

CE
0344

Denver[®]
BIOMEDICAL

PLEURX^{*}

Drainage Kit

Catalog No. 50-7510

■ Instructions for Use

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*U.S. Patent No. 5,484,401

Table of Contents

Warranty	2
Warnings	3
Cautions	3
The Pleurx Catheter.	4
The Pleurx Drainage Kit.	4
Sterility	4
How to drain using the Pleurx Drainage Kit	6
Getting started.	6
Connecting the drainage bottle.	7
Draining fluid	9
Final steps	10
Placing a new dressing.	11
Changing the drainage bottle	13
Emptying the vacuum bottle.	15
Frequently Asked Questions	15
Glossary.	17
Additional Drainage Supplies.	17

You should have been trained by a nurse or doctor in the correct way to use the items in this kit. If you have any problems or questions about draining fluid from your chest or abdomen, contact your doctor or nurse.

Read this entire pamphlet carefully before draining the fluid from your chest.

Warranty

Denver Biomedical, Inc. warrants that this medical device is free from defects in both materials and workmanship. THE ABOVE WARRANTIES ARE IN LIEU OF ALL OTHER WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Suitability for use of the medical device for any surgical procedure shall be determined by the user. Denver Biomedical, Inc. shall not be liable for incidental or consequential damages of any kind.

Warnings

Do not drain more than 1000 ml (one full bottle) of fluid from your chest at any one time or 2000 ml (two full bottles) of fluid from your abdomen.

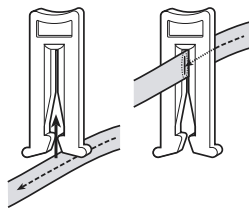
It is normal to feel some pain when draining fluid. If you feel pain when draining, clamp the drainage line to slow or stop the flow of fluid for a few minutes. If you don't feel better after doing this or the pain is severe, contact your nurse or doctor. Pain may be an indication of infection.

Keep the valve on your Pleurx Catheter and the access tip on the drainage line clean. Keep them away from other objects to help avoid contamination.

Do not use scissors or other sharp objects near the Pleurx Catheter.

If you accidentally cut the catheter follow these steps:

- a. Pinch the catheter closed between your fingers.
- b. Slip the blue emergency slide clamp over the catheter, and push the catheter completely into the small end of the clamp. This will close the catheter.
- c. Notify your doctor immediately.



Do not put anything except the access tip of the drainage line into the Pleurx Catheter valve, since this could damage the valve. A damaged valve might let air be pulled into your chest cavity (if the Pleurx Catheter is in your chest) or let fluid leak out through the valve.

Cautions

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Fluid collected in the drainage bottle is not sterile. To ensure that fluid collected in the bottle does not flow back into the catheter, clamp the white clamp on the drainage line when you are finished draining. Do not invert the bottle and hold it above your catheter site.

When not draining, the clamp on the drainage line must be completely closed or the vacuum in the bottle may be lost. Make sure that the valve and the access tip are locked together when draining. If they are accidentally separated, they may become contaminated and the vacuum in the bottle may be lost. If this occurs, clean the valve with an alcohol pad and use a new drainage bottle.

The alcohol pads are flammable. Do not expose the pads to an open flame.

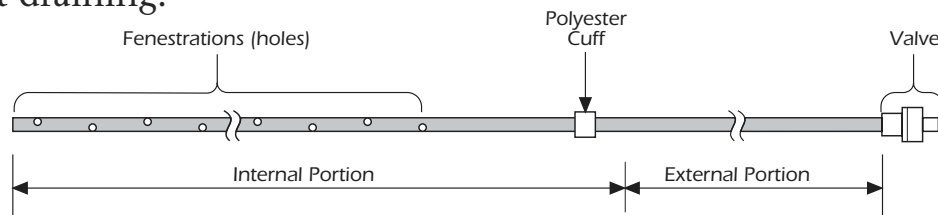
CHEST: Potential complications of draining the pleural space include but may not be limited to, pneumothorax, re-expansion pulmonary edema, hypotension, circulatory collapse and infection.

ABDOMEN: Potential complications of draining fluid from the abdomen include but may not be limited to, hypotension, circulatory collapse, electrolyte imbalance, protein depletion, ascites leakage, peritonitis, wound infection, and loculations of the peritoneal space.

The tape used in the packaging of this product contains natural rubber latex, which may cause allergic reactions.

The Pleurx Catheter

The Pleurx Catheter may be placed in your chest to drain fluid from around your lungs or it may be placed in your abdomen to drain fluid that builds up in that area. Your doctor has placed the Pleurx Catheter to allow you to drain fluid from your chest or abdomen while you are at home. Part of the catheter is inside your body and has several holes that allow fluid to enter the catheter. The fluid is drained through the outer end of the catheter. There is a valve at the outer end of your catheter that prevents air from entering and fluid from leaking out when you are not draining.



