

vas-cath

**Soft-Cell® and Opti-Flow®
Hemodialysis Apheresis
Catheters**

Nursing Procedure Manual

Opti-Flow is not available in the U.S.

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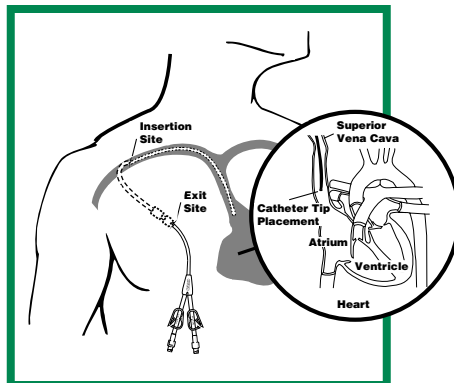
Introduction

Description of Catheters

The **Soft-Cell**® and **Opti-Flow**® Dual Lumen Catheters are made of Bodysoft® radiopaque polyurethane. The catheter comes with a Tissue Ingrowth Cuff for tissue anchoring and may be ordered with a VitaCuff Antimicrobial Cuff.

Placement

The catheter tip is placed via one of the large central veins and should dwell at the junction of the superior vena cava and the right atrium. The proximal end of the catheter is tunneled subcutaneously for several inches to the desired exit site. The Tissue Ingrowth Cuff, attached to the catheter, is positioned in the tunnel. The cuff helps secure the catheter through fibrous tissue ingrowth and creates a physical barrier to help reduce the potential for infection caused by the migration of bacteria through the subcutaneous tunnel.



Indications For Use

The **Vas-Cath Soft-Cell** and **Opti-Flow** dual lumen hemodialysis catheters are indicated for use in attaining short term or long term vascular access for hemodialysis, hemoperfusion or apheresis therapy via the jugular or subclavian vein.

VitaCuff® Antimicrobial Cuff

Description

The **VitaCuff** device is designed to help provide protection against infections related to vascular access catheters. The outer, tissue-interfacing surface of the **VitaCuff** device may help reduce the incidence of infection by incorporating an antimicrobial agent into the porous collagen matrix.

The **VitaCuff** device is comprised of two concentric layers of material.

The internal layer is constructed of specially formulated and processed medical grade silicone elastomer. The external, tissue-interfacing layer is VitaGuard® antimicrobial collagen matrix. The antimicrobial activity of the **VitaGuard** material is attributable to the silver ions bound to the collagen matrix. The activity lasts until the **VitaGuard** matrix is completely absorbed by the tissue in four to six weeks.

The **VitaGuard** collagen sponge is initially in a compressed state for ease of insertion. After placement, the matrix absorbs physiological fluids, quickly expands to approximately twice its original size, and helps provide an antimicrobial barrier and a physical barrier at the exit site.



Tissue ingrowth into the **VitaGuard** collagen matrix occurs in a few days, further securing the catheter in place, and reducing catheter movement.

CAUTION: The antimicrobial cuff is not intended to be used as a treatment for catheter related infections. The antimicrobial cuff does not provide protection against “blood seeding” infection or antimicrobial barrier and a physical infusate-related infection. It is not intended to provide protection from bacteria for longer than one month.

Contraindications

1. The device is contraindicated for: use in patients with severe thrombocytopenia or coagulopathy.
2. The antimicrobial cuff should not be used on patients with known sensitivities to silver ions or collagen.

Warnings

Signs of Pinch-off - Subclavian Placements Only

Clinical:

- Difficulty with blood withdrawal
- Resistance to infusion of fluids
- Patient position changes required for infusion of fluids or blood withdrawal

Radiologic:

- Grade 1 or 2 distortion on chest X-ray.
Pinch-off should be evaluated for degree of severity prior to explantation. Patients indicating any degree of catheter distortion at the clavicle/first rib area should be followed diligently. There are grades of pinch-off that should be recognized with appropriate chest x-ray as follows:^{1,2}

Grade	Severity	Recommended Action
Grade 0	No distortion	No action.
Grade 1	Distortion present without luminal narrowing	Chest x-ray should be taken every one to three months to monitor progression of pinch off to grade 2 distortion. Shoulder positioning during chest x-rays should be noted as it can contribute to changes in distortion grades.
Grade 2	Distortion present with luminal narrowing	Removal of the catheter should be considered.
Grade 3	Catheter transection or fracture	Prompt removal of the catheter.

