

Instructions For Use



**Groshong<sup>®</sup> NXT** &  
NXT ClearVue<sup>®</sup>  
**PICCs**



**BAIRD**

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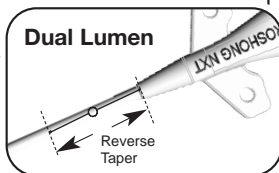
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## Product Description

**Groshong\* NXT** peripherally inserted Central Catheters are made from specially formulated and processed medical grade materials, in a tray with accessories for reliable long (greater than 30 days) or short (less than 30 days) term vascular access.

- The **Groshong NXT** dual-lumen catheter features a reverse-taper catheter design.
- For Superior Vena Cava (SVC) placement, measure from the planned insertion site to the right clavicular head, then down to the third intercostal space. Use the 45 or 55cm mark as reference for point of insertion.
- Catheter does not require "s" curve for dressing and securement.



### Groshong\* Valve Function

The **Groshong\*** catheter incorporates the patented, 3-position, pressure-sensitive **Groshong\*** valve. The valve is located near the rounded, closed, radiopaque catheter tip and allows fluid infusion and blood aspiration. When not in use, the valve restricts blood backflow and air embolism by remaining closed.

The **Groshong\*** valve is designed to remain closed between -7 and 80 mm Hg. Since the normal central venous pressure range in the superior vena cava is 0 to 5 mm Hg, the valve remains closed at normal central venous pressure. Pressure in the superior vena cava must exceed 80 mm Hg to open the valve inward. Also, negative pressure (vacuum) will cause the valve to open inward, allowing blood aspiration.

Positive pressure into the catheter (gravity, pump, syringe) will open the valve outward, allowing fluid infusion. The need for the anticoagulant effect of heparin is eliminated because the closed valve prevents blood from entering the catheter and clotting. If the catheter is aspirated, pulling the valve inward, it must be flushed with normal saline to clear blood from the lumen and allow the valve to return to its normal closed position.



**ASPIRATION**  
Negative Pressure



**INFUSION**  
Positive Pressure



**CLOSED**  
Neutral Pressure

**The benefits provided by the Groshong\* valve are:**

1. Increased patient safety due to reduced risk of air embolism or bleedback.
2. Elimination of the need for heparin flushing to maintain catheter patency.
3. Reduced need for catheter clamping.
4. Reduced need for flushing when the catheter is not in use.

**Groshong\* NXT** dual-lumen catheters have **Groshong\*** valves which are rotated and staggered, allowing the simultaneous infusion of incompatible drugs. Refer to the appropriate drug labeling for indications, contraindications, warnings, precautions, dosage and administration information. Each lumen of a dual-lumen catheter is treated separately for maintenance and irrigation purposes.

## **Indications**

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The **Groshong\* NXT** PICC provides short (less than 30 days) or long (greater than 30 days) term peripheral access to the central venous system for intravenous therapy or blood sampling.

## **Contraindications:**

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The **Groshong\* NXT** PICC is contraindicated whenever:

- The presence of device related infection, bacteremia, or septicemia is known or suspected.
- The patient's body size is insufficient to accommodate the size of the implanted device.
- Past irradiation of prospective insertion site.
- Previous episodes of venous thrombosis or vascular surgical procedures at the prospective placement site.
- Local tissue factors will prevent proper device stabilization and/or access.

## **ChlorPrep\* One-Step Applicator Contraindications:**

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- Do not use in children less than 2 months of age because of the potential for excessive skin irritation and increased drug absorption.
- Do not use on patients with known allergies to chlorhexidine gluconate or isopropyl alcohol.

- Do not use for lumbar puncture or in contact with meninges.
- Do not use on open skin wounds or as a general skin cleanser.

