

Aspira^{*}
DRAINAGE SYSTEM

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* 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 approved Aspira* Drainage Bag or Bottle 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 or Universal Tubing Adapter.

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

Indications For Use:

The Aspira* 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 fluid 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 System approved devices 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.
- **When using the Luer Adapter or Universal Tubing Adapter to access the catheter, attach the adapter to the syringe or wall suction line prior to attachment to the catheter.**
- Do not attempt to pass a wire, needle or other device through the valve.
- The Luer Adapter and Universal Tubing Adapter create an open pathway into or out of the catheter; to close the pathway when not in use, tighten the pinch clamp.
- Do not flush or attempt to clear an occluded catheter with a syringe smaller than 10 mL.
- Do not use if package is damaged.
- Sterilized using ethylene oxide. Do not resterilize.

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.
- Avoid puncturing or lacerating the liver, bowel or any abdominal organs with the introducer needle.
- 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.
- Sutures should not be tied around the catheter itself. The provided suture wings will secure the catheter without compromising catheter patency.
- Use only the Luer Adapter or Universal Tubing Adapter to access the catheter with a syringe, wall suction unit, water seal drainage system or glass vacuum bottle per instructions below.

Prior to Placement:

- Ensure the expiration date has not passed.
- Inspect kit to ensure all components are included.
- Use only the Luer Adapter or Universal Tubing Adapter to access the catheter with a syringe or wall suction per instruction below.

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.
- Do not access the catheter valve with anything other than Aspira* Drainage System approved devices.
- 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:

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

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 guidewire through the introducer needle into the peritoneal cavity. (fig. 1c)

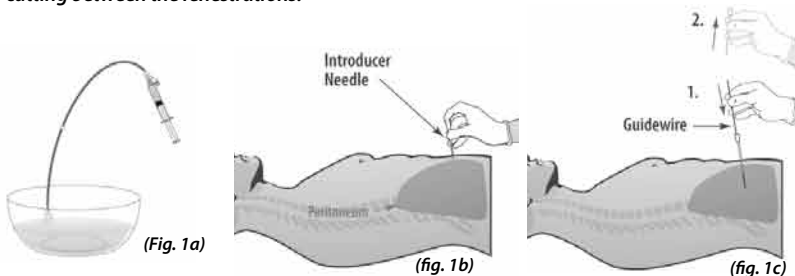
NOTE: If using over-the-wire technique, select a guidewire that is approximately 1 1/2 times the length of the catheter.

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)

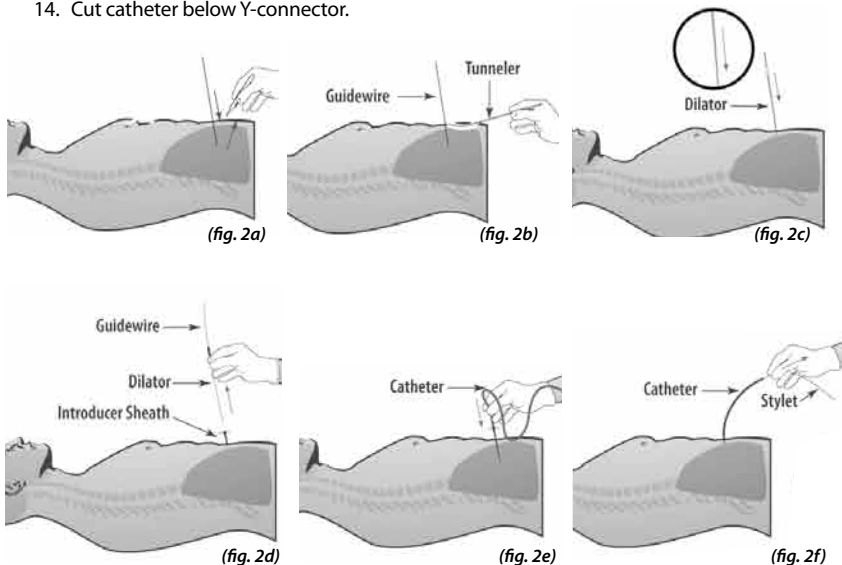
- Thread the peel-apart introducer sheath over the guidewire into the peritoneal cavity. (fig. 2d)
- Remove the guidewire and dilator as a unit, leaving the peel-apart introducer sheath in place. (fig. 2d)

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.