Pleurx Catheter

The Pleurx Drainage Kit and Vacuum Bottles may be used to drain fluid through the Pleurx Catheter whether it is placed in your chest or abdomen. Always use the Pleurx Drainage Kit and Vacuum Bottles for draining fluid from your chest or abdomen to avoid damage to the Pleurx Catheter and to provide the best performance.

The Pleurx Drainage Kit

The Drainage Kit provides the supplies you need to drain the fluid from your chest or abdomen. The items in the kit are:

- 1 - Plastic vacuum bottle (1000 ml) with attached drainage line
- 1 - Procedure Pack containing the following items:
 - 1 - self-adhesive dressing
 - 1 - blue wrapping (wrapped around the following items)
 - 1 - pair of gloves
 - 1 - valve cap
 - 1 - blue emergency slide clamp
 - 4 - gauze pads (4" x 4")
 - 1 - foam catheter pad
- 3 - Alcohol pads/swabs (70% isopropyl alcohol)

Sterility

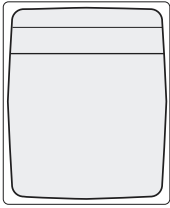
The Procedure Pack, drainage line (attached to the Vacuum Bottle) and the outer surface of the Vacuum Bottle in this kit have been sterilized. As long as the packaging is not damaged or opened, these items are sterile. These products are for single use only and are not to be resterilized.

Denver Biomedical, Inc. will not be responsible for any product that is resterilized, nor accept for credit or exchange any product that has been opened but not used.

