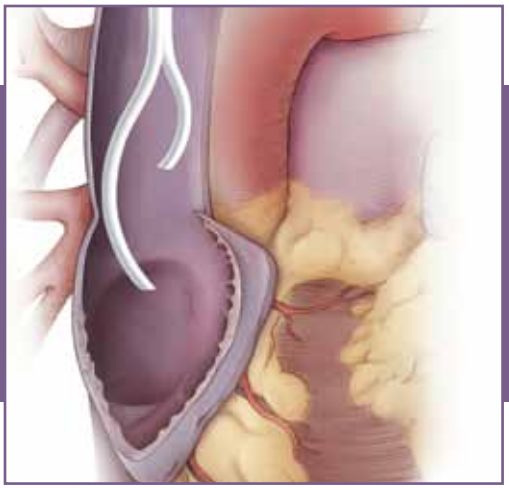
MERIT MEDICAL™

Centros®



CentrosFLO™

LONG-TERM HEMODIALYSIS CATHETER

INSTRUCTIONS FOR USE

CentrosFLO™ | Centros®

LONG-TERM HEMODIALYSIS CATHETER

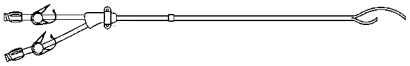
INSTRUCTIONS FOR USE

INDICATIONS FOR USE:
- The Centros® and CentrosFLO™ chronic hemodialysis catheter are indicated for use in attaining long-term vascular access for hemodialysis and apheresis.
- Catheter 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.
- Catheter should be removed in accordance with Center for Disease Control (CDC) and Kidney Disease Outcomes Quality Initiative (K-DOQI) guidelines.

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 peelable 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 chronic 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.
- 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.



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

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 bifurcate.
- In the event that a clamp breaks, replace the catheter at the earliest opportunity.
- This catheter is for single patient use only.
- Do not resterilize the catheter or accessories by any method.
- 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 damaged.
- Do not use catheter or accessories if any sign of product damage is visible.

STERILIZED BY ETHYLENE OXIDE STERILE EO

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

CATHETER PRECAUTIONS:
The Centros and CentrosFLO hemodialysis catheter materials have been tested for compatibility with the following cleaning solutions:
- ChloraPrep®
- Alcavis® 50
- Aqueous-based Povidone Iodine
- Shur-Clens®
- Epi-Clenz®
- Hydrogen peroxide
- Silver sulfadiazine cream 1%

- 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.

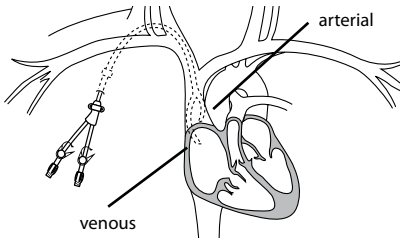
INSERTION SITES:

The right internal jugular vein is the primary anatomical location for 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. 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.

DIRECTIONS FOR SELDINGER INSERTION USING A PEELAWAY INTRODUCER:

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, and 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 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.

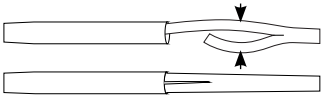
7. Make a small secondary incision at the exit site on the chest wall below the clavicle. Make the incision at the exit site wide enough to accommodate the catheter and dilate skin with hemostats.

8. 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.

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

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



10. 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 subcutaneous tissue during tunneling. Over-expansion may delay or prevent cuff in-growth.

11. 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.

12. Using small hemostats, compress the cuff and push through the exit site while pulling gently on the catheter.

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 methods, see the OVER-THE-WIRE TECHNIQUE section.

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.

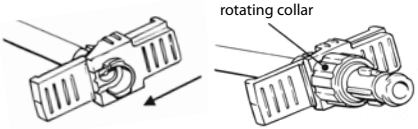
CAUTION: The sheath is not intended to create a complete two-way seal nor is it intended for arterial use.

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. Close the valve on peelaway sheath then insert the dilator through the valve and lock in place using the rotating collar. **NOTE** - Optional dilation:

- To ease insertion of the peelaway introducer, some physicians prefer to dilate the vein before inserting the introducer.

rotating collar



• 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.

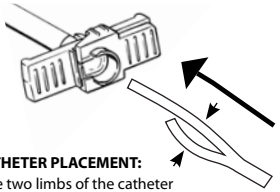
2. While maintaining guidewire position in the vein, advance the locked peelaway introducer and dilator assembly over the exposed guidewire and into the vein.

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

3. Hold the sheath in place and unlock the dilator assembly by turning the rotating collar. Gently withdraw the dilator and wire from the sheath leaving the valved introducer in place.

NOTE: Leaving the guidewire in place after removing the dilator may cause the valve to leak.

CAUTION: Care should be taken not to advance the peelaway sheath too far into the vessel as a potential kink would create an impasse to the catheter.



