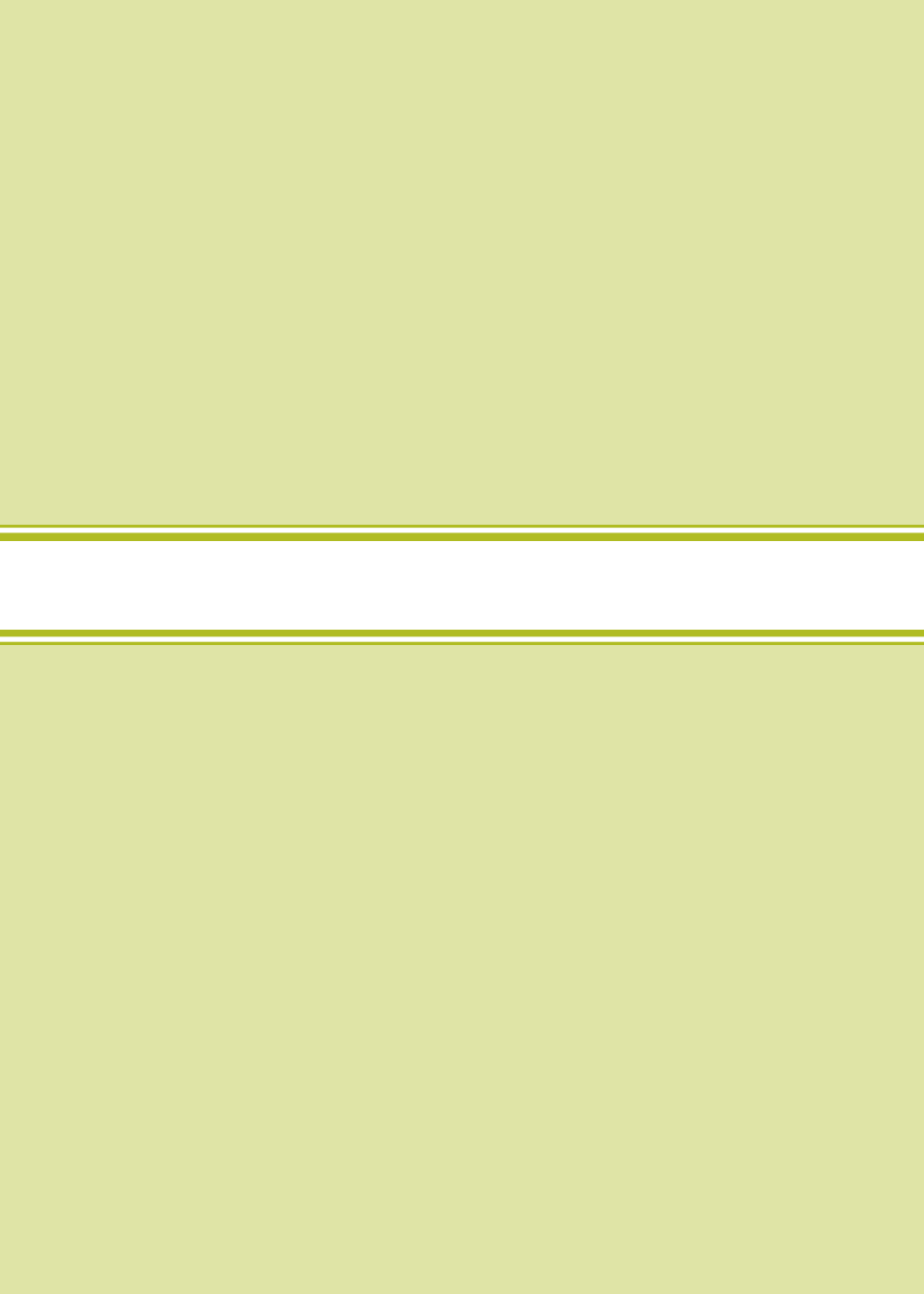




Aspira* Peritoneal Drainage Catheter

Instructions For Use



Product Description:

The Aspira* Peritoneal Drainage Catheter is a tunneled, long-term catheter used to drain accumulated fluid from the peritoneal cavity to relieve symptoms associated with malignant ascites. The catheter is implanted in the patient's peritoneal cavity enabling the patient to perform intermittent malignant ascites drainage at home. Drainage is achieved using the Aspira* Peritoneal Drainage System.

