

Centros[®] *CentrosFLO[®]*

LONG-TERM HEMODIALYSIS CATHETER

INSTRUCTIONS FOR USE



CentrosFLO®

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INDICATIONS FOR USE:

- The Centros® and CentrosFLO® long-term hemodialysis catheter are indicated for use in attaining long-term vascular access for hemodialysis and apheresis.
- It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient.
- This catheter is indicated for > 30 days (long-term) placement.

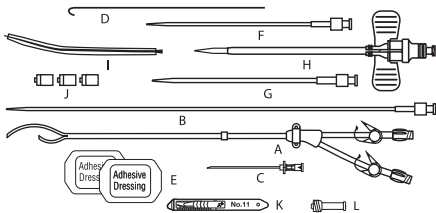
CONTRAINDICATIONS:

- This catheter is intended for long-term vascular access only and should NOT be used for any purpose other than indicated in these instructions.
- This catheter is not intended for pediatric use.
- The valved peelaway introducer sheath is NOT designed for use in the arterial system or as a hemostatic device.

Read instructions for use carefully before using device.

DESCRIPTION:

- The Centros and CentrosFLO long-term hemodialysis catheter is a dual lumen radiopaque catheter with a polyester cuff. The catheter is 15 French, featuring an innovative, dual radiused distal configuration. Some configurations have distal arterial and venous sideholes. This distinctively shaped design is intended to leverage the outside of the arc of both the arterial and venous lumens with the intention of eliminating the vein walls as an obstruction.
- A stiffening stylet is included with the catheter for Over-The-Wire technique (stylet).
- By convention, the outflow lumen carrying blood from the body is called "arterial" and is marked red and the lumen returning blood is called "venous" and is marked blue.



Complete kit includes the following components:

- 1) 15 French Long Term Hemodialysis Catheter

(A)

- 1) Stiffening stylet (B)
- 1) 18 Gauge X 2.75" (7cm) Introducer needle (C)
- 1) 0.038" X 80 cm J-tip Guide Wire (D)
- 2) Adhesive Dressing (E)
- 1) 12 Fr Dilator (F)
- 1) 14 Fr Dilator (G)
- 1) Dial Ease™ 16F Peel-Away Sheath Introducer (H)
- 1) Tunneler with Sleeve (I)
- 3) Injection Cap (J)
- 1) Safety Scalpel (K)
- 1) Spacer (L)

POTENTIAL COMPLICATIONS:

Before attempting the insertion of the catheter, the physician should be familiar with the following complications and their emergency treatment should they occur:

- Air Embolus
- Allergic Reactions
- Bacteremia
- Bleeding at the site
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catheter damage due to compression between clavicle and first rib
- Catheter Embolism
- Catheter Occlusion
- Catheter or cuff erosion through the skin
- Central Venous Thrombosis
- Endocarditis
- Exit Site Infection
- Exit Site Necrosis
- Exsanguination
- Extravasation
- Fibrin sheath formation
- Hemothorax
- Hematoma
- Hemorrhage
- Inflammation
- Necrosis or scarring of skin over the implant area
- Laceration of the Vessel
- Lumen Thrombosis
- Mediastinal Injury
- Perforation of the Vessel
- Pleural Injury
- Pneumothorax
- Pulmonary Emboli
- Retroperitoneal Bleed
- Right Atrial Puncture
- Risks normally associated with local and general anesthesia, surgery, and post-operative recovery
- Septicemia
- Spontaneous Catheter Tip Malposition or Retraction
- Subclavian Artery Puncture
- Subcutaneous Hematoma
- Superior Vena Cava Puncture
- Thoracic Duct Laceration
- Thrombocytopenia

- Thromboembolism
- Tunnel Infection
- Ventricular Thrombosis
- Vessel Erosion
- Vascular Thrombosis

Before attempting the insertion, ensure that you are familiar with the above complications and their emergency treatment should any of them occur.

WARNINGS:

- In the rare event that a hub or connector separates from any component during insertion or use, take all necessary steps and precautions to prevent blood loss or air embolism and remove catheter.
- Do not advance the guidewire or catheter if unusual resistance is encountered.
- Do not insert or withdraw the guidewire forcibly from any component. The wire may break or unravel. If the guidewire becomes damaged, the introducer needle (or sheath introducer) and guidewire must be removed together.
- Use of excessive force on the catheter may cause the suture wing to detach from the bifurcation.
- In the event that a clamp breaks, replace the catheter at the earliest opportunity.
- For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Contents sterile and non-pyrogenic in unopened, undamaged package.
- Do not use catheter or accessories if package is opened or damaged.
- Do not use catheter or accessories if any sign of product damage is visible.

