ProGuide™
chronic dialysis catheter

INSTRUCTIONS FOR USE

MERITMEDICAL®

English

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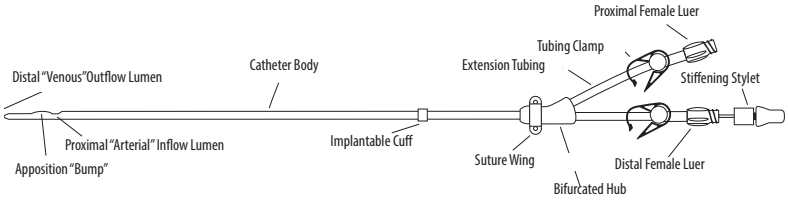
DESCRIPTION
The ProGuide Chronic Hemodialysis Catheter is made of soft radiopaque polyurethane called Carbothane®. It is available in 14.5 French size and a variety of lengths. The catheter shaft is divided internally into two separate lumens by a septum. It allows flow rates as high as 500 mL/min. The catheter has a white tissue ingrowth cuff to help anchor the catheter in position.



INDICATIONS FOR USE
The ProGuide Chronic Dialysis Catheter is indicated for use in attaining long-term vascular access for hemodialysis and apheresis.

It may be implanted percutaneously and is primarily placed in the internal jugular or subclavian vein of an adult patient.

Catheters greater than 40 cm are intended for femoral vein insertion.

GENERAL CAUTION STATEMENTS
- Read instructions for use carefully before using device.
- RX ONLY - Federal Law (USA) restricts the device to sale by or on the order of a physician.
- Single Patient Use Only
- Sterilized by Ethylene Oxide (EO)
- Sterile and non-pyrogenic only if packaging is not opened, damaged or broken.
- Do not resterilize the catheter or components by any method. The manufacturer will not be liable for any damages caused by reuse of the catheter or accessories.
- Do not use the catheter or accessories if the packaging is open, damaged or compromised.
- Do not use the catheter or accessories if any sign of product damage is visible.

CONTRAINDICATIONS
- The ProGuide Chronic Dialysis Catheter is intended for long-term vascular access and should not be used for any purpose other than indicated in these instructions.

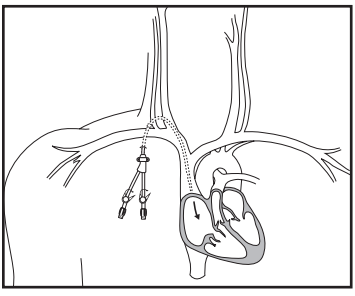
POTENTIAL COMPLICATIONS
The use of an indwelling central venous catheter provides an important means of venous access for critically ill patients; however, the potential exists for serious complications. Before attempting the insertion of the ProGuide catheter, the physician should be familiar with the following complications and their emergency treatment should they occur:

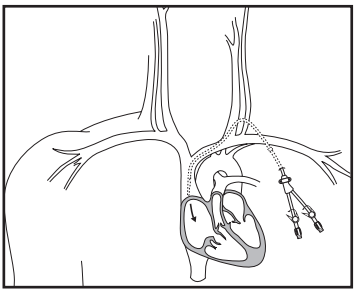
- Air embolism
- Bleeding at site
- Cardiac arrhythmia
- Catheter or cuff erosion through the skin
- Catheter occlusion
- Central venous thrombosis
- Catheter-related sepsis (septicemia)
- Exit site infection
- Extravasation
- Fibrin sheath formation
- Hemorrhage
- Hydrothorax
- Inflammation, necrosis or scarring of skin over implant area
- Laceration of vessels or viscus
- Mediastinal injury
- Pleural Injury
- Pulmonary emboli
- Right atrial puncture
- Subclavian artery puncture
- Thoracic duct injury (laceration)
- Thrombocytopenia
- Vascular (venous) thrombosis
- Vessel erosion
- Bacteremia
- Brachial plexus injury
- Cardiac tamponade
- Catheter embolism
- Catheter damage due to compression between the clavicle and first rib
- Endocarditis
- Exit site necrosis
- Exsanguination
- Hematoma
- Hemothorax
- Inferior vena cava puncture
- Intolerance reaction to implanted device
- Lumen thrombosis
- Perforation of vessels or viscus
- Pneumothorax
- Retroperitoneal bleeding
- Spontaneous catheter tip malposition or retraction
- Thromboembolism
- Tunnel infection
- Ventricular thrombosis
- Risks normally associated with local and general anesthesia, surgery, and post-operative recovery