Drainage Kit Contents

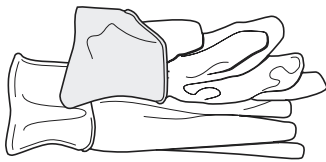
Procedure Pack

Self-Adhesive Dressing

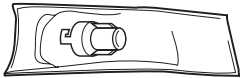


Blue Wrapping around the following

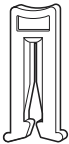
Gloves



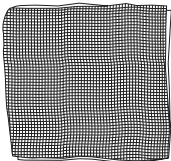
Catheter Valve Cap



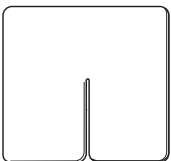
Blue Emergency Slide Clamp



Gauze Pads



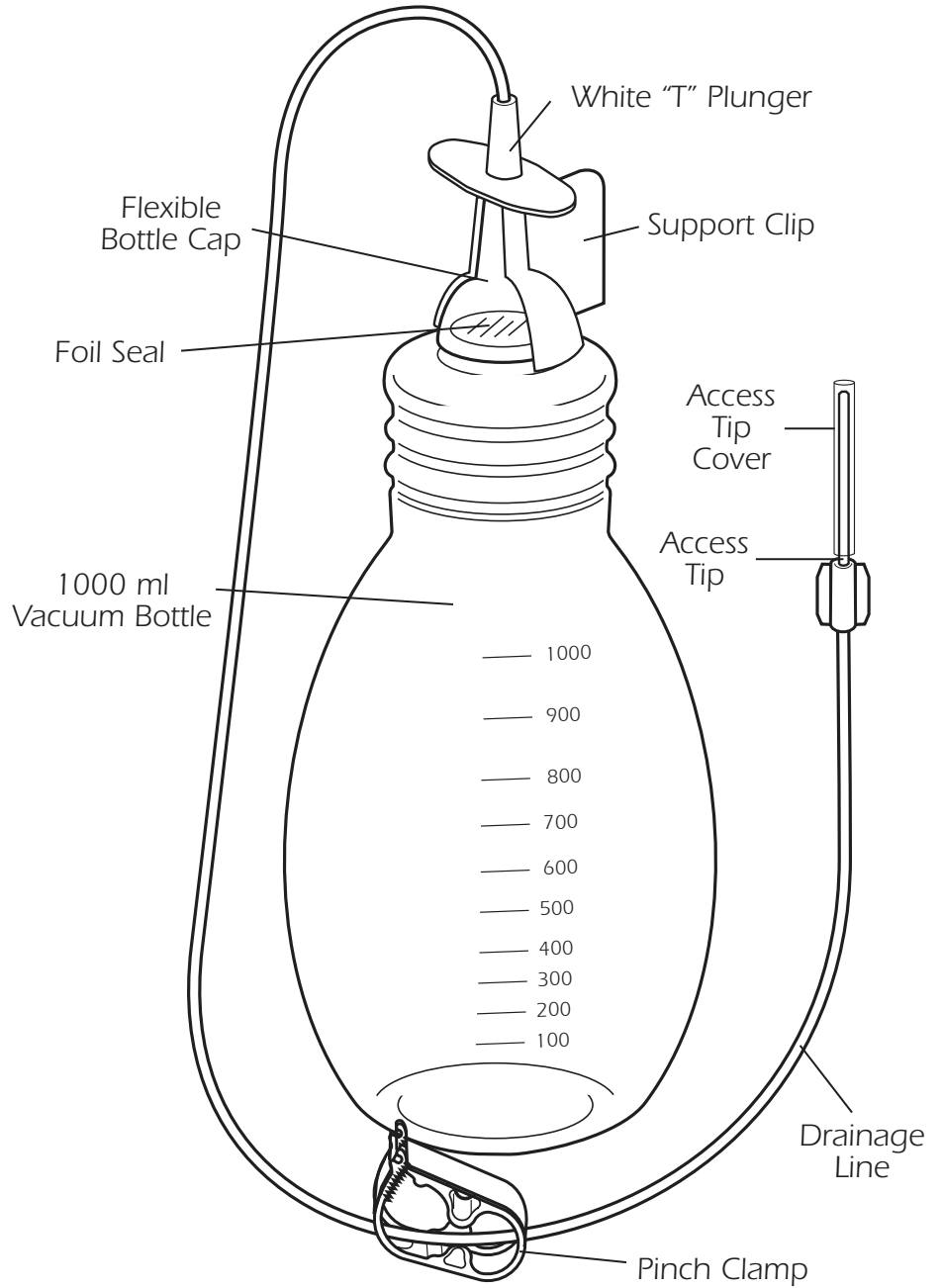
Foam Catheter Pad



Alcohol Pads/Swabs



Plastic Vacuum Bottle

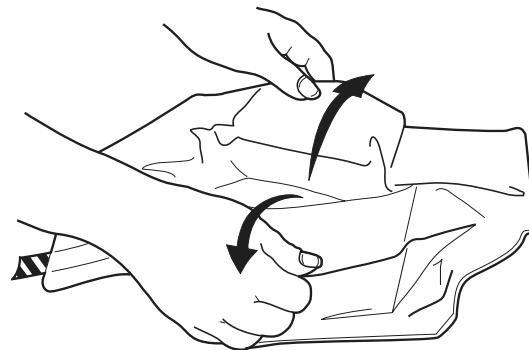
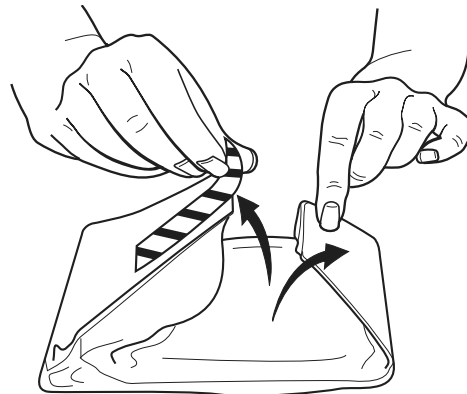


How to drain using the Pleurx Drainage Kit

Now that your doctor or nurse has trained you on the drainage procedure, you should find it easy to follow these step-by-step directions. You should drain as directed by your doctor, usually every one to two days. Do not change frequency or drain more fluid than your doctor has recommended without first consulting your doctor.

Getting started

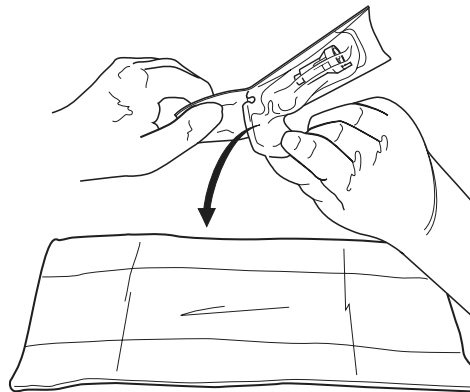
1. Set up a clean, clear workspace on a table or counter.
2. **Thoroughly** wash your hands with soap and water for at least 1 minute.
3. Remove the dressing from over your catheter. If you see any redness, swelling or fluid around the catheter, finish this drainage procedure and contact your doctor or nurse.
4. Open the Drainage Kit bag.
5. Open the Procedure Pack bag by peeling the front and the back of the pouch apart, starting at the top. Set the adhesive dressing aside.
6. Set the bundle with the blue wrapping on your workspace. Remove the tape. Carefully unfold the blue wrapping by pulling on the outside of the wrapping. Leave the enclosed items on the wrapping. The items and the inside of the wrapping are sterile, so don't touch them with your ungloved hands or other non-sterile items.
7. Open the Vacuum Bottle bag and remove the bottle with the attached drainage line. The items in the bag are sterile. It is especially important that the access tip remain sterile. If the cover has fallen off of the access tip, make sure that you do not touch the tip with your hand or anything non-sterile. Set the bottle near the blue wrapping and place the access tip on the wrapping near the other sterile items.
8. Tear open the three alcohol pads, but do not remove the pads from the pouches. The alcohol pads are sterile on the inside, but not on the outside, so place them on the blue wrapping, a short distance from the sterile items.



9. Pick up one glove by the wrist and put it on. Pick up the other glove by the wrist and put it on the other hand. Both gloves fit either hand. Be careful not to let the outside of the gloves touch anything non-sterile, such as your skin or clothing.