The primary components of the system are the Aspira* Peritoneal Drainage Catheter and the Aspira* Drainage Kit. The proximal end of the catheter has a valve that prevents fluid or air from moving in or out of the peritoneal cavity until the valve is activated. The valve can be activated by the Aspira* Drainage Kit or by connecting the catheter to a wall suction unit, water seal drainage system, glass vacuum bottle, syringe, or other appropriate method using the Luer Adapter. Fluid drains by connecting the drainage bag to the catheter, pumping the in-line siphon chamber to initiate flow, and allowing gravity to drain the fluid. When draining fluid using a wall suction unit, water seal drainage system, glass vacuum bottle, syringe, or other appropriate method, fluid drains by connecting the drainage unit to the Luer Adapter and then to the catheter.

The peritoneal drainage catheter provides patients with a convenient and compassionate way to relieve malignant ascites symptoms at home.

Indications For Use:

The Aspira* Peritoneal Drainage System is indicated for intermittent drainage of recurrent and symptomatic malignant ascites. The catheter is intended for long-term access of the peritoneal cavity in order to relieve symptoms such as dyspnea or other symptoms associated with malignant ascites.

Contraindications, Warnings and Precautions:

Contraindications:

This device is contraindicated under the following conditions:

- Known or suspected peritoneal cavity infection.
- Known or suspected coagulopathy or other hemorrhagic tendency.
- Peritoneal cavity is multi-loculated in a way that drainage from a single location is not expected to effectively relieve related symptoms.
- Patient medical condition including their anatomy is insufficient to accommodate an indwelling drainage catheter.
- Patient is known or suspected to be allergic to materials contained in the device.
- Patient has a medical history of symptom palliation failure by peritoneal drainage.

Warnings:

- Intended for Single Use. DO NOT REUSE. Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of the patient.
- Do not use excessive force on the valve or catheter. Excessive force or incorrect usage may damage the device, or cause accidental catheter dislodgement.
- Accessing the catheter valve with anything other than the Aspira* Drainage Bag or Luer Adapter may damage the valve.
- Dispose of the used product in accordance with accepted medical practice and applicable local, state and federal regulations. Used product may present a potential biohazard.
- **Do not attempt to pass a wire, needle or other device through the valve.**
- **Do not leave the Luer Adapter connected to the catheter when not connected to a suction source. The Luer Adapter creates an open pathway into or out of the catheter.**
- Do not flush or attempt to clear an occluded catheter with a syringe smaller than 10 ml.

Precautions:

- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Carefully read and follow instructions prior to using this device.
- Insertion or removal of this device is only to be done by qualified health professionals.
- Follow aseptic techniques when inserting the catheter.
- Sterilized by Ethylene Oxide. Do not resterilize.

Prior to Placement:

- Check the package for damage before opening.
- Ensure the expiration date has not passed.
- Inspect kit to ensure all components are included.

During Placement:

- Do not allow the device to contact sharp instruments. Mechanical damage may occur. Use only smooth edged atraumatic clamps or forceps.
- Care must be taken to avoid damaging the peritoneal wall or organs contained in the peritoneum.
- Do not use the catheter if it is damaged.
- Carefully follow the catheter valve connection technique described in the instructions to ensure proper connection and avoid catheter damage.
- If guidewire must be withdrawn while the needle is inserted, remove both the needle and guidewire as a unit to prevent the needle from damaging or shearing the guidewire.

After Placement:

- Do not use the catheter if it is damaged.
- Do not attempt to repair the catheter if damage has occurred within 5 cm of the exit site.
- Use only the Luer Adapter or Aspira* Drainage Bag to access the catheter valve.
- Be careful not to dislodge the catheter when assembling the valve.