STERILIZED BY ETHYLENE OXIDE

RX Only: CAUTION: Federal Law (USA) restricts the device to sale by or on the order of a physician.

CATHETER PRECAUTIONS:

- Alcohol or alcohol containing antiseptics (such as chlorhexidine) may be used to clean catheter exit site; however, care should be taken to avoid prolonged or excessive contact of the catheter with the solution.
- Acetone, ExSept, Alcavis 50, and PEG

(polyethylene glycol) containing ointments can cause failure of this device and should not be used on this catheter. Refer to the Site Care Section for a list of preferred alternatives.

- The catheter should be accessed or have site care only when the staff and patient wear a mask and the staff wears clean gloves.
- Clamping of the tubing repeatedly in the same location may weaken tubing. Avoid clamping near the Luers and hub of the catheter.
- Do not use sharp instruments near the extension tubing or catheter lumen.
- Repeated overtightening of blood lines, syringes, and caps will reduce connector life and could lead to potential connector failure.
- Use only Luer lock (threaded) connectors with this catheter.
- Examine catheter lumen and extensions before and after each treatment for damage.
- To prevent disconnections, assure the security of all caps and bloodline connections prior to and between treatments.
- Excessive force should NOT be used to flush obstructed lumen. DO NOT use a syringe smaller than 10 ml (cc).
- Do not use scissors to remove dressing.

INSERTION SITES:

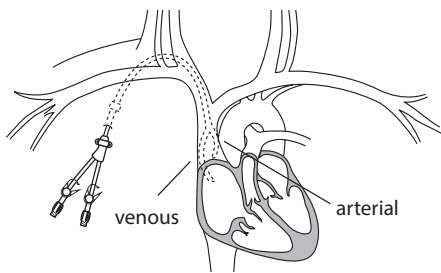
The right internal jugular vein is the primary anatomical location for long-term hemodialysis catheters. However, the left internal jugular vein, as well as the external jugular veins and subclavian veins can also be a consideration. As with all invasive procedures, the physician will assess the anatomical and physiological needs of the patient to determine the most appropriate catheter entry site. The catheter is available in various lengths to accommodate the varying anatomical differences of patients as well as the differences between right and left side approaches.

RIGHT INTERNAL JUGULAR VEIN

- The patient should be in a modified Trendelenburg position, with the upper chest exposed and the head turned slightly to the side opposite the insertion area. A small rolled towel may be inserted between the shoulder blades to facilitate the extension of the chest area.
- Have patient lift his/her head from the bed to define the sternocleidomastoid muscle. Catheterization will be performed at the apex of a triangle formed between the two heads of the sternocleidomastoid muscle above the clavicle. The carotid artery should be palpated medial to the point of catheter insertion.
- Using ultrasound, ensure the jugular vein is patent and distendent. The Centros & CentrosFLO should always be placed so that the end of the arterial lumen (shorter tip) is positioned towards the patient's left, as shown

below. This allows the venous tip to curve away from the lower vena cava and right atrial wall. For catheters placed through the right IJ, this means that the arterial hub is on the upper and outer side of the curving catheter. For catheters placed through the left IJ, the arterial hub is on the lower and inner side of the catheter.

- Confirm final position of catheter with chest x-ray or fluoroscopy. Routine x-ray should always follow the initial insertion of this catheter to confirm proper tip placement prior to use. To optimize self-centering tip design, the contact point of the curved arterial tip should be positioned in the lower third of the vena cava, with the venous tip in the right atrium or at the junction of the right atrium and superior vena cava. Alternatively, both tips of the catheter may be placed in the right atrium under fluoroscopy as recommended by the 2006 Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines.



WARNING:

- Patients requiring ventilator support are at increased risk of pneumothorax during subclavian and Jugular vein cannulation, which may cause complications.

This IFU includes three techniques for placing the catheter, one using a peelaway introducer, two using an over-the-wire method, and three a catheter exchange using an over-the-wire method. The following instructions for insertion of the needle, guide wire and tunneling the catheter are the same regardless of insertion method. Follow the Direction for Seldinger Insertion and then pick the insertion technique (one, two or three) you prefer.

