

Aspira^{*}
PLEURAL DRAINAGE SYSTEM

Aspira^{} Pleural Drainage Catheter*

Instructions For Use

BARD
Access Systems

Product Description:

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

The primary components of the system are the Aspira* Pleural Drainage Catheter and the Aspira* Pleural Drainage Kit. The proximal end of the catheter has a valve that prevents fluid or air from moving in or out of the pleural space until the valve is activated. The valve can be activated by the Aspira* Pleural Drainage Kit or by connecting the catheter to wall suction or a syringe 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 or a syringe, fluid drains by connecting the drainage unit to the luer adapter and then to the catheter.

The pleural drainage catheter provides patients with a convenient and compassionate way to relieve pleural effusion symptoms at home.

Indications For Use:

The Aspira* Pleural Drainage System is indicated for intermittent drainage of recurrent and symptomatic pleural effusions. The catheter is intended for long-term access of the pleural cavity in order to relieve symptoms such as dyspnea and chest discomfort associated with malignant pleural effusions and other recurrent effusions.

Contraindications, Warnings and Precautions:

Contraindications:

This device is contraindicated under the following conditions:

- Known or suspected pleural cavity infection or sepsis.
- Known or suspected coagulopathy or other hemorrhagic tendency.
- Pleural cavity is multi-loculated in a way that drainage from a single location is not expected to effectively relieve symptoms, such as dyspnea and chest discomfort.
- Patient medical condition including their anatomy is insufficient to accommodate an indwelling drainage catheter.
- Dyspnea developed by other medical conditions is irrelevant to the pleural effusion.
- Patient is known or suspected to be allergic to materials contained in the device.
- Patient has a medical history of symptom palliation failure by pleural drainage.

Warnings:

- Do not re-use. Intended for single patient use.
- 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* Pleural 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.
- **When using the Luer 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.**
- 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 puncturing the lung.
- 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* Pleural 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 pleural fluid may result in any of the following complications:

- Pneumothorax
- Infection
- Exposure to body fluids
- Empyema
- Leakage
- Hypotension subsequent to drainage
- Skin irritation or infection
- Splenic or hepatic laceration
- Re-expansion pulmonary edema
- Occlusion
- Pain during fluid removal
- Hemothorax
- Catheter malposition
- Accidental catheter dislodgement or removal
- Tumor seeding
- Catheter or cuff erosion through skin

Insertion Instructions:

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

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 pleural space and aspirate fluid to confirm proper positioning. (fig. 1b)

CAUTION: Avoid puncturing the lung with the introducer needle.

7. Remove the syringe from the introducer needle.
8. Insert the guidewire through the introducer needle into the pleural space. (fig. 1c)

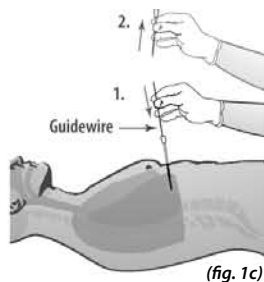
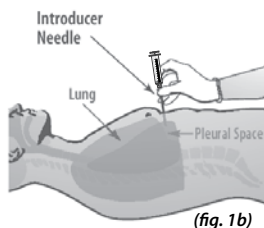
NOTE: If using over-the-wire technique, select a guidewire that is approximately 1 1/2 times the length of the catheter.

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:

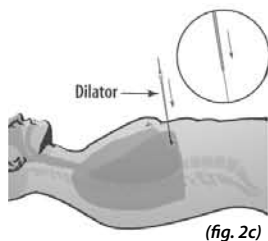
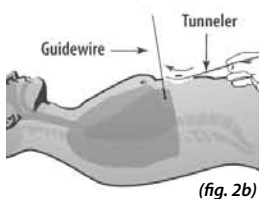
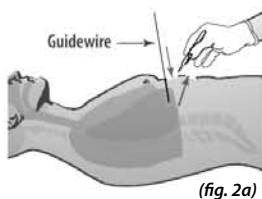
1. Make an incision at the desired catheter insertion site. Make another incision inferior and medial to the insertion site at a distance selected for tunnel length (generally 5 to 8 cm). (fig. 2a)
2. Create tunnel between the 2 incision sites. (fig. 2b)
3. Attach distal end of the catheter to the tunneler.
4. Thread tunneler and catheter from inferior incision or catheter exit site to incision at the guidewire 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 pleural space. (fig. 2d)
9. Remove the guidewire and dilator as a unit, leaving the peel-apart introducer sheath in place. (fig. 2d)