Possible Complications:

Inserting the catheter and draining the ascitic fluid may result in any of the following complications:

- Infection
- Exposure to bodily fluids
- Peritonitis
- Leakage
- Hypotension subsequent to drainage
- Skin irritation or infection
- Splenic or hepatic laceration
- Occlusion
- Pain during fluid removal
- Catheter malposition
- Accidental catheter dislodgement, breakage or removal
- Tumor seeding
- Catheter or cuff erosion through skin
- Hemoperitoneum
- Bowel damage
- Abdominal wall cellulitis
- Electrolyte imbalance
- Sepsis
- Protein depletion
- Loculation of peritoneal cavity
- Hematoma

Insertion Instructions:

Before beginning this procedure, read the “Contraindications, Warnings and Precautions” and “Possible Complications” sections of this manual.

There are three possible placement techniques: antegrade, retrograde and over-the-wire. The following are common steps that apply to all three placement techniques listed above.

Common Steps:

1. Select the site for catheter insertion.
2. Create sterile field and open tray. Surgically prep and drape the operative site.
3. Perform adequate anesthesia.
4. Flush catheter through Y-connector to hydrate stylet. Allow catheter to soak in saline. (fig. 1a)
5. Attach the introducer needle to the syringe. (fig. 1b)
6. Insert the introducer needle into the peritoneal cavity and aspirate fluid to confirm proper positioning. (fig. 1b)

CAUTION: Avoid puncturing or lacerating the liver, bowel or any abdominal organs with the introducer needle.

7. Remove the syringe from the introducer needle.

8. Insert the floppy end of the guidewire through the introducer needle into the peritoneal cavity. (fig. 1c)

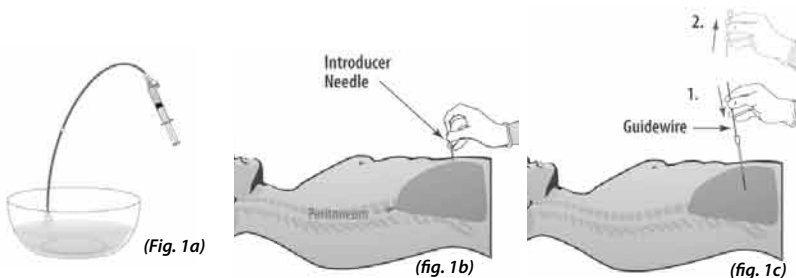
NOTE: If using over-the-wire technique, select a guidewire that is approximately 1 1/2 times the length of the catheter.

9. Remove the introducer needle over the guidewire and discard it. (fig. 1c)

CAUTION: If guidewire must be withdrawn while the needle is inserted, remove both the needle and guidewire as a unit to prevent the needle from damaging or shearing the guidewire.

10. Estimate desired length of catheter. Trim catheter if necessary.

NOTE: If fenestrated section is too long for the patient, it may be trimmed to length by cutting between the fenestrations.



Antegrade Tunnel Insertion Procedure:

1. Make an incision at the desired catheter insertion site. Make another incision superior and medial to the insertion site at a distance selected for tunnel length (generally 5 to 8 cm). (fig. 2a)
2. Create tunnel between the 2 incision sites. (fig. 2b)
3. Attach distal end of the catheter to the tunneler.
4. Thread tunneler and catheter from superior incision or catheter exit site to incision at the insertion site.
5. Pull the catheter through the tunnel until the cuff is appropriately positioned.
6. Separate the catheter from the tunneler.
7. Dilate the insertion site, guiding the dilators over the wire. (fig. 2c)
8. Thread the peel-apart introducer sheath over the guidewire into the peritoneal cavity. (fig. 2d)
9. Remove the guidewire and dilator as a unit, leaving the peel-apart introducer sheath in place. (fig. 2d)