DIRECTIONS FOR SELDINGER INSERTION

K-DOQI Guidelines recommend the use of ultrasound guidance and fluoroscopy for placement. **NOTE:** Mini access ("micropuncture") is recommended. Follow manufacturer's guidelines for proper insertion technique.

- Read instructions carefully before using this device. The catheter should be inserted, manipulated, exchanged and/or removed by a qualified, licensed physician or other qualified health care professional under the direction of a physician.
- 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.

- Use standard hospital protocols when applicable.
1. Strict aseptic technique must be used during insertion, maintenance, and catheter removal procedures. Provide a sterile operative field. Use sterile drapes, instruments, and accessories. Shave the skin above and below the insertion site. Perform surgical scrub. Wear gown, cap, gloves, and mask. Have patient wear mask.
 2. The selection of the appropriate catheter length is at the sole discretion of the physician. To achieve proper tip placement, proper catheter length selection is important. Routine x-ray should always follow the initial insertion of this catheter to confirm proper placement prior to use.
 3. Administer sufficient local anesthetic to completely anesthetize the insertion site.
 4. Determine site for needle entry into vein. Insert the introducer needle with attached syringe (not included) into the target vein using ultrasound in real time if possible. Aspirate to ensure proper placement in 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.

5. Remove the syringe and place thumb over the end of the needle to prevent blood loss or air embolism. Draw flexible end of guidewire back into advancer so that only the end of the guidewire is visible. Insert advancer's distal end into the needle hub. Advance guidewire with forward motion into and past the needle hub into the target vein. Observe progress of the wire with fluoroscopy when possible and advance the wire into the superior vena cava.

CAUTION: Monitor patient for arrhythmia throughout this procedure. Cardiac arrhythmia may result if guidewire is allowed to pass into the right atrium or ventricle. The guidewire should be held securely during this procedure.

CAUTION: Do not advance the guidewire or catheter if unusual resistance is encountered.

PRECAUTION: The length of the guide wire inserted is determined by the size of the patient and the anatomical site used.

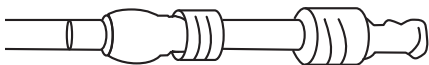
6. Remove needle and leave guidewire in the vena cava.
7. Make a small secondary incision at the exit

site on the chest wall below the clavicle. Make the incision at the exit site wide enough to accommodate the catheter and dilate skin with hemostats.

8. Remove the blue tip protector from the distal tips of the catheter.
9. Irrigate catheter with saline, then clamp catheter extension sets to ensure that the saline is not inadvertently drained from lumens.

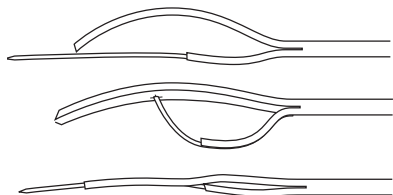
NOTE: Use only the clamps provided on the extension sets.

OPTIONAL STEP FOR USING STIFFENING STYLET TO ALIGN CATHETER TIPS



Some physicians may choose to place the stiffening stylet in the catheter prior to the tunneling step and for placement through the valved peelaway introducer. A spacer is provided for those that select this option.

- a. Remove protective cover from stylet.
- b. Attach the male end of the spacer to the catheter's arterial (red) Luer lock and tighten.
- c. Unclamp the arterial lumen clamp and insert the stylet through the spacer/arterial (red) lumen until the tip of the stylet exits the arterial tip. Tighten the male Luer lock collar of the stylet to the arterial Luer lock connection. The stylet will protrude from the arterial tip.

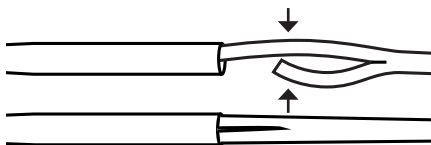


- d. Grasp the arterial tip with the protruding stylet in one hand and carefully bend back the venous tip with the other hand. Slightly bend the stylet shaft and insert the distal tip of the stylet through the guidewire slit (marked with +) located in the venous lumen and thread it down aligning the catheter tips.
- e. Irrigate stiffening stylet with saline. Attach a sterile sealing cap onto the stylet Luer. Ensure that cap and spacer connections are tight.