- **Use of ointments with this catheter can cause failure of this device.**
- Alcohol or acetone based solutions should not be used to clean the catheter or skin site as the clamping extensions and luer lock connectors may be adversely affected. Povidone iodine solution is the recommended antiseptic solution to be used.
- 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.
- Place all clamps only near the center of the polyurethane extension pieces. Polyurethane 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.
- Enzymes in blood and heparin may cause temporary sticking of the extensions when clamped for extended periods of time. To release, open clamp and slide away, gently rotating the tube between fingers and thumb until the tubing separates.
- Before dialysis begins, all connections to the extracorporeal circuit must be checked carefully. During all dialysis procedures frequent visual inspection must be conducted to detect leaks and prevent blood loss or entry of air into the extracorporeal circuit and check that the extensions are intact. Excess blood leakage may lead to patient shock.

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- Accessories and components used in conjunction with this catheter must incorporate luer-lock adapters.
 - Failure to clamp extensions when not in use may lead to air embolism.
 - Repeated over tightening of blood lines, syringes and caps may reduce connector life and may 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.
 - In the rare event of a leak, the catheter must be clamped immediately. Necessary remedial action must be taken prior to resuming dialysis or infusion procedure.
 - To avoid damage to vessels and viscus, infusion pressures should not exceed 25 psi. The use of a 10cc or larger syringe is recommended because smaller syringes generate more pressure than larger syringes. Note: A three pound force on the plunger of a 3cc syringe generates pressure in excess of 25 psi whereas the same three pound force on the plunger of a 10cc syringe generates less than 10psi of pressure.
 - When catheter damage or connector separation occurs, the catheter should be immediately clamped or kinked closed to prevent any possibility of air embolism or loss of blood.
 - Follow Universal Precautions when inserting and maintaining this device.
 - The heparin solution must be aspirated out of both lumens immediately prior to using the catheter to prevent systemic heparinization of the patient.

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
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catheter or Cuff Erosion Through Skin
- Catheter Embolism
- Catheter or Cuff Occlusion
- Catheter Occlusion, Damage or Breakage due to Compression Between the Clavicle and First Rib
- Catheter-related Sepsis
- Endocarditis
- Exit Site Infection
- Exit Site Necrosis
- Extravasation
- Fibrin Sheath Formation
- Hematoma
- Hemothorax
- Hydrothorax
- Inflammation, Necrosis or Scarring of the Skin Over Implant Area
- Intolerance Reaction to Implanted Device
- Laceration of Vessels or Viscus
- Perforation of Vessels or Viscus
- Pneumothorax
- Spontaneous Catheter Tip Malposition or Retraction
- Thoracic Duct Injury
- Thromboembolism
- Venous Thrombosis
- Ventricular Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local and General Anesthesia, Surgery, and Post-Operative Recovery

These and other complications are well documented in medical literature and should be carefully considered before placing the catheter.

References:

1. Hinke, D.H.; Zandt-Stastny, D.A.; Goodman, L.R.; et al. Pinch-off syndrome: A complication of implantable subclavian venous access devices. *Radiology* 177: 353-356, 1990.
2. Ingle, Rebecca,; Nace, Corinne, Venous Access Devices: Catheter Pinch-off and Fracture, 1993, **Bard Access Systems**



emodialysis and Apheresis Catheter Irrigation Procedure

Purpose

To maintain catheter patency.

Routine Maintenance

Prior to initiation of therapy or reinstallation of fresh heparinized saline, the indwelling heparin should be aspirated from the catheter and the lumen(s) flushed with 10cc sterile normal saline. Flush each lumen with 10cc sterile normal saline and then heparin lock as per protocol ensuring correct volume for the catheter.

Supplies

- Povidone-iodine wipes
- 2 10cc syringes with attached 1 in. needle, filled with 10cc normal saline
- 2 10cc syringes filled with catheter priming volume of heparinized saline

NOTE: The appropriate heparin concentration and flushing frequency should be based on the duration of the interdialytic period, patient's medical condition, laboratory tests, and prior experience. Heparin concentrations of 1000-5000 USP units/ml have been found to be effective for maintaining the patency of hemodialysis and apheresis catheters.

Recommended Heparin Protocol

1. Aspirate heparin lock pre-dialysis.
2. Flush both lumens pre and post dialysis with a minimum 10cc saline. For Opti-Flow catheters, the minimum is 16cc saline.
3. The most effective and commonly used heparin concentration is 5,000 units/ml/lumen.
4. Total volume of each heparin solution must be equal to the internal volume of each lumen.
5. Inject heparin quickly to ensure the heparin completely fills the lumens of the catheter.
6. Maintain positive pressure while clamping extensions and attach sterile injection caps.
7. Re-heparinize with the recommended heparin concentration post dialysis.