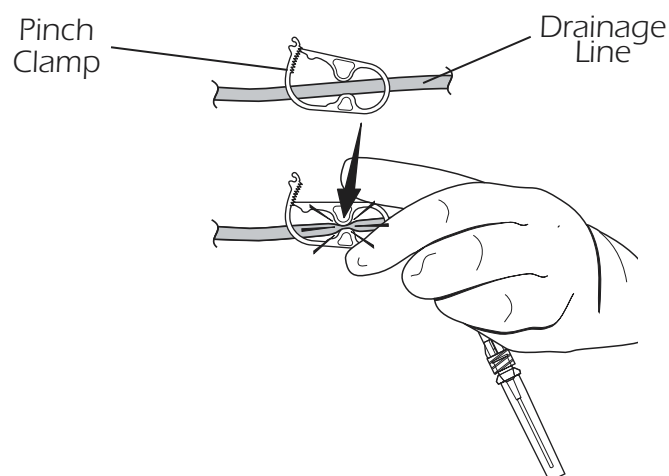


10. Peel open the pouch containing the valve cap and let the cap fall onto the sterile blue wrapping.

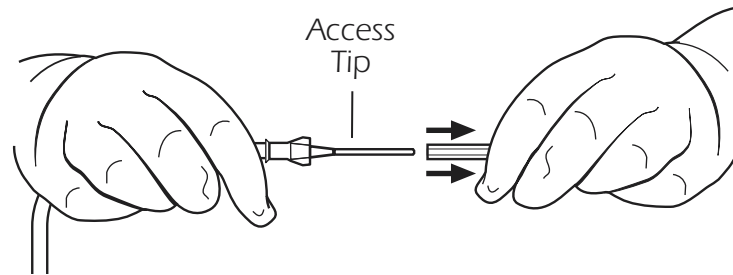


Connecting the drainage bottle

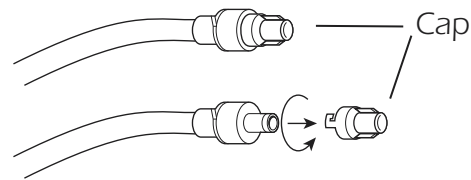
1. Squeeze the clamp on the drainage line **completely closed**.



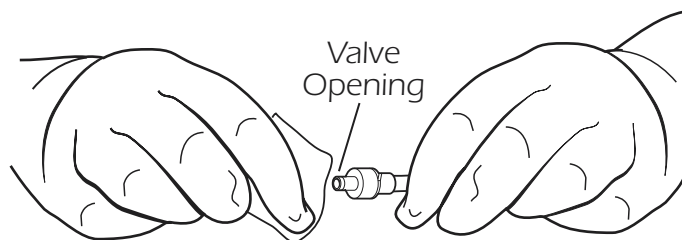
2. Hold the drainage line near the access tip and remove the cover from the access tip with your other hand by twisting it and pulling gently. Set the access tip back on the sterile blue wrapping.



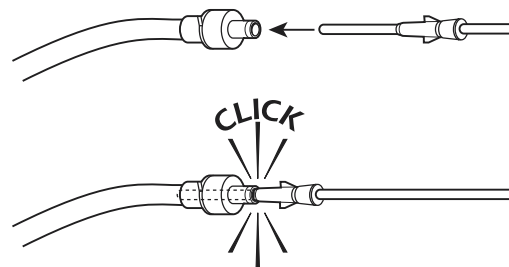
3. Hold the base of the catheter valve and remove the cap by twisting it counterclockwise and pulling gently. Discard the cap.



4. While holding the base of the catheter valve in one hand, clean around the valve opening with an alcohol pad.



5. Continue holding the catheter near the valve. Pick up the drainage line with your other hand and insert the access tip securely into the catheter valve. You will feel and hear a click when the access tip and valve are locked together.

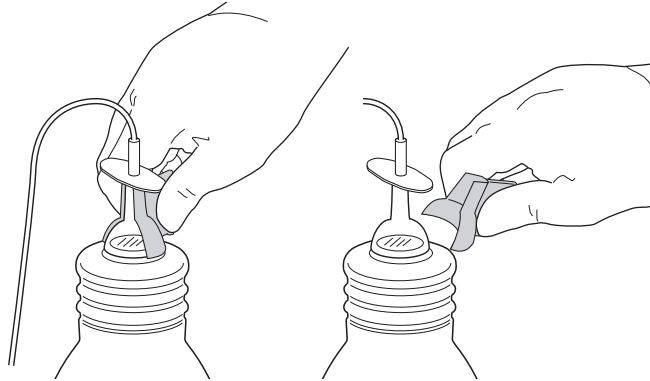


Warning: Keep the valve on your Pleurx Catheter and the access tip on the drainage line clean. Keep them away from other objects to help avoid contamination.