These and other complications are well documented in medical literature and should be carefully considered before placing the catheter. Placement and care of hemodialysis catheters should be performed by persons knowledgeable of the risks involved and qualified in the procedures.

INSERTION SITES
The right internal jugular vein is a preferred anatomical location for chronic dialysis catheters. However, the left internal jugular vein, as well as the external jugular veins and subclavian veins can also be a consideration. As with all invasive procedures, the physician will assess the anatomical and physiological needs of the patient to determine the most appropriate catheter entry site. ProGuide is available in various lengths to accommodate the varying anatomical differences of patients as well as the differences between right and left side approaches. Catheters greater than 40 cm long are typically placed in the femoral vein.

PLACEMENT INTO RIGHT OR LEFT INTERNAL JUGULAR VEIN





WARNING: Patients requiring ventilator support are at increased risk of pneumothorax during subclavian vein cannulation.
WARNING: Extended use of the subclavian vein may be associated with subclavian vein stenosis and thrombosis.
WARNING: The risk of infection is increased with femoral vein insertion.
WARNING: Failure to verify catheter placement with fluoroscopy may result in serious trauma or fatal complications.

PREPARATION INSTRUCTIONS
1. Read instructions carefully before using this device. The catheter should be inserted, manipulated, and removed by a qualified, licensed physician or other qualified health care professional under the direction of a physician.
2. The medical techniques and procedures described in these instructions for use do not represent all medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgment in treating any specific patient.
3. The selection of the appropriate catheter length is at the sole discretion of the physician. To achieve correct tip placement, proper catheter length selection is important. Routine fluoroscopy should always follow the initial insertion of this catheter to confirm appropriate placement prior to use.

SITE PREPARATION

1. The patient should be placed in a modified Trendelenburg position, with the upper chest exposed and the head turned slightly to the opposite side of the insertion site.
2. For internal jugular placement, have patient lift his/her head from the bed to define the sternomastoid muscle. The venous entry site will be performed at the apex of a triangle formed between the two heads of the sternomastoid muscle. The apex should be approximately three finger breadths above the clavicle.
3. Prepare and maintain a sterile field throughout the procedure using standard institutional protocol for implantable devices.
   PRECAUTION: Follow Universal Precautions when inserting and maintaining this device. Due to the risk of exposure to bloodborne pathogens, health care professionals should always use standard blood and body fluid precautions in the care of all patients. Sterile technique should always be followed.
4. Prepare the sterile field and access site using an approved prep solution and standard Surgical technique.
   PRECAUTION: Use standard hospital protocols when applicable.
5. (If applicable) Administer local anesthesia to the insertion site and the path for the subcutaneous tunnel.

INSERTION TECHNIQUE (1) - COMMON STEPS
PERCUTANEOUS ENTRY INTO RIGHT INTERNAL JUGULAR VEIN
WITH A VALVED PEELAWAY SHEATH INTRODUCER