10. Extend tunneling sleeve fully and slide the catheter tips into sleeve as far as possible.

NOTE: Do not use excessive force when extending the tunneler sleeve fully and when manipulating the tunneler.

NOTE: There is a slight interference fit between catheter and the tunneling sleeve.



11. Insert the tunneler into the exit site and into the subcutaneous tissue. Create a short subcutaneous tunnel. DO NOT tunnel through muscle. Advance the tip of the tunneler through the lateral portion of the incision.

WARNING: Do not over-expand the cutaneous tissue during tunneling. Over-expansion may delay or prevent cuff in-growth.

12. Pull and push the tunneling sleeve into the tunnel gently until the tip of the sleeve emerges from the primary incision. Push the catheter through the tunnel while pulling the sleeve from primary incision.
13. Using small hemostats, compress the cuff and push through the exit site while pulling gently on the catheter.
14. Remove Catheter from tunneler.

CAUTION: DO NOT pull tunneler out of the primary incision at an angle. Keep tunneler straight to prevent damage to the catheter tip. The catheter can be bent slightly.

CAUTION: The tunnel should be made with care to avoid damage to surrounding vessels. Avoid tunneling through muscle.

NOTE: A tunnel with a gentle arc lessens the risk of kinking. The tunnel should be short enough to keep the hub of the catheter from entering the exit site, yet long enough to keep the cuff 2 cm (minimum) from the skin opening.

NOTE: For alternate insertion method, see INSERTION TECHNIQUE TWO.

15. INSERTION TECHNIQUE ONE INTRODUCTION OF THE VALVED PEELAWAY INTRODUCER:

PRECAUTIONS:

- Dilators and catheters should be removed slowly from the sheath. Rapid removal may damage the valve membranes resulting in blood flow through the valve. Never advance or withdraw guidewire or sheath when resistance is met. Determine cause by fluoroscopy and take remedial action.
- Aspiration and saline flushing of the sheath, dilator, and valve should be performed to help minimize the potential for air embolism

and clot formation.

CAUTION: The sheath is intended for one time use only. Read instructions prior to use.

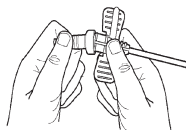
- To ease insertion of the peelaway introducer, some physicians prefer to dilate the vein before inserting the introducer.
- Thread the blue dilator(s) over the end of the guidewire and advance into the vein using a rotating motion to assist passage through the tissue.

CAUTION: As the dilator(s) pass through the tissue and into the vasculature, ensure that the guidewire does not advance further into the vein.

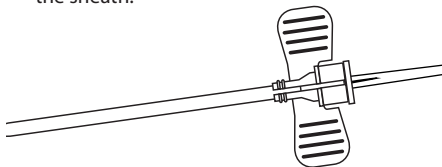
- A. Insert vessel dilator into sheath until the dilator cap folds over valve housing and secures the dilator onto sheath assembly.

WARNING: Never leave the sheath in place as an indwelling catheter. Damage to the vein will occur.

- B. Thread the dilator/sheath assembly over the guide wire.
- C. Advance the dilator and sheath together with a twisting motion over the guide wire and into the vessel. Fluoroscopic observation may be advisable. Attaching a clamp or hemostat to the proximal end of the guide wire will prevent inadvertently advancing the guide wire entirely into the patient.
- D. Once assembly is fully introduced into the venous system, separate the dilator cap from the sheath valve housing by rocking the dilator cap off the hub.



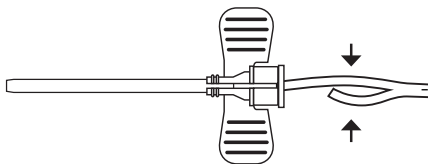
- E. Slowly retract the guide wire and dilator, leaving the sheath in position. The hemostasis valve will reduce the loss of blood and the inadvertent aspiration of air through the sheath.



DIALYSIS CATHETER PLACEMENT:

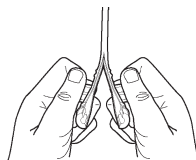
- F. Squeeze the two limbs of the catheter together and advance the distal section of the catheter through the peel-away hemostatic valved dialysis sheath introducer and into the vein. Or, if using the stiffening stylet/spacer to align the tips of the catheter

as noted in optional step above, thread previously aligned tips through the peel-away hemostatic valved dialysis 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.

