DECATHLON* DF

Long-Term Hemodialysis Catheter

INSTRUCTIONS FOR USE

DESCRIPTION

The Decathlon* DF catheters are made of radiopaque polyurethane, and allow for flow rates as high as 500 ml/min. The catheter shaft is divided internally into two separate lumens by a septum allowing hemodialysis without the use of a "single needle" system. The catheter comes with a white retention cuff for tissue ingrowth to anchor the catheter.

The Decathlon* DF catheters have two separate free floating tips, separated at a fixed point.

STERILE EO

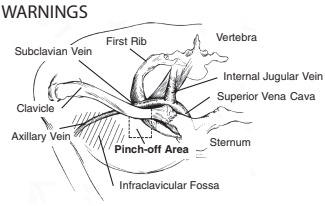
INDICATIONS FOR USE

The Decathlon* DF long-term hemodialysis catheter is indicated for use in attaining short-term or long-term vascular access for hemodialysis, hemoperfusion or apheresis therapy. Access is attained via the internal jugular vein, external jugular vein, subclavian vein, or femoral vein.

CONTRAINDICATION

This device is contraindicated for patients exhibiting severe, uncontrolled thrombocytopenia or coagulopathy.

WARNINGS



WARNING: Percutaneous insertion of the catheter should be made into the axillary-subclavian vein at the junction of the outer and mid-thirds of the clavicle lateral to the thoracic outlet. The catheter should not be inserted into the subclavian vein medially, because such placement can lead to compression of the catheter between the first rib and clavicle and can lead to damage or fracture and embolization of the catheter. [1] Fluoroscopic or radiographic confirmation of catheter tip placement should be helpful in demonstrating that the catheter is not being pinched by the first rib and clavicle. [1]

- Alcohol or alcohol-containing antiseptics (such as chlorhexidine) may be used to clean the catheter/skin site; however, care should be taken to avoid prolonged or excessive contact with the solution(s). Solutions should be allowed to completely dry before applying dressing.
- Acetone and Polyethylene Glycol (PEG)-containing ointments can cause failure of this device and should not be used with polyurethane catheters. Chlorhexidine patches or bacitracin zinc ointments (e.g., Polysporin* ointment) are the preferred alternative.
- Follow Universal Precautions when inserting and maintaining this device.
- Cardiac arrhythmias may result if the guidewire and/or stylet touches the walls of the right atrium. Use cardiac rhythm monitoring to detect arrhythmias.
- Close all clamps only in the center of the extension legs. Extensions may develop cuts or tears if subjected to excessive pulling or contact with rough edges. Repeated clamping near or on the Luer-lock connectors may cause tubing fatigue and possible disconnection.
- Catheters should be implanted carefully.
- Any sharp or acute angles that could compromise the opening of the catheter lumens need to be avoided.
- To prevent air embolism and/or blood loss put patient in Trendelenburg position and always place thumb over the exposed orifice of the sheath introducer.
- To avoid damage to vessels and viscus, infusion pressures should not exceed 25 psi (172 kPa). The use of a 10 mL or larger syringe is recommended because smaller syringes generate more pressure than larger syringes. Note: A three pound (13.3 Newton) force on the plunger of a 3 mL syringe generates pressure in excess of 30 psi (206 kPa) whereas the same three pound (13.3 Newton) force on the plunger of a 10 mL syringe generates less than 15 psi (103 kPa) of pressure.
- Accessories and components used in conjunction with this catheter should incorporate Luer-lock adapters.
- The heparin solution must be aspirated out of both lumens immediately prior to using the catheter to prevent systemic heparinization of the patient.
- Failure to clamp extensions when not in use may lead to air embolism.
- In the rare event of a leak, the catheter should be clamped immediately. Necessary remedial action must be taken prior to resuming dialysis or infusion procedure.
- The risk of infection is increased with femoral vein insertion.
- Do not resterilize the catheter or components by any method. The manufacturer will not be liable for any damages caused by reuse of the catheter or accessories.
- Cannulation of the left internal jugular vein was reportedly associated with a higher incidence of complications compared to catheter placement in the right internal jugular vein.[7]
- Alcohol should not be used to lock, soak or declot polyurethane Dialysis Catheters because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.
- Intended for Single Use. DO NOT REUSE. Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of the patient.