### Warnings:

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#### Groshong\* NXT PICC

- Intended for Single Patient Use. **DO NOT REUSE. Bard Access Systems, Inc.** products are single use devices and should never be reimplanted. Reuse carries with it the attendant concern of cross-infection regardless of the cleaning or sterilization method. Resterilization of incompletely cleaned devices may not be effective. Any device that has been contaminated by blood should not be reused or resterilized.
- This is not a right atrium catheter. Avoid positioning the catheter tip in the right atrium. Placement or migration of the catheter tip into the right atrium may cause cardiac arrhythmia, myocardial erosion or cardiac tamponade. The risk of these complications may be more likely in neonatal patients.
- After use, this product may be a potential biohazard. Handle and discard in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

#### ChloroPrep\* One-Step Applicator

- Flammable, keep away from fire or flame.
- Do not use with electrocautery procedures.
- For external use only.
- When using this product keep out of eyes, ears, and mouth. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a physician.
- Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.
- Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

### Precautions:

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- Carefully read and follow all instructions prior to use.
- **Caution:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- Only qualified healthcare practitioners should insert, manipulate and remove these devices.
- To minimize the risk of catheter breakage and embolization, the suture wing and / or adapter must be secured in place.

- Never use force to remove the stylet. Resistance can damage the catheter. If resistance or bunching of the catheter is observed, stop stylet withdrawal and allow the catheter to return to normal shape. Withdraw both the catheter and stylet together approximately 2 cm and reattempt stylet removal. Repeat this procedure until the stylet is easily removed.
- To reduce potential for blood backflow into the catheter tip, always remove needles or needleless caps slowly while injecting the last 0.5 ml of saline.
- Follow Universal Precautions when inserting and maintaining the catheter.
- Follow all contraindications, warnings, precautions and instructions for all infusates as specified by its manufacturer.
- Use aseptic techniques whenever the catheter lumen is opened or connected to other devices. Chlorhexidine gluconate is the suggested antiseptic to use. Acetone and tincture of iodine should not be used. 2% Chlorhexidine gluconate /70% isopropyl alcohol swabsticks may be used for dressing changes. Povidone-iodine may also be used as an antiseptic.
- The fluid level in the catheter will drop if the catheter connector is held above the level of the patient's heart and opened to air. To help prevent a drop in the fluid level (and thus air entry) while changing injection caps, hold the connector below the level of the patient's heart before removing the injection cap.

***I. Prior to beginning placement procedure, do the following:***

- Examine the package carefully before opening to confirm its integrity and that the expiration date has not passed. The device is supplied in a sterile package and is non-pyrogenic. Do not use if package is damaged, opened or the expiration date has passed. Sterilized by ethylene oxide. Do not Resterilize.
- Inspect kit for inclusion of all components.
- Flush the catheter with sterile normal saline prior to use.

***II. To avert device damage and/or patient injury during placement.***

- Avoid accidental device contact with sharp instruments and mechanical damage to the catheter material. Use only smooth-edged atraumatic clamps or forceps.
- Avoid perforating, tearing or fracturing the catheter when using a guidewire.
- Do not use the catheter if there is any evidence of mechanical damage or leaking.
- Avoid sharp or acute angles during implantation which could compromise the patency of the catheter lumen(s).

- Use suture wings to secure the catheter without compromising catheter patency.
- Do not place sutures around catheter.

### **III. After placement, observe the following precautions to avoid device damage and/or patient injury:**

- Do not use the device if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture, fragmentation and possible embolism and surgical removal.
- Accessories and components used in conjunction with this device should incorporate Luer lock connections.
- If signs of extravasation exist, discontinue injections. Begin appropriate medical intervention immediately.
- Infusion pressure greater than 25 psi (172 kPa) may damage blood vessels and viscus and is not recommended. **DO NOT USE A SYRINGE SMALLER THAN 10 ml!**
- For those unfamiliar with the procedure, published studies and a video are available from **Bard Access Systems, Inc.** depicting insertion and maintenance techniques.
- For further information or questions, please call 800-443-3385 or 801-595-0700.

## **Possible Complications**

The potential exists for serious complications including the following:

- Air Embolism
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catheter Erosion Through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter-related Sepsis
- Endocarditis
- Exit Site Infection
- Exit Site Necrosis
- Extravasation
- Fibrin Sheath Formation
- Hematoma
- Intolerance Reaction to Implanted Device
- Laceration of Vessels or Viscus
- Myocardial Erosion
- Perforation of Vessels or Viscus
- Phlebitis
- Spontaneous Catheter Tip Malposition or Retraction
- Thromboembolism
- Venous Thrombosis
- Ventricular Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local or General Anesthesia, Surgery and Post Operative Recovery

## Insertion Instructions

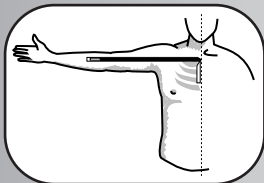
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### 1. Identify the Vein and Insertion Site



- Apply a tourniquet above the anticipated insertion site.
- Select a vein based on patient assessment. Veins of the antecubital fossa are recommended (basilic, cephalic median cubital veins) with the basilic preferred.
- Release tourniquet.