- G. Advance the catheter tip to appropriate site as noted in the Insertion Sites section.



- H. Sharply snap the tabs of valve housing in a plane perpendicular to the long axis of the sheath to split the valve and peel sheath apart while withdrawing from the vessel.

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.

- I. Remove the sheath completely from the patient and catheter. If stiffening stylet was used to align catheter tips, disconnect the spacer from the arterial Luer of the catheter and remove the stiffening stylet/spacer/cap from the catheter.
- J. Make any adjustments to the catheter under fluoroscopy. Assure the catheter tip is placed in the correct location as noted in the Insertion Sites section above.
- K. Press the remaining catheter loop ("knuckle") gently into the subcutaneous pocket created at the venous entry site.
- L. Observe the apex of the catheter at the primary incision. If a kink is visible, dilate beneath the catheter using hemostats to create a pocket for the catheter apex.

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.

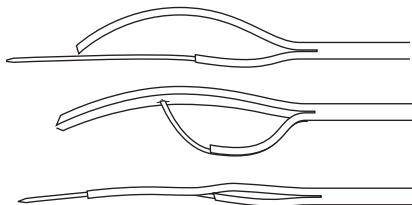
Continue to the Closure section (Step # 18) to finalize catheter placement.

16. INSERTION TECHNIQUE TWO DIRECTIONS FOR SELDINGER INSERTION USING OVER-THE-WIRE METHOD

CAUTION: Over the wire placement should only be performed by a physician familiar with this technique. The peelaway introducer is not used with this placement.

NOTE: For Over-The-Wire Placement Method, do not use the spacer provided in the kit.

- A. Irrigate catheter with saline, and then clamp the venous (blue) lumen to ensure that the saline is not inadvertently drained from the lumen.
- B. Remove protective cover from the stylet.
- C. Unclamp the arterial lumen clamp and insert the stylet through the arterial (red) lumen until the tip of the stylet exits the arterial tip. Tighten the male Luer lock collar of the stylet to the arterial Luer lock connection. The stylet will protrude through the end of the arterial lumen.



- D. Grasp the arterial tip with the protruding stylet in one hand and carefully bend back the venous tip with the other hand. Slightly bend the stylet shaft and insert the distal tip of the stylet through the guidewire slit (marked with +) located in the venous lumen and thread it down until it exits the distal tip of the venous lumen aligning the catheter tips.
- E. To ease the insertion of the catheter some physicians prefer to dilate the vein before inserting the catheter.
- F. Thread the blue dilator(s) over the end of the guidewire and advance into the vein using a rotating motion to assist passage through the tissue. Remove dilator(s) when vein is sufficiently dilated, leaving the guide wire in place. Apply pressure to insertion site when dilators are removed.

CAUTION: As the dilator(s) pass through the tissue and into the vasculature, ensure the guidewire does not advance further into the vein.

- G. Irrigate the stylet with saline.
- H. Thread the distal tip of the stylet over the proximal end of the guidewire and into the vein until the guidewire exits the arterial (red) Luer connection. (Ensure the guide wire does not advance further into the vein.)
- I. While maintaining guidewire position in the vein, advance catheter to the desired location.

CAUTION: DO NOT advance guide wire with catheter into vein. Cardiac arrhythmia may result if guide wire is allowed to pass into the right atrium. The guide wire should be held securely during catheter placement.

PRECAUTION: To help minimize the potential for catheter kinking, it may be necessary to advance in small steps by grasping the catheter close to the insertion site.

- J. Gently remove the stylet and guidewire from the arterial (red) lumen leaving the catheter in place and close the arterial extension clamp.
- K. Press the remaining catheter loop ("knuckle") gently into the subcutaneous pocket created at the venous entry site.
- L. Observe the apex of the catheter at the primary incision. If a kink is visible, dilate beneath the catheter using hemostats to create a pocket for the catheter apex.
- M. Make any adjustments to the catheter under fluoroscopy. Assess the catheter tip is placed in the correct location as noted in the Insertion Sites Section above.

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. INSERTION TECHNIQUE THREE: DIRECTIONS FOR CATHETER EXCHANGE USING OVER-THE-WIRE METHOD

NOTE: This method is only used to replace an existing catheter that may have failed. All steps needed to perform this method are contained within this section.