- 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.

- Peel away the introducer sheath keeping the catheter in place.
- Remove stylet from catheter. (fig. 2f)
- Place slide clamp on the catheter immediately proximal to the exit site.
- Cut catheter below Y-connector.



Retrograde Tunnel Insertion Procedure:

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

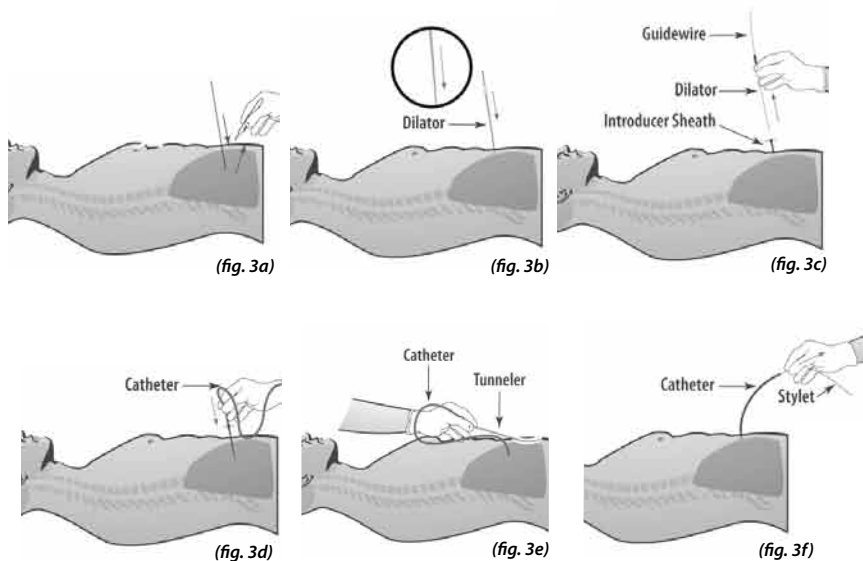
- Pass the distal tip of the catheter into the peel-apart introducer sheath ensuring that all fenestrations are within the peritoneal space. (fig. 3d)

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.

NOTE: Keep 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.

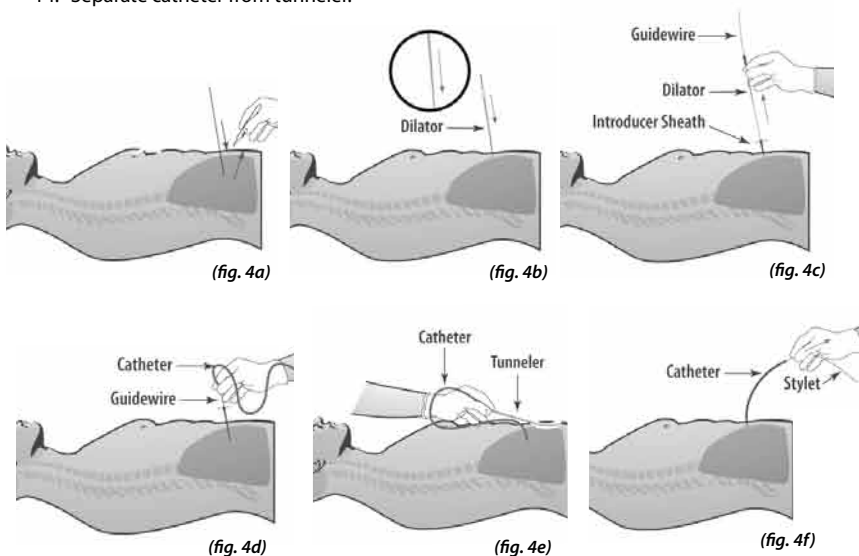


Over the Wire Insertion Procedure:

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. Advance catheter over valve stem until it is past the shoulder. (fig. 1)

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 to ensure a secure connection.