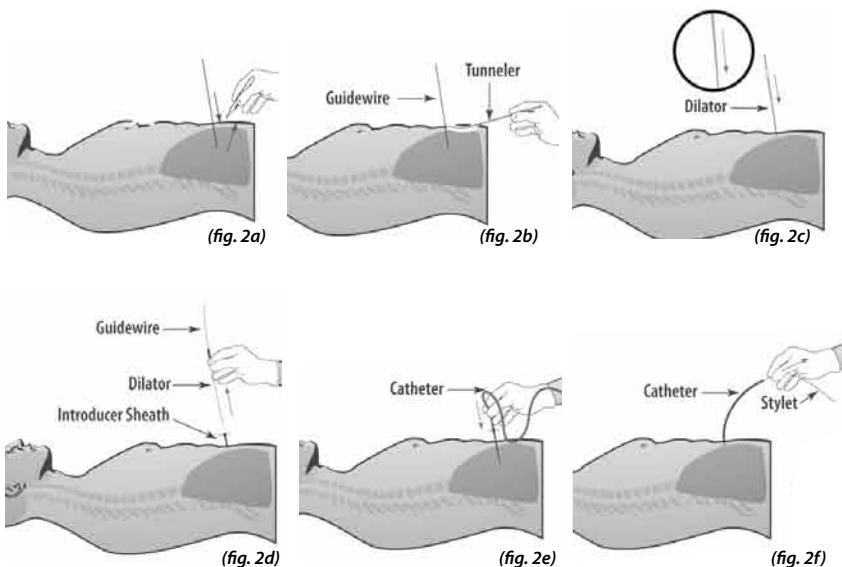
NOTE: Do not pinch the introducer sheath. Instead, place thumb over the sheath hub to prevent excess fluid from draining out of the peritoneal cavity.

10. Pass the distal tip of the catheter into the peel-apart introducer sheath ensuring that all fenestrations are within the peritoneal cavity. (fig. 2e)

NOTE: The most proximal fenestration is placed through the barium stripe to enable verification of the catheter placement using fluoroscopy or x-ray.

11. Peel away the introducer sheath keeping the catheter in place.

12. Remove stylet from catheter. (fig. 2f)
13. Place slide clamp on the catheter immediately proximal to the exit site.
14. Cut catheter below Y-connector.



Retrograde Tunnel Insertion Procedure:

1. Make an incision at the desired catheter insertion site. (fig. 3a)
2. Dilate the insertion site, guiding the dilators over the wire. (fig. 3b)
3. Thread the peel-apart introducer sheath over the guidewire into the peritoneal cavity. (fig. 3c)
4. Remove the guidewire and dilator as a unit. (fig. 3c)

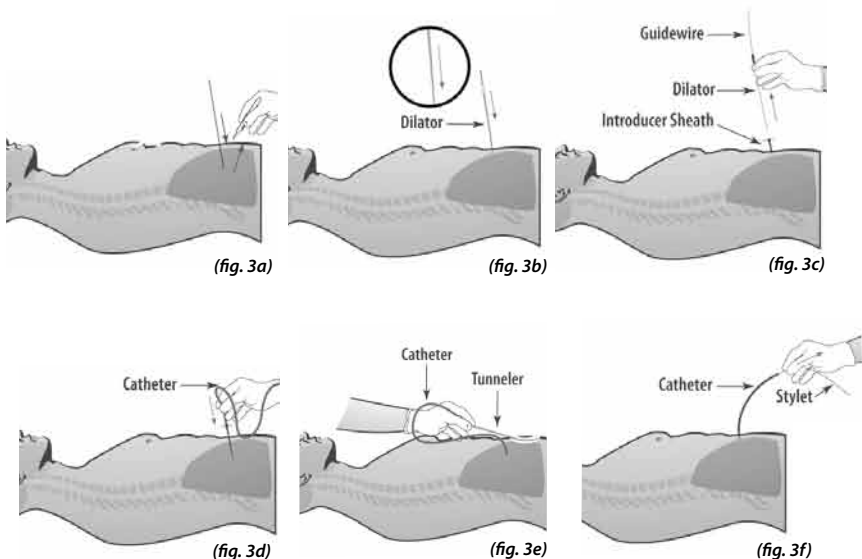
NOTE: Do not pinch the introducer sheath. Instead, place thumb over the sheath hub to prevent excess fluid from draining out of the peritoneal cavity.

