



Aspira® Pleural Drainage Catheter

INSTRUCTIONS FOR USE



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 Drainage System.

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 approved Aspira Drainage System devices.

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

INDICATIONS FOR USE

The Aspira 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.

CLINICAL BENEFITS

The Aspira Drainage System provides patients with a convenient and compassionate way to relieve pleural effusion symptoms at home.

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 fluid 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

- For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may 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.
- Do not access the catheter valve with anything other than Aspira Drainage System approved devices

- Accessing the catheter valve with anything other than Aspira Drainage System approved devices may damage the valve.
- After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal.
- 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.
- 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 attempt to pass a guide 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

- **ONLY** Caution - Federal Law (USA) restricts this device to sale by or on the order of a physician.
- Insertion or removal of this device is only to be done by qualified health professionals.
- Follow aseptic techniques when inserting the catheter.
- If guide wire must be withdrawn while the needle is inserted, remove both the needle and guide wire as a unit to prevent the needle from damaging or shearing the guide wire.
- 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 system, water seal drainage system or evacuated bottle other than Aspira Evacuated Drainage Bottles per instructions below.

PRIOR TO PLACEMENT

- Inspect kit to ensure all components are included.
- Use only the Luer Adapter or the 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 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 the guide wire must be withdrawn while the needle is inserted, remove both the needle and guide wire as a unit to prevent the needle from damaging or shearing the guide wire.

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 with anything other than Aspira Drainage System approved devices.
- Be careful not to dislodge the catheter when assembling the valve.

POTENTIAL COMPLICATIONS

Potential complications (in alphabetical order) of inserting the catheter and draining the pleural fluid may result in any of the following complications:

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

INSERTION INSTRUCTIONS

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

Possible placement techniques are: 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 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 guide wire through the introducer needle into the pleural space. (fig. 1c)

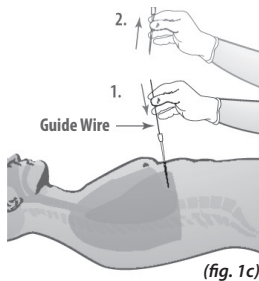
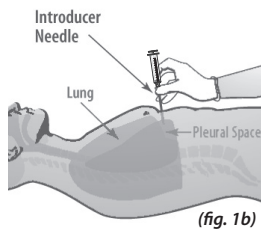
NOTE: If using over-the-wire technique, select a guide wire that is approximately 1 1/2 times the length of the catheter.

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

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

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

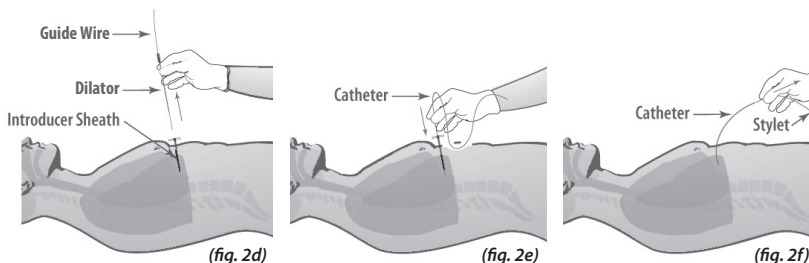
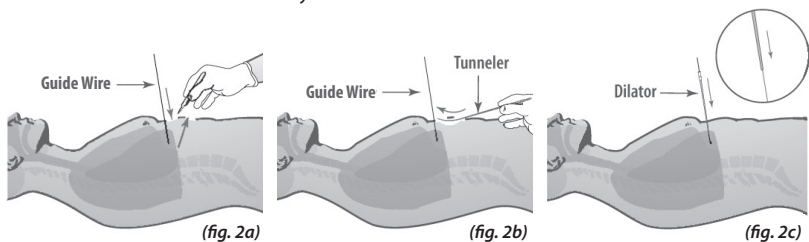
1. Make an incision at the desired catheter insertion site. Make another incision inferior and medial to the insertion site at a distance selected for tunnel length (generally 5 to 8 cm). (fig. 2a)
2. Create a tunnel between the two incision sites. (fig. 2b)
3. Attach distal end of the catheter to the tunneler.
4. Thread tunneler and catheter from the inferior incision or catheter exit site to the 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 guide wire. (fig. 2c)
8. Thread the peel-apart introducer sheath over the guide wire into the pleural space. (fig. 2d)
9. Remove the guide wire 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)

