BioFlo DuraMax®

with ENDEXO® Technology
Chronic Hemodialysis Catheter

EN

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℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Any serious incident which has occurred with the use of this device should be reported to Merit Medical at CustomerService-SouthJordan@Merit.com and to the National Competent Authority. Refer to the following web address for contact information for the Competent Authorities. https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_vigilance_contact_points.pdf

The instructions for use are available electronically at www.merit.com.

For a copy of the Summary of Safety and Clinical Performance for this device, please review Eudamed at ec.europa.eu/tools/eudamed where it is linked to the basic UDI-DI. The basic UDI-DI for the device is 0884450BUDI651Q6. Pending availability of the Eudamed site, the SSCP may also be accessed at the following link: http://www.merit.com/sscp/

This implantable device is provided with a patient guide, implant card, and implant card instructions. A patient guide is available electronically at www.merit.com/peripheral-intervention/access/renal-therapies-accessories/bioflo-duramax/. The implanting clinician is responsible for reviewing the patient guide with the patient. The implanting clinician is also required to complete the information on the implant card, and provide the completed implant card.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your sales representative. Inspect prior to use to verify that no damage has occurred during shipping.

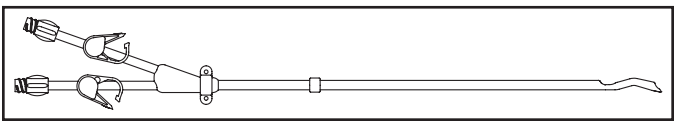
For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also 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.

The BioFlo DuraMax® with ENDEXO® Technology Hemodialysis Catheter is to be treated as contaminated biomedical waste subsequent to use. Used or unused devices should be disposed of in accordance with hospital, administrative and/or local government policy for such items. Sharps such as the safety scalpel and introducer needle should be disposed of in a sharps container.

Uncontaminated device packaging should be recycled if applicable, or disposed of as common waste in accordance with hospital, administrative and/or local government policy for such items.

DEVICE DESCRIPTION

The BioFlo DuraMax with ENDEXO Technology Hemodialysis Catheter is manufactured from soft radiopaque Carbothane with ENDEXO material that provides increased patient comfort while providing excellent biocompatibility.



BioFlo DuraMax with ENDEXO Technology Chronic Hemodialysis Catheter is available in multiple packaging configurations:

- Catheter Only – consists of the catheter and two injection caps.
- Basic Kit with Single Valve Sheath/Dilator – consists of

- BioFlo DuraMax Dialysis Catheter
- 16F Single Valved Peelable Sheath Dilator
- 12F Dilator
- 14F Dilator
- Tri-Ball Tunneler with Sleeve
- Injection Caps
- #11 Blade Safety Scalpel
- 0.038 inches J/Flex Guidewire
- Adhesive Wound Dressing
- 18 G X 2-3/4 Introducer Needle

- Basic Kit with valved splittable introducer Sheath/Dilator – consists of
  - BioFlo DuraMax Dialysis Catheter
  - 16F Dual Valved Peelable Sheath Dilator
  - 12F Dilator
  - 14F Dilator
  - Tri-Ball Tunneler with Sleeve
  - Injection Caps
  - #11Blade Safety Scalpel
  - 0.038 inches J/Flex Guidewire
  - Adhesive Wound Dressing
  - 18 G X 2-3/4 Introducer Needle
- VascPak™ Kit with single valve Sheath/Dilator – consists of
  - BioFlo DuraMax Dialysis Catheter
  - 16F Single Valved Peelable Sheath Dilator
  - 12F Dilator
  - 14F Dilator
  - Tri-Ball Tunneler with Sleeve
  - Injection Caps
  - Adhesive Wound Dressing
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  - 12F Dilator
  - 14F Dilator
  - Tri-Ball Tunneler with Sleeve
  - Injection Caps
  - Adhesive Wound Dressing

The ENDEXO technology is a passive, non-active polymer technology that has been shown to be effective in reducing thrombus accumulation (based on platelet count). Reduction of thrombus accumulation was evaluated using acute in vitro models. The results of an in-vivo sheep study during 31 day indwelling time demonstrated that the BioFlo DuraMax with ENDEXO Technology Chronic Hemodialysis Catheter has thromboresistance characteristics comparable to a heparin coated hemodialysis catheter legally marketed in the US. Pre-clinical in vitro evaluations do not necessarily predict clinical performance with respect to thrombus formation. Catheter shaft is made of Carbothane 3585A with 20% barium sulfate for radiopacity, 2% Endexo plastic polymer and 0.2% teal colorant. It has permanent exposure to blood.

Note: ENDEXO Technology is intended to reduce catheter-related thrombus, and is not intended to treat or eliminate existing thrombus.

INTENDED USE

- The BioFlo DuraMax with ENDEXO Technology Chronic Hemodialysis Catheter is indicated for use in attaining Long-Term vascular access for Hemodialysis in adults.
- Catheters greater than 40 cm are intended for femoral vein insertion.