CAUTIONS

- Repeated over tightening of blood lines, syringes and caps will reduce connector life and could lead to potential connector failure. In case of damage, clamp the catheter between the patient and the damaged area with a smooth-edged, atraumatic clamp.
- Sterile and non-pyrogenic only if packaging is not opened, damaged or broken.
- Read the instructions for use carefully before using this device.
- CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
- Left sided placement in particular, may provide unique challenges due to the right angles formed by the innominate vein and at the left brachiocephalic junction with the SVC.[5,8]
- Care should be taken NOT to force the dilator sheath introducer assembly into the vessel during insertion as vessel damage including perforation could result.
- Stylet is intended for use over a guidewire to aid in placement. Inserting the stylet into the venotomy without tracking over a guidewire could result in vessel damage including perforation.
- Failure to retract the stylet when inserting the tunneler into the catheter tip can result in damage to the stylet.
- Ensure that the catheter does not move out of the vein while removing the insertion stylet.
- Care should be taken not to advance the split sheath too far into vessel as a potential kink would create an impasse to the catheter.
- Ensure that the introducer sheath is only torn externally. Catheter may need to be further pushed into the vessel as sheath is torn.
- For optimal product performance, do not insert any portion of the cuff into the vein.
- If the microintroducer guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to prevent the needle from damaging or shearing the guidewire.
- Before attempting the insertion of Decathlon* DF catheters, ensure that you are familiar with the complications listed below and their emergency treatment should any of them occur.
- The complications listed below as well as other complications are well documented in medical literature and should be carefully considered before placing the catheter. Placement and care of Decathlon* DF catheters should be performed by persons knowledgeable of the risks involved and qualified in the procedures.

POSSIBLE COMPLICATIONS

The use of an indwelling central venous catheter provides an important means of venous access for critically ill patients; however, the potential exists for serious complications including the following:

- Air Embolism
- Arterial Puncture
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catheter or Cuff Erosion Through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter Occlusion, Damage or Breakage due to Compression Between the Clavicle and First Rib [1]
- Catheter-related Sepsis
- Endocarditis
- Exit Site Infection
- Exit Site Necrosis
- Extravasation
- Fibrin Sheath Formation
- Hematoma
- Hemomediastinum
- Hemothorax
- Hydrothorax
- Inflammation,Necrosis or scarring of skin over implant area
- Intolerance Reaction to Implanted Device
- Laceration of Vessels or Viscus
- Perforation of Vessels or Viscus
- Pneumothorax
- Thoracic Duct Injury
- Thromboembolism
- Venous Stenosis
- Venous Thrombosis
- Ventricular Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local and General Anesthesia, Surgery, and Post-Operative Recovery

INSERTION TECHNIQUE (1) Percutaneous Placement Procedure of the Decathlon* DF catheter with cuff using the Bard Access Systems, Inc. split sheath introducer:

For percutaneous placement, the catheter is inserted in either the subclavian vein or internal jugular vein through a split sheath introducer. It has been reported that right side, internal jugular placement is the preferred initial location of consideration for percutaneous insertion. [6,9] The patient should be placed in Trendelenburg position with the head turned to the opposite side of the entry site.

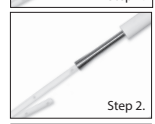
A (COMMON STEPS).

CATHETERS MUST BE INSERTED UNDER STRICT ASEPTIC CONDITIONS.
WARNING: Cannulation of the left internal jugular vein was reportedly associated with a higher incidence of complications compared to catheter placement in the right internal jugular vein. [7]
CAUTION: As reported in literature, left sided catheter placement may provide unique challenges due to the right angles formed by the innominate vein and at the left brachiocephalic junction with the SVC. [5,8]