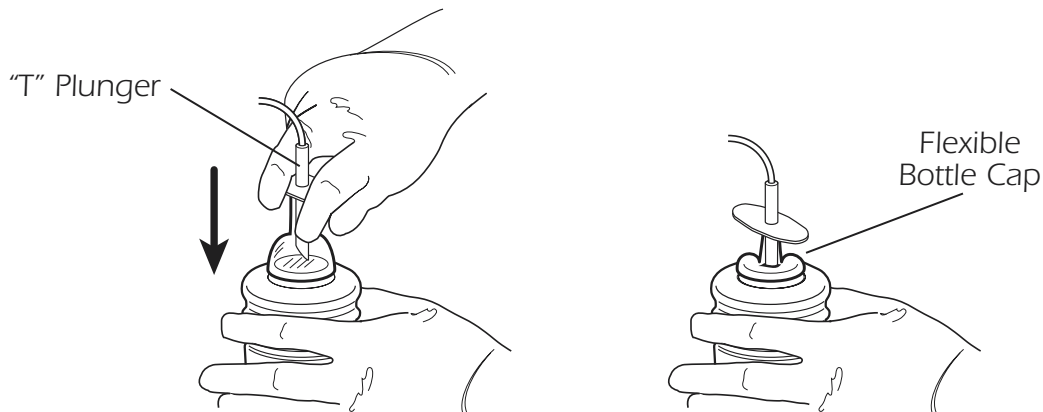
Warning: Do not put anything except the access tip of the drainage line into the Pleurx Catheter valve, since this could damage the valve. A damaged valve might let air be pulled into your chest cavity (if the Pleurx Catheter is in your chest) or let fluid leak out through the valve.

Draining fluid

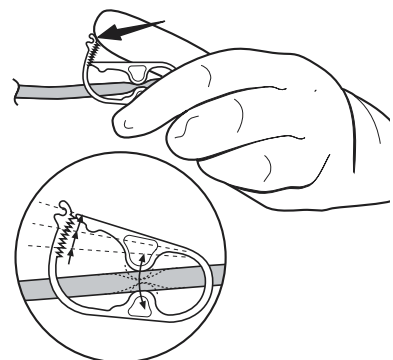
1. The support clip on the vacuum bottle insures that the vacuum seal on the bottle is not broken before you are ready. Remove the support clip by grasping the upper part of the flange and pulling outward.



2. Hold the bottle steady with one hand and push down the white "T" plunger with the other hand to puncture the foil seal. The vacuum in the bottle will pull the flexible bottle cap down as shown below.



3. Release the clamp on the drainage line to begin drainage. Fluid will flow into the vacuum bottle. You can slow the flow by squeezing the clamp partially closed.



- The flow into the bottle may slow down when the fluid is almost completely drained. When the flow stops or the 1000 ml bottle is filled, squeeze the clamp on the drainage line completely closed. The drainage will usually take 5-15 minutes.

Warning: It is normal to feel some pain when draining fluid. If you feel pain when draining, clamp the drainage line to slow or stop the flow of fluid for a few minutes. If you don't feel better after doing this or the pain is severe, contact your nurse or doctor. Pain may be an indication of infection.

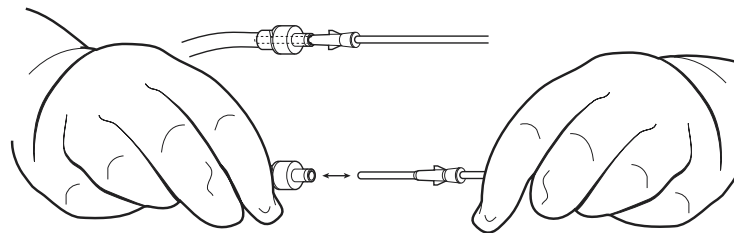
Warning: Do not drain more than 1000 ml (one full bottle) of fluid from your chest at any one time or 2000 ml (two full bottles) of fluid from your abdomen.

Warning: Do not use scissors or other sharp objects near the Pleurx Catheter.

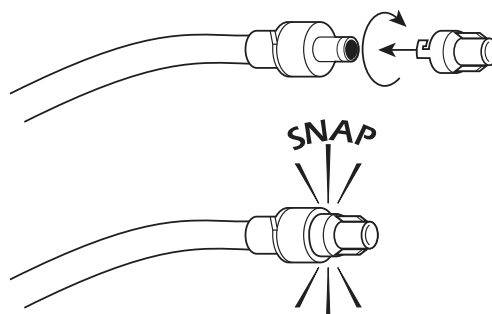
Note: The blue slide clamp should be used if you accidentally cut the catheter. See Warnings and Cautions on page 3.

Final steps

- With the drainage line in one gloved hand and the catheter valve in the other hand, pull the access tip out of the valve in a firm, smooth motion. Set the drainage line down.