INDICATIONS FOR USE:

The BioFlo DuraMax with ENDEXO Technology Chronic Hemodialysis Catheter is indicated for adult patients with End-stage Kidney Disease who require long-term vascular access for hemodialysis

CLINICAL BENEFITS

The placement of the BioFlo DuraMax with ENDEXO Technology Chronic Hemodialysis Catheter, as compared to other approaches to long term vascular access (such as arteriovenous fistulas or grafts) makes it possible to begin hemodialysis immediately, if necessary. The BioFlo Duramax with ENDEXO Technology Chronic Hemodialysis Catheter may also provide a vascular access alternative when other alternatives are not possible, when other approaches fail, or when individual patient circumstances make other alternatives less desirable for long term vascular access.

The catheter is an option for immediate (may be used right away) and long term use (>30 days) for vascular access, which makes it possible to remove toxins by means of hemodialysis from the blood. This may, in turn, reduce short term complications of uremia. The positive impact for the patient is the ability to receive immediate and long term hemodialysis via the catheter wherein complications associated with toxin build up can be avoided.

INTENDED PATIENT POPULATION:

This catheter can be used in adult patients with End-stage Kidney Disease who require long-term vascular access for hemodialysis.

INTENDED USERS

- The BioFlo DuraMax with ENDEXO Technology Chronic Hemodialysis Catheter should be inserted, manipulated, and removed by a qualified,

licensed implanting clinician or other qualified health care professional under the direction of an implanting clinician.

- This device should be used only by implanting clinicians and healthcare professionals already trained in dialysis access, catheter care and maintenance. Users may receive additional product training, as needed, from a clinical team representative from Merit Medical by contacting customer service at +1800-356-3748.

CONTRAINDICATIONS

- The catheter is intended for Long-Term vascular access only and should not be used for any purpose other than indicated in these instructions.
- The presence of other device related infection, bacteremia, or septicemia is known or suspected.
- Severe chronic obstructive lung disease exists.
- Past irradiation of prospective insertion site has occurred.
- Previous episodes of venous thrombosis or vascular surgical procedures at the prospective placement site have occurred.
- Local tissue factors that will prevent proper device stabilization and/or access.
- The valved peelable introducer sheaths are not designed for use in the arterial system

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 pull force on the catheter may cause the suture wing to detach from the bifurcate.
- To avoid air embolism close the valve in the single valved peelable sheath prior to insertion of dilator and remove the guidewire and dilator from the valved peelable sheath immediately after sheath insertion.
- Do not use acetone on any part of the catheter tubing. Exposure to this agent may cause catheter damage.
- The catheter should be used with caution and only after careful consideration in patients who are at risk of bleeding complications.
- Guidewire, Tunneler, Scalpel and Introducer Needle contain cobalt. Cobalt is classified as CMR 1B and is present in a concentration above 0.1% weight by weight.

PRECAUTIONS

- Do not use sharp instruments near the extension tubing or catheter lumen.
- Do not use scissors to remove dressing.
- Catheter will be damaged if clamps other than what is provided with this kit are used.
- In the event a clamp breaks, replace the catheter at the earliest opportunity.
- Clamping of the tubing repeatedly in the same location may weaken tubing. Avoid clamping near the luers and hub of the catheter.
- Examine catheter lumen and extensions before and after each treatment for damage.
- To prevent accidents, assure the security of all caps and bloodline connections prior to and between treatments.
- Use only Luer Lock (threaded) Connectors with this catheter.
- Repeated over tightening of bloodlines, syringes, and caps will reduce connector life and could lead to potential connector failure.
- If using an introducer sheath other than the one provided, verify that the catheter fits easily through the introducer sheath.
- 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 can tear when subjected to excessive force or rough edges.

- Avoid sharp or acute angles during implantation which could compromise catheter functionality.
- Excessive force should not be used to flush obstructed lumen. Do not use a smaller syringe than 10 mL.
- Scrub catheter luer lock connectors with an appropriate antiseptic after cap is removed and before accessing. Perform every time catheter is accessed or disconnected.
- If luer lock connectors are cleansed with a cleansing solution, allow the solution to dry fully before applying catheter end caps. Tape end caps between treatments to safeguard them against accidental removal.
- It is not recommended to insert the catheter through a previously stented vessel as the catheter may dislodge the stent causing it to migrate.
- Catheters placed via the femoral vein should be planned carefully in terms of insertion site, tunnel, and exit site. Consideration should be made of the possibility of permanent access in that limb. If an arteriovenous fistula or graft may be created in that limb, then placement of a catheter in the anatomy of that limb should be avoided if at all possible. Exit sites and tunnel tracts should be chosen carefully so as to:
  1. Minimize interference with patient mobility.
  2. Maximize patient comfort.
  3. Maintain as wide and gentle a curve as possible to minimize potential for catheter kinking.
  4. Minimize infection risk.
  5. Minimize catheter length (while allowing for the prior considerations) so as to maximize the potential blood flow of the catheter. Catheters placed via the femoral vein will generally have lower blood flow than catheters placed via the internal jugular vein.
- Some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their catheter locked with heparinized saline.