VENOUS ACCESS AND GUIDE WIRE INSERTION

1. K-DOQI Guidelines recommend the use of ultrasound guidance.
   NOTE: Mini access ("micropuncture") is recommended. Follow manufacturer's guidelines for proper insertion technique.
   Insert the introducer needle with an attached syringe and advance it into the target vein, in the direction of blood flow. Aspirate gently as the insertion is made. Aspirate a small amount of blood to ensure the needle is correctly positioned in the vein.
   PRECAUTION: If arterial blood is aspirated, remove the needle and apply immediate pressure to the site for at least 15 minutes. Ensure that the bleeding has stopped and that no hematoma has developed before attempting to cannulate the vein again.
2. When the vein has been entered, remove the syringe leaving the needle in place and place thumb over the hub of the needle to minimize blood loss and / or air embolism.
3. Insert the distal end of the marker guide wire into the needle hub (or mini access introducer hub) and pass it into the vasculature.
   PRECAUTION: If using the "J" tipped wire provided, draw the tip of the wire back into the straightener so that only the tip of the wire is exposed.
4. Advance the guide wire with forward motion until the tip resides at the junction of the superior vena cava and right atrium.
   WARNING: Cardiac arrhythmias may result if the guide wire is allowed to pass into the right atrium.
   CAUTION: Do not advance the guide wire or catheter if unusual resistance is encountered.
   CAUTION: Do not insert or withdraw the guide wire forcibly from any component. The wire may break or unravel. If the guide wire becomes damaged and must be removed while the needle (or sheath introducer) is inserted, the guide wire and needle should be removed together.
   PRECAUTION: The length of the guide wire inserted is determined by the size of the patient and the anatomical site used.
   PRECAUTION: Depth markings on the wire will help determine indwelling depth. Always confirm proper guide wire position using fluoroscopy.
5. Remove the needle (or mini access introducer), leaving the guide wire in place. The guide wire should be held securely during the procedure. The introducer needle must be removed first.

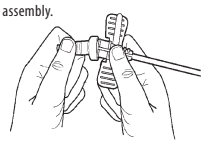
CATHETER PREPARATION AND SUBCUTANEOUS TRACT DILATION

1. Remove the stiffening stylet from the venous lumen.
   PRECAUTION: The ProGuide catheter is packaged with a guide wire stiffening stylet to facilitate placement using the over-the-wire technique and is not used with a peelaway introducer insertion technique (see insertion technique 2 for use of stiffener component).
2. Irrigate each lumen of the catheter with heparinized saline and clamp each extension prior to catheter insertion.
   WARNING: The heparin solution must be aspirated out of both lumens immediately prior to using the catheter to prevent systemic heparinization of the patient.
   WARNING: To minimize the risk of air embolism, keep the catheter clamped at all times when not in use or when attached to a syringe, IV tubing, or bloodlines.
   WARNING: Patients requiring ventilator support are at increased risk of pneumothorax during subclavian vein cannulation.
   CAUTION: Do not clamp the dual lumen portion of the catheter body. Clamp only the clear extension tubing.
   PRECAUTION: Only clamp the catheter with the in-line tubing clamps provided.
3. Determine the catheter exit site on the chest wall, approximately 8-10 cm below the clavicle that is below and parallel to the venous puncture site.
   PRECAUTION: A tunnel with a wide, gentle arc lessens the risk of catheter kinking. The distance of the tunnel should be short enough to keep the bifurcated junction from entering the exit site, yet long enough to keep the cuff 2-3 cm (minimum) from the skin opening site.
4. Make a small incision at the desired exit site of the tunneled catheter on the chest wall. The incision should be wide enough to accommodate the cuff, approximately 1 cm.
5. Use blunt dissection to create the subcutaneous tunnel opening at the catheter exit site for the white tissue ingrowth cuff, midway between the skin exit site and the venous entry site, approximately 2-3 cm (minimum) from the catheter exit site.
   WARNING: Do not over-expand the subcutaneous tissue during tunneling. Over-expansion may delay or prevent cuff in-growth.
6. Make a second incision above and parallel to the first, at the venous insertion site. Enlarge the cutaneous site with a scalpel and create a small pocket with blunt dissection to accommodate the small remaining catheter loop ("knuckle") of the catheter after the peel-away sheath is removed.
7. Attach the tunneler to the catheter's venous lumen. Slide the tip of the catheter over the tri-ball connection until it rests adjacent to the sheath stop.
8. Slide the tunneler sheath over the catheter making certain that the sleeve covers the arterial lumen. This will reduce the drag in the subcutaneous tunnel as the apparitional bump and arterial port pass through the tissue.
9. With the blunt tunneler, gently lead the catheter and tunneler connection into the exit site and create a subcutaneous tunnel from the catheter exit site to emerge at the venous entry site.
   CAUTION: The tunnel should be made with care to avoid damage to surrounding vessels. Avoid tunneling through muscle.
   CAUTION: Do not pull or tug the catheter tubing. If resistance is encountered, further blunt dissection may facilitate insertion. The catheter should not be forced through the tunnel.
10. After tunneling the catheter, the tunneler can be removed by sliding the tunneler sheath away from the catheter and pulling the tunneler from the distal tip of the catheter.
    CAUTION: Avoid damage to the catheter by using a slight twisting motion.
    CAUTION: To avoid damage to the catheter tip, keep the tunneler straight and do not pull it out at an angle.
    CAUTION: Inspect catheter tip for damage before proceeding with procedure