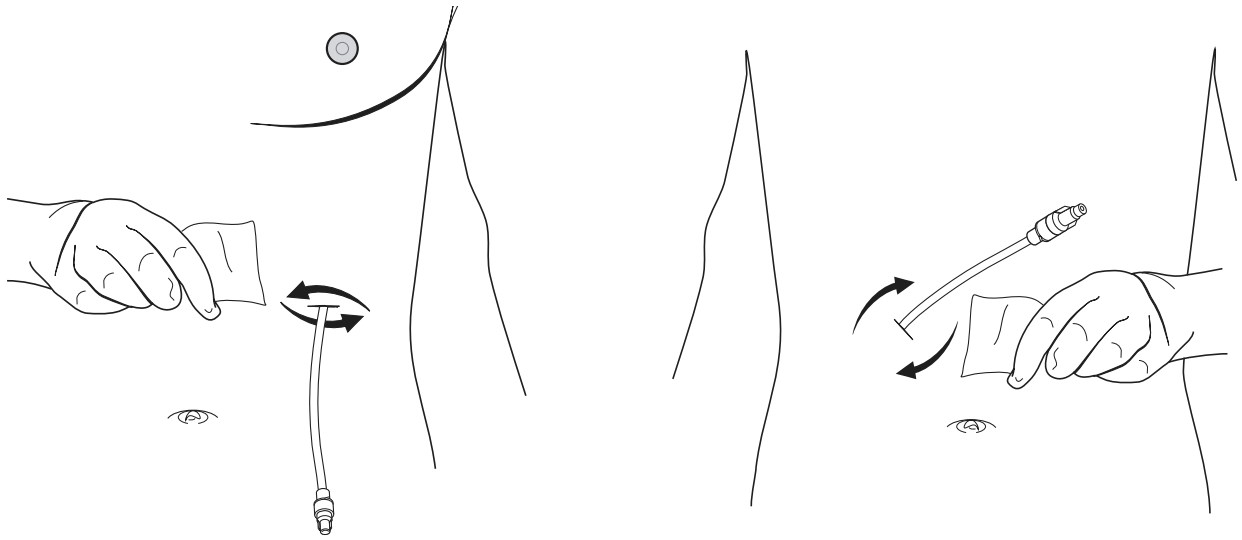


- Clean the valve with an alcohol pad.
- Place the new cap over the catheter valve and twist it clockwise until it snaps into its locked position.

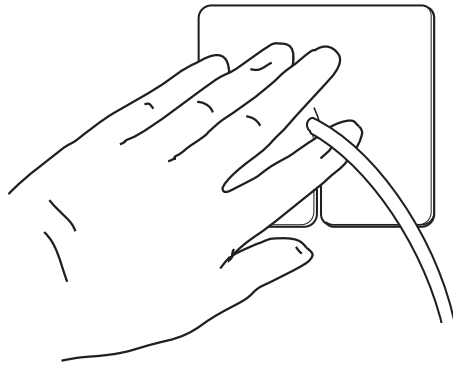


Placing a new dressing

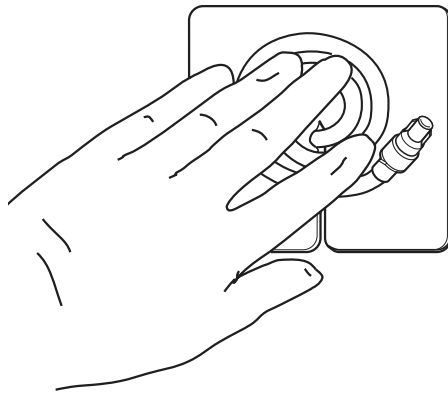
1. Clean around the catheter site with an alcohol pad.



2. Place the foam catheter pad around the catheter.



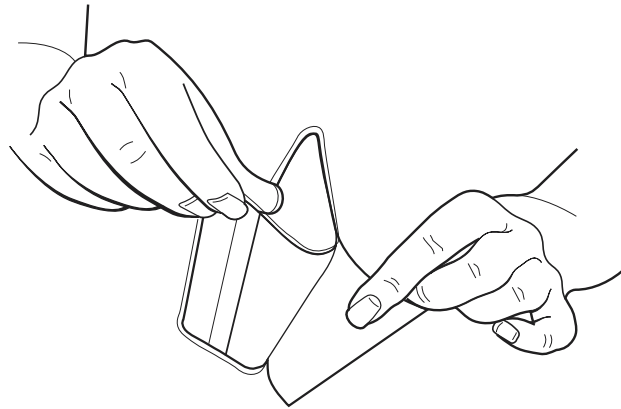
3. Wind the catheter into loops and place it over the foam pad.