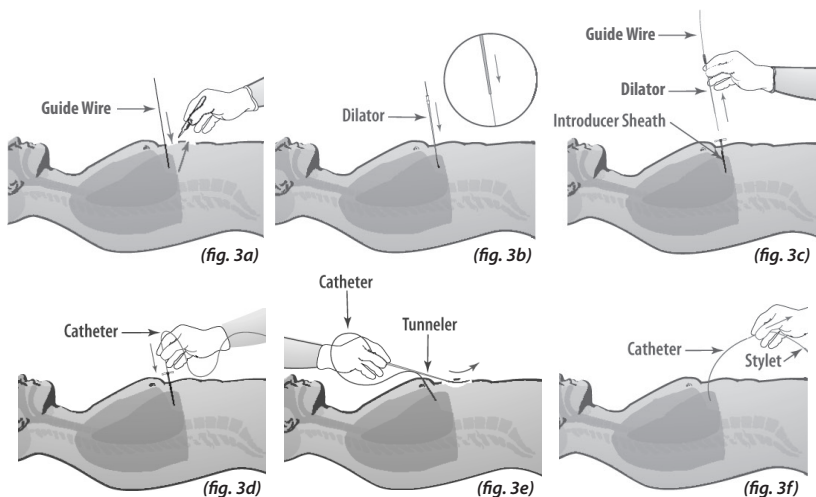
NOTE: The most proximal fenestration is placed through the barium stripe to enable verification of the catheter placement using fluoroscopy or x-ray.

11. Peel away the introducer sheath keeping the catheter in place.
12. Remove the stylet from the catheter. (fig. 2f)
13. Place the slide clamp on the catheter immediately proximal to the exit site.
14. Cut catheter below Y-connector.
15. Go to "Catheter to Valve Assembly Connection Procedure" section.



RETROGRADE TUNNEL INSERTION PROCEDURE

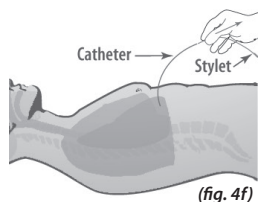
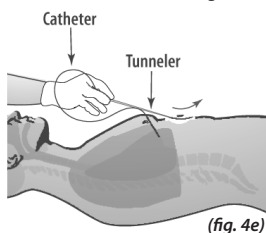
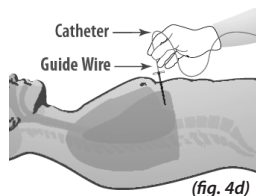
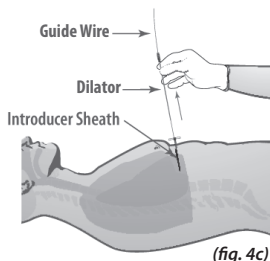
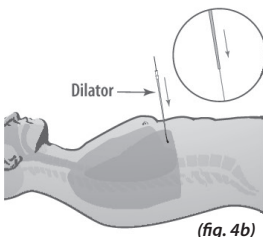
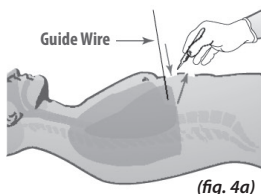
1. Make an incision at the desired catheter insertion site. (fig. 3a)
2. Dilate the insertion site, guiding the dilators over the guide wire. (fig. 3b)
3. Thread the peel-apart introducer sheath over the guide wire into the pleural space. (fig. 3c)
4. Remove the guide wire and dilator as a unit. (fig. 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 away the introducer sheath.
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 two 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 the tunneler.
12. Thread tunneler and catheter from the insertion site to the incision at the catheter exit site.
13. Pull the catheter through the tunnel until the cuff is appropriately positioned.
14. Place the slide clamp on the catheter immediately proximal to the exit site.
15. Separate the catheter from the tunneler.
16. Go to "Catheter to Valve Connection" section.



