POST DIALYSIS

1. To maintain patency between treatments a heparin lock must be created in each lumen of the catheter.
2. 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.

WARNING: The heparin solution must be aspirated out of both lumens immediately prior to using the catheter to prevent systemic heparinization of the patient.

Priming Volumes		
Insertion Length (cm)	*Arterial Volume (ml)*	*Venous Volume (ml)*
Sraight		
12	1.4	1.4
19	1.6	1.7
Pre-Curved		
12 PC & PC-2	1.4	1.4
15 PC-2	1.5	1.6
17 PC-2	1.6	1.6
19 PC	1.6	1.7
19 PC2	1.7	1.7
23 PC & PC-2	1.8	1.8

Performance Guideline: Flow Rate vs Lumen Pressure	
Soft Cell* Catheter (19cm. STR)	
	300 ml/min
Venous	178 mmHg
Arterial	-215 mmHg

CARE AND MAINTENANCE

1. 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.
2. The exit site should be checked daily. Sterile technique, including facemask, hand washing and sterile gloves must be used for these procedures.
3. Carefully remove the dressing and inspect the exit site for inflammation, swelling and tenderness. Notify physician immediately if signs of infection are present.
4. Clean the exit site with an antimicrobial solution following your institution's protocol. Clean from the catheter working outward in a circular motion.
5. **WARNING: Acetone and PEG-containing ointments can cause failure of this device and should not be used with polyurethane catheters. Chlorhexidine patches are the preferred alternative.**
6. Dress the catheter as described above under "D (Common Steps)."

TROUBLESHOOTING

PATIENT WITH FEVER
Unusual signs or symptoms (i.e. fever, chills) occurring immediately following the procedure may indicate septic thrombosis. If this does result, the catheter should be removed.

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

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

REFERENCES:

1 Aitken, D.R. and Minton, J.P. "The Pinch-Off Sign: A Warning of Impending Problems with Permanent Subclavian Catheters", American Journal of Surgery, Vol. 148, Nov. 1984, pp.633-638.
2 Mickley, V., "Central venous catheters: many questions: few answers", Nephrol Dial Transplant, (2002) 17:1368-1373.
3 National Kidney Foundation K/DOQI GUIDELINES 2000.
4 Sulek, CA., Blas, ML., Lobato, EB "A randomized study of left versus right internal juglar vein cannulation in adults." J Clin Anesth. 2000 Mar;12(2):142-5.
5 Tan, P.L., Gibson, M., "Central Venous Catheters: the role of radiology", Clin Rad. 2006, 61:13-22.
6 Octavio, Bella, Colemenares, Garcia, and Flores; "Right Versus Left Internal Vein Catheterization for Hemodialysis: Complications and Impact on Ipsilateral Access Creation"; Artifical Organs; 2004 28(8):728-733.

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: December, 2007

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BARD

BARD **Access Systems**

Soft-Cell* Dual Lumen Catheter

Instructions For Use
For Soft-Cell* Straight and Precurved (PC) Catheters

DESCRIPTION

The straight and pre-curved polyurethane catheter with white retention cuff is divided into two separate lumens by a septum allowing hemodialysis without the use of a "single needle" system.

CAUTION: STERILE AND NON-PYROGENIC ONLY IF PACKAGING IS NOT OPENED, DAMAGED OR BROKEN.

STERILE EO STERILIZED WITH ETHYLENE OXIDE.

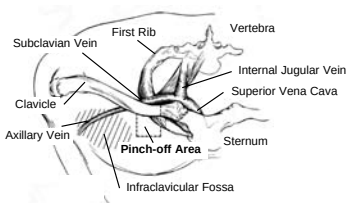
SINGLE PATIENT USE ONLY.

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.

INDICATIONS FOR USE

The **Soft-Cell*** dual lumen hemodialysis catheter is indicated for use in attaining short-term or long-term vascular access for hemodialysis, hemoperfusion or apheresis therapy via the jugular or subclavian vein.



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]

WARNINGS

- **Acetone and PEG-containing ointments can cause failure of this device and should not be used with polyurethane catheters. Chlorhexidine patches are the preferred alternative.**
- 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.
- Do not resterilize the catheter or components by any method. The manufacturer will not be liable for any damages caused by re-use of the catheter or accessories.
- Place all clamps only in 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.
- 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 force (13.3 N) on the plunger of a 3 ml syringe generates pressure in excess of 30 psi (206 kPa) whereas the same three pound force (13.3N) on the plunger of a 10 ml syringe generates less than 15psi (103 kPa) of pressure.
- Follow Universal Precautions when inserting and maintaining this device.
- Accessories and components used in conjunction with this catheter should incorporate luer-lock adapters.
- Catheters should be implanted carefully to avoid any sharp or acute angles which could compromise the opening of the catheter lumens.
- To prevent air embolism and/or blood loss, place thumb over the exposed orifice of the sheath introducer.
- 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.
- Do not allow the guidewire to further advance into the vein. Cardiac arrythmias may result if the guidewire is allowed to pass into the right atrium.
- 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 vien.[4]

CAUTION

- 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.
- Left sided placement in particular, may provide unique challeges due to the right angles formed by the innominate vein and at the left brachiocephalic junction with the SVC.[2,5]
- Care should be taken NOT to force the dilator shealth introducer assembly into the vessel during insertion as vessel damage including perforation could result.
- Before attempting the insertion of **Soft-Cell*** catheters, ensure that you are familiar with the following complications and their emergency treatment should any of them occur.

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 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
- 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
- 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. Placement and care of **Soft-Cell*** hemodialysis catheters should be performed by persons knowledgeable of the risks involved and qualified in the procedures.