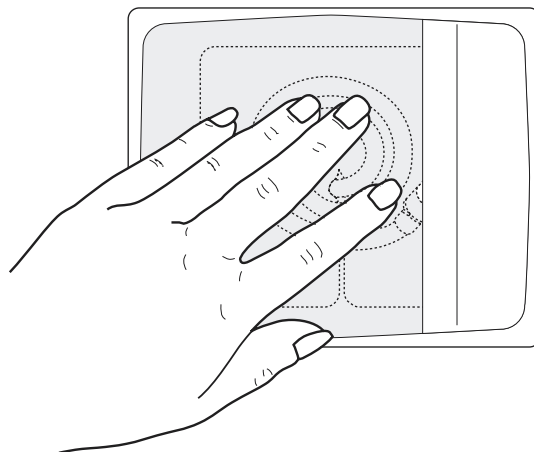
4. Cover the catheter with the gauze pads.



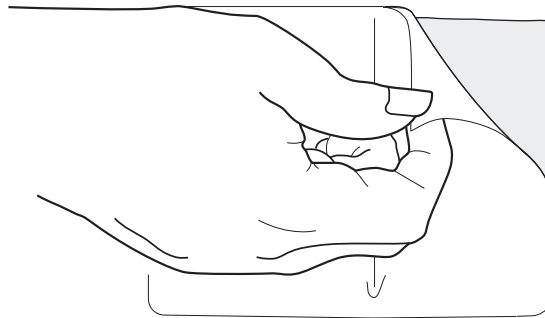
5. Remove the gloves from both hands.
6. Take the self-adhesive dressing and peel away the larger of the two pieces of paper backing from the dressing.



7. Center the dressing over the gauze pads and press it down.



8. There is a plastic covering that needs to be removed from the dressing. Starting at one of the corners where the paper backing remains, bend the shiny plastic covering back slightly and pinch the corner of the paper and dressing to separate the plastic covering from the dressing. You may find it easier to separate a corner of the paper from the dressing and use the tip of your finger or fingernail to start separating the plastic covering from the dressing. (This is similar to the way you would remove a piece of tape or an adhesive tag.) Peel the plastic covering from the dressing.



9. Remove the remaining paper backing from the dressing and press it down.

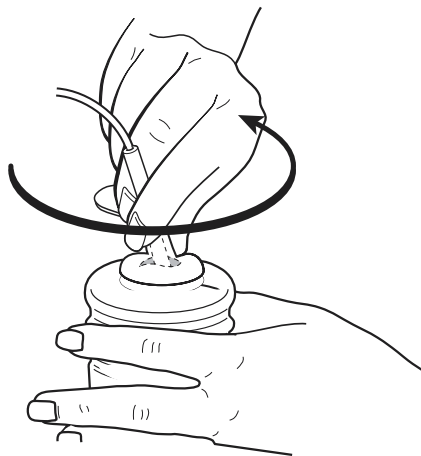
Changing the drainage bottle

If you need to change to a new bottle for any reason the procedure follows the same steps.

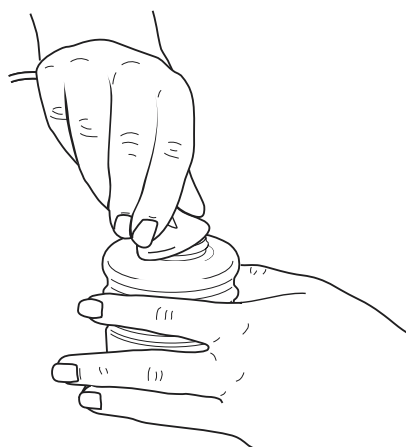
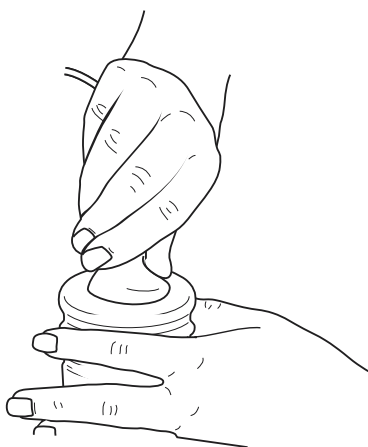
1. Open the second Vacuum Bottle bag and remove the bottle with the attached drainage line. The items in the bag are sterile. It is especially important that the access tip remain sterile. If the cover has fallen off of the access tip, make sure that you do not touch the tip with your hand or anything non-sterile. Set the bottle near the blue wrapping and place the access tip on the wrapping near the other sterile items.
2. Squeeze the clamp on the drainage line **completely closed**.
3. Hold the drainage line near the access tip and remove the cover from the access tip with your other hand by twisting it and pulling gently. Set the access tip back on the sterile blue wrapping.
4. To remove the used bottle, hold the drainage line in one gloved hand and the catheter valve in the other gloved hand, pull the access tip of the used bottle out of the valve in a firm, smooth motion. Set the drainage line down.
5. Continue holding the catheter near the valve. Pick up the new drainage line with your other hand and insert the access tip securely into the catheter valve. You will feel and hear a click when the access tip and valve are locked together.
6. Resume following these instructions for use beginning with Draining Fluid on p. 9. You do not need to clean the valve between bottles.