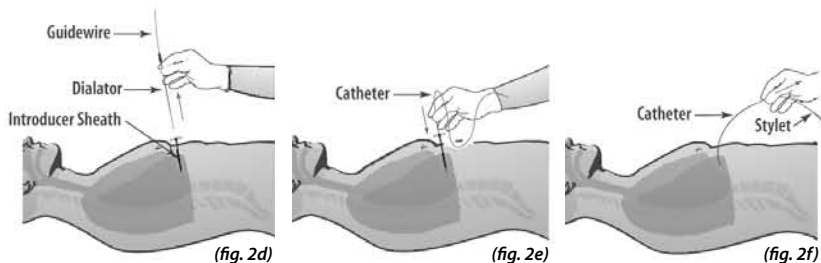
NOTE: Do not pinch the introducer sheath. Instead, place thumb over the sheath hub to prevent either air entering or excess fluid draining from the pleural space.

10. Pass the distal tip of the catheter into the peel-apart introducer sheath ensuring that all fenestrations are within the pleural space. (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 pleural space. (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 either air entering or excess fluid draining from the pleural space.

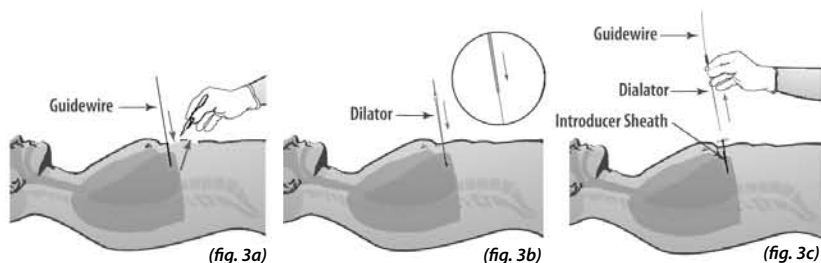
5. Pass the distal tip of the catheter into the peel-apart introducer sheath ensuring that all fenestrations are within the pleural space. (fig. 3d)

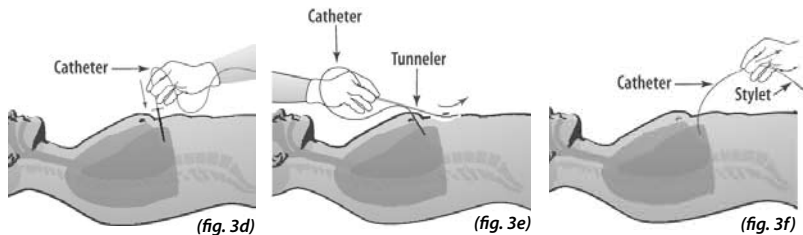
NOTE: The most proximal fenestration is placed through the barium stripe to enable verification of catheter placement using fluoroscopy or x-ray.

6. Peel apart the introducer sheath.

NOTE: Keep the catheter in place.