References:

1. Paul, Jan; Conrad, Diann; Dunagan, Colleen. Management of Dialysis Catheters; Journal of Intravenous Nursing, Vol. 20 No. 5, September/October 1997.
2. Haire, William D., Edney, James A; Landmark, James D., Kessinger, Anne. "Thrombotic Complications of Subclavian Apheresis Catheters in Cancer Patients: Prevention with Heparin Infusion, Journal of Clinical Apheresis 188-191 (1990)

Catheter Removal

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.

Disposal

After use, the catheter and accessories may be a potential bio-hazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Post Dialysis

To maintain patency between treatments a heparin lock must be created in each lumen of the catheter. Inject 5000 units of heparin per ml. of saline (or a concentration approved by your institution) into each lumen in amounts equal to the priming volume of each lumen. To ensure that each lumen is totally filled, inject vigorously and clamp extension while under positive pressure. Attach a sterile injection cap to each clamping extension.

Priming Volumes:

Soft-Cell Catheters

Insertion	Arterial Volume	Venous Volume
12 cm	1.3cc	1.4cc
19 cm	1.5cc	1.6cc
23cm	1.7cc	1.8cc

**Straight*

Opti-Flow Catheters

Insertion Length	Arterial Volume	Venous Volume
19 cm	1.9mL	2.0mL
23 cm	2.1mL	2.2mL
27cm	2.3mL	2.4mL
35cm	2.5mL	2.7mL

**Pre-curved (PC)*

Insertion Length	Arterial Volume	Venous Volume
19 cm	1.9mL	2.0mL
23 cm	2.1mL	2.2mL
27cm	2.3mL	2.4mL

**Pre-curved (PC-2)*

Insertion Length	Arterial Volume	Venous Volume
19 cm	2.1mL	2.2mL
23 cm	2.2mL	2.3mL

Performance Guidelines:

Opti-Flow Catheter Flow rate vs venous pressures*

	250 ml/min	400 ml/min
Forward	116 mm/Hg	166 mm/Hg
Reverse	93 mm/Hg	141 mm/Hg

* As suggested by *In vitro* data

Note: Reverse flow will result in higher recirculation

Soft-Cell Catheter Flow rates*

250-300 mL/min



Dressing Change Procedure

Purpose

To prevent infection of the hemodialysis catheter.

Frequency

Change sterile dressing over exit site at each treatment.

Care and Maintenance

The care 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.

*Sterile technique, including face mask, handwashing and sterile gloves must be used for procedures.

Procedure

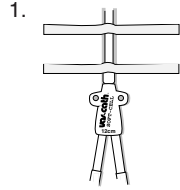
1. Follow aseptic technique throughout catheter care.
2. Wash hands thoroughly.
3. Carefully remove old dressing and discard. Avoid tugging on the catheter, or the use of scissors, or other sharp objects near the catheter.
4. The catheter exit site must be checked daily. Inspect catheter exit site for swelling, inflammation, or exudate. Notify physician if signs of infection are present.
5. Wash hands thoroughly.
6. Put on sterile gloves.
7. Clean catheter exit site with an antimicrobial solution following your institution's protocol.

Dress the Catheter

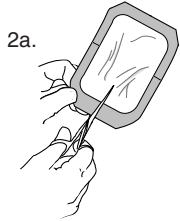
Warning: Use of ointments with this catheter can cause failure of this device.

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

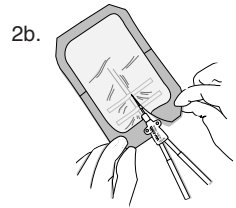
Optional: Place a pre-cut gauze dressing over the exit site, fitting it snugly around the catheter. Place a 2 in. x 2 in. (5 cm x 5 cm) gauze over the pre-cut gauze and catheter. Apply the cover dressing per the following.



2. Apply a cover dressing, leaving the extension legs exposed. If using an occlusive or film-style dressing, the following is recommended.
 - 2a. Cut a 1-2 inch (3-5 cm) slit in the short side of an occlusive dressing using sterile scissors. Remove the backing sheet.



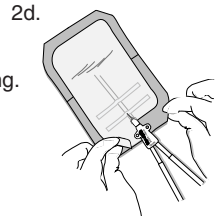
- 2b. Viewing catheter site through the dressing, place the dressing on the skin so that the slit is over the catheter hub. Press one side of dressing into place while holding the other side off the skin.



- 2c. Partially remove the frame portion of the dressing near the catheter hub that has already been secured to the skin.