Emptying the vacuum bottle

1. Hold the bottle steady with one hand and push down on the “T” plunger, then move it in a circular motion to make a larger opening in the foil seal.



2. Next you need to remove the drainage line from the bottle. Release the white clamp on the drainage line to release any vacuum that may be left in the bottle. The drainage line is attached with a flexible cap. Place your thumb on the edge of the cap and push the cap sideways and down into the bottle opening to loosen the cap from the bottle rim. Grasp the cap and pull it away from the loosened side of the bottle top.



3. Empty the bottle into the toilet or sink.
4. Place the bottle in a plastic bag, seal tightly, and discard.

Frequently Asked Questions

Q: How often should I drain the fluid from my chest or abdomen?

A: You should drain fluid as directed by your doctor, usually every one to two days. Consult your doctor before changing the frequency of your drainage.

Chest – If you keep your chest fairly free of fluid, you will be less likely to feel short of breath. You will also be more likely to permanently stop the fluid from building up, so that the catheter can be removed.

Abdomen – If you drain regularly, you will probably have less abdominal pressure and discomfort.

Q: **Chest** – What if I still feel short of breath after I have finished draining.

A: **Chest** – You should not drain more than 1000 ml per drainage. Therefore, you should use only one, 1000 ml bottle. Notify your doctor if you continue to feel short of breath after the 1000 ml bottle is full.

Q: When will I know that the catheter can be removed?

A: When you try to drain fluid 3 times in a row, and each time less than 50 ml drains into the bottle, you should see your doctor to find out if the catheter can be removed or if it needs to be replaced. (See next question.)

Q: What does it mean if the volume of my drainage is smaller or if I do not drain any fluid?

A: There are three reasons that this might occur.

1. If you drained normally the last time and your drainage suddenly stops or you cannot drain at all this time, some debris in the fluid may have clogged the line to the bottle. Squeeze the catheter and the drainage line gently. If drainage does not begin, follow the instructions for changing to another bottle. If the drainage does not start when you use a second bottle, call your doctor. There may be another reason that you are not draining.
2. If your drainage is a little less each time that you drain and the current amount of drainage is much smaller than previously, the fluid may be drying up and it may be time for the catheter to be removed. Call your doctor.
3. If the fluid goes away suddenly or if the amount of drainage gradually declines, it is possible that the catheter may be clogged. Call your doctor.

Q: How long will the catheter be in my chest or abdomen?

A: **Chest** – The catheter will be in your chest until fluid stops draining from your chest. The amount of time will vary from patient to patient, anywhere

from a few weeks to several months.

Abdomen – Fluid build-up is not likely to stop in the abdomen. You may keep the catheter in place as long as you need it.

Q: What should I do if the color of the fluid changes from the usual color?

A: Any change in the appearance of the fluid should be reported to your doctor.

Q: Can I take a shower with the catheter in place?

A: Yes, if a self-adhesive dressing, like the one in the Procedure Pack, is securely attached to your skin, you can get wet. The self-adhesive dressing is designed to keep fluid out. Be sure the dressing is completely and securely attached and that the catheter and gauze pads are all contained underneath it. If the gauze becomes wet when showering, remove the dressing immediately, clean and dry the area and apply a new dressing as instructed on pages 11-13.

Q: What happens if the Pleurx catheter is accidentally pulled out?

A: The Pleurx Catheter has a polyester cuff that is normally under the skin where the catheter is inserted. This cuff and the sutures where the catheter exits your body, help to keep the catheter in place. In the very unlikely event that the catheter is pulled out, cover the exit site with a sterile dressing and seek immediate medical attention

Glossary of Terms

Pneumothorax: air in the space between the lungs and the chest wall

Re-expansion pulmonary edema: accumulation of fluid in the lung associated with very rapid drainage of a pleural effusion

Hypotension: low blood pressure

Circulatory collapse: sudden drop in blood pressure; shock

Electrolyte imbalance: change in the normal level of certain chemical in the body, such as sodium or potassium

Ascites: liquid that builds up in the abdomen

Peritonitis: infection of the peritoneum

Protein depletion: reduction in the amount of protein in the blood

Peritoneum: membranes that line the inside of the abdomen and surround the abdominal organs

Peritoneal space: space in the abdomen formed by the inner and outer membranes of the peritoneum

Additional Drainage Supplies

<i>Product Description</i>	<i>Catalog Number</i>
<input type="checkbox"/> Pleurx Drainage Kit (1000 ml bottle)	50-7510
<input type="checkbox"/> Pleurx Drainage Kit (500 ml bottle)	50-7500
<input type="checkbox"/> Vacuum Bottle (1000 ml) with Drainage Line	50-7210
<input type="checkbox"/> Vacuum Bottle (500 ml) with Drainage Line	50-7205
<input type="checkbox"/> Drainage Line Set	50-7225
<input type="checkbox"/> Replacement Valve Cap	50-7235

Contact your doctor, home health care company, or Denver Biomedical, Inc. about how to obtain supplies.