INTRODUCTION OF THE VALVED PEELAWAY INTRODUCER

CAUTION: The sheath is not intended to create a complete two-way seal nor is it intended for arterial use.
CAUTION: The sheath is designed to reduce blood loss but it is not a hemostasis valve. The valve may substantially reduce the rate of blood flow but some blood loss through the valve may occur.

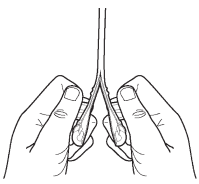
1. Insert vessel dilator into sheath until the dilator cap folds over valve housing and secures the dilator onto sheath assembly.
   NOTE - Optional dilation:
   - To ease insertion of the peelaway introducer, some physicians prefer to dilate the vein before inserting the introducer.
   - Thread the dilator(s) over the end of the guide wire and advance into the vein using a rotating motion to assist passage through the tissue.
   CAUTION: As the dilator(s) pass through the tissue and into the vasculature, ensure that the guide wire does not advance further into the vein.



2. While maintaining guide wire position in the vein, advance the locked peelaway introducer and dilator assembly over the exposed guide wire and into the vein.
   WARNING: Never leave the sheath in place as an indwelling catheter. Damage to the vein will occur.
3. Hold the sheath in place and separate the dilator cap from the sheath valve housing by rocking the dilator cap off the hub. Gently withdraw the dilator and wire from the sheath leaving the valved introducer in place.
   NOTE: Leaving the guide wire in place after removing the dilator may cause the valve to leak.
   CAUTION: Care should be taken not to advance the split sheath too far into the vessel as a potential kink would create an impasse to the catheter.

DIALYSIS CATHETER PLACEMENT

1. Advance the distal section of the catheter through the valved sheath introducer and into the vein.
   PRECAUTION: To help minimize catheter kinking, it may be necessary to advance in small steps by grasping the catheter close to the sheath.
2. Advance the catheter tip to the junction of the superior vena cava and right atrium.
3. With the catheter advanced and positioned, sharply snap the tabs of the valve housing in a plane perpendicular to the long axis of the sheath to split the valve and peel partially away from the catheter.
   CAUTION: Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible and peel the sheath only a few centimeters at a time.
4. Remove the sheath completely from the patient and catheter.
5. Press the remaining catheter loop ("knuckle") gently into the subcutaneous pocket created at the venous entry site.
   WARNING: Catheters should be implanted carefully to avoid any sharp or acute angles which could compromise the flow of blood or occlude the opening of the catheter lumens.
   PRECAUTION: For optimal product performance do not insert any portion of the cuff into the vein.



