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 must be checked daily. Sterile technique, including face mask, 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 daily with chlorhexidine gluconate or povidone iodine.
5. Cover the exit site with occlusive 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.

CATHETER REMOVAL
After removing the catheter, apply manual pressure to the puncture site for 10-15 minutes until no signs of bleeding are present. Then apply an occlusive dressing for 8 hours.

DISPOSAL
After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and 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 sepsis. If this results, 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 occluded arterial holes resulting from a clot or by side holes contacting the wall of the vein. If manipulation of the catheter through rotation or reversing arterial and venous lines does not help, then the physician may attempt to clot the clot with a thrombolytic agent (e.g. 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. If this or the recommended 3 day femoral or 4 week subclavian/jugular indwelling period has elapsed, then a straight "over the guidewire exchange" can be used at the physician's discretion.

REFERENCE

REFERENCES

Other references available upon request.

Radiologic Signs of Pinch-Off

<table>
<thead>
<tr>
<th>Grade</th>
<th>Severity</th>
<th>Recommended Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 0</td>
<td>No Distortion</td>
<td>No action.</td>
</tr>
<tr>
<td>Grade 1</td>
<td>Distortion present without luminal narrowing</td>
<td>Chest x-ray should be taken 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.</td>
</tr>
<tr>
<td>Grade 2</td>
<td>Distortion present with luminal narrowing</td>
<td>Removal of the catheter should be considered.</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Catheter transaction or fracture</td>
<td>Prompt removal of the catheter.</td>
</tr>
</tbody>
</table>

Signs of Pinch-off

Clinical:
• Difficulty with blood withdrawal.
• Resistance to infusion of fluids.
• Patient position changes required for infusion of fluids or blood withdrawal.

Radiologic (see table)
• 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

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2. Polysporin is a registered trademark of Johnson & Johnson, Inc. or an affiliate.

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Bard Access Systems, Inc.
605 North 5600 West
Salt Lake City, UT 84116 U.S.A.
801-522-5000
Clinical Information Hotline: 1-800-443-3385
Ordering Information: 1-800-545-0890

0719617 0901R

WARNINGS
• SUBCLAVIAN ONLY. Pinch-off Prevention: Percutaneous insertion of the catheter must be made into the axillary-subclavian vein at the junction of the outer and mid-third of the clavicle lateral to the thoracic outlet. The catheter must 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. Fluoroscopic or radiographic confirmation of catheter tip placement can be helpful in demonstrating that the catheter is not being pinched by the first rib and clavicle.

An 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 the product use, the user can contact Bard Access Systems, Inc. to see if additional product information is available. Revision date: January, 2009.
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 tubing between fingers and thumb until the tubing separates.

To avoid damage to vessels and vascus, infusion pressures must not exceed 25 psi (172 kPa). The use of a 10 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 must incorporate Luer-lock adapters in order to avoid inadvertent disconnection.

Catheters should be implanted carefully to avoid any sharp or acute angles which could compromise the opening of the catheter lumens.

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. Excess blood leakage may lead to patient shock.

In the rare event of a leak, the catheter must be clamped immediately. Necessary remedial action must be taken prior to resuming dialysis procedures.

If the dual lumen catheter is not used immediately for treatment, follow the suggested Catheter Patency Guidelines.

Failure to clamp extensions when not in use may lead to air embolism.

Verify the catheter tip location must be confirmed by x-ray to ensure proper placement.

For optimal product performance and to avoid complications, do not insert any portion of the curve into the vein.

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

For jugular and subclavian insertion, the patient must be placed on a cardiac monitor during this procedure. Cardiac arrhythmia may result if the guidewire is allowed to pass into the right atrium.

15. Pinch guidewire and Niagara* catheter together, advance together in 5 to 10 cm increments (retract wire as needed). Do not twist the catheter during over-the-needle insertion.