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 guide wire. (fig. 4b)

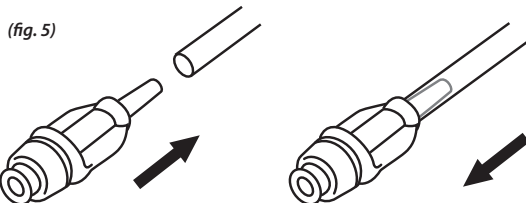
3. Thread the peel-apart introducer sheath over the guide wire into the pleural space. (fig. 4c)
 4. Remove the dilator leaving the guide wire and peel-apart introducer in place. (fig. 4c)
 5. Pass the catheter over the guide wire and through the peel-apart introducer. Ensure that all fenestrations lay 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 introducer 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 two incision sites. (fig. 4e)
 9. Remove the guide wire 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 the incision at the catheter exit site.
 12. Pull the catheter through the tunnel until the cuff is appropriately positioned.
 13. Place the slide clamp on the catheter immediately proximal to the exit site.
 14. Separate the catheter from the tunneler.
 15. Go to "Catheter to Valve Assembly Connection Procedure" section.



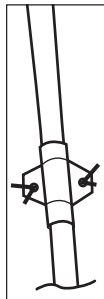
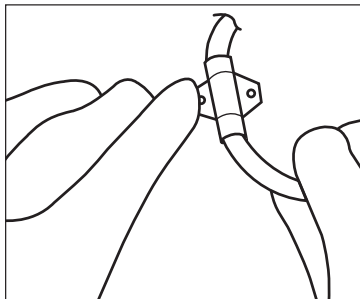
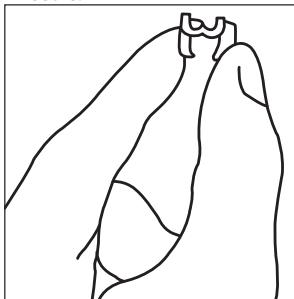
CATHETER TO VALVE ASSEMBLY CONNECTION PROCEDURE

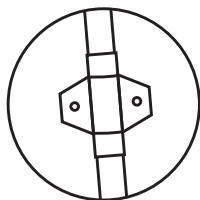
1. Advance the catheter over the valve stem until it is past the shoulder. (fig. 5)

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

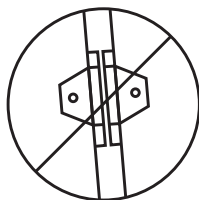


2. Remove slide clamp from the catheter.
3. Ensure patency using the Luer Adapter. (see "Using A Syringe" section)
WARNING: When using the Luer Adapter or the Universal Tubing Adapter to access the catheter, the adapter must be attached to the syringe or wall suction line prior to attaching to the catheter.
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.
7. Pinch the movable suture wings together to open the split underside of the wing body.
8. Position suture wing on catheter near insertion site and release.
9. Secure wing in place with suture through holes in wing. Avoid nicking catheter with suture needle.





RIGHT



WRONG

INITIAL DRAINAGE PROCEDURE

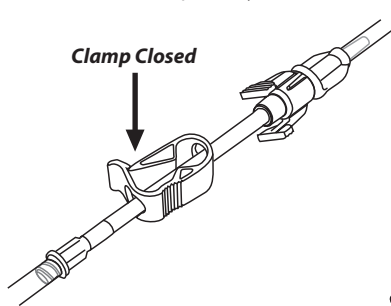
After catheter placement, perform fluid drainage using an approved Aspira Drainage System device.

CAUTION: Use only the Luer Adapter or Universal Tubing Adapter to access the catheter with a syringe, wall suction system, water seal drainage system, or evacuated bottle other than Aspira Evacuated Drainage Bottles per instructions below.

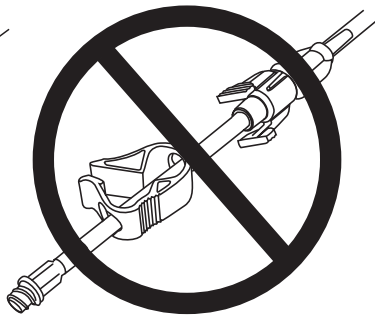
NOTE: When using the Aspira Drainage Kit, follow the instructions for use supplied.

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 line prior to attaching 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 the pinch clamp.



