hub. Remove the compression clamp on the catheter and aspirate. Good blood flow must be achieved from both the arterial and venous side of the catheter or catheter repositioning may be required.
- 33) Once good blood flow is established, flush the catheter lumen with saline. Tighten the catheter extension set.
- 34) Connect the catheter extension set and re-clamp on the catheter, and then aspirate to ensure there is no air in the saline-washed extension sets. Close the clamp of the extension set and close it with the female luer tip with the injection cap
- 35) Patency heparin or other anti-coagulant lock should be used in accordance with hospital protocol. Proper cleaning of catheters is mandatory to prevent intraluminal thrombus. Each catheter will be different and it is important to read the priming volume printed on the catheter. Use positive intermittent flushing ("turbulent flow technique") and remove the flush syringe to reduce blood flow into the catheter while under pressure.
- 36) Record Catheter Lot number, size, length, and working volume in the patient file.

#### **D. Device Security**

- 37) Any portion of the catheter exposed in the venotomy area should be implanted subcutaneously. Simply cut the skin to an appropriate length, implant this section, and then suture the venotomy closed.
- 38) Medical Equipment must be secured. By using the tunnel method above, the mobility and accidental removal of the catheter is less likely. The addition of 3 - 0 non-absorbable sutures (not silk) can aid stability. Place approximately 1 to 2 cm from the exit site to reduce suture infection. Do not suture the catheter tube. Use a catheter fixation flap, a movable fixation flap, or other fixation devices.

#### **Fixing by sewing**

1. Take the flexible part of the moving wing and hold it until the internal slit opens. spread the wings. Position it over the catheter in the desired area.
2. Pull the rigid part of the movable blade onto the flexible blades.
3. Sew the wings to the patient's skin through the holes.
4. Put occlusive dressing on venotomy and exit sites.



**Figure 6**

## Application problems common to most insertion techniques

<b>Arterpuncture</b>	It is usually prominent but may be overlooked in a patient who is hypoxic or hypotensive. Withdraw the needle and apply steady pressure directly to the area for at least 10 minutes or longer if there is persistent bleeding. If there is minimal swelling then try again or choose a different route.
<b>Suspected pneumothorax</b>	If air is easily aspirated into the syringe (note that this can occur if the needle is not firmly attached to the syringe), or the patient begins to have shortness of breath. Leave the procedure in this field. Obtain chest X-ray and, if confirmed, place an intercostal drain. If access is absolutely necessary, then try another route on the SAME SIDE or femoral vein. DO NOT try subclavian or jugular on the other side as bilateral pneumothoraxes are produced.
<b>Arrhythmias during the procedure</b>	It is usually inserted too far (into the right ventricle) from the catheter or wire. The average length of the catheter required for an internal jugular or subclavian approach for an adult is 15cm. If it is longer than this, withdraw the wire or catheter.
<b>air embolism</b>	This may occur especially in the hypovolemic patient if the needle or cannula is left in the vein while it is open to air. This is avoided by ensuring that the patient is positioned upside down (for the jugular and subclavian tracts) and the guidewire or catheter is immediately passed down the needle.
<b>Does not pass to wire needle</b>	Check that the needle is still in the vein. Wash with isotonic. Try to hold the needle so that the uv will lie along the surface of the container. Carefully rotate the needle if its tip lies against the vessel wall. Reattach the syringe and aspirate to check if it is still in the vein. When the wire goes through the needle but not into the vein, it should be pulled back very slowly. <b>If there is any noticeable resistance, the needle should be pulled out while the wire is still in and the procedure should be repeated. This reduces the risk of cutting the end of the wire with the needle tip.</b>
<b>Permanent bleeding on the entrance side</b>	Apply constant pressure directly with the sterile dressing. Bleeding should usually stop unless there is a clotting abnormality. If there is arterial or venous rupture, there may be persistent severe bleeding and may require surgical exploration.

### Considerations for Accessing Catheters and Cleaning of Catheter Exit Sites

Infection control measures that should be used for all HD catheters include the following:

- Catheter exit to ensure proper positioning of the catheter and avoid infection by experienced personnel at each HD session prior to opening and accessing the catheter / port catheter system. The area should be examined.
- Changing the exit site dressing at each HD treatment using a clear dressing or gauze and tape.
- After catheter insertion and at the end of each dialysis session, skin at the catheter exit site using povidone iodine ointment or mupirocin ointment followed by chlorhexidine or povidone iodine solution Use of dry gauze along with disinfection is recommended.
- Use of surgical masks for staff and patient, and use of aseptic technique to prevent catheter contamination, including all catheter or port catheter system connection, use of clean gloves for disconnection, and dressing procedures.
- Catheter hub caps or bloodline connectors are soaked with povidone iodine for 3 to 5 minutes and then allowed to dry before separation.
- Catheter lumen should never be left in the open air. A cap or syringe should be placed on or in the catheter lumen, maintaining a clean area under the catheter connectors.