1. Provide a sterile field throughout the procedure. The operator should wear a cap, mask, sterile gown, sterile gloves, and use a large sterile drape to cover the patient.
2. Prepare the access site using standard surgical technique and drape the prepped area with sterile towels. If hair removal is necessary, use clippers or depilatories. Next, scrub the entire area preferably with chlorhexidine gluconate unless contraindicated in which case povidone-iodine solution may be used. Use a back-and-forth friction scrub for at least 30 seconds [10]. Do not wipe or blot. Allow antiseptic solution to air dry completely before puncturing the site.
3. (If applicable) Administer local anaesthesia to the insertion site and the path for subcutaneous tunnel.
4. Flush each lumen with heparin solution prior to insertion and clamp the extension legs. If using stylet, do not clamp the arterial (red) lumen until the arterial insertion stylet and guidewire are removed. Clamping will kink the stylet and prevent guidewire passage.
5. Insert the introducer needle with an attached syringe to the desired location. Aspirate gently as the insertion is made.
6. When the vein has been entered, remove the syringe leaving the needle in place.
7. If using a micropuncture set, insert the flexible end of the microintroducer guidewire into the needle. Advance the microintroducer guidewire as far as appropriate. Verify correct positioning, using fluoroscopy or ultrasound.
   - Gently withdraw and remove the needle, while holding the guidewire in position.
     CAUTION: If the microintroducer guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to prevent the needle from damaging or shearing the guidewire.
     Advance the small sheath and dilator together as a unit over the microintroducer guidewire, using a slight rotational motion. Advance the unit into the vein as far as appropriate.
     Withdraw the dilator and microintroducer guidewire, leaving the small sheath in place.
     WARNING: Place a thumb over the orifice of the sheath to minimize blood loss and risk of air aspiration.
8. The standard guidewire can be inserted into the needle hub and passed through the needle. Advance the standard guidewire to the desired location in the vessel.
9. If using a microintroducer, gently withdraw and remove the small sheath, while holding the standard guidewire in position.
10. Remove the needle while holding the guidewire in place. Wipe the guidewire clean and secure it in place.
    CAUTION: Do not pull back standard guidewire over needle bevel as this could sever the end of the guidewire. The introducer needle must be removed first.
11. Make a small incision at the insertion site. Make a second incision at the desired exit site of the catheter.
12. Go to B (Common Steps).

B (COMMON STEPS)


Step 1.


Step 2.


Step 3.

1. If using stylet, unscrew the stylet hub from the arterial Luer-lock connector and retract stylet until it is no longer visible at the arterial lumen tip.
   CAUTION: Failure to retract the stylet when inserting the tunneler into the catheter tip can result in damage to the stylet.
2. With a tunneler, create a subcutaneous tunnel from the catheter exit site to emerge at the venous entry site. If using the Bard Access Systems, Inc. tunneler (see steps 1 to 3 on the right), attach the catheter to the tunneler so that the catheter's venous tip slides over the barbed connection and rests adjacent to the sheath stop. This allows the catheter to be threaded through the tissue as the tunnel is created. Slide the sheath found on the tunneler over the venous tip/tunneler connection until it stops. In addition, ensure the open end of sheath is covering the arterial tip. This will reduce the drag on the arterial tip in the skin tunnel and secure the catheter to the tunneler. (After positioning cuff, tunneler can be removed by sliding sheath away from the catheter and pulling tunneler from venous tip.) The catheter should not be forced through the tunnel.
3. Position the white retention cuff approximately midway between the skin exit site and the venous entry site, 3 cm minimum, from the venous entry site. Detach tunneler from catheter.
4. If using stylet, push the stylet back into catheter and tighten stylet hub onto arterial catheter Luer-lock connector. Thread stylet tip into proximal side of the venous end hole and allow stylet tip to protrude from tip of catheter.