Drainage Line - Luer Adapter - Catheter



Luer Adapter - Catheter

ASPIRA DRAINAGE BAG

1. Please refer to the instructions for use when performing drainage procedures with the Aspira Drainage Bag supplied with the Aspira Drainage Kit.

ASPIRA EVACUATED DRAINAGE BOTTLE

1. Please refer to the instructions for use when performing drainage procedures with the Aspira Evacuated Drainage Bottle supplied with the Aspira Drainage Kit/Dressing Kit.

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 pleural space.
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 procedures, disconnect the Luer Adapter from catheter valve between drainages.

USING A WALL SUCTION SYSTEM

1. Connect the Luer Adapter or Universal Tubing Adapter to the wall suction line and activate the pinch clamp.
2. Attach the opposite end of the tubing to wall suction.
3. Push the Luer Adapter or the Universal Tubing Adapter and suction line onto the catheter valve until you hear or feel a click. Tug gently to ensure connection is secure. Open the pinch clamp.
4. Initiate drainage.
5. When ready to disconnect wall suction, pinch the wings on the Luer Adapter or the Universal Tubing Adapter until it easily comes away from the catheter valve.
NOTE: Continuous or intermittent wall suction is acceptable.
WARNING: The Luer Adapter and the 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.

USING A WATER SEAL DRAINAGE SYSTEM

1. Connect the Luer Adapter or the Universal Tubing Adapter to the water seal drainage system line and activate the pinch clamp.
2. Push the Luer Adapter or the Universal Tubing Adapter and drainage line onto the catheter valve until you hear or feel a click. Tug gently to ensure connection is secure. Open the pinch clamp and drain.
3. When ready to disconnect wall suction, pinch the wings on the Luer Adapter or the Universal Tubing Adapter until it easily comes away from the catheter valve.
WARNING: The Luer Adapter and the 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.

USING AN EVACUATED BOTTLE OTHER THAN AN ASPIRA EVACUATED DRAINAGE BOTTLE

1. Attach appropriate tubing to the Luer Adapter or the Universal Tubing Adapter and activate the pinch clamp.
2. Attach the other end of the tubing to an appropriate device to access the evacuated bottle.
3. Push the Luer Adapter or the Universal Tubing Adapter onto the catheter valve until you hear or feel a click. Tug gently to ensure connection is secure.
4. Open the pinch clamp and drain into the evacuated bottle.
5. When ready to disconnect, pinch the wings on the Luer Adapter or Universal Tubing Adapter until it easily comes away from the catheter valve.
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 the pinch clamp.

DRESSING THE CATHETER

WEEKLY DRESSING PROCEDURE (OPTION #1)

1. Wipe the end of the catheter valve with a new 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.
NOTE: Make sure the exit site and skin around it are dry before completing the dressing.
4. Lay the catheter straight down toward the patient's waist.
5. Place the gauze over the top of the catheter.
6. Hold gauze, catheter and split gauze or foam pad in place with one hand.
7. 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.
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 a new 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.
NOTE: Make sure the exit site and skin around it are dry before completing the dressing.
4. Coil the catheter on top of the split gauze or foam pad. Place gauze on top of the coiled catheter.
5. Hold gauze, coiled catheter and split gauze or foam 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 and/or patient guide 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 dec clotting 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

Pien, G.W.; Gant, M.J.; Washam, C.L.; Sberman, 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.

SYMBOL	DESIGNATION
	Use By: YYYY-MM-DD
	Lot Number
	Catalog Number
	Do Not Re-sterilize
	Do Not Use If Package is Damaged and Consult Instruction for Use
	Single Use
	Caution
	Sterilized Using Ethylene Oxide
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Medical Device
	Unique Device Identifier
	Single sterile barrier system with protective packaging
	Consult Instructions for Use For electronic copy scan QR code, or go to www.merit.com/ifu and enter IFU ID. For printed copy, call U.S.A. or EU Customer Service
	Manufacturer
	Distance from cuff to proximal fenestration



www.merit.com



Manufacturer:

Merit Medical Systems, Inc.
1600 West Merit Parkway,
South Jordan, Utah 84095 U.S.A.
1-801-253-1600
U.S.A Customer Service 1-800-356-3748