5. Pass the distal tip of the catheter into the peel-apart introducer sheath ensuring that all fenestrations are within the peritoneal space. (fig. 3d)

NOTE: The most proximal fenestration is placed through the barium stripe to enable verification of catheter placement using fluoroscopy or x-ray.

6. Peel away the introducer sheath keeping the catheter in place.
7. Make an incision superior and medial to the insertion site at a distance selected for tunnel length (generally 5 to 8 cm).
8. Create a tunnel between the 2 incision sites. (fig. 3e)
9. Remove the stylet from the catheter. (fig. 3f)
10. Cut catheter below Y-connector.
11. Attach proximal end of the catheter to tunneler.
12. Thread tunneler and catheter from insertion site to incision at catheter exit site.

13. Pull the catheter through the tunnel until the cuff is appropriately positioned.
14. Place slide clamp on the catheter immediately proximal to the exit site.
15. Separate the catheter from the tunneler.



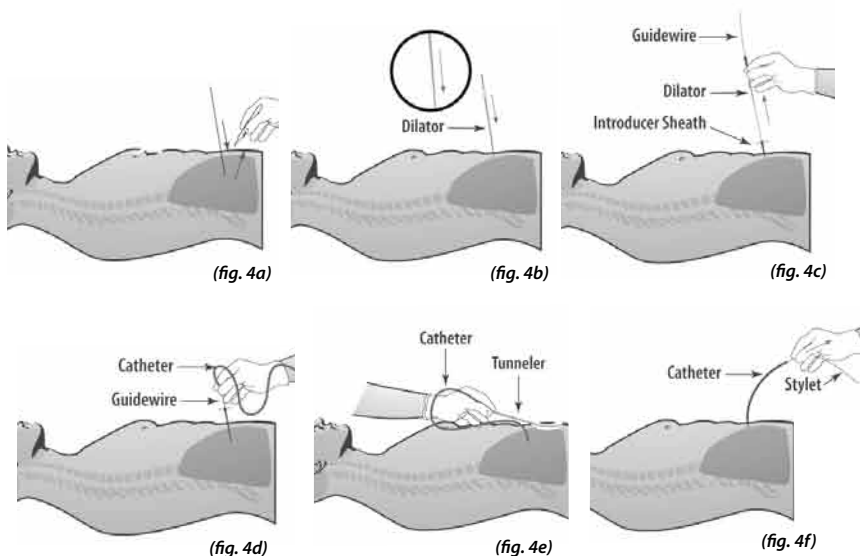
Over the Wire Insertion Procedure:

1. Make an incision at the desired catheter insertion site. (fig. 4a)
2. Dilate the insertion site, guiding the dilators over the wire. (fig. 4b)
3. Thread the peel-apart introducer sheath over the guidewire into the peritoneal cavity. (fig. 4c)
4. Remove dilator leaving the wire and peel-apart introducer in place. (fig. 4c)
5. Pass catheter over the guidewire and through peel-apart introducer. Ensure that all fenestrations lay within the peritoneal cavity. (fig. 4d)

NOTE: The most proximal fenestration is placed through the barium stripe to enable verification of placement using fluoroscopy or x-ray.

6. Peel away the sheath keeping the catheter in place.
7. Make an incision superior and medial to the insertion site at a distance selected for tunnel length (generally 5-8 cm).
8. Create a tunnel between the 2 incision sites. (fig. 4e)
9. Remove the guidewire and stylet from the catheter as a unit. (fig. 4f)
10. Cut catheter below Y-connector. Attach proximal end to tunneler.
11. Thread tunneler and catheter from insertion site to incision at catheter exit site.
12. Pull the catheter through the tunnel until cuff is appropriately positioned.
13. Place slide clamp on catheter immediately proximal to exit site.

14. Separate catheter from tunneler.



Catheter to Valve Connection Procedure:

1. Slide catheter valve clamp onto catheter. (fig. 1)
2. Advance catheter over valve stem until it contacts the shoulder. (fig. 2)
3. Slide valve clamp over valve stem and advance it until you hear or feel a click. (fig. 3)

NOTE: Once the catheter and valve assembly are connected, they cannot be removed and reused. To replace valve assembly, trim catheter below the valve assembly and attach a new valve assembly and valve clamp to ensure a secure connection.