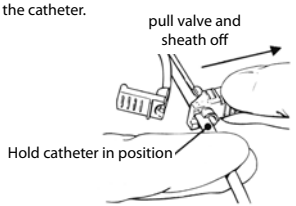
DIALYSIS CATHETER PLACEMENT:
1. Squeeze the two limbs of the catheter together and advance the distal section of the catheter through the valved sheath introducer and into the vein.

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 appropriate site as noted in the "insertion sites" section.

3. With the catheter advanced and positioned, crack the sheath handle in half and peel partially away from the catheter.

4. Near the valve, hold the catheter firmly in position and pull the valve off the catheter.



PRECAUTION: It is normal to experience some resistance while pulling the catheter through the slit on the valve.

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.

5. Remove the sheath completely from the patient and catheter.

6. Press the remaining catheter loop ("knuckle") gently into the subcutaneous pocket created at the venous entry site.

7. 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.

8. 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.

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

9. 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.

10. Fill each lumen with heparinized saline (priming volume is printed on the extension tubing I.D. tags).

11. Clamp the extensions immediately after flushing.

CAUTION: Ensure that extension set clamps are closed between uses.

12. 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 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.

13. Correctly position the cuff and tunneled portion of the catheter.

14. Confirm proper tip placement with fluoroscopy.

15. Make any adjustments of catheter tip under fluoroscopy.

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

16. Secure and dress the catheter as noted in "Secure Catheter and Dress wound" section.

SECURE CATHETER AND DRESS WOUND:
17. 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.

18. Cover the insertion and exit site with an occlusive dressing.

19. Catheter must be secured/sutured for entire duration of implantation.

20. 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 sets with 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 patient shock.
- 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.

1. 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

	Lumen	
Catheter Length (tip-to-cuff)	Arterial (mL)	Venous (mL)
15 Straight	1.7	1.8
17 Straight	1.8	1.8
19 Straight	1.8	2.0
23 Straight	1.9	2.0
27 Straight	2.2	2.2
31 Straight	2.3	2.4

2. Ensure that the extension set clamps are closed.

3. Remove sealing caps from the extensions.

4. Attach a syringe containing heparinized saline to the female luer of each extension.

5. Open extension clamps.

6. Aspirate to ensure that no air will be forced into the patient.

7. Inject heparinized saline into each lumen using quick bolus technique.

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

8. Close extension clamps.

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

9. Remove syringes.

10. 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 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.
- 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.

OVER-THE-WIRE TECHNIQUE:
CAUTION: Over the wire placement should only be performed by a physician familiar with this technique. The peelaway sheath is not used with this placement.

1. Advance guidewire with forward motion through the introducer needle into the target vein.

2. Remove needle leaving the guidewire in the target vein.

3. Thread dilator(s) over guidewire into the vein (a slight twisting motion may be used). Remove dilator(s) when vein is sufficiently dilated, leaving the guidewire in place. Apply pressure to incision when dilators are removed.

4. Thread the proximal end of the guidewire through the distal tip of the venous lumen and the slit as indicated by the + sign on the catheter.

5. Thread the guidewire through the distal tip of the arterial lumen and through the catheter lumen until the proximal end of the guidewire exits the arterial luer on the extension set.

6. Advance the catheter until the distal tip of the arterial lumen is within the primary incision.

NOTE: Ensure blood is coming out of the arterial lumen while advancing the catheter.

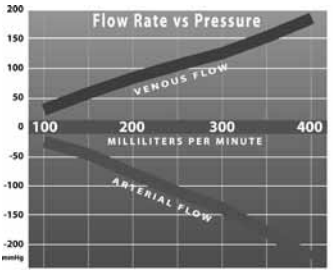
CAUTION: DO NOT advance guidewire with catheter into vein. Cardiac arrhythmia may result if guidewire is allowed to pass into the right atrium. The guidewire should be held securely during catheter placement.

7. Gently remove the guidewire, leaving catheter in place.

8. Make any adjustments to catheter under fluoroscopy.

9. Continue with step number 7 under "Dialysis Catheter Placement" section.

Flow vs. Pressure Data



NOTE: Flow testing represents optimum bench test laboratory conditions. 23cm tip-cuff catheter samples were used in a simulated blood and anatomical model.

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.

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

MERIT MEDICAL™

Manufacturer: www.merit.com
Merit Medical Systems, Inc. South Jordan, Utah 84095
U.S.A. 1-801-253-1600 U.S.A. Customer Service 1-800-356-3748
Authorized Representative:
EC REP Merit Medical Ireland Ltd,
Parkmore Business Park West, Galway, Ireland
European Customer Service by Country:
Belgium 0800 72906; France 0800 916030; Germany 0800 1820871;
Ireland 091 703700; Neth. 0800 0228184; U.K. 0800 9731151

ID 042312 402490001/C