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

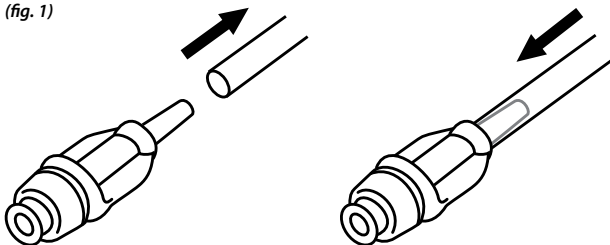
WARNING: When using the Luer Adapter or the Universal Tubing Adapter to access the catheter, the adapter must be attached to the syringe or wall suction prior to attaching to the catheter.

4. Palpate the catheter along the tunnel track to ensure proper positioning without kinks.

5. Suture the incision sites as needed.
6. 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.

(fig. 1)



Initial Drainage Procedure:

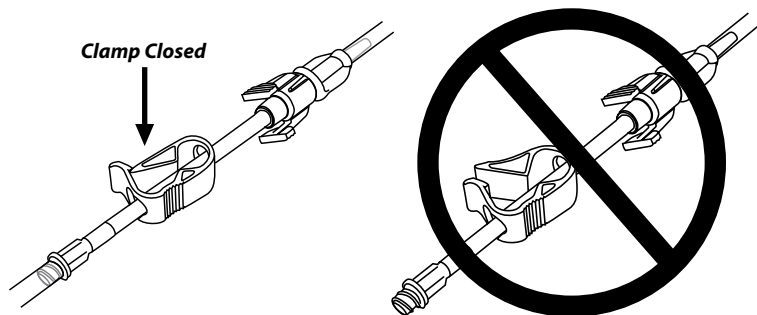
After catheter placement, perform fluid drainage using an Aspira* Drainage System approved device, syringe, standard wall suction unit, or other appropriate method.

CAUTION: Use only the Luer Adapter or Universal Tubing 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: When using the Luer Adapter or Universal Tubing Adapter to access the catheter, the adapter must be attached to the adapter to the syringe or wall suction line prior to attachment to the catheter.

WARNING: The Luer Adapter and Universal Tubing Adapter create an open pathway into or out of the catheter; to close the pathway when not in use, tighten pinch clamp.



Drainage Line - Luer Adapter - Catheter

Luer Adapter - Catheter

Bard Aspira® Drainage Bag or Bottle:

1. Please refer to the instructions for use when performing drainage procedures with the Aspira® Drainage Bag or Bottle.

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 or Universal Tubing Adapter to a Medi-Vac® Non-Conductive Suction Tube.
2. Attach the opposite end of the tubing to wall suction. Activate the pinch clamp.
3. Push the Luer Adapter or Universal Tubing Adapter onto the catheter valve until you hear or feel a click. Tug gently to ensure connection is secure. Open the pinch clamp.
4. Initiate Drain.
5. When ready to disconnect wall suction, pinch the wings on the Luer Adapter or Universal Tubing Adapter until it easily comes away from the catheter valve.

NOTE: Continuous or intermittent wall suction is acceptable.

WARNING: The Luer Adapter creates an open pathway into or out of the catheter; to close the pathway when not in use, tighten pinch clamp.

Using a Glass Vacuum Bottle:

1. Attach male-to-male vinyl connecting tube to the Luer Adapter.
2. Attach the other end of the tubing to an 18 G percutaneous entry needle. Activate the pinch clamp.
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. Open the pinch clamp.
5. When drainage is complete, pinch the wings of the Luer Adapter until it easily comes away from the catheter valve.

WARNING: The Luer Adapter or Universal Tubing Adapter creates an open pathway into or out of the catheter; to close the pathway when not in use, tighten pinch clamp.

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 or foam pad on the skin around the catheter.
4. Lay the catheter straight down toward the patient's waist.
5. Place gauze over top of the catheter.
6. Hold gauze, catheter, and split gauze or foam pad in place with one hand.
7. Place clear dressing on the skin around exit site.
8. **Optional:** Tape the catheter to the skin where it is most comfortable for the patient.

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 or foam pad on the skin around the catheter.
4. Coil the catheter on top of the pad. Place gauze on top of the coiled catheter.
5. Hold gauze, coiled catheter and split pad in position.
6. Place clear dressing over the catheter and gauze. Make sure the clear dressing sticks to the skin around the gauze. Smooth down the dressing edges.

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 Aspira* Valve Assembly / Repair Kit may be used to replace the valve.

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.

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.

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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.

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