C INSERTION TECHNIQUE (1): PERCUTANEOUS PLACEMENT

1. Unlock, remove, and discard stylet.
   CAUTION: Stylet is intended for use over a guidewire to aid in placement. Inserting the stylet into the venotomy without tracking over a guidewire could result in vessel damage including perforation.
2. Fill the catheter lumens with heparinized saline solution.
3. Advance the dilator sheath introducer assembly over the exposed guidewire into the vessel.
   CAUTION: Care should be taken NOT to force the dilator sheath introducer assembly into the vessel during insertion as vessel damage including perforation could result. As reported in literature, left sided catheter placement may provide unique challenges due to the right angles formed by the innominate vein and at the left brachiocephalic junction with the SVC. [5,8]
   WARNING: Cardiac arrhythmias may result if the guidewire is allowed to touch the walls of the right atrium.
4. Withdraw the vessel dilator and guidewire, leaving the introducer sheath in place.
   CAUTION: Care should be taken not to advance the split sheath too far into vessel as a potential kink would create an impasse to the catheter.
   WARNING: To prevent air embolism and/or blood loss, place thumb over the exposed orifice of the sheath introducer.
5. Remove thumb and feed distal section of catheter into the sheath introducer. Advance the catheter tip. Catheter tip placement, tip orientation and proper length selection is left to the discretion of the physician. However, routine x-ray should always follow the initial insertion to confirm proper placement of the catheter tips prior to use. The recommended tip location is at the junction of the superior vena cava/right atrium (SVC/RA) or in the mid right atrium. [6] All tip placements should be confirmed by fluoroscopy.
6. With the catheter advanced, peel away the sheath by gripping the "T" handle and breaking it apart with a downward and outward motion to initiate separation and withdrawal of the sheath.
   CAUTION: Ensure that the introducer sheath is only torn externally. Catheter may need to be further pushed into the vessel as sheath is torn.
   CAUTION: For optimal product performance, do not insert any portion of the cuff into the vein.
7. Go to D (Common Steps).

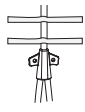
D (COMMON STEPS)

1. Confirm catheter patency by releasing clamp and aspirating blood through each lumen.
2. Flush each lumen with 10 mL sterile saline using a 10 mL or larger syringe.
   WARNING: To avoid damage to vessels and viscus, infusion pressures should not exceed 25 psi (172 kPa). The use of a 10 mL or larger syringe is recommended because smaller syringes generate more pressure than larger syringes
3. Inject heparin solution into each lumen in amounts equal to the priming volumes as printed on the catheter clamps. Be sure to clamp each lumen immediately. WARNING: Failure to clamp extensions when not in use may lead to air embolism.
4. For additional security, suture the entire entry site, or use a Statlock® Catheter Stabilization device to anchor the catheter.
5. Follow your hospital protocol for dressing change and exit site care. Allow alcohol-containing agents (e.g., Chloraprep* solution) to air dry completely before dressing catheter.
   WARNING: Acetone and PEG-containing ointments can cause failure of this device and should not be used with polyurethane catheters. Chlorhexidine patches or bacitracin zinc ointments (e.g., Polysporin* ointment) are the preferred alternative.
6. Verify the catheter tip location with x-ray or fluoroscopy.

Recommended Dressing Technique

1. Secure the catheter to the skin using one or two sterile tape strips.

   Optional: Place a pre-cut gauze dressing over the exit site, fitting it snugly around the catheter. Place a 2 in. x 2 in. (5 cm x 5 cm) gauze over the pre-cut gauze and catheter.



2. Apply a cover dressing, leaving the extension legs exposed. If using a sterile, transparent, semipermeable dressing, the following is recommended:

2a. Cut a 1-2 inch (3 - 5 cm) slit in the short side of the dressing using sterile scissors. Remove the backing sheet.

2b. Viewing catheter site through the dressing on the skin so that the slit is over the catheter hub. Press one side of dressing into place while holding the other side off the skin.

2c. Partially remove the frame portion of the dressing near the catheter hub which is already secured to the skin.

2d. Overlap the unsecured side of the dressing slightly over the secured side to seal dressing under catheter hub. Carefully remove the frame from the dressing while firmly smoothing down the edges. Smooth down the entire dressing.

WARNING: Acetone and PEG-containing ointments can cause failure of this device and should not be used with polyurethane catheters. Chlorhexidine patches or bacitracin zinc ointments (e.g., Polysporin* ointment) are the preferred alternative.

INSERTION TECHNIQUE (2) Surgical Cutdown Procedure:

The catheter may be inserted into the superior vena cava via the subclavian vein, external jugular vein or the internal jugular vein (standard operating room procedure). For surgical cutdown procedure, the patient should be placed in Trendelenburg position with the head turned to the opposite side of the entry site.