6. Attach syringes to both extensions and open the clamps. Confirm correct placement and catheter function by aspirating blood from both lumens. Flush each lumen with heparinized saline (priming volume is printed on the extension tubing clamp). Blood should aspirate easily.
   PRECAUTION: If either lumen exhibits excessive resistance to blood aspiration, the catheter may need to be rotated or repositioned to obtain adequate blood flow.
   PRECAUTION: It is recommended that the "venous" luer connection be oriented cephalad (toward the head).
7. Clamp the extensions immediately after flushing.
8. Remove the syringes and replace with injection caps.
   PRECAUTION: Avoid air embolism by keeping extension tubing clamped at all times when not in use and by aspirating then irrigating the catheter prior to each use. Always aspirate first then irrigate the catheter prior to each use. With each change in tubing connections, purge air from the catheter and all connecting tubing and caps.
9. Correctly position the cuff and tunneled portion of the catheter.

10. Confirm proper tip placement with fluoroscopy. The distal "venous" tip should be positioned at the junction of the superior vena cava and right atrium or into the right atrium for optimal blood flow.
    WARNING: Failure to verify catheter placement with fluoroscopy may result in serious trauma or fatal complications.
11. Secure and dress the catheter as noted in "Securement and Dressing"

INSERTION TECHNIQUE (2) - COMMON STEPS PERCUTANEOUS ENTRY INTO RIGHT INTERNAL JUGULAR VEIN WITH AN OVER-THE-WIRE TECHNIQUE

VENOUS ACCESS AND GUIDE WIRE INSERTION

1. K-DOQI Guidelines recommend the use of ultrasound guidance.
   NOTE: Mini access ("micropuncture") is recommended. Follow manufacturers guidelines for proper insertion technique.
   Insert the introducer needle with an attached syringe and advance it into the target vein, in the direction of blood flow. Aspirate gently as the insertion is made. Aspirate a small amount of blood to ensure the needle is correctly positioned in the vein.
   PRECAUTION: If arterial blood is aspirated, remove the needle and apply immediate pressure to the site for at least 15 minutes. Ensure that the bleeding has stopped and that no hematoma has developed before attempting to cannulate the vein again.
2. When the vein has been entered, remove the syringe leaving the needle in place and place thumb over the hub of the needle to minimize blood loss and / or air embolism.
3. Insert the distal end of the marker guide wire into the needle hub (or mini access introducer hub) and pass it into the vasculature.
   PRECAUTION: If using the "J" tipped wire provided, draw the tip of the wire back into the straightener so that only the tip of the wire is exposed.
4. Advance the guide wire with forward motion until the tip resides in the junction of the superior vena cava and right atrium.
   WARNING: Cardiac arrhythmias may result if the guide wire is allowed to pass into the right atrium.
   CAUTION: Do not advance the guide wire or catheter if unusual resistance is encountered.
   CAUTION: Do not insert or withdraw the guide wire forcibly from any component. The wire may break or unravel. If the guide wire becomes damaged and must be removed while the needle (or sheath introducer) is inserted, the guide wire and needle should be removed together.
   PRECAUTION: The length of the guide wire inserted is determined by the size of the patient and the anatomical site used.
   PRECAUTION: Always confirm proper guide wire position using fluoroscopy. Depth markings on the wire will help determine indwelling depth.
5. Remove the needle (or mini access introducer), leaving the guide wire in place. The guide wire should be held securely during the procedure. The introducer needle must be removed first.