INSERTION TECHNIQUE (1) Percutaneous Placement Procedure of the **Soft-Cell*** catheter with Cuff using the **Bard Access Systems** Split-Kit* Introducer System:

For percutaneous placement, the catheter is inserted in either the subclavian vein, external jugular or internal jugular through a 13F split sheath. It has been reported that right side, internal juglar placement is the preferred initial location of consideration for percutanenous insertion.[3,6] 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.[4]

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.[2,5]

1. Provide a sterile field throughout the procedure. Gloves, masks, gowns, sterile drapes and equipment must be used.
2. Place the patient in the Trendelenburg position with the head turned to the opposite side of the entry site.
3. Prepare the access site using standard surgical technique and drape the prepped area with sterile towels. Since the catheter is inserted into the right atrium, the right side of the patient is preferred because it offers a more direct route to the right atrium.
4. Administer local anaesthesia to the insertion site and the path for subcutaneous tunnel (if applicable).
5. Flush each lumen with heparinized saline prior to insertion and clamp the extension tubes.
6. Follow normal accepted practices for vessel puncture with an introducer needle.
7. Insert the desired tip of the guidewire through the introducer needle into the vessel. If using the "J" end of the guidewire, pull back on the wire with your thumb until the tip of the Trigger* guidewire dispenser is flush with the distal tip of the wire. The "J", now straight, can be inserted into the needle hub and the guidewire passed through the needle. Advance the guidewire to the desired location in the vessel.
8. Remove the needle while holding the guidewire in place. Wipe the guidewire clean and secure it in place.
   CAUTION Do not pull back guidewire over needle bevel as this could sever the end of the guidewire. The introducer needle must be removed first.
9. Make a small incision at the insertion site. Make a second incision at the desired exit site of the catheter.
10. B (Common Steps).

B (COMMON STEPS)

1. With a tunneler, create a short subcutaneous tunnel from the exit site to emerge at the venous entry site. Attach the catheter to the tunneler so that the catheter can be threaded through the tissue as the tunnel is created. If using the **Bard Access Systems** tunneler, slide the sheath found on the tunneler over the venous tip/tunneler connection and ensure open end of sheath is covering the arterial opening of the catheter. This will reduce the drag on the arterial protrusion in the skin tunnel. (After positioning cuff, tunneler can be removed by sliding sheath away from the catheter and twisting and pulling tunneler from venous tip.)
   THE CATHETER SHOULD NOT BE FORCED THROUGH THE TUNNEL.
2. Position the white retention cuff approximately midway between the skin exit site and the venous entry site, about 2cm minimum, from the venous entry site.

C (PERCUTANEOUS PLACEMENT)

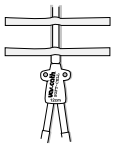
1. Fill the catheter lumens with heparinized saline. It is recommended that the venous lumen, as indicated by the blue luer connector, be oriented cephalad. (Should be automatic with pre-curved version of catheter).
2. Advance the dilator sheath introducer assembly over the exposed guidewire into the 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. [2,5]
   WARNING: Do not allow the guidewire to further advance into the vein. Cardiac arrythmias may result if the guidewire is allowed to pass into the right atrium.
3. 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.
4. Remove thumb and feed distal section of catheter into the sheath introducer.
5. 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.
6. D (Common Steps).

D (COMMON STEPS)

1. To check catheter patency attach a 10 ml syringe with sterile normal saline to each lumen of the catheter. Release the catheter clamp and aspirate blood through each lumen. Once flow is satisfactory, flush both lumens with heparinized saline in amounts equal to the priming volume of each lumen. Clamp each lumen immediately.
   WARNING: FAILURE TO CLAMP CAN LEAD TO AIR EMBOLISM.
2. For additional security, suture the entry site.
3. Manage the exit site per your institution's protocol.
4. Dress the catheter.
   WARNING: USE OF PEG-CONTAINING OINTMENTS WITH THIS CATHETER CAN CAUSE FAILURE OF THIS DEVICE.

Recommended Dressing Technique

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



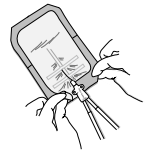
Optional: Place a pre-cut gauze dressing over the exit site, fitting it snugly around the catheter. Place a 2 in. x 2 in. (5 cm x 5 cm) gauze over the pre-cut gauze and catheter.

2. Apply a cover dressing, leaving the extension legs exposed. If using an occlusive or film-style dressing, the following is recommended:

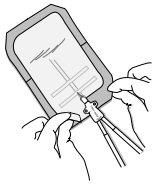
2a. Cut a 1-2 inch (3 - 5 cm) slit in the short side of an occlusive dressing using sterile scissors. Remove the backing sheet.

2b. Viewing catheter site through the dressing 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.



Please do not use any PEG-containing ointments in either the exit site care or in the catheter extension leg dressing.

5. Verify the catheter and tip location with x-ray or fluoroscopy.

INSERTION TECHNIQUE (2) Surgical Cutdown Procedure:

The catheter may be inserted in the subclavian vein, external jugular vein or the internal jugular vein. (standard operating room procedure).

1. Go to A (Common Steps).
2. 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.
3. 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.
4. Go to B (Common Steps).
5. Fill the catheter lumens with heparinized saline. Insert the catheter through a small venotomy in the selected vein. Advance the catheter tip to the desired location at the junction of the superior vena cava and right atrium. It is recommended that the venous lumen, as indicated by the blue luer connector, be oriented cephalad. (Should be automatic with pre-curved version of catheter) The cuff should be outside of the vein.
6. Go to D (Common Steps)

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 biohazard. Handle and dispose of in accordance with accepted medical practice and with applicable local, state and federal laws and regulations.