- A. Use local anesthesia and lidocaine as appropriate in the catheter tract.
- B. Enlarge the exit site with hemostats and loosen tissue around the catheter cuff.
- C. Irrigate catheter with saline, and then clamp the lumens to ensure that the saline is not inadvertently drained from the lumens.
- D. Remove protective cover from the stylet.
- E. Unclamp the arterial lumen clamp and insert the stylet through the arterial (red) lumen until the tip of the stylet exits the arterial tip. Tighten the male Luer lock collar of the stylet to the arterial Luer lock connection. The stylet

will protrude through the end of the arterial lumen.

- F. Grasp the arterial tip with the protruding stylet in one hand and carefully bend back the venous tip with the other hand. Slightly bend the stylet shaft and insert the distal tip of the stylet through the guide wire slit (marked with +) located in the venous lumen and thread it down until it exits the distal tip of the venous lumen aligning the catheter tips.
- G. Irrigate the stylet with saline.
- H. Remove the injection cap and open the clamp of existing catheter. Insert the guide wire into the existing catheter and advance as far as appropriate per hospital protocol.
- I. Remove existing catheter with care while maintaining guide wire position.
- J. Thread the distal tip of the stylet over the proximal end of the guide wire through the subcutaneous tunnel and into the vein until the catheter tip is located in the desired location.

CAUTION: DO NOT advance guide wire with catheter into vein. Cardiac arrhythmia may result if guide wire is allowed to pass into the right atrium. The guide wire should be held securely during catheter placement.

PRECAUTION: To help minimize the potential for catheter kinking, it may be necessary to advance in small steps by grasping the catheter close to the insertion site.

- K. Gently remove the stylet and guidewire from the arterial (red) lumen leaving the catheter in place and close the arterial extension clamp.
- L. Make any adjustments to the catheter under fluoroscopy. Assure the catheter tip is placed in the correct location as noted in the Insertion Sites Section above.

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.

CLOSURE

- 18. Attach syringes to both extensions and open the clamps. Confirm correct placement and catheter function by aspirating blood from both lumens. Blood should aspirate easily from both arterial and venous sides.

PRECAUTION: If either side exhibits excessive resistance to blood aspiration, the catheter may need to be rotated or repositioned to obtain adequate blood flows.

- 19. Once adequate aspiration has been achieved, both lumens should be irrigated with saline filled syringes using quick bolus technique. Assure that extension clamps are open during irrigation procedure.
- 20. Attach syringes with heparinized saline and infuse each lumen with heparinized saline (priming volume is printed on the extension tubing I.D. tags).
- 21. Clamp the extensions immediately after flushing.

CAUTION: Ensure that extension clamps are closed between uses.

- 22. Remove the syringes and replace with injection caps.

PRECAUTION: Avoid air embolism by keeping extension tubing clamped at all times when catheter is not in use and by aspirating then irrigating the catheter with saline prior to each use. Always aspirate first then irrigate the catheter prior to each use.

WARNING: Failure to verify catheter placement with fluoroscopy may result in serious trauma or fatal complications.

SECURE CATHETER AND DRESS WOUND:

- 23. Suture the catheter to the skin using the suture wing. Do not suture the catheter tubing.

CAUTION: Care must be taken when using sharp objects or needles in close proximity to catheter tubing. Contact from sharp objects may cause catheter failure.

- 24. Cover the insertion and exit site with an occlusive dressing.
- 25. Catheter must be secured/sutured for entire duration of implantation.
- 26. Record catheter length and catheter lot number on patient's chart.

WARNING: Confirm final position of catheter placement with fluoroscopy or x-ray.

HEMODIALYSIS TREATMENT:

The heparinized saline solution must be removed from each lumen prior to treatment to prevent systemic heparinization of the patient. Aspiration should be based on dialysis unit protocol. Before dialysis begins all connections to catheter and extracorporeal circuits should be examined carefully. Tubing should be properly primed with saline. Frequent visual inspection should be conducted to detect leaks to prevent blood loss or air embolism. If a leak is found, the catheter should be clamped immediately.

CAUTION: Only clamp extension tubing with extension (in-line) clamps provided. DO NOT

clamp the catheter body tubing.

- Necessary remedial action must be taken prior to the continuation of the dialysis treatment if a leak is detected.