#### **Measures:**

Patients should not swim, shower or wet the dressing while bathing.

- Excessive sweating or accidental wetting will cause the dressing to stick, medical or nursing staff should change the dressing under sterile conditions.

#### **• Skin cleansing should include the following steps:**

1. Apply solution/clean in circular motions, working in the catheter exit area.
2. Cover an area of 10 cm in diameter.
3. Repeat this step twice. Do not rinse or remove excess solution from the skin.
4. Allow the solution to dry completely before

applying the dressing.

• **Use 2 wipes to clean the connection between any CVC hub and cover:**

- a. Grasp the connection with 1 cloth.
- b. For up to 10 cm catheter, use second cloth to clean the catheter connection.
- c. Vigorously clean the hub connection area and cover with the first cloth. Discard the cloth.
- d. Do not drop the connection area when cleared

• To clean the catheter section adjacent to the skin, gently clean the top and bottom sections of the catheter, starting at the exit site and working outward.

**Connection to the dialysis machine:**

- Heparin solution should be removed from each lumen prior to treatment to avoid systemic heparinization of each patient.  
Aspiration should be based on the dialysis unit protocol.

- Connections to the catheter and extracorporeal circuits should be carefully examined prior to dialysis.
- Frequent visual inspection should be performed to detect leaks to prevent blood loss and air embolism.
- If a leak is found, the catheter should be tightened immediately.

**Precaution**

- It is only clamped with the sequential clamp given.

- Necessary corrective action should be taken before the continuation of dialysis treatment.

**Note:** Excessive blood loss causes the patient to go into shock.

- Hemodialysis should be performed under the physician's instructions.

**PRECAUTION AGAINST MISUSE:**

The reasons may be:

- **Selecting the wrong size or length of catheter is reflected in the catheter flow rate capacity.**
- **Incorrect placement of the catheter tip can affect the flow rate.**
- **Avoid entangling the catheter in the tunnel area or the flow rate may decrease.**
- **Improper heparinization of the catheter during dialysis can cause blood clots and blockage of the catheter. Improper heparinization of the catheter between dialysis may result in thrombus formation.**
- **Aggressively, male luer insertion catheters can cause cracks in female luers.**
- **Incorrect connection of the catheter extension line(s) by connecting the venous line of the dialysis blood line to the catheter extension line dedicated to the arterial line and marked in red. This can lead to a high circulation rate of up to 37%, which can cause inefficient dialysis.**

**End of Dialysis**

At the end of the dialysis session, tighten the catheter extension line (s) and close the catheter with the injection cap. This should be followed by the operation of the catheter by injecting heparin or equivalent (depending on the operation of the catheter volume and extension line) through the injection caps. Loosen the catheter, then inject the heparin and tighten immediately to lock the heparin inside the catheter.

**Catheter Dysfunction Prevention and Treatment**

Catheters that become dysfunctional should be evaluated. Dysfunction is defined as the inability to maintain extracorporeal blood flow of 300 mL/min (for adult size catheter) or more at a pre-pump arterial pressure of less than -250 mmHg.

## **Catheter Disorder Symptoms: Evaluation Phase**

- Canopy pump flow rates < 300 mL/min
- Arterial pressure increases (< -250 mm Hg)
- Venous pressure increases (> 250 mm Hg)

The conductivity decreases (< 1.2): the ratio of the blood pump flow to the absolute value of the pre-pump pressure

- Blood cannot be freely aspirated (late manifestation)
- Frequent pressure alarms - not responsive to patient repositioning or catheter flushing

### **Measures:**

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

### **Causes of Early Catheter Dysfunction**

Mechanical compression (Pinch-off syndrome (POS) inside the subclavian catheter)

Entanglements (openings in the tunnel)

Incorrect sutures due to catheter displacement

Coagulation or occlusion of margin holes due to fibrin sheath formation or wall adhesion

Medication Prescriptions (some antibody locks or IVIG rupture)

