

Hickman\*

 **TriFusion\***  
Catheter

Triple Lumen Long-Term  
Central Venous Catheter

**Instructions For Use**

**BAIRD**

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# Introduction

## Description:

**Hickman\* TriFusion\*** Triple Lumen Long-Term Central Venous Catheter is constructed of specially formulated and processed polyurethane. The catheters are radiopaque with female luer locking adapters and SureCuff\* tissue ingrowth cuff for fixation of the catheters in a subcutaneous tunnel. Each catheter is provided in a double sterile package.

## Placement:

The catheter is placed into one of the large central veins so the tip lies in the superior vena cava above the right atrium. It is tunnelled subcutaneously to the desired exit site. The **SureCuff\*** Tissue Ingrowth Cuff, attached to the catheter, is positioned 3-5 cms below the skin exit site in the tunnel. The cuff promotes tissue ingrowth to secure the catheter in place.

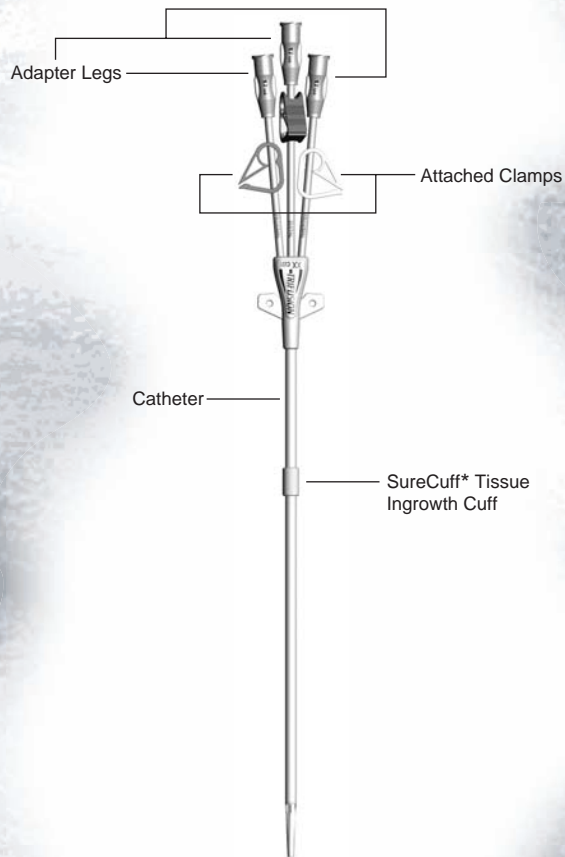
## Use of Lumens:

Use the distal lumen, as indicated by the blue clamp, for blood return and during apheresis. Use a proximal lumen, as indicated by the red or white clamp, for blood products.

Hickman\*

TriFusion\*

Triple Lumen Long-Term  
Configuration



## Indications For Use

The **Hickman\* TriFusion\*** Triple Lumen Long-Term Central Venous Catheter is indicated for use in attaining short-term or long-term vascular access for intravenous infusion therapy and blood sampling via the internal jugular vein, external jugular vein, and subclavian vein.

All **Hickman\* TriFusion\*** catheters are designed for apheresis, and the administration of I.V. fluids, blood products, drugs, and parenteral nutrition solutions, as well as blood withdrawal. The **Hickman\* TriFusion\*** catheter incorporates three large, equal size lumens appropriate for apheresis procedures.

# Contraindications, Warnings, and Precautions

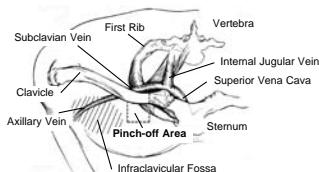
## Contraindications

The device 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.
- The patient is known or is suspected to be allergic to materials contained in the device.
- Severe chronic obstructive lung disease exists (percutaneous subclavian placement only.)
- 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.

## Warnings:

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 may cause to compression of the catheter between the first rib and clavicle which can lead to damage or fracture and embolization of the catheter.<sup>1</sup> 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.<sup>1</sup>



## Continued Warnings:

### 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:

- 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: 2,3

Grade	Severity	Recommended Action
Grade 0	No distortion	No action.
Grade 1	Distortion present <b>without</b> 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.

- When using alcohol or alcohol containing antiseptics with polyurethane catheters, care should be taken to avoid prolonged or excessive contact. Solutions should be allowed to completely dry before applying an occlusive dressing. Chlorhexidine gluconate and/or povidone iodine are the suggested antiseptics to use.
- Alcohol should not be used to soak or clot polyurethane catheters because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.
- Ensure the solution is completely dry before applying an occlusive dressing.

## Continued 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.
- Cardiac arrhythmias may result if the guidewire is allowed to pass into the right atrium.
- 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 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.
- To avoid damage to vessels and viscus, infusion pressures should not exceed 25 psi (172 kPa). The use of a 10ml 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 3ml syringe generates pressure in excess of 30 psi (206 kPa) whereas the same three pound (13.3 Newton) force on the plunger of a 10ml 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 all 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 the infusion procedure.
- 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.
- Do not exceed flow rates of 140 ml per minute.