ADVERSE EVENTS/POTENTIAL COMPLICATIONS:

- Air Embolus
- Bacteremia
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Central Venous Thrombosis
- Endocarditis
- Exit Site Infection
- Exsanguination
- Femoral Artery Laceration
- Femoral Nerve Injury
- Fibrin Sheath Formation
- Hematoma
- Hemorrhage
- Hemothorax
- Inferior Vena Cava Puncture
- Inflammation
- Laceration of the Vessel
- Lumen Thrombosis
- Mediastinal Injury
- Perforation of the Vessel
- Pleural Injury
- Pneumothorax
- Pulmonary Embolism
- Retroperitoneal Bleed
- Right Atrial Puncture
- Septicemia
- Subclavian Artery Puncture
- Subcutaneous Hematoma
- Superior Vena Cava Puncture
- Thoracic Duct Laceration
- Tunnel Infection
- Vascular Thrombosis
- Venous Stenosis

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

HOW SUPPLIED

Store in a cool, dry, place. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

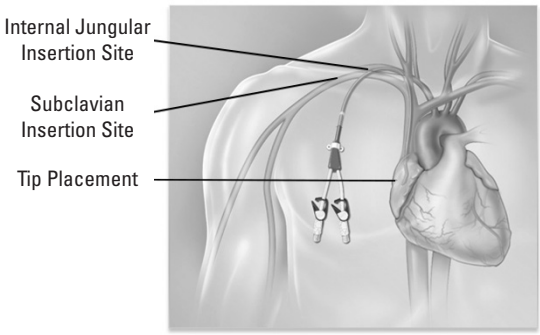
INSERTION SITES

The BioFlo DuraMax Dialysis Catheter may be inserted percutaneously and is ideally placed in the jugular vein. Although this catheter may be placed in the subclavian vein, the internal jugular is the preferred site. Catheters greater than 40 cm length (tip to cuff) are designed for femoral vein insertion.

DIRECTIONS FOR USE

- 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 sternomastoid muscle. Catheterization will be performed at the apex of a triangle formed between the two heads of the sternomastoid muscle. The apex should be approximately three fingerbreadths above the clavicle. The carotid artery should be palpated medial to the point of catheter insertion.
- Note the position of the subclavian vein, which is posterior to the clavicle, superior to the first rib, and anterior to the subclavian artery. (At a point just lateral to the angle made by the clavicle and the first rib.)

WARNING:

- Patients requiring ventilator support are at increased risk of pneumothorax during subclavian vein cannulation, which may cause complications.
- Extended use of the subclavian vein may be associated with subclavian vein stenosis.

- The patient should lie completely on his/her back. Both femoral arteries should be palpated for site selection and consequence assessment. The knee on the same side of the insertion site should be flexed and the thigh abducted. Place the foot across the opposite leg. The femoral vein is then posterior/medial to the artery.

Precaution: The incidence of infection may be increased with femoral vein insertion.

- Confirm final position of catheter with chest x-ray. Routine x-ray should always follow the initial insertion of this catheter to confirm proper tip placement prior to use.
- Femoral Catheter tip placement is recommended at the junction of the iliac vein and the inferior vena cava.

DIRECTIONS FOR SELDINGER INSERTION

- 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 an implanting clinician.
- 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 implanting clinician's experience and judgment in treating any specific patient.
- Use standard hospital protocols when applicable.

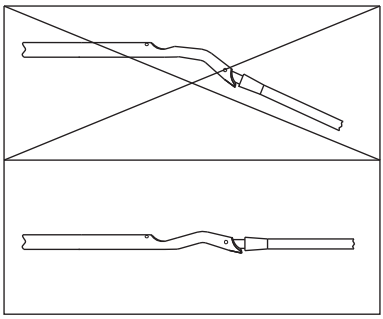
1. Strict aseptic technique must be used during insertion, maintenance, and catheter removal procedures. Provide a sterile operative field. The Operating Room is the preferred location for catheter placement. Use maximal barrier precautions including the use of a cap, mask, sterile gown, sterile gloves, and a sterile full body drape for the insertion of central venous catheters. Have patient wear mask. Shave the skin above and below the insertion site. Prepare clean skin with a > 0.5% chlorhexidine preparation with alcohol before central venous catheter insertion. If there is a contraindication to chlorhexidine, tincture of iodine, an iodophor, or 70% alcohol can be used as alternatives. Antiseptics should be allowed to dry according to the manufacturer's recommendation prior to placing the catheter.
2. The selection of the appropriate catheter length is at the sole discretion of the implanting clinician. 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. Make a small incision at the exit site on the chest wall approximately 8 – 10 cm below the clavicle. Make a second incision above and parallel to the first, at the insertion site. Make the incision at the exit site wide enough to accommodate the cuff, approximately 1 cm.
5. Use blunt dissection to create the subcutaneous tunnel opening. Attach the catheter to the trocar (a slight twisting motion may be helpful). Slide catheter tunneling sleeve over the catheter making certain that the sleeve covers the distal tip of the catheter. Insert the trocar into the exit site and create a short subcutaneous tunnel. Do not tunnel through muscle. The tunnel should be made with care in order to prevent damage to surrounding vessels.