- 2d. Overlap the unsecured side of the dressing slightly over the secured side to seal dressing under the catheter hub. Carefully remove the frame from the dressing while firmly smoothing down the edges. Smooth down the entire dressing. **Please do not use any ointments in either the exit site care or in the catheter extension leg dressing.**



References:

Howard, M. Patricia, Eisenberg, Patti G. Gianino, M. Stephanie, "Dressing a Central Venous Catheter a Better Way", Nursing, March 1992, pgs. 60-61

Core Curriculum for Nephrology Nursing, Third Edition: American Nephrology Nurses Association, 1995

Clearing Occluded Catheters

Purpose

To restore patency to an occluded catheter.

Supplies

- 1 - Sterile injection cap
- 5,000 IU/cc urokinase (catheter priming volume) 2,4,5,6,7
- 1 - 10cc syringe with attached 1 in. needle
- 1 - 10cc sterile normal saline-filled syringe with attached 1 in. needle
- Povidone-iodine wipes

Procedure

1. Wash hands.
2. Apply smooth-edged atraumatic clamp to silicone clamping sleeve.
3. Remove injection cap, attach an empty 10cc syringe, release clamp, and attempt to aspirate. If aspiration is successful, withdraw clots, clamp catheter, and attach saline-filled syringe. Release clamp and flush catheter with 10 ml. normal saline. Clamp catheter. Replace cap per Injection Cap Change Procedure. If aspiration is unsuccessful, proceed to step 4.

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4. Obtain physician's order for the use of urokinase 5,000 IU/cc to de clot the catheter.
 5. Draw up enough urokinase 5,000 IU/cc into a 10cc syringe to equal the internal volume of the catheter
 6. Aseptically attach the urokinase-filled syringe to the catheter hub. Release clamp and slowly and gently inject the urokinase solution into the catheter. To avoid catheter rupture, do not force entire amount into catheter.
 7. Leave 10cc syringe attached to catheter. Do not attempt to aspirate for 30-60 minutes.
 8. After 30-60 minutes, attempt to aspirate the drug and residual clot. If unsuccessful, repeat urokinase instillation.
 9. When patency is restored, aspirate 5cc of blood to assure removal of all drug and clots.
 10. Clamp catheter, remove blood-filled syringe, and replace it with a 10cc syringe filled with normal saline. Open clamp and flush catheter to verify patency.
 11. Clamp catheter and remove syringe.
 12. Attach sterile heparin-filled injection cap and flush catheter with heparin per Catheter Irrigation Procedure.

References:

1. Bjeletich, J., "Declotting Central Venous Catheters with Urokinase in the Home by Nurse Clinicians", NITA, Nov/Dec 1987, pp. 428-430.
2. Faubion, WC, Bollish, SJ, Wesley, JR, "Central Venous Catheter Occlusion Treated by Thrombolytic Agents", Nutritional Support Services, Vol. 3, No. 2, 1983, pp. 24-26.
3. Pennington, CR, Pithic, AD, "Ethanol Lock in the Management of Catheter Occlusion", Journal of Parenteral & Enteral Nutrition, Vol. 11, No. 5, 1987, pp. 507-508.

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4. Shulman, RJ, Reed, T., Pitre, D., Laine, L., "Use of Hydrochloric Acid to Clear Obstructed Central Venous Catheters," *Journal of Parenteral & Enteral Nutrition*, Vol. 12, No. 6, 1988, pp. 509-510.
 5. Holcombe, BJ, Forloines-Lynn, S, Garmhausen, LW, "Restoring Patency of Long-Term Central Venous Access Devices", *Journal of Intravenous Nursing*, Vol. 15, No. 1, January/February 1992, pp. 36-41.
 6. Northsea, Cynthia, "Using Urokinase to Restore Patency in Double Lumen Catheters.", *ANNA Journal*, August 1994, Vol. 21 No. 5
 7. Bagnall-Reeb, Holly, Ryder, Marcia, Anglin, Mary Ann, "Venous Access Device Occlusions, Independent Study Module, Oncology Nursing Society, 1993 Abbott Laboratories.



Troubleshooting Guide

I. Aspiration Difficulties

A. Possible Causes

1. Failure to flush according to Catheter Irrigation Procedure, resulting in lumen obstruction.
2. Catheter tip sucking up to vein wall with aspiration.
3. Blood clot, fibrin sheath, or particulate matter obstructing lumen when catheter is aspirated.
 - A clot or other obstruction in the catheter lumen can produce a one-way valve effect. During infusion, the catheter wall expands slightly and allows fluid to flow around the plug. During aspiration, the catheter wall contracts slightly, tightening down around the obstruction and preventing aspiration.
 - Fibrin sheaths usually begin to form within a few days after the insertion of a central venous catheter. If it has grown enough to extend to the tip of the catheter, it may be pulled into and obstruct the catheter opening when aspiration is attempted, but offer no resistance to infusion.
4. Compression or transection of the catheter between the clavicle and first rib (“pinch-off area”).
5. Kinked catheter outside or inside the body.
 - Suture constriction at the catheter skin exit site, cuff, or vessel insertion site.
 - Catheter may be pulled too tight through skin tunnel, causing kink at vessel insertion site, or where it curves into the subcutaneous tunnel.
 - Catheter may be curled or kinked within the vessel, or under the dressing.
 - Catheters with pre-curve design must be maintained in their pre-curved position.