CATHETER PREPARATION AND SUBCUTANEOUS TRACT DILATION

1. The ProGuide catheter is packaged with a guide wire stiffening stylet positioned in the venous lumen to facilitate placement using the over-the-wire technique.
2. Withdraw the stiffening stylet approximately 2-3 cm and confirm that the stylet tip is not visible at the end of the catheter.
3. Irrigate the arterial lumen and stiffening stylet with heparinized saline and clamp the red arterial extension prior to catheter insertion.
   WARNING: The heparin solution must be aspirated out of both lumens immediately prior to using the catheter to prevent systemic heparinization of the patient.
   WARNING: To minimize the risk of air embolism, keep the catheter clamped at all times when not in use or when attached to a syringe, IV tubing, or bloodlines.
   WARNING: Patients requiring ventilator support are at increased risk of pneumothorax during subclavian vein cannulation.
   CAUTION: Do not clamp the dual lumen portion of the catheter body. Clamp only the clear extension tubing.
   PRECAUTION: Only clamp the catheter with the in-line tubing clamps provided.
4. Determine the catheter exit site on the chest wall, approximately 8-10 cm below the clavicle that is below and parallel to the venous puncture site.
   PRECAUTION: A tunnel with a wide, gentle arc lessens the risk of catheter kinking. The distance of the tunnel should be short enough to keep the bifurcated junction from entering the exit site, yet long enough to keep the cuff 2-3 cm (minimum) from the skin opening site.
5. Make a small incision at the desired exit site of the tunneled catheter on the chest wall. The incision should be wide enough to accommodate the cuff, approximately 1 cm.
6. Use blunt dissection to create the subcutaneous tunnel opening at the catheter exit site for the white tissue ingrowth cuff, midway between the skin exit site and the venous entry site, approximately 2-3 cm minimum from the catheter exit site.
   WARNING: Do not over-expand the subcutaneous tissue during tunneling. Over-expansion may delay or prevent cuff in-growth.
7. Make a second incision above and parallel to the first, at the venous insertion site. Enlarge the cutaneous site with a scalpel and create a small pocket with blunt dissection to accommodate the small remaining catheter loop ("knuckle") of the catheter.
8. Attach the tunneler to the catheter's venous lumen. Slide the tip of the catheter over the tri-ball connection until it rests adjacent to the sheath stop.
9. Slide the tunneler sheath over the catheter making certain that the sleeve covers the arterial lumen. This will reduce the drag in the subcutaneous tunnel as the apposition bump and arterial port pass through the tissue.
10. With the blunt tunneler, gently lead the catheter and tunneler connection into the exit site and create a subcutaneous tunnel from the catheter exit site to emerge at the venous entry site.
    CAUTION: The tunnel should be made with care to avoid damage to surrounding vessels. Avoid tunneling through muscle.
    CAUTION: Do not pull or tug the catheter tubing. If resistance is encountered, further blunt dissection may facilitate insertion. The catheter should not be forced through the tunnel.
11. After tunneling the catheter, the tunneler can be removed by sliding the tunneler sheath away from the catheter and pulling the tunneler from the distal tip of the catheter.
    CAUTION: Avoid damage to the catheter by using a slight twisting motion.
    CAUTION: To avoid damage to the catheter tip, keep the tunneler straight and do not pull it out at an angle.
    CAUTION: Inspect catheter tip for damage before proceeding with procedure.
12. Remove the stylet label and tighten down the luer lock nut of the stylet to the blue venous luer lock connection.
13. Thread the distal tip of the stylet with the catheter over the proximal tip of the guide wire until the guide wire exits the venous luer connection.
14. While maintaining guide wire position in the vein, advance catheter to the junction of the superior vena cava and right atrium to ensure optimal blood flow.
    PRECAUTION: To help minimize catheter kinking, it may be necessary to advance in small steps by grasping the catheter close to the skin.
15. Remove the stylet and guide wire from the venous lumen.
16. Press the small remaining catheter loop ("knuckle") gently into the subcutaneous pocket created at the venous entry site.
    WARNING: Catheters should be implanted carefully to avoid any sharp or acute angles which could compromise the flow of blood or occlude the opening of the catheter lumens.
    PRECAUTION: For optimal product performance do not insert any portion of the cuff into the vein.
17. Make any adjustments to the catheter insertion depth and tip position under fluoroscopy.
18. Attach syringes to both extensions and open the clamps. Confirm correct placement and catheter function by aspirating blood from both lumens. Flush each lumen with heparinized saline (priming volume is printed on the extension tubing clamp). Blood should aspirate easily.
    PRECAUTION: If either lumen exhibits excessive resistance to blood aspiration, the catheter may need to be rotated or repositioned to obtain adequate blood flow.
    PRECAUTION: To maintain patency, a heparin lock must be created in both lumens.
    PRECAUTION: It is recommended that the "venous" lumen be oriented cephalad (toward the head).
19. Clamp the extensions immediately after flushing.
20. Remove the syringes and replace with injection caps.
    CAUTION: Avoid air embolism by keeping extension tubing clamped at all times when not in use and by aspirating then irrigating the catheter prior to each use.
21. Correctly position the cuff and tunneled portion of the catheter.
22. Confirm proper tip placement with fluoroscopy. The distal "venous" tip should be positioned at the junction of the superior vena cava and right atrium or into the right atrium for optimal blood flow.
    WARNING: Failure to verify catheter placement with fluoroscopy may result in serious trauma or fatal complications.