Patient position, especially with poorly fixed and secure catheter

Loss of catheter integrity with infection

Crush, tear, or repeated cracking of the catheter extension

### **The following methods should be used for the treatment of dysfunctional or dysfunctional catheters:**

- Fix the incorrectly positioned catheter using the clamp.
- Change the patient position, have him cough or wash vigorously (if no resistance is felt) work to remove the side punctures and remove a pathway from the vein wall.
- If fibrin sheath is present, scrape off the fibrin sheath using a clamp.
- Replacement of a thrombosed catheter over a guidewire is done if a fibrin catheter is present or mispositioned, or if the catheter is of insufficient length.
- Use of thrombolytics according to hospital protocol.
- Infected HD should be based on type of catheter therapy and extent of infection.
- All catheter-borne infections, except catheter exit site infections, should be addressed before initiating parenteral therapy with an appropriate antibiotic(s) for the suspected organism(s).
- Definitive antibiotic therapy should be based on the isolated organism(s).
- The catheter should be changed whenever possible, and in most cases as soon as possible within 72 hours of starting antibiotic therapy, and this change does not require a negative pre-exchange blood culture result. Follow-up cultures are needed 1 week after discontinuation of antibiotic therapy.
- Crushing of the catheter extension can be resolved by replacing the damaged part. The catheter extension is clamped between the catheter and the damaged part. Cut the catheter tubing at the damaged part and reattach it with a female luer.

### **Treatment of tunneled cuffed catheter infection**

Tunneled cuffed catheter infection is a serious problem. Appropriate treatment depends on the nature of the infection:

#### **A. Catheter exit site infections,**

characterized by

exit site redness, crusting and exudate in the absence of systemic manifestations and negative blood cultures, and should be treated as follows: 1. Provide appropriate local exit site care, administer topical antibiotics; Do not remove the catheter. 2. If tunnel drainage is present, treat with parenteral antibiotics (anti-staphylococcal, anti-streptococcal exit site cultures awaiting treatment) in addition to the appropriate local measures below. Definitive treatment should be based on culture results. Do not remove the catheter as long as the infection responds to treatment. If the infection does not respond to treatment, remove the catheter and replace with a different tunnel and exit site.

#### **B. Catheter-associated bacteremia**

should generally be treated by initiating parenteral therapy with an antibiotic(s) appropriate for the suspected organism(s), such as Staphylococci and Streptococci. Definitive treatment should be based on the isolated organism(s).

If the patient remains symptomatic for more than 36 hours, the catheter should be removed in all cases.

The catheter should also be removed in any clinically unstable patient.

A new permanent access should not be placed until

blood cultures taken after discontinuation of antibiotic therapy have been negative for at least 48 hours .

#### **Catheter Removal**

##### **Warnings**

- Only a physician familiar with appropriate techniques should perform the following procedures.





















##### **Precautions**

• **Always review hospital or unit protocol, potential complications and management, warnings and precautions prior to catheter removal.**

- a) Remove any dressing and suture material.
- b) Instruct the patient to take a full breath and release.
- c) Remove catheters required for local anesthetic infiltration in the exit site and cuff area.
- d) Cut any sutures.
- e) Palpate the cuff in the tunnel, making a 2 cm incision over the cuff and parallel to the catheter.
- f) Carefully dissect around the Dacron cuff to free it from subcutaneous tissue and fibrous sheaths.
- g) Grasp the cuff with the clamp and cut the catheter between the cuff and the insertion site.
- h) Remove the remaining catheter through the incision made over the cuff.
- i) Withdraw the proximal portion of the catheter from the exit site and do not pull through the incision on the cuff.
- j) Apply pressure to the tunnel area for 10-15 minutes or until the bleeding stops.
- k) Instruct the patient to stand in an upright position for a minimum of 2 hours.

**Disposal of the Catheter** The used catheter should be disposed of in accordance with hospital protocol or in a hygienic container to avoid possible contamination and cross-infection.

## Symbols Used in Labeling

SYMBOL	SYMBOL NAME	SYMBOL	SYMBOL NAME
	Notified Body		Product code
	EO Sterilized		Barcode
	Lot number		Temperature Storage Conditions
	Disposable		Do not resterilize
	See operating instructions		Attention
	Production date		DataMatrix Code
	Expiration date		Should Only Be Used by an Expert
	Do not use if package is damaged		Does not contain latex.
	keep away from sunlight		non-pyrogenic
	Manufacturer		keep dry

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