Warning: Do not over–expand subcutaneous tissue during tunneling. Over-expansion may delay/prevent cuff in-growth.

6. Lead catheter into the tunnel gently. Do not pull or tug the catheter tubing. If resistance is encountered, further blunt dissection may facilitate insertion. Remove the catheter from the trocar with a slight twisting motion to avoid damage to the catheter.

Precaution: Do not pull tunneler out at an angle. Keep tunneler straight to prevent damage to catheter tip.



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

7. Irrigate catheter with saline, then clamp catheter extensions to assure that saline is not inadvertently drained from lumens. Use clamps provided.

Precaution: Do not clamp the dual lumen portion of the catheter. Clamp only the extensions. Do not use serrated forceps, use only the in-line clamps provided.

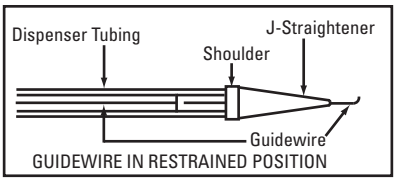
8. Insert the introducer needle with attached syringe into the target vein. Aspirate to insure proper placement. Use ultrasound guidance to place catheter (if this technology is available) to reduce the number of cannulation attempts and mechanical complications. Ultrasound guidance should only be used by those fully trained in its technique.
9. 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.

Caution: The length of the wire inserted is determined by the size of the patient. Monitor patient for arrhythmia throughout this procedure. The patient should be placed on a cardiac monitor during this procedure. Cardiac arrhythmias may result if guidewire is allowed to pass into the right atrium. The guidewire should be held securely during this procedure.

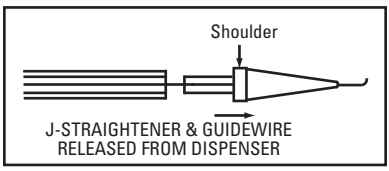
10. Remove needle, leaving guidewire in the target vein. Enlarge cutaneous puncture site with scalpel.

CAPTIVE® J-STRAIGHTENER USE INSTRUCTIONS

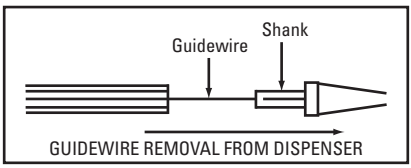
11. Grasp the shoulder of the Captive J-Straightener between the forefinger and thumb.



12. Gently pull on the Captive J-Straightener shoulder until it is just removed from the dispenser tubing.



13. Holding the guidewire and the shank of the Captive J-Straightener, fully withdraw the guidewire from the dispenser.



Caution: DO NOT grasp and pull the guidewire prior to releasing the Captive J-Straightener. Damage to the guidewire may occur if it is pulled against the restraint of the Captive J-Straightener.

VALVED SPLITTABLE INTRODUCER SHEATH INSTRUCTIONS

Precautions: Dilators and catheters should be removed slowly from the sheath. Rapid removal may damage the valve members resulting in blood flow through the valve. Never advance or withdraw guide wire or sheath when resistance is met. Determine cause by fluoroscopy and take remedial action.

14. Insert vessel dilator into sheath until the dilator cap folds over valve housing and secures the dilator onto sheath assembly.
15. Thread the dilator/sheath assembly over the guide wire.
16. 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.
17. 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. (see figure A).

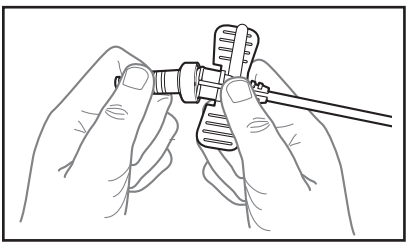


Figure A

18. Slowly retract the guide wire and dilator, leaving the sheath in position. The valve will reduce the loss of blood and the inadvertent aspiration of air through the sheath.
19. Introduce catheter through the valve/sheath and advance it into position.
20. 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. (see figure B).