NOTE: Excessive blood loss may lead to patientshock.

- Hemodialysis should be performed under physician's instructions.

ANTICOAGULANT SOLUTION FOR THE CATHETER:

- If the catheter is not to be used immediately for treatment, follow the suggested catheter patency guidelines.
 - To maintain patency between treatments, heparinized saline or other anticoagulant solution lock must be created in each lumen of the catheter.
 - Follow hospital protocol for heparinized saline concentration.
27. Draw solution into two syringes, corresponding to the amount designated on the arterial and venous I.D. tags (as shown below). Ensure that the syringes are free of air.

PRIMING VOLUMES

Catheter Length (CM, tip-to-cuff)	Lumen Arterial (mL)	Venous (mL)
15 Straight	1.5	1.6
17 Straight	1.6	1.7
19 Straight	1.7	1.8
23 Straight	1.9	1.9
27 Straight	2.0	2.1
31 Straight	2.2	2.2

28. Ensure that the extension clamps are closed.
29. Remove injection caps from the extensions.
30. Attach a syringe containing heparinized saline to the female Luer of each extension.
31. Open extension clamps.
32. Aspirate to ensure that no air will be forced into the patient.
33. Inject heparinized saline into each lumen using quick bolus technique.

NOTE: Each lumen should be completely filled with heparinized saline to ensure effectiveness.

34. Close extension clamps.

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

35. Remove syringes.

36. Attach a sterile sealing cap onto the female Luers of the extensions.

NOTE: No further anticoagulant solution is necessary between treatments provided the lumens are not being aspirated or flushed.

SITE CARE:

WARNING: DO NOT use acetone, ExSept, Alcavis 50, or PEG-containing ointments of any kind with this catheter.

- Clean skin around catheter. Cover the exit site with occlusive dressing and leave extensions, clamps, and caps exposed for access by staff.

The Centros and CentrosFLO hemodialysis catheter materials have been tested for compatibility with the following cleaning solutions:

- 70% isopropyl alcohol wipes
- Chlorahexadine Gluconate (Betasept 4%)
- Chloraprep
- Hydrogen Peroxide
- Povidone Iodine (Betadine)
- Petrol based ointments (Bacitracin)
- Mineral based ointments (Neosporin)
- Shur-Cleans
- Wound dressings must be kept clean and dry.

CAUTION: Patients must not swim, shower, or soak dressing while bathing.

- If profuse perspiration or accidental wetting compromises adhesion of dressing, the medical or nursing staff must change the dressing under sterile conditions.

CATHETER PERFORMANCE:

CAUTION: Always review hospital or unit protocol, potential complications and their treatment, warnings, and precautions prior to undertaking any type of mechanical or chemical intervention in response to catheter performance problems.

WARNING: Only a physician familiar with the appropriate techniques should attempt the procedures within this IFU.

INSUFFICIENT FLOWS:

The following may cause insufficient blood flows for dialysis:

- Kinked catheter, usually in subcutaneous tract.
- Occluded arterial and/or venous lumen due to clotting or fibrin sheath around the catheter.

Solutions include:

- Chemical intervention utilizing a thrombolytic agent.
- Vigorous flushing of the catheter with saline.

MANAGEMENT OF ONE-WAY OBSTRUCTIONS:

One-way obstructions exist when a lumen can be flushed easily but blood cannot be aspirated. This

is usually caused by tip malposition but is sometimes due to a clot or fibrin sheath. One of the following adjustments may resolve the obstruction:

- Reposition catheter
- Reposition patient
- Have patient cough
- Provided there is no resistance, flush the catheter vigorously with sterile normal saline to try to open or move the tip.
- Other interventions as above.

INFECTION:

There is a risk of infection related to use of the catheter.

CAUTION: Due to the risk of exposure to Human Immunodeficiency Virus (HIV) or other blood borne pathogens, health care professionals should always use universal blood and body fluid precautions in the care of all patients.

- Sterile technique should always be strictly adhered to.
- Clinically recognized infection at a catheter exit site should be treated promptly with the appropriate antibiotic therapy.
- If a fever occurs in a patient with a catheter in place, take cultures from a peripheral site (or dialysis line) and from one catheter lumen. Culture catheter exit site if purulence is seen. Implement the appropriate antibiotic therapy and consider removing catheter if there are signs of sepsis. Wait 48 hours before catheter replacement. Insertion should be made on opposite side of original catheter exit site, if possible.