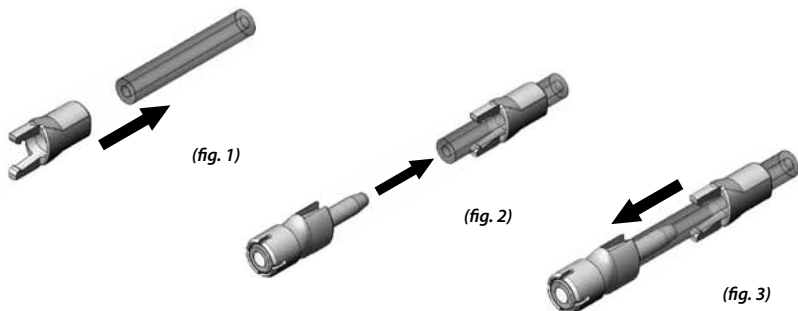
NOTE: If the valve clamp does not snap easily into place, hold the catheter and valve stem between your thumb and index finger and roll. Slide the valve clamp into place.

4. Remove slide clamp from the catheter.
5. Ensure patency using the Luer Adapter. (see using a syringe)

WARNING: Do not leave the Luer Adapter connected to the catheter when not connected to a suction source. The Luer Adapter creates an open pathway into or out of the catheter.

6. Palpate the catheter along the tunnel track to ensure proper positioning without kinks.
7. Suture the incision sites as needed.
8. Secure the catheter to the skin near the exit site using the provided suture wings or as instructed by institution protocol.

CAUTION: Sutures should not be tied around the catheter itself. The provided suture wings will secure the catheter without compromising catheter patency.



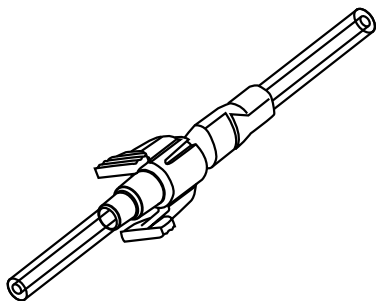
Initial Drainage Procedure:

After catheter placement, perform fluid drainage using an Aspira® Drainage Bag, syringe, standard wall suction unit, water seal drainage system, glass vacuum bottle or other appropriate method.

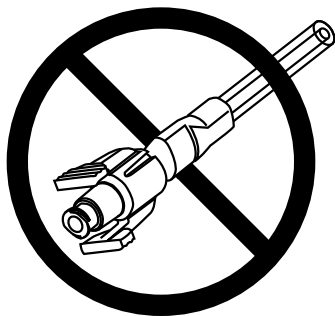
CAUTION: Use only the Luer Adapter to access the catheter with a syringe, wall suction unit, water seal drainage system or glass vacuum bottle per instructions below.

NOTE: When using the Aspira® Drainage Kit, follow instructions for use supplied.

WARNING: Do not leave the Luer Adapter connected to the catheter when not connected to suction source. The Luer Adapter creates an open pathway into or out of the catheter.



Drainage Line - Luer Adapter - Catheter



Luer Adapter - Catheter

Using a Syringe:

1. Connect supplied Luer Adapter to the syringe.
2. Push the Luer Adapter and syringe onto the catheter until you hear or feel a click. Tug gently to ensure connection is secure.
3. Pull back on the syringe plunger to draw fluid out of the peritoneal cavity.
4. When drainage is complete, disconnect Luer Adapter and syringe by squeezing the wings on the Luer Adapter and gently pulling to separate it from the catheter valve.

NOTE: If necessary to repeat procedure, disconnect Luer Adapter from catheter valve between drainages.

Using a Wall Suction Unit:

1. Connect the Luer Adapter to a Medi-Vac* Non-Conductive Suction Tube (e.g. Cardinal Health; Cat. N620A).
2. Attach the opposite end of the tubing to wall suction.
3. Push the Luer Adapter onto the catheter valve until you hear or feel a click. Tug gently to ensure connection is secure.
4. When ready to disconnect wall suction, pinch the wings on the Luer Adapter until it easily comes away from the catheter valve.