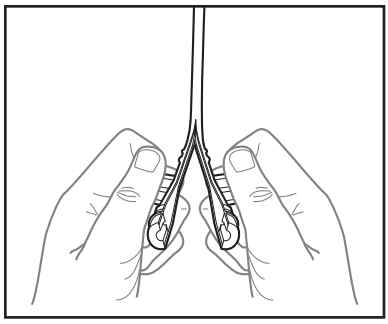


Figure B

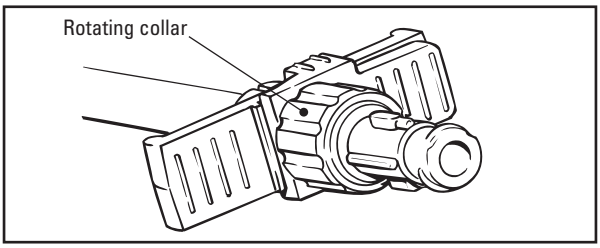
21. Remove the sheath from the patient.

SINGLE VALVE SHEATH INSTRUCTIONS

CAUTIONS:

- The Valved Peelable Introducer Sheath is designed to reduce blood loss and the risk of air intake but it is not a hemostasis valve.
- It is not intended to create a complete two-way seal nor is it intended for arterial use.
- The valve will substantially reduce air intake. At -12 mm Hg vacuum pressure the Valved Peelable Introducer Sheath may allow up to 4 cc/sec of air to pass through the valve.
- The valve will substantially reduce the rate of blood flow but some blood loss through the valve may occur.

22. Remove the dilator from the sheath and slide the valve over the sheath opening. Insert the dilator through the valve and lock in place using the rotating collar.



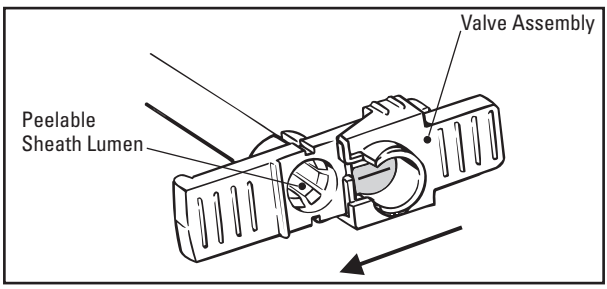
23. Advance the introducer/dilator assembly over the guidewire and into the vein.

Note: If alternate sheath is used, follow manufacturer's instructions.

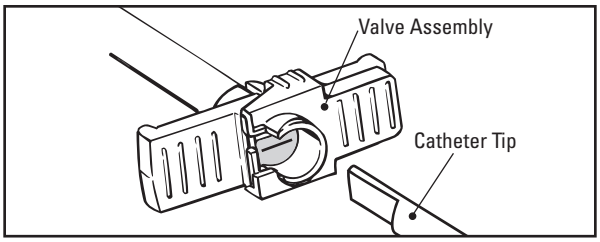
Caution: Never leave sheath in place as an indwelling catheter. Damage to vein will occur.

24. Remove the dilator and guidewire from the introducer/dilator assembly by unlocking the rotating collar and gently withdrawing the dilator from the sheath.

Note: If the procedure does not allow the use of a valve, slide the valve away from the sheath opening and use as a standard sheath.

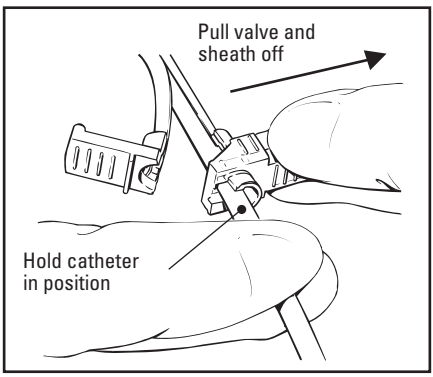


25. Advance distal tip of catheter through the valve. To prevent kinking the catheter, it may be necessary to advance in small steps by grasping the catheter close to the sheath.



26. After the catheter has been positioned, crack the sheath handle in half.
27. Peel the non-valved side of the handle partially away from the catheter.
28. Near the valve, hold the catheter firmly in position and pull the valve off of the catheter.

Note: 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 tear the sheath only a few centimeters at a time.

29. Remove the sheath from the patient.
30. Make any adjustments to catheter under fluoroscopy. The distal tip should be positioned at the level of the caval atrial junction or into the right midatrium to ensure optimal blood flow.
31. Attach syringes to both extensions and open clamps. Blood should aspirate easily from both arterial and venous sides. If either side exhibits excessive resistance to blood aspiration, the catheter may need to be rotated or repositioned to obtain adequate blood flows.
32. 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.
33. Close the extension clamps, remove the syringes, and place an injection cap on each luer lock connector. Avoid air embolism by keeping extension tubing clamped at all times when not in use and by aspirating then irrigating the catheter with saline prior to each use. With each change in tubing connections, purge air from the catheter and all connecting tubing and caps.
34. To maintain patency, a heparin lock must be created in both lumens. Refer to hospital heparinization guidelines.

Precaution: Assure that all air has been aspirated from the catheter and extensions. Failure to do so may result in air embolism.