### 2. Patient Position/ Catheter Measurement



- Position the arm at a 90° angle.
- For SVC placement, measure from the planned insertion site over to the sternal notch, then down to the third intercostal space.
- Note that the external measurement can never exactly duplicate the internal venous anatomy.

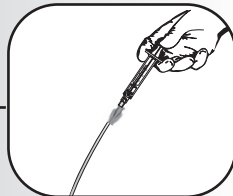
### 3. Preflush the Catheter

#### Dual Lumen



- Attach prefilled syringe to the Luer attachment on the extension set.
- Preflush catheter with sterile normal saline or heparinized saline to wet hydrophilic stylet.
- The syringe may be left attached during procedure.

#### Single Lumen



- Attach prefilled syringe to luer attachment on flushable stylet.
- Preflush catheter with sterile normal saline or heparinized saline to wet stylet.
- The syringe may be left attached during procedure.

### 4. Prepare for Insertion

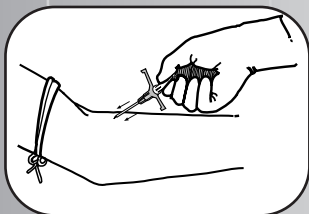
- Set-up the sterile field.
- Prepare the site with the **ChloraPrep\*** One-Step Applicator or according to institutional policy using sterile technique.
  - Pinch the wings on the **ChloraPrep\*** One-Step Applicator to break the ampule and release the antiseptic. **Do not touch the sponge.**
  - Wet the sponge by repeatedly pressing and releasing the sponge against the treatment area until fluid is visible on the skin.
  - Use repeated back-and-forth strokes of the sponge for approximately 30 seconds. Completely wet the treatment area with antiseptic. Allow the area to dry for approximately 30 seconds.
- **Do not blot or wipe away.**
  - Maximum treatment area for one applicator is approximately 130 cm<sup>2</sup> (approximately 4 x 5 in.). Discard the applicator after a single use.
- Remove and discard gloves.

### 5. Apply Tourniquet and Drape

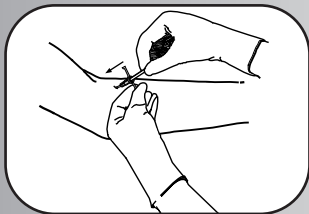
- Apply the tourniquet above the intended insertion site to distend the vessel.
- Put on sterile non-powdered gloves. Powdered gloves should be washed before use.
- Drape the patient by placing the fenestrated drape over the anticipated puncture site.

### 6. Perform Venipuncture

#### Splittable

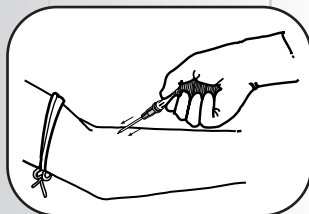


- Remove the needle guard.
- Grip only the needle hub during insertion. Do not apply excessive pressure to the T-handles.
- Perform venipuncture and observe for flashback.

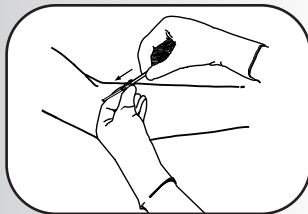


- Holding the needle stationary, advance the introducer sheath into the vessel by pushing forward.

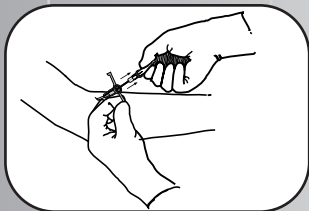
#### Non-Splittable



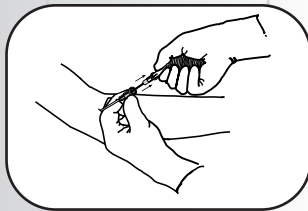
- Remove the needle guard.
- Grip only the needle hub during insertion.
- Perform venipuncture and observe for flashback.