1. Go to A (Common Steps).
2. Skip B (Common Steps).
3. Skip C (Insertion Technique (1) Percutaneous Placement).
4. Locate the desired vessel for insertion of the catheter with a small incision. NOTE: If performing a jugular insertion and external vein is not of adequate size to accommodate the catheter, the internal vein may be used. A purse string suture may be used to secure catheter in the internal vein.
5. Make a small incision at the desired exit site of the catheter, in the area between the nipple and right sternal border. Make the incision just large enough to accommodate the implantable cuff.
6. Go to B (Common Steps).
7. If not using a stylet, the proximal end of the guidewire must be inserted into the small venous end hole of the distal-most tip, and threaded into the end hole of the arterial tip, passing through the arterial lumen until it extends out the arterial Luer-lock connector (red). If using stylet, thread the proximal end of the guidewire through the distal tip of the stylet until the guidewire extends out the stylet Luer-lock connector.
8. Insert the catheter through a small venotomy in the selected vein. Advance the catheter tip. Catheter tip placement, tip orientation and proper length selection is left to the discretion of the physician. However, routine x-ray should always follow the initial insertion to confirm proper placement of the catheter tips prior to use. The recommended tip location is at the junction of the superior vena cava/right atrium (SVC/RA) or in the mid right atrium.[6] All tip placements should be confirmed by fluoroscopy.
   CAUTION: For optimal product performance, do not insert any portion of the cuff into the vein.
   WARNING: Cardiac arrhythmias may result if the guidewire and/or stylet is allowed to touch the walls of the right atrium.
9. Remove the guidewire and stylet while applying forward pressure on the catheter so it does not withdraw.
   CAUTION: Ensure that the catheter does not move out of the vein while removing the insertion stylet.
10. Go to D (Common Steps)

INSERTION TECHNIQUE (3) Sheathless Procedure[2]:

For sheathless placement, the catheter is preferably inserted into the internal jugular vein. For the sheathless procedure, the patient should be placed in Trendelenburg position with the head turned to the opposite side of the entry site.

1. Go to A (Common Steps).
2. Go to B (Common Steps).
3. Skip C (Insertion Technique (1) Percutaneous Placement).
4. Sequentially dilate (guiding dilators over the guidewire), the venous puncture site to accommodate the catheter (dilate vessel to at least the same French size as the catheter, and preferably to 1.5 F larger).
5. After removing the dilator, keep the guidewire in the venous system while applying digital compression at the puncture site to maintain hemostasis.
6. If not using a stylet, the proximal end of the guidewire must be inserted into the small venous end hole of the distal-most tip, and threaded into the end hole of the arterial tip, passing through the arterial lumen until it extends out the arterial Luer-lock connector (red). If using stylet, thread the proximal end of the guidewire through the distal tip of the stylet until the guidewire extends out the stylet Luer-lock connector.

7. To minimize the risk of air embolism, clamp the venous extension leg (indicated by the blue Luer-lock connector).
8. Advance the catheter over the wire, until the tip reaches the desired location. Note that some resistance may be experienced when passing the catheter through the soft tissues, but this should subside once the catheter tip is intravascular.
   CAUTION: For optimal product performance, do not insert any portion of the cuff into the vein.
   WARNING: Cardiac arrhythmias may result if the guidewire and/or stylet is allowed to touch the walls of the right atrium.
9. Remove the guidewire and stylet (if applicable) while applying forward pressure on the catheter so it does not withdraw.
   CAUTION: Ensure that the catheter does not move out of the vein while removing the insertion stylet.
10. Go to D (Common Steps).

INSERTION TECHNIQUE (4) Femoral Vein Placement Procedure:

For femoral placement, the patient should be positioned supine, and the catheter tip should be inserted to the junction of the iliac vein and inferior vena cava.[3] WARNING: The risk of infection is increased with femoral vein insertion.
Note: Catheters greater than 40 cm are intended for femoral vein insertion.

1. Assess the right and left femoral areas for suitability for catheter placement. Ultrasound may be helpful.
2. On the same side as the insertion site, the patient's knee should be flexed, and the thigh abducted with the foot placed across the opposing leg.
3. Locate the femoral vein, posterior/medial to the femoral artery.
4. Go to A (Common Steps).
5. Go to B (Common Steps), directing tunnel laterally to decrease the risk of infection.[4]
6. Go to C (Insertion Technique (1) Percutaneous Placement).