35. Once the catheter is locked with heparin, close the clamps and install injection caps onto the extensions' female luers.
36. Confirm proper tip placement with fluoroscopy. The distal venous tip should be positioned at the level of the caval atrial junction or into the right midatrium to ensure optimal blood flow.

Precaution: Failure to verify catheter placement may result in serious trauma or fatal complications.

Catheter Securement And Securement Dressing:

37. Suture insertion site closed. Suture the catheter to the skin using the suture wing. 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.

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

38. Cover the insertion and exit site with securement dressing.
39. Catheter must be secured/sutured for entire duration of implantation.
40. Record catheter length and catheter lot number on patient's chart.

HEMODIALYSIS TREATMENT

NOTE: When a syringe or blood line is being attached directly to the catheter hub, the luer connection should be made while holding catheter hub firmly, rather than holding any other part of the catheter. When a syringe or blood line is being attached to an injection cap, the luer connection should be made while holding the injection cap rather than the catheter hub, or any part of the catheter.

Avoid twisting of the catheter while making connection to the hub. Do not use hemostats to secure or remove devices with luer lock hub connections.

- The heparin 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.
- 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.

Precaution: Only clamp catheter with in-line clamps provided.

- Necessary remedial action must be taken prior to the continuation of the dialysis treatment.

Note: Excessive blood loss may lead to patient shock.

- Hemodialysis should be performed under implanting clinician's instructions.

HEPARINIZATION

- If the catheter is not to be used immediately for treatment, follow the suggested catheter patency guidelines.
- To maintain patency between treatments, a heparin lock must be created in each lumen of the catheter.
- Follow hospital protocol for heparin lock frequency and concentration.

1. Draw heparin into two syringes, corresponding to the amount designated on the arterial and venous extensions. Assure that the syringes are free of air.

NOTE: Consideration should be given to the priming volume of each lumen as designated on the catheter clamps in order to avoid systemic effects of the locking solution.

Table 1: Priming Volumes

Catheter Length	Lumen	
	Arterial (ml)	Venous (ml)
20 cm	1.8	1.9
22 cm	1.9	2.1
24 cm	2.0	2.1
28 cm	2.2	2.3
32 cm	2.3	2.4
36 cm	2.5	2.6
40 cm	2.7	2.8
48 cm	3.1	3.2
55 cm	3.4	3.7

2. Remove injection caps from the extensions.
3. Attach a syringe containing heparin solution to the female luer of each extension.

4. Open extension clamps.
5. Aspirate to insure that no air will be forced into the patient.
6. Inject heparin into each lumen using quick bolus technique.

Note: Each lumen should be completely filled with heparin to ensure effectiveness.

7. Close extension clamps.

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

8. Remove syringes.
9. Attach a sterile injection cap onto the female luers of the extensions.

- In most instances, no further heparin is necessary for 48-72 hours, provided the lumens have not been aspirated or flushed.

SITE CARE

- 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.
- The CDC recommends the following for site care agents and/or skin antiseptics for chronic hemodialysis catheters[1]:
  - Use of alcohol-based chlorhexidine (>0.5%) solution as the first line skin antiseptic for catheter exit site care. Alternatives for patients with chlorhexidine intolerance: Povidone-iodine (preferably with alcohol) or 70% alcohol
  - Apply povidone-iodine ointment or bacitracin/gramicidin/polymyxin B ointment during catheter dressing change. Alternative: Triple antibiotic ointment (bacitracin/neomycin/polymyxin B)
- Antiseptics should be allowed to dry according to the manufacturer's recommendation prior to placing the catheter.
- Apply antibiotic ointment or povidone iodine ointments to catheter exit site during dressing changes.
- Use either sterile gauze or sterile, transparent, semipermeable securement dressing to cover the catheter site. Leave extensions, clamps, and caps exposed for access by staff.
- If a patient is diaphoretic or if the site is bleeding or oozing use a gauze dressing until this is resolved.
- Securement dressings must be kept clean and dry. Replace catheter site dressing if the dressing becomes damp, loosened, or visibly soiled.
- Replace transparent securement dressings used on tunneled or implanted CVC sites no more than once per week (unless the securement dressing is soiled or loose) until the insertion site has healed.

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

- If profuse perspiration or accidental wetting compromises adhesion of dressing, the medical or nursing staff must change the securement dressing under sterile conditions.
- The BioFlo DuraMax with ENDEXO Technology Hemodialysis Catheter has been tested for compatibility with the following site care agents or antiseptics (data on file). Refer to institutional protocols and/or licensed clinician's order for specific site care instructions.