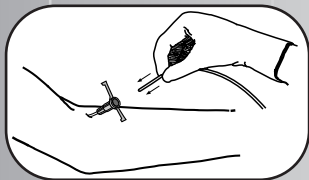
- Holding the needle stationary, advance the introducer sheath into the vessel by pushing forward.

**7. Withdraw the Introducer Needle****Splitable**

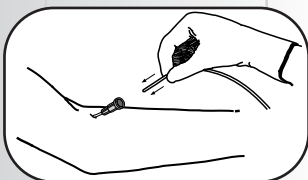
- Support the introducer sheath to avoid displacement.
- Apply slight pressure on the vessel above the insertion site to minimize blood flow.
- Release the tourniquet.
- Withdraw the needle from the introducer sheath.

**Non-Splitable**

- Support the introducer sheath to avoid displacement.
- Apply slight pressure on the vessel above the insertion site to minimize blood flow.
- Release the tourniquet.
- Withdraw the needle from the introducer sheath.

**8. Insert and Advance the Catheter****Splitable**

- Insert the catheter into the introducer.
- Advance the catheter slowly.

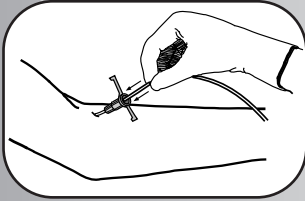
**Non-Splitable**

- Insert the catheter into the introducer.
- Advance the catheter slowly.

Note: Resistance may be felt approximately 7cm distal of catheter hub when introducing the dual-lumen catheter into the sheath due to an increase in O.D. The introducer may be partially split, but not removed to facilitate insertion of the catheter past this point if necessary.

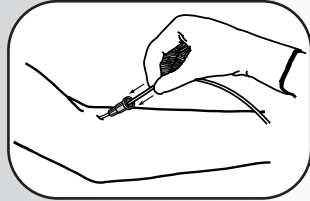
### 9. Complete Catheter Insertion

#### Splitable



- Continue to advance the catheter. For central placement, when the tip has advanced to the shoulder, have the patient turn head (chin on shoulder) toward the insertion side to prevent possible cannulation into the jugular vein.
- Position the arm at a 90° angle, maintaining sterility. Complete catheter advancement to the desired position (45 or 55cm mark). Catheter depth markings are in centimeters.

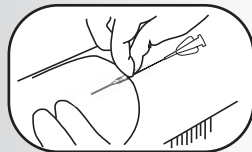
#### Non-Splittable



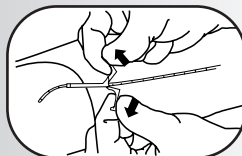
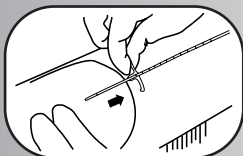
- Continue to advance the catheter. For central placement, when the tip has advanced to the shoulder, have the patient turn head (chin on shoulder) toward the insertion side to prevent possible cannulation into the jugular vein.
  - Position the arm at a 90° angle, maintaining sterility. Complete catheter advancement to the desired position (45 or 55cm mark). Catheter depth markings are in centimeters.
- **Warning:** This is not a right atrium catheter. Avoid positioning the catheter tip in the right atrium. Placement or migration of the catheter tip into the right atrium may cause cardiac arrhythmia, myocardial erosion or cardiac tamponade. The risk of these complications may be more likely in neonatal patients.

### 10a. Non-Splittable Introducer

- Introducer sheath is left on the catheter at this time.



### 10b. Remove Splitable Introducer



- Stabilize the catheter position by applying pressure to the vein distal to the introducer sheath.
- Withdraw the introducer sheath from the vein and away from the site.
- Split the introducer sheath and peel it away from the catheter.