7. Make an incision inferior 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.



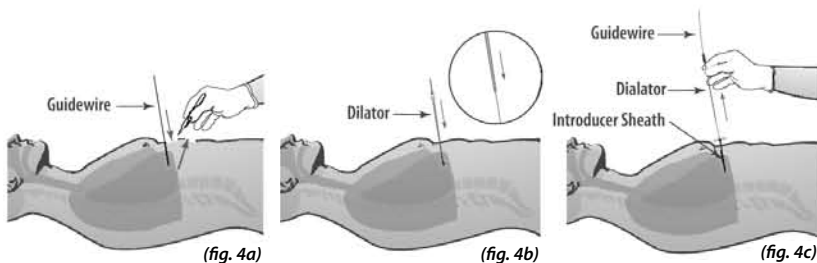


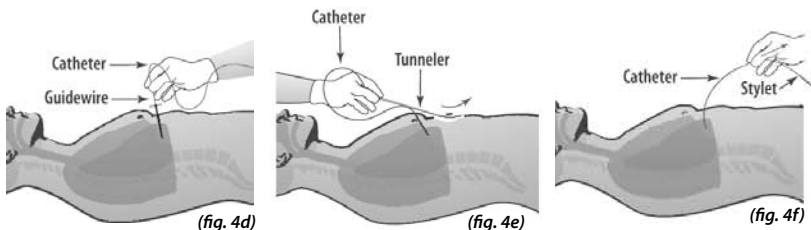
Over the Wire Insertion Procedure:

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 pleural space. (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 pleural space. (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 inferior 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:

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.

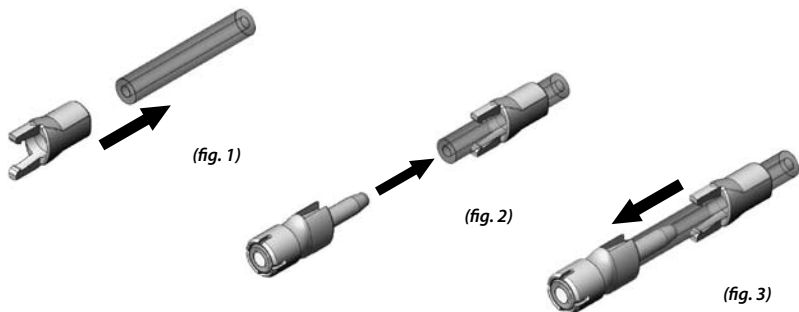
NOTE: If the valve clamp does not snap easily into place, hold the catheter and valve stem between your thumb and index finger and roll. Slide the valve clamp into place.

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

WARNING: When using the Luer Adapter to access the catheter, the adapter must be attached to the syringe or wall suction line prior to attaching to 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® Pleural Drainage Bag, syringe, standard wall suction unit or other appropriate method.

CAUTION: Use only the Luer Adapter to access the catheter with a syringe or wall suction per instructions below.

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

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

Using A Syringe:

1. Connect supplied Luer Adapter to the syringe.
2. Push the 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 pleural space.
4. When drainage is complete, disconnect adapter and syringe by squeezing the wings on the 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 adapter to the wall suction line.
2. Push the adapter and suction line onto the catheter until you hear or feel a click. Tug gently to ensure connection is secure.
3. Initiate drainage.
4. When drainage is complete, disconnect adapter and wall suction line by squeezing the wings on the adapter and gently pulling to separate it from the catheter valve.

Dressing the Catheter:

Weekly Dressing Procedure:

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

Alternative Dressing Procedure (with every drainage procedure):

1. Place the valve protective cap over the top of the catheter valve.
2. 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.
3. Hold gauze, coiled catheter and split gauze pad in position.
4. 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 Pleural Drainage Kit instructions or patient guide for use for regular pleural drainage and catheter maintenance information.

Catheters that present resistance to flushing and aspiration may be partially or completely occluded. Do not flush against resistance. Do not flush with a syringe smaller than 10 ml. 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.

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

References:

- Pien, G.W.; Gant, M.J.; Washam, C.L.; Sterman, D.H. "Use of an implantable Pleural Catheter for Trapped Lung Syndrome in Patients with Malignant Pleural Effusion.", *Chest*, Vol. 119, No. 6, June 2001, pp. 1641-1646.
- Putnam, J.B. "Malignant Pleural Effusions", *Surgical Clinics of North America*, Vol. 82, 2002, pp. 867-883.
- Pollak, J.S. "Malignant Pleural Effusions: Treatment with Tunneled Long-Term Drainage Catheters", *Current Opinion in Pulmonary Medicine*, Vol. 8, No. 4, pp. 302-307.
- Brubacher, S.; Gobel, B.H. "Use of the Pleurx Pleural Catheter for the Management of Malignant Pleural Effusions", *Clinical Journal of Oncology Nursing*, Vol. 7, No. 1, January/February 2003, pp. 35-38.

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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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U.S. patents pending.

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