SECUREMENT AND DRESSING

1. Suture the pocket created for the small remaining catheter loop ("knuckle") at the venous entry site.
2. If necessary, suture the catheter exit site.
3. Suture the catheter to the skin with the suture wing.
   WARNING: Do not suture through any part of the catheter. If sutures are used to secure the catheter, make sure they do not occlude or cut the catheter. Catheter tubing may tear when subjected to excessive force or rough edges.
   PRECAUTION: The catheter must be secured / sutured for the entire duration of implantation.
4. Apply transparent site dressing to catheter exit site and the tunneled insertion site using standard institutional protocol.
   WARNING: Do not use sharp instruments near the extension tubing or catheter body.
   WARNING: Do not use scissors to remove dressing.
   WARNING: Alcohol or alcohol-containing antiseptics may be used to clean the catheter/skin site; however, care should be taken to avoid prolonged or excessive contact with the solution(s).
   WARNING: Acetone and PEG-containing ointments can cause failure of this device and should not be used with polyurethane catheters.
5. Record the catheter length and catheter lot number on the patient's chart. Note in the chart that Acetone and PEG-containing ointments should not be used with this device.

SITE CARE

1. Clean the skin around the catheter.
   WARNING: Use of ointments/creams at the wound site is not recommended.
2. Cover the exit site with occlusive dressing and leave extensions, clamps, and caps exposed for access by dialysis team.
3. Wound dressings must be kept clean and dry.
   CAUTION: Patients must not swim or soak the dressing unless instructed by a physician.
   PRECAUTION: If profuse perspiration or accidental wetting compromises adhesion of the dressing, the medical and nursing staff must change the dressing under sterile conditions.

CATHETER REMOVAL

As with all invasive procedures, the physician will assess the anatomical and physiological needs of the patient to determine the most appropriate catheter removal technique. The white implantable retention cuff facilitates tissue ingrowth, therefore the catheter must be surgically removed.

WARNING - Only a physician familiar with the appropriate removal techniques should attempt to remove an implanted chronic dialysis catheter.
CAUTION: Always review institutional protocol, potential complications and their treatment, warnings and precautions prior to catheter removal.

CAUTION STATEMENTS REGARDING HEMODIALYSIS TREATMENT

- Hemodialysis should be performed under a physician's instruction using approved institutional protocol.
- The heparin solution must be removed from each lumen prior to treatment to avoid systemic heparinization of the patient. Aspiration should be based on

institutional protocol.
- Before dialysis begins, all connections to the catheter and extracorporeal circuits should be examined carefully.
- Accessories and components used in conjunction with this catheter should incorporate luer-lock adapters.
- Frequent visual inspection should be conducted to detect leaks and to minimize blood loss or air embolism.
- Repeated over-tightening of blood lines, syringes and caps will reduce connector life and could lead to potential connector failure.
- If a leak in the catheter tubing or hub occurs, or if a connector separates from any component during insertion or use, clamp the catheter and take all necessary steps and precautions to prevent blood loss or air embolism.
- To minimize the risk of air embolism, keep the catheter clamped at all times when not attached to a syringe, IV tubing, or bloodlines.
- Close all clamps in the center of the extension tubing. Repeated clamping near or on the luer lock connectors may cause tubing fatigue and possible disconnection.
- Clamping of the tubing repeatedly in the same location may weaken the tubing. Extension tubing may develop cuts or tears if subjected to excessive pulling or contact with rough edges.