Decathlon* DF Catheter Flow Rates, Venous and Arterial Pressures – Please refer to the insert for complete Flow Rate Information and Charts.

CARE AND MAINTENANCE

The care and and maintenance of the catheter requires well trained, skilled personnel following a detailed protocol. The protocol should include a directive that the catheter is not to be used for any purpose other than the prescribed therapy.

Accessing Catheter, Cap Changes, Dressing Changes[6]

- Experienced personnel
- Use aseptic technique
- Proper hand hygiene
- Clean gloves to access catheter and remove dressing and sterile gloves for dressing changes
- Surgical mask (1 for the patient and 1 for the healthcare professional)
- Catheter exit site should be examined for signs of infection and dressings should be changed at each dialysis treatment.
- Catheter Luer-lock connectors with end caps attached should be soaked for 3 to 5 minutes in povidone iodine and then allowed to dry before separation.
- Carefully remove the dressing and inspect the exit site for inflammation, swelling and tenderness. Notify physician immediately if signs of infection are present.

Exit Site Cleaning[11]

- Use aseptic technique (as outlined above).
- Clean the exit site at each dialysis treatment with chlorhexidine gluconate unless contraindicated. Apply antiseptic per manufacturer's recommendations. Allow to air dry completely.
- Cover the exit site with sterile, transparent, semipermeable dressing or per hospital protocol.

Recommended Cleaning Solutions

Catheter Luer-lock Connectors/End Caps:
- Povidone iodine (allow connectors/end caps to soak for 3 to 5 minutes) [8]

WARNING: Alcohol should not be used to lock, soak or declot polyurethane Dialysis Catheters because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.

Hand cleaner solutions are not intended to be used for disinfecting our dialysis catheter Luer-lock connectors.

Exit Site:
- Chlorhexidine gluconate 2% solution (preferred) [6, 10, 11, 12, 13]
- Chlorhexidine gluconate 4% solution
- Dilute aqueous sodium hypochlorite
- 0.55% sodium hypochlorite solution
- Povidone iodine
- Hydrogen peroxide
- Chlorhexidine patches
- Bacitracin zinc ointments in petrolatum bases

WARNING: Acetone and PEG-containing ointments can cause failure of this device and should not be used with polyurethane catheters. Chlorhexidine patches or bacitracin zinc ointments (e.g., Polysporin* ointment) are the preferred alternative.

POST DIALYSIS

Use aseptic technique (as outlined above).

1. Flush arterial and venous lumens with a minimum of 10 mL of sterile saline.
   WARNING: To avoid damage to vessels and viscus, infusion pressures must not exceed 25 psi (172 kPa). The use of a 10 mL or larger syringe is recommended because smaller syringes generate more pressure than larger syringes.
2. Inject heparin solution into both the arterial and venous lumens of the catheter. The appropriate heparin solution concentration and flushing frequency should be based on hospital protocol. Heparin solution of 1,000 to 5,000 units/mL has been found to be effective for maintaining the patency of hemodialysis and apheresis catheters. When injecting heparin solution, inject quickly and clamp extension while under positive pressure. Heparin solution volume to lock each lumen must be equal to the priming volume of each lumen. Priming volumes are marked on each lumen.
3. Clean catheter Luer-lock connectors per hospital protocol. Attach sterile end caps to both the arterial and the venous clamping extension pieces.
   WARNING: To prevent systemic heparinization of the patient, the heparin solution must be aspirated out of both lumens immediately prior to using the catheter. In most instances, no further heparin solution injection is necessary for 48-72 hours, provided the catheter has not been aspirated or flushed.

CATHETER REMOVAL

Evaluate the catheter routinely and promptly remove any nonessential catheter[11] per physician's orders. The white retention cuff facilitates tissue in-growth. The catheter must be surgically removed. Free the cuff from the tissue and pull the catheter gently and smoothly. After removing the catheter, apply manual pressure to the puncture site for 10-15 minutes until no signs of bleeding are present. Then apply sterile, transparent, semipermeable dressing or dressing per hospital protocol for a minimum of 8 hours. Follow hospital protocol regarding bedrest after catheter removal.