NOTE: Continuous or intermittent wall suction is acceptable.

WARNING: Do not leave the Luer Adapter connected to the catheter when not connected to a suction source. The Luer Adapter creates an open pathway into or out of the catheter.

Using a Water Seal Drainage System (e.g. Pleur-evac* or Atrium* Container):

1. Attach the coned end of the vinyl connecting tube (e.g. Cook, CTU14.0-30-ST) to the water seal drainage system.
2. Attach the male end of the vinyl connecting tube to the Luer Adapter.
3. Push the Luer Adapter onto the catheter valve until you hear or feel a click. Tug gently to ensure connection is secure.
4. To disconnect, pinch the wings of the Luer Adapter until it easily comes away from the valve.

WARNING: Do not leave the Luer Adapter connected to the catheter when not connected to a suction source. The Luer Adapter creates an open pathway into or out of the catheter.

Using a Glass Vacuum Bottle:

1. Attach male-to-male vinyl connecting tube (e.g. Cook, VCT14.0-60-P-MM) to the Luer Adapter.
2. Attach the other end of the tubing to an 18 G percutaneous entry needle (e.g. Cook, SDN-18-7.0).
3. Push the Luer Adapter onto the catheter valve until you hear or feel a click. Tug gently to ensure connection is secure.
4. Puncture the vacuum bottle seal with needle.
5. When drainage is complete, pinch the wings of the Luer Adapter until it easily comes away from the catheter valve.

WARNING: Do not leave the Luer Adapter connected to the catheter when not connected to a suction source. The Luer Adapter creates an open pathway into or out of the catheter.

Dressing the Catheter:

Weekly Dressing Procedure (option #1):

1. Wipe the end of the catheter valve with an alcohol pad.
2. Place the valve protective cap on the catheter valve.
3. Place a split gauze pad on the skin around the catheter. Lay the catheter straight down toward the waist and place gauze on top of split gauze pad.
4. Hold gauze and split gauze pad in position.
5. Place the transparent dressing over the gauze.
6. Tape catheter to patient's skin.

Alternative Dressing Procedure (with every drainage procedure) (option #2):

1. Wipe the end of the catheter valve with an alcohol pad.
2. Place the valve protective cap on the catheter valve.
3. Place a split gauze pad on the skin around the catheter. Coil the catheter on top of the pad and place gauze on top of the coiled catheter.
4. Hold gauze, coiled catheter and split gauze pad in position.
5. Place the transparent dressing over the catheter and gauze.

Catheter Removal:

The 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.

Catheter Maintenance:

See Dressing Kit and Drainage Kit instructions for use or patient guide for regular peritoneal drainage and catheter maintenance information.

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, a declotting procedure may be followed per institution protocol.

WARNING: Do not flush or attempt to clear an occluded catheter with a syringe smaller than 10 ml.

In the case of valve or catheter damage, the Repair Kit (product code: 4991506) may be used to replace the valve.

References:

Belfort, M.A.; Stevens, P. J.; DeHaek, K.; Soeters, R.; Krige, J.E.J. "A New Approach to the Management of Malignant Ascites; a Permanently Implanted Abdominal Drain", *European Journal of Surgical Oncology*, Vol. 16, No. 1, February 1990, pp. 47-53.

Bui, C.; Martin, C. J.; Currow, D. J. "Effective Community Palliation of Intractable Malignant Ascites with a Permanently Implanted Abdominal Drain", *Journal of Palliative Medicine*, Vol. 2, No. 3, Fall 1999, pp. 319-321.

Richard III, H. M.; Coldwell, D. M.; Boyd-Kranis, R. L.; Murthy, R; Van Echo, D. A. "Pleurx Tunneled Catheter in the Management of Malignant Ascites", *Journal of Vascular and Interventional Radiology*, Vol. 12 No. 3, March 2001, pp. 373-375.

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Aspira^{*}

PERITONEAL

DRAINAGE SYSTEM

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: December 2009

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