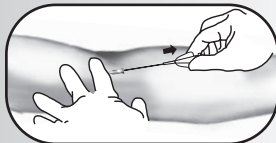
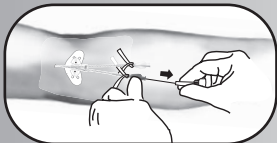
### 11. Attach Suture Wings



- A. If the single or dual lumen catheter **is not** inserted to the bifurcation/connector;
- Remove the suture wing from the delivery card
  - Squeeze the suture wing together so that it splits open
  - Place the suture wing around the catheter near the venipuncture site
  - Apply **StatLock\*** stabilization device to the suture wing and secure to skin
- B. If the catheter **is** inserted to the bifurcation/connector;
- Apply **StatLock\*** stabilization device to the catheter and secure to skin

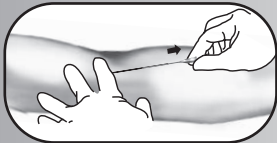
**Caution** To minimize the risk of catheter breakage and embolization, the suture wing, “Y” adapter, and/or connector must be secured in place. See step 18.

### 12. Remove the Stylet/ Assembly



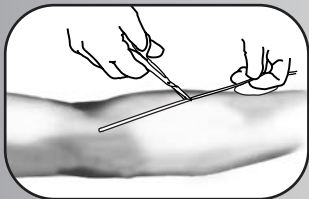
- Stabilize the catheter position by applying light pressure to the vein distal to the insertion site.
- Slowly remove the stylet.
- **Caution:** Never use force to remove the stylet. Resistance can damage the catheter. If resistance or bunching of the catheter is observed, stop stylet withdrawal and allow the catheter to return to normal shape. Withdraw both the catheter and stylet together approximately 2 cm and reattempt stylet removal. Repeat this procedure until the stylet is easily removed.

### 13. Remove Non-Splittable Introducer



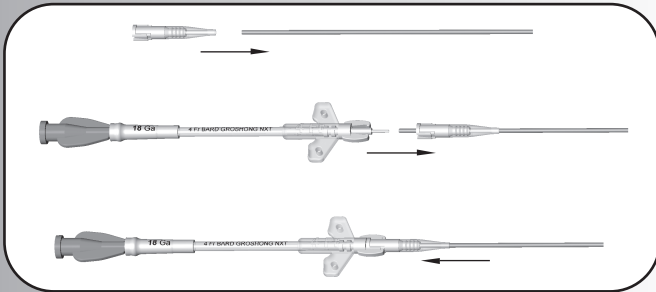
- Remove non-Splittable introducer.
- Slide the non-Splittable introducer off the proximal end of the catheter.

### 14. Modification of Catheter Length *Single Lumen Catheters Only*



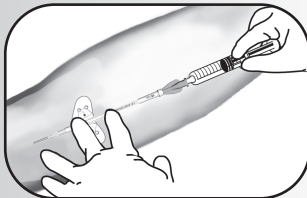
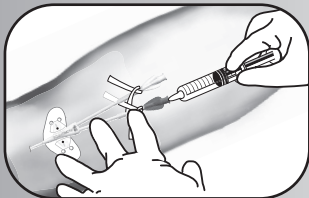
- Using a sharp scalpel or sterile scissors, carefully cut the catheter leaving at least 4 cm to 7 cm of the catheter for connector attachment.
- Inspect cut surface to assure there is no loose material.

### 15. Attach Connector to Single Lumen Catheters



- Retrieve the oversleeve portion of the connector and advance it over the end of the catheter. If you feel some resistance while advancing the oversleeve, gently twist back and forth or spin to ease its passage over the catheter.
- Gently advance the catheter onto the connector blunt until it butts up against the colored plastic body. The catheter should lie flat on the blunt without any kinks.
- With a straight motion, slide the oversleeve portion of the connector and the **StatLock**<sup>\*</sup> stabilization device compatible connector with extension leg together, aligning the grooves on the oversleeve portion of the connector with the barbs on the **StatLock**<sup>\*</sup> stabilization device compatible connector and extension leg. Do not twist.  
**Note:** Connector portions must be gripped on plastic areas for proper assembly. Do not grip on distal portion of oversleeve.
- Advance completely until the connector barbs are fully attached. A tactile, locking sensation will confirm that the two pieces are properly engaged. There may be a small gap between the oversleeve and the **StatLock**<sup>\*</sup> stabilization device compatible connector with extension leg.