Site Care Agent or Antiseptic	BioFlo DuraMax with ENDEXO Technology Hemodialysis Catheter
1-Chlorohexane	√
70% Isopropyl Alcohol **	√
Hydrogen Peroxide 3%	√
Chloraprep One Step	√
Chlorhexidne Gluconate 4% Solution	√
Povidine-iodine 10% Topical Solution	√
Polysporin Ointment	√
Triple Antibiotic Ointment (Regular Strength)	√

Bacitracin Plus Ointment	√

** Compatibility has not been established for locking of catheters with alcohol. Ethanol locking has been shown to negatively impact the integrity and performance of polyurethane catheter materials [2,3]

1. https://www.cdc.gov/dialysis/prevention-tools/catheter-compatibility-information.html
2. Crnich, C et al. The effects of prolonged ethanol exposure on the mechanical properties of polyurethane and silicone catheters used for intravascular access. Infect Control Hosp Epidemiol. 2005 Aug; 26(8); 708-14.
3. Mermel, L and Alang, N. (2014). Adverse effects associated with ethanol catheter lock solutions: a systematic review. Journal of Antimicrobial Chemotherapy. 69(10), p. 2611-2619.

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 an implanting clinician familiar with the appropriate techniques should attempt the following procedures.

Insufficient Flows:

The following may cause insufficient blood flows:

- Occluded arterial hole due to clotting or fibrin sheath.

Solutions Include:

- Chemical intervention utilizing a thrombolytic agent.

Management of One-Way Obstruction:

One-way obstructions exist when a lumen can be flushed easily but blood cannot be aspirated. This is usually caused by tip malposition.

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 move the tip away from the vessel wall.

Infection:

Precaution: Due to the risk of exposure to HIV (Human Immunodeficiency Virus) 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 a minimum of two blood cultures from a site distant from catheter exit site. If blood culture is positive, the catheter must be removed immediately and the appropriate antibiotic therapy initiated. Wait 48 hours before catheter replacement. Insertion should be made on opposite side of original catheter exit site, if possible.

CATHETER REMOVAL

Warning: Only an implanting clinician familiar with the appropriate techniques should attempt the following procedures.

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

1. Palpate the catheter exit tunnel to locate the cuff.
2. Administer sufficient local anesthetic to exit site and cuff location to completely anesthetize the area.
3. Cut sutures from suture wing. Follow hospital protocol for removal of skin sutures.
4. Make a 2 cm incision over the cuff, parallel to the catheter.
5. Dissect down to the cuff using blunt and sharp dissection as indicated.

6. When visible, grasp cuff with clamp.
7. Clamp catheter between the cuff and the insertion site.
8. Cut catheter between cuff and exit site. Withdraw internal portion of catheter through the incision in the tunnel.
9. Remove remaining section of catheter (i.e. portion in tunnel) through the exit site.

Precaution: Do not pull distal end of catheter through incision as contamination of wound may occur.

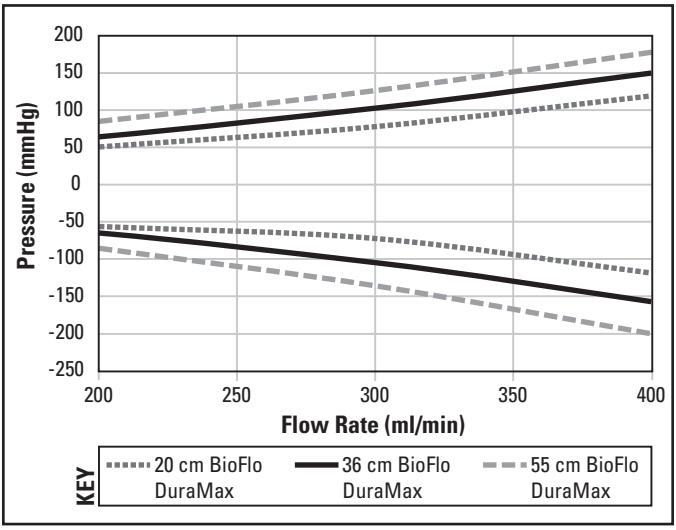
10. Apply pressure to proximal tunnel for approximately 10-15 minutes or until bleeding stops.
11. Suture incision and apply dressing in a manner to promote optimal healing.
12. Check catheter integrity for tears and measure catheter when removed. It must be equal to the length of catheter when it was inserted.