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6. Malposition of catheter tip (i.e. jugular vein, outside of vein).
 7. Improper catheter length selection for patient size.

B. Possible Solutions

1. Visually check catheter for any exterior kinks, or constricting sutures. Check operative report, or with placement physician, for placement of sutures. If sutures are present, their removal may release the constriction and allow aspiration, if sufficient time has elapsed for tissue ingrowth.
2. If no resistance to infusion is felt, attempt to flush with 10cc normal saline. Then pull back gently on syringe plunger 2-3cc, pause and proceed with aspiration.
3. If resistance to infusion is felt, check for signs of extravasation. If present, notify physician of possible catheter leakage or transection and embolization. If not present, see step 5.
4. Attempt to aspirate with a 20cc syringe (creates a greater vacuum).
5. Move patient's arm, shoulder and head to see if a change in position will allow aspiration. If aspiration can only be accomplished with the patient in a certain position, the patient should be examined to see if the catheter has been placed in the "pinch-off" area. See step 7.
6. Obtain physician's order and instill urokinase 5000 IU/ml per Clearing Occluded Catheters Procedure.
7. Obtain physician's order for a chest x-ray or dye study to determine the position of the catheter.
 - If the catheter tip is not in the superior vena cava, the catheter should be repositioned.
 - If the catheter tip is not in a vein, the catheter should be replaced.
 - If the catheter has been placed through the "pinch-off" area, between the clavicle and the first rib, and is being compressed enough to interfere with infusion or aspiration, it is at risk for catheter transection and embolization. The physician should evaluate the patient for catheter replacement.

References:

Aitken, Delmar R., and Minton, John P., "The Pinch-Off Sign": A Warning of Impending Problems with Permanent Subclavian Catheters". American Journal of Surgery, Vol. 148, November 1984, pp. 633-636.

Rubenstein, Richard B., et al, "**Hickman** Catheter Separation", Journal of Parenteral and Enteral Nutrition, Vol. 9, No. 6, Nov/Dec 1985, pp. 754-757.

II. Patient with Fever

Infection:

Symptoms:

- Inflammation at exit site
- Fever
- Positive site culture/ or blood cultures.

If signs of infection are present:

- Notify physician
- Culture site drainage, follow hospital protocol for central-line site infection.
- Cleanse area as per site maintenance care.

III. Insufficient Flow

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

IV. Catheter Exchange

It may become necessary to exchange the indwelling catheter over a guidewire due to infection or a persistent rise in pressures or decrease of flow rates which cannot be rectified through troubleshooting.

Catheter Occlusion

A. Possible Causes

1. Blood clot completely obstructing lumen.
2. May be kinked, coiled, damaged, or compressed between the clavicle and the first rib.
3. Catheter tip may not be within vein.
4. If sutures were used during the placement of the catheter, they can tighten and restrict flow.
5. May be partially or completely transected. Transection can occur from the repeated pressure of the clavicle and the first rib on the catheter during normal movement if it is placed through the “pinch-off” area. For Subclavian placements only.

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6. Improper catheter length for patient size.
 7. Venous lumens must be cephalad for straight and pre-curved catheters .

B. Possible Solutions

1. Attempt to aspirate blood clot.
2. Move patient's arm, shoulder and head to see if position change affects ability to infuse. If so, see step 5 (could be pinch-off).
3. Inspect patient and operative report for presence of sutures around the catheter. If sutures are too tight, they should be removed.
4. Obtain physician's order and instill urokinase or other solution per Clearing Occluded Catheters Procedure.
5. Obtain physician's order for a chest x-ray or dye study to determine the position of the catheter.
 - If the catheter tip is not in the superior vena cava, the catheter should be repositioned.
 - If the catheter tip is not in a vein, the catheter should be replaced.
 - If the catheter has been placed through the "pinch-off" area, between the clavicle and the first rib, and is being compressed enough to interfere with infusion or aspiration, it is at risk for catheter transection and embolization. The physician should evaluate the patient for catheter replacement.

References:

See "Aspiration Difficulties."

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Patents Pending.

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