DISPOSAL

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and all applicable local, state and federal laws and regulations.

TROUBLESHOOTING

PATIENT WITH FEVER

Patient with fever and chills following the procedure may be indicative of catheter-related bacteremia. If bacteremia is present, removal of the catheter may be indicated.

INSUFFICIENT FLOW

Excessive force must not be used to flush an obstructed lumen. Insufficient blood flow may be caused by an occluded tip resulting from a clot or by contacting the wall of the vein. If manipulation of the catheter or reversing arterial and venous lines does not help, then the physician may attempt to dissolve the clot with a thrombolytic agent (e.g., TPA, Cathflo* Activase* thrombolytic). Physician discretion advised.

CATHETER EXCHANGE

Do not routinely replace dialysis catheters to prevent catheter-related infections[13]. It may become necessary to exchange the indwelling catheter due to a persistent rise in pressures or decrease of flow rates which cannot be rectified through troubleshooting. Catheter exchanges should be performed under strict aseptic conditions in which the physician should wear a cap, mask, sterile gown, sterile gloves, and use a large sterile drape to cover the patient.

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Other references available upon request.

An issued or revision date for these instructions is included for the users information. In the event two years have elapsed between this date and product use, the user should contact Bard Access Systems, Inc. to see if additional product information is available.

Revision date: August 2012.

BARD

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Attention, see instructions for use
LOT Lot Number
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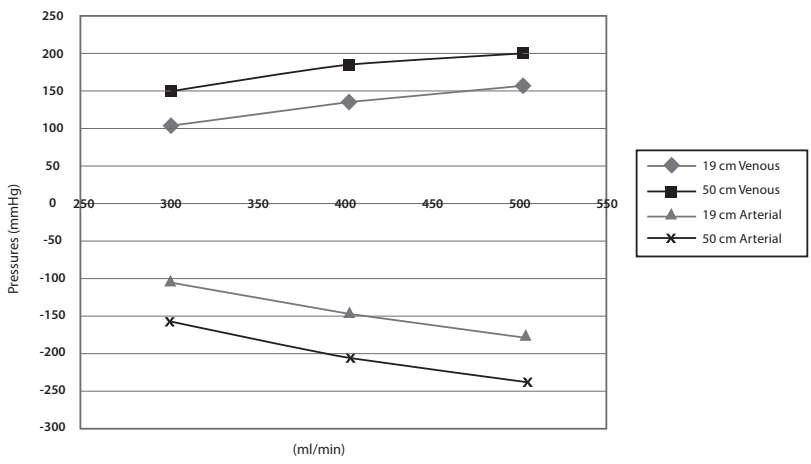
Non-pyrogenic
Manufacturer
Rx Only
This product does not contain DEHP
This product and packaging do not contain natural rubber latex
STERILE EO Sterilized using Ethylene oxide

0734702 1208R

DECATHLON* DF
Long-Term Hemodialysis Catheter

Flow Rate Information
Decathlon* DF Long Term Dialysis Catheter

Decathlon* DF Straight Catheter Flow Rate[2] vs Venous and Arterial Pressure[1]



1 As suggested by in vitro data, using a blood simulant approximating the viscosity of whole blood.
2 Testing using blood pump settings. See Instructions for Use.

Decathlon* DF Straight Catheter Flow Rate[2] vs Average Venous and Arterial Pressure[1]

19 cm				
Flow	Forward Flow (mmHg)		Reverse Flow (mmHg)	
(mL/min)	Venous	Arterial	Venous	Arterial
300	103	-106	92	-111
400	136	-143		
500	162	-173	141	-180

50 cm				
Flow	Forward Flow (mmHg)		Reverse Flow (mmHg)	
(mL/min)	Venous	Arterial	Venous	Arterial
300	151	-169	141	-165
400	180	-209		
500	199	-235	188	-241

1 As suggested by in vitro data, using a blood simulant approximating the viscosity of whole blood.
2 Testing using blood pump settings.

As issued or revision date for these instructions is included for the user's information. In the event two years have elapsed between this date and product use, the user should contact Bard Access Systems, Inc. to see if additional product information is available.
Revision Date: October 2012

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BARD

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