CATHETER REMOVAL:

WARNING: Only a physician familiar with the appropriate techniques should attempt the following procedures.

CAUTION: Always review hospital or unit protocol, potential complications and their treatment, warnings, and precautions prior to catheter removal.

37. Palpate the catheter exit tunnel to locate the cuff.
38. Administer sufficient local anesthetic to exit site and cuff location to completely anesthetize the area.
39. Cut sutures from suture wing. Follow hospital protocol for removal of skin sutures.
40. Make a 2 cm incision over the cuff, parallel to the catheter.
41. Dissect down to the cuff using blunt and sharp dissection as indicated. Isolate catheter and surrounding tunnel between cuff and jugular vein. Place loop of suture through subcutaneous and deep tissue surrounding the tunnel.
42. Free cuff from surrounding tissue.
43. Cut tunnel just lateral and medial to cuff. Avoid cutting the catheter.
44. Withdraw the catheter through the exit site.
45. Pull suture tight.
46. Close primary incision.
47. Apply pressure to proximal tunnel for approximately 10-15 minutes or until bleeding stops.
48. Suture incision and apply dressing in a manner to promote optimal healing.

Check catheter integrity for tears and measure catheter when removed. It must equal the length of the catheter when it was inserted.

Forward Flow Mean Arterial and Venous Back Pressures mmHg

Flow Rate (mL/min)		250		350		450	
Lumen		Arterial	Venous	Arterial	Venous	Arterial	Venous
Catheter Length	15 cm	-78.2	55.2	-119.3	109.1	-167.5	160.3
	17 cm	-78.6	60.9	-122.3	117.3	-169.7	163.5
	19 cm	-80.9	63.8	-127.0	125.7	-178.2	176.9
	23 cm	-93.7	66.3	-141.7	130.2	-190.8	174.8
	27 cm	-100.3	68.9	-153.9	134.7	-211.1	185.7
	31 cm	-110.3	83.4	-170.4	156.0	-239.1	207.4

Reverse Flow Mean Arterial and Venous Back Pressures mmHg

Flow Rate (mL/min)		250		350		450	
Lumen		Arterial	Venous	Arterial	Venous	Arterial	Venous
Catheter Length	15 cm	42.0	-90.9	91.3	-143.6	141.8	-199.5
	17 cm	47.4	-95.9	98.6	-154.3	146.8	-216.4
	19 cm	47.9	-102.4	103.3	-165.3	151.2	-234.3
	23 cm	47.4	-118.9	107.6	-186.4	150.1	-255.2
	27 cm	52.1	-121.1	111.6	-190.7	158.4	-263.9
	31 cm	64.8	-134.7	133.2	-213.7	173.7	-289.3

NOTE:

Flow testing represents optimum bench test laboratory conditions on non-aged samples (n=30) used in a simulated blood (38% glycerin in water).

Maximum Flow Rates:

The maximum recommended flow rate for all lengths of catheters in the forward flow direction is 450 mL/min. The maximum recommended flow rate in the reverse flow direction is 450 mL/min for catheter lengths from 15-19 cm and 350 mL/min for catheter lengths from 23-31 cm

Flow vs. Pressure Data RECIRCULATION RATES:

Forward Direction: < 1% Reverse Direction: < 11% for CentroFLO and < 13% for Centros.

NOTE: The design of the catheter is intended to keep the lumens patent in the forward direction. Operating in reverse modality is typically unnecessary.

NOTE: Testing was performed using fresh bovine blood and Merit's longest catheter in a set up to simulate catheter performance in a vessel. Recirculation was defined as ratio of inflow blood sample to outflow blood sample.

REFERENCES: LeBanc, M., Bosc, J., Paganini, E., & Canaud, B., Central Venous Dialysis Catheter Dysfunction: Advances in Renal Replacement Therapy. 1997;4(4):377-389. Hirsch, D., Bergen, P., & Jindal, K., Polyurethane Catheters for Long-Term Hemodialysis Access: Artificial Organs. 1997;21(5):349-354. Centros and Centrosflo are registered and unregistered trademarks of Merit Medical Systems, Inc.

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Catheter kit contents will include (1) Hemodialysis Catheter and accessories. For exact kit contents refer to the product label.



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