## Precautions:

- Carefully read and follow all instructions prior to use.
- Only qualified healthcare practitioners should insert, manipulate and remove these devices.
- 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.
- Sterilized with Ethylene Oxide.
- Single Patient Use Only
- **CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.
- Follow Universal Precautions when inserting and maintaining the catheter.
- Follow all contraindications, warnings, cautions, precautions and instructions for all infusates as specified by its manufacturer.

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

- Examine package carefully before opening to confirm its integrity and that the expiration date has not passed. The device is supplied in a double 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.
- Fill (prime) each lumen of the device with sterile heparinized saline or normal saline solution to help avoid air embolism.
- When using an introducer kit, verify that the catheter fits easily through the introducer sheath.

### 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.

## Continued Precautions:

- 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).
- If sutures are used to secure the catheter, make sure they do not occlude or cut the catheter.
- When using percutaneous introducers:
  - Carefully insert the introducer and catheter to avoid inadvertent penetration to vital structures in the thorax.
  - To avoid blood vessel damage, do not allow the percutaneous introducer sheath to remain indwelling in the blood vessel without the internal support of a catheter or dilator.
  - Simultaneously advance the sheath and dilator with rotational motion to help prevent sheath damage.
- **CAUTION:** If the 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.
- **CAUTION:** Care should be taken not to advance the introducer sheath too far into vessel as a potential kink would create an impasse to the catheter.
- **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.

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

- Do not use the catheter if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to retraction, 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!**

## 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 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.

Before attempting the insertion of Hickman\* TriFusion\* catheters, ensure that you are familiar with the above complications and their emergency treatment should any of them occur.

Placement and care of Hickman\* TriFusion\* catheters should be performed by persons knowledgeable of the risks involved and qualified in the procedures.

# Hickman\* TriFusion\* Triple Lumen Long-Term Central Venous Catheter Placement Procedures

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

## **A (COMMON STEPS). CATHETERS MUST BE INSERTED UNDER STRICT ASEPTIC CONDITIONS.**

1. Provide a sterile field throughout the procedure. Gloves, masks, gowns, sterile drapes and equipment must be used.
2. Prepare the access site using standard surgical technique and drape the prepped area with sterile towels.
3. (If applicable) Administer local anaesthesia to the insertion site and the path for subcutaneous tunnel.
4. Flush each lumen with heparinized saline prior to insertion and clamp the extension legs.
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 guidewire into the needle. Advance the 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 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 guidewire, using a slight rotational motion. Advance the unit into the vein as far as appropriate.
  - Withdraw the dilator and guidewire, leaving the small sheath in place.
  - **WARNING:** To prevent air embolism and/or blood loss, place thumb over the exposed orifice of the sheath introducer.

8. 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.
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:** If the 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.
11. Make a small incision at the insertion site. Make a second incision at the desired exit site of the catheter.
12. B (Common Steps).

## **B (COMMON STEPS)**

1. With a tunneler, create a subcutaneous tunnel from the catheter exit site to emerge at the venous entry site. Attach the catheter to the tunneler so that the catheter’s distal 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. If using the **Bard Access Systems, Inc.** tunneler, slide the sheath found on the tunneler over the distal tip/tunneler connection and ensure the open end of sheath is covering the proximal tip. This will reduce the drag on the proximal tip in the skin tunnel. (After positioning cuff, tunneler can be removed by sliding sheath away from the catheter and pulling tunneler from distal 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.
2. Advance the dilator sheath introducer assembly over the exposed guidewire into the vessel.

**WARNING:** Cardiac arrhythmias 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 if placement will not be over the guidewire. If the catheter will be placed over the guidewire, remove the vessel dilator and leave the guidewire in place.

**CAUTION:** Care should be taken not to advance the introducer 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 and over the guidewire if still in place. Advance the catheter tip to the junction of the superior vena cava and right atrium.
5. With the catheter advanced, remove the guidewire if still in place and 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.

6. D (Common Steps).

#### D (COMMON STEPS)

1. To check catheter patency attach a 10ml 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, or use a StatLock\* device to anchor the catheter.
3. Manage the exit site per your institution's protocol.
4. Dress the catheter.

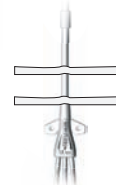
**WARNING:** Acetone and PEG-containing ointments can cause failure of this device and should not be used with polyurethane catheters. Chlorhexidine patches are the preferred alternative.

5. Verify the catheter and 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 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.

Do not use any acetone or PEG containing ointments in either the exit site care or in the catheter extension leg dressing. Chlorhexidine patches are recommended for this use.