16. The five depth markings in one cm. increments may be used to determine insertion depth. The insertion line (just below rotatable suture wing), represents total insertion length.

Make sure the catheter (blue lumen) is cephalad (closest to the head). This will help prevent arteriofemoral insufficiency of the catheter during dialysis. The catheter tip must be in the lower superior vena cava for optimal performance.

CAUTION: For jugular and subclavian insertion, the catheter tip must be located above the junction of the superior vena cava and right atrium.

17. The flexible end of a guidewire is inserted through the introducer needle into the vein. Squeeze the suture wing together so that it splits open and place the wing around the catheter near the venipuncture site.

18. The guidewire and venous insertion stylet are removed, and the venous clamp is closed. Both lumens are irrigated again with heparinized saline filled syringes. (It is necessary to open the extension clamps during the irrigation procedure). Both the arterial and venous clamps are now closed and the injection caps are placed over the ends of each Luer-lock connector on the extension pieces.

19. The rotatable, pre-attached suture wing is oriented to the skin surface and the catheter is attached using either a Statlock* stabilization device or suture.

20. When placing the catheter, use the removable suture wing to minimize movement at the exit site. 1.) Using your fingers, squeeze the suture wing together so that it splits open and place the wing around the catheter near the venipuncture site. 2.) Secure the wing onto the catheter by tying sutures around the wing using the suture grooves. 3.) Secure the removable wing in place by suturing through the holes or by using adhesive wound closures.

WARNING: For optimal product performance and to avoid complications, do not insert any portion of the curve into the vein.

21. A sterile adhesive transparent dressing is used to cover the skin exit site.

22. The Niagara* dual lumen catheter is now ready for use. The arterial lumen of the catheter is connected to the arterial side of the extracorporeal circuit. The venous lumen of the catheter is connected to the venous side of the extracorporeal circuit.

CATHETER PATENCY GUIDELINES

1. Flush arterial and venous lumens with a minimum of 10 ml of sterile saline.

2. Inject a heparin solution of 5000 units per 500 ml of saline into both the arterial and venous lumens of the catheter. When injecting heparin, inject quickly to insure that the heparin completely fills the lumen of the catheter. The total volume of each heparin solution must be equal to the internal volume of each lumen. Each lumen must be completely filled with a heparin solution. The priming volume is indicated on each lumen.

3. Attach the sterile injection 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 injection is necessary for 48-72 hours, provided the catheter has not been aspirated or flushed.

PERFORMANCE GUIDELINES: Flow rate vs venous pressures

As suggested by In vitro data, using a blood simulae approximating the viscosity of whole blood.

Niagara* (13.5 F)

<table>
<thead>
<tr>
<th>Configuration</th>
<th>Arterial</th>
<th>Venous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Straight (24 cm)</td>
<td>190 mmHg</td>
<td>-164 mmHg</td>
</tr>
<tr>
<td>Pre-Curved (20 cm)*</td>
<td>187 mmHg</td>
<td>-206 mmHg</td>
</tr>
<tr>
<td>Curved Extension (24 cm)*</td>
<td>197 mmHg</td>
<td>-175 mmHg</td>
</tr>
</tbody>
</table>

Niagara* Slim-Cath* (12.0 F)

<table>
<thead>
<tr>
<th>Configuration</th>
<th>Arterial</th>
<th>Venous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Straight (24 cm)</td>
<td>156 mmHg</td>
<td>-151 mmHg</td>
</tr>
<tr>
<td>Pre-Curved (20 cm)*</td>
<td>221 mmHg</td>
<td>-148 mmHg</td>
</tr>
<tr>
<td>Curved Extension (24 cm)</td>
<td>183 mmHg</td>
<td>-171 mmHg</td>
</tr>
</tbody>
</table>

* Pre-Curved: Pre-curved catheter shaft with straight extension legs. (Not for sale in the United States)  
Curved Extension: Straight catheter shaft with curved extension legs. (For sale only in the United States)