POST DIALYSIS HEPARINIZATION

Follow institutional protocol for heparin concentration. If the catheter is not to be used immediately for treatment, follow the suggested catheter patency guidelines.

1. Draw the heparin / saline solution into two syringes, corresponding to the amount designated on the arterial and venous extension tubing clamp. Assure that the syringes are free of air.
2. Attach a syringe containing heparin solution.
3. Open the extension tubing clamp.
4. Aspirate to ensure that no air will be forced into the patient.
5. Inject the heparin solution into each lumen using a quick bolus technique.

PRECAUTION: To maintain patency between treatments, a heparin lock must be created in each lumen of the catheter.

6. Close extension clamps.

PRECAUTION: Extension clamps should only be open for aspiration, flushing, and dialysis treatment.

7. Remove syringes.

PRECAUTION: In most instances, no further heparin flush will be necessary for 48-72 hours, provided the lumens have not been aspirated or flushed.

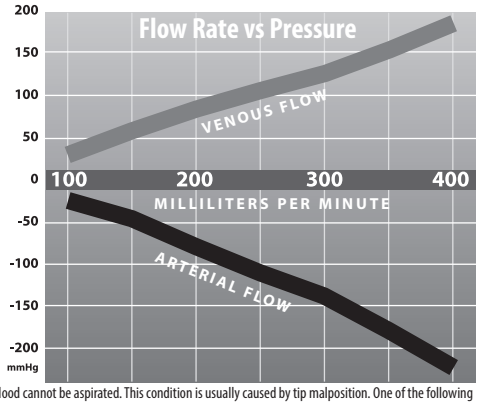
8. Assure luers are capped.

CATHETER PERFORMANCE PRIMING VOLUMES

- The priming volumes of both the arterial and venous lumens are printed on each extension tubing clamp.

FLOW RATE

- Typical flow rate vs. pressure with the ProGuide 14.5 FR X 28 cm (tip to hub) catheter (with side holes)



TROUBLESHOOTING INSUFFICIENT FLOWS

Treatment for insufficient flow will be at the discretion of the physician. Excessive force should not be used to flush an obstructed lumen. Insufficient blood flow may be caused by an occluded lumen due to clotting or fibrin sheath or because the arterial hole is contacting the vein wall. If manipulation of the catheter or reversing arterial and venous lines does not help, the physician may attempt to dissolve the clot with a thrombolytic agent.

MANAGEMENT OF ONE-WAY OBSTRUCTIONS

One-way obstructions exist when a lumen can be flushed easily but blood cannot be aspirated. This condition is usually caused by tip malposition. One of the following adjustments may resolve the obstruction:

- Reposition the catheter
- Reposition the patient
- Have the patient cough
- Provided there is no resistance, flush the catheter vigorously with sterile normal saline to try to move the tip away from the vessel wall.

INFECTION

Catheter related infection is a serious concern of indwelling catheters. Follow institutional protocol when removing the catheter.

SYMBOL	DESIGNATION
	Single Use
℞ ONLY	Caution - Federal Law (USA) restricts this device to sale by or on the order of a physician.
STERILE EO	Sterilized Using Ethylene Oxide
	Do Not Use if Package is Damaged
	Non-pyrogenic
	Caution: Consult accompanying documents. Read instructions prior to use.

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www.merit.com

Manufacturer:
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1600 West Merit Parkway, South Jordan, Utah 84095 U.S.A. 1-801-253-1600
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