## INSERTION TECHNIQUE ( 2 ) Surgical Cutdown Procedure:

The catheter may be inserted into the superior vena cava via the sub-clavian 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. 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. Insert the catheter through a small venotomy in the selected vein. Advance the catheter tip to the junction of the superior vena cava and right atrium. It is recommended that the distal lumen, as indicated by the blue clamp, be oriented cephalad.  
**CAUTION:** For optimal product performance, do not insert any portion of the cuff into 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.

After use, the catheter and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and all applicable laws and regulations.

## Patient Information - Catheter Care and Maintenance

### CARE AND MAINTENANCE

1. Povidone iodine, dilute aqueous sodium hypochlorite solution, chlorhexidine gluconate 4%, or chlorhexidine gluconate 2% solution are the suggested antiseptics to use.  
**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.
2. 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.
3. The exit site should be checked daily. Aseptic technique, including facemasks, for nurse and patient hand washing, and gloves must be used for these procedures.
4. Carefully remove the dressing and inspect the exit site for inflammation, swelling and tenderness. Notify physician immediately if signs of infection are present.
5. Clean the exit site with an antimicrobial solution following your institution's protocol. Clean from the catheter working outward in a circular motion.
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 lumen resulting from a clot or by contacting the wall of the vein. If manipulation of the catheter or reversing lumens 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.

## Clamping the Catheter

Selection of the catheter clamp is very important since the catheter is vital to your care. The wrong clamp can damage the catheter. Follow these three rules for clamping:

1. Use only smooth-edged clamps.
2. Follow the directions of your doctor or nurse regarding when to clamp.

Hickman\* TriFusion\* catheters come with pre-attached clamps.



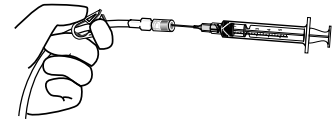
## Flushing the Catheter and "Heparin Lock" Procedure

### Supplies you will need:

- Alcohol or povidone iodine wipe.
- 10ml syringe with attached 1 inch (2.5 cm) needle filled with 2.5 ml of heparin, prepared for use
- Tape

### The steps in the procedure are:

1. Collect your supplies in a convenient place.
2. Wash your hands thoroughly.
3. Remove the tape that is around the injection cap.
4. Clean the cap with an alcohol or povidone iodine wipe. If you use the iodine wipe, allow the cap to air dry for two minutes -- be sure not to touch the cap during this time. Do not blow on the area or allow the clean cap to dangle since this increases the chance of contamination of the area with germs.
5. Remove the needle cover and carefully insert the needle into the center of the catheter injection cap.
6. Release the clamp.
7. Inject the heparin into the catheter. As you inject the last 0.5 ml of heparin solution, withdraw the needle from the injection cap. If you are flushing the catheter of a child, do not flush too rapidly because the child's circulatory system is small and sensitive to rapid changes in volume and pressure.
8. Remove the needle from the injection cap. Discard the syringe and needle in a biohazard container.
9. Retape the cap as outlined in the injection cap change procedure.



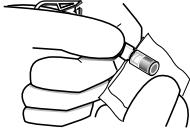
Use a separate syringe to flush each lumen with sterile heparin solution.

## Changing the Injection Cap

### Supplies you will need:

- Sterile injection cap.
- Catheter clamp
- Tape
- Alcohol or povidone iodine wipe.

### The procedure to change the cap:

1. Wash your hands thoroughly.
2. Be sure the catheter is securely clamped over the reinforced sleeve or tape tab.
3. Open the package of the new injection cap and prepare according to your instructions. Be sure the cap does not touch the outer surface of the package.  
**Note:** You may need to pre-fill the injection cap with heparin if it is a long cap with significant air space. Your doctor or nurse will teach you this additional procedure.
4. Remove the old tape from around the cap by unpeeling the tape.  
**NEVER** attempt to cut the tape with scissors as you may damage the catheter.
5. Using an alcohol or povidone iodine wipe, clean around the place where the cap is connected to the catheter. Allow to air dry.
6. While holding the catheter connector below the level of your heart, unscrew the old cap and discard. (The fluid level in the catheter will drop part-way into the catheter if the connector is held above the level of your heart.)  

7. Pick up the new cap only by the top and remove the sterile tip protector. Attach the new cap by firmly screwing it onto the catheter connector.
8. Cut a 5 cm piece of tape and make tabs on each end by folding back 1 cm. Apply the sticky part of the tape around the connection of the cap and catheter and fasten securely.  
Press ends of the tape together. The tabs on the end of the tape will enable you to remove it very easily.

## REFERENCES:

- <sup>1</sup> 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.
- <sup>2</sup> 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.
- <sup>3</sup> Ingle, Rebecca.; Nace, Corinne, Venous Access Devices: Catheter Pinch-off and Fracture, 1993, **Bard Access Systems, Inc.**

Other references available upon request.

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 to see if additional product information is available.

Revised Date: March 2007

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**Bard Access Systems, Inc.**

Salt Lake City, Utah 84116 USA

801-595-0700

Customer Service: 800-545-0890

Clinical Information: 800-443-3385

**[www.bardaccess.com](http://www.bardaccess.com)**