Table 2: Flow vs. Pressure Data

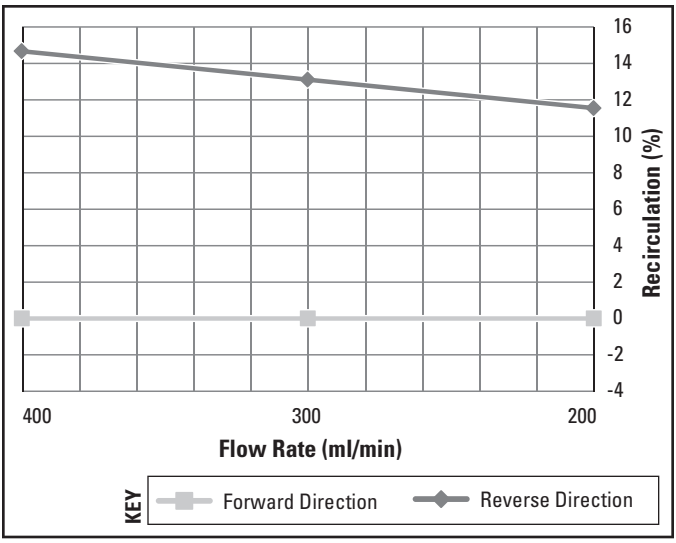
Catheter Length (cm)	Pressure at flow (mm Hg)					
	400 ml/min		300 ml/min		200 ml/min	
	A	V	A	V	A	V
20 cm Straight	-132	130	-86	89	-64	68
22 cm Straight	-134	130	-82	87	-59	71
24 cm Straight	-136	138	-83	89	-58	59
28 cm Straight	-161	139	-107	95	-75	75
32 cm Straight	-165	159	-108	102	-81	74
36 cm Straight	-164	160	-109	113	-67	84
40 cm Straight	-169	173	-112	118	-71	88
48 cm Straight	-198	180	-142	129	-80	89
55 cm Straight	-220	197	-151	141	-92	104

NOTE: FLOW TESTING REPRESENTS LABORATORY RESULTS FROM SIMULATED USE TESTING. A SIMULATED SOLUTION REPRESENTING BLOOD WITH A VISCOSITY OF 3.0 ± .1cp @ 37 + 5°C WAS USED FOR THE TESTING.

Graph 1: Pressure vs. Flow Rate



Graph 2: Recirculation



NOTE: RECIRCULATION REPRESENTS LABORATORY RESULTS FROM SIMULATED USE TESTING

In compliance with the requirements of 21CFR Part 801.15, a glossary of symbols which appear without accompanying text within the product labeling is provided below

Symbol	Ref	Title of Symbol	Meaning of Symbol
	5.1.1	Manufacturer	Indicates the medical device manufacturer.[a]
	5.1.3	Date of manufacture	Indicates the date when the medical device was manufactured.[a]
	5.1.4	Use-by date	Indicates the date after which the medical device is not to be used.[a]
LOT	5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.[a]
REF	5.1.6	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.[a]
	5.1.8	Importer	Indicates the entity importing the medical device into the locale.[a]
STERILE EO	5.2.3	Sterilized using ethylene oxide	Indicates the medical device has been sterilized using ethylene oxide.[a]
2 STERILIZE	5.2.6	Do not resterilize	Indicates a medical device that is not to be resterilized.[a]
	5.2.8	Do not use if package is damaged and consult instructions for use.	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.[a]
	5.2.11	Single sterile barrier system	Indicates a single sterile barrier system.[a]
	5.2.12	Double sterile barrier system	Indicates a double sterile barrier system.[a]
	5.2.13	Single sterile barrier system with protective packaging inside	Indicates a single sterile barrier system with protective packaging inside.[a]
	5.3.2	Keep away from sunlight	Indicates a medical device that needs protection from light sources.[a]
	5.3.4	Keep dry	Indicates a medical device that needs to be protected from moisture.[a]
27°C	5.3.6	Upper limit of temperature	Indicates the upper limit of temperature to which the medical device can be safely exposed.[a]
	5.4.2	Do not re-use	Indicates a medical device that is intended for one single use only, or for use on a single patient during a single procedure.[a]

Symbol	Ref	Title of Symbol	Meaning of Symbol
	5.4.3	Consult instructions for use or consult electronic instructions for use ifu.angiodynamics.com	Indicates the need for the user to consult the instruction for use.[a]
 Cobalt	5.4.10	Contains hazardous substances	Indicates a medical device that contains substances that can be carcinogenic, mutagenic, reprotoxic (CMR) or substances with endocrine disrupting properties.[a] Contains cobalt as a component of stainless steel at levels ≤ 0.4%. This device is not intended for use in the stomach. Exposure of the stainless steel to highly acidic fluids such as gastric fluid can result in leaching of the cobalt from the stainless steel. Cobalt is listed in EC 1272/2008 as a carcinogen class 1B and a reproductive toxin class 1B
	5.7.7	Medical device	Indicates the items is a medical device.[a]
	5.7.10	Unique Device Identifier	Indicates a carrier that contains unique device identifier information.[a]
	NA	Rx only	Caution: (US) Federal law restricts this device to sale by or on the order of a licensed practitioner.[b]
	NA	Universal Product Number	A Universal Product Number (UPN) code represents the manufacturer's number for an item.
	NA	Quantity in package	To indicate that the adjacent number reflects the number of units contained in the package.
	1135	Recyclable Package	Recyclable Package.[c]
	NA	Non-pyrogenic	Only for products that directly or indirectly contact circulating blood. Not applicable to products with no potential blood contact.

a. EN ISO 15223-1 - Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied.
b. 21 CFR 801.109 - Code of Federal Regulations.
c. EN ISO 14021 Environmental labels and declarations. Self-declared environmental claims (Type II environmental labeling)

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405304001_002 ID 2024-05-13