### 16. Aspirate and Flush



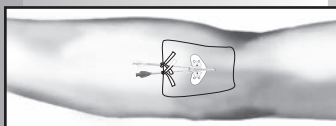
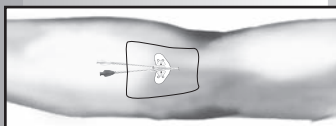
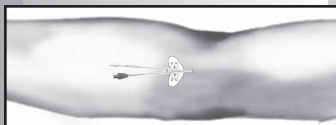
- Attach primed extension set and/or saline-filled syringe.
- Aspirate for adequate blood return and flush each lumen of the catheter with 10ml normal saline to ensure patency.
- **Note:** When infusion volume is a concern in small or pediatric patients, flush with 3ml per lumen.
- **Note:** If the single-lumen catheter will not aspirate and infuse immediately after insertion and connector assembly, the catheter may be kinked within the connector assembly. If this is the case, trim the catheter just distal to the connector oversleeve (clear) and attach a new connector following step 15 for proper assembly. If this situation persists, verify radiographically that the catheter is not kinked inside the vessel.
- **Caution:** To reduce potential for blood backflow into the catheter tip, always remove needles or needleless caps slowly while injecting the last 0.5 ml of saline.

### 17. Verify Placement

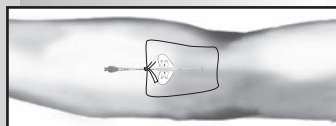
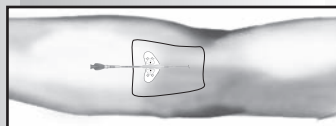
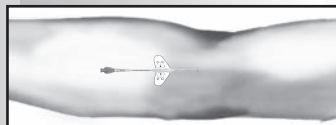
- Verify catheter tip location radiographically.

**18. Securing the Groshong\* NXT PICC:**

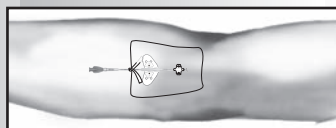
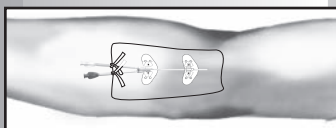
**Dual-Lumen  
insertion to bifurcation**



**Singe-Lumen insertion**



**Catheter inserted within 7cm of bifurcation**



## **Suggested Catheter Maintenance**

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The catheter should be maintained in accordance with standard hospital protocols.

Suggested catheter maintenance is as follows:

- **Dressing Changes**

Assess the dressing in the first 24 hours for accumulation of blood, fluid or moisture beneath the dressing. During all dressing changes, assess the external length of the catheter to determine if migration of the catheter has occurred. Periodically confirm catheter placement, tip location, patency and security of dressing.

- **Flushing**

For intermittent use, flush the catheter with saline once each week or after each use. **Note:** When infusion volume is a concern in small or pediatric patients, flush with 3ml per lumen. **Caution:** To reduce potential for blood backflow into the catheter tip, always remove needles or needleless caps slowly while injecting the last 0.5 ml of saline.

- **Occluded or Partially Occluded Catheter**

Catheters that present resistance to flushing and aspiration may be partially or completely occluded. Do not flush against resistance. If the lumen will neither flush nor aspirate and it has been determined that the catheter is occluded with blood, a declotting procedure per institution protocol may be appropriate.

## **Catheter Removal**

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- Remove dressing.
- Grasp catheter near insertion site.
- Remove slowly. Do not use excessive force.
- If resistance is felt, stop removal. Apply warm compress and wait 20-30 minutes.
- Resume removal procedure.
- Examine catheter tip for completeness and to determine that the entire catheter has been removed.

## ChloraPrep One-Step Applicator Active Ingredients

- Chlorhexidine gluconate 2% w/v...antiseptic
- Isopropyl alcohol 70% v/v...antiseptic

## Inactive Ingredients

- USP purified water

For further information or questions regarding ChloraPrep One-Step Applicator call:  
1-800-523-0502 (8 a.m.-5 p.m. CST)

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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 product use, the user should contact **Bard Access Systems, Inc.** to see if additional product information is available.

Revised date: March, 2007

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Covered by one or more of the following U. S. Patents: D498,844; 5160,325; 5,810,789.

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