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Denver[®]
BIOMEDICAL

PLEURX^{*}

Drainage Kit

Catalog No. 50-7500

■ Instructions for Use

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

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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 the fluid from your chest, 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 of fluid from your chest at any one time.

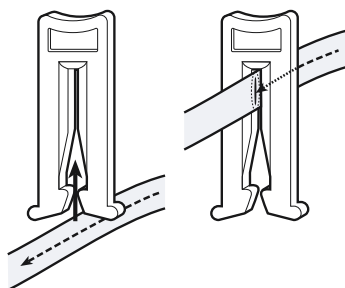
It is normal to feel some pain when draining fluid. If you feel pain in your chest when draining, clamp the drainage line to slow or stop the flow of fluid for a few minutes. If you don't feel better after doing this, contact your nurse or doctor.

Keep the valve on your Pleurx Pleural 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 Pleural Catheter.

If you accidentally cut the catheter follow these steps:

- Pinch the catheter closed between your fingers.
- 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.
- Notify your doctor immediately.



Do not put anything except the access tip of the drainage line into the Pleurx Pleural Catheter valve, since this could damage the valve. A damaged valve might let air be pulled into your chest cavity 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.

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.

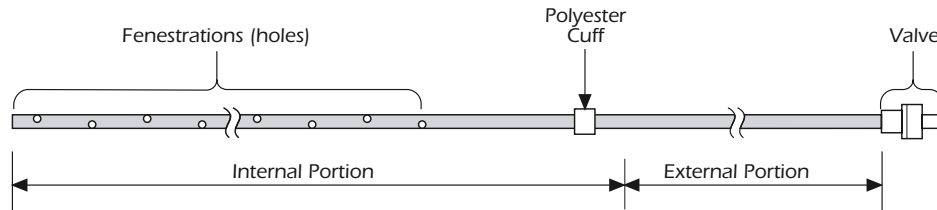
The alcohol pads are flammable. Do not expose the pads to an open flame.

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

This product contains natural rubber latex, which may cause allergic reactions.

The Pleurx Catheter

Your doctor has placed the Pleurx Catheter to allow you to drain fluid from your chest while you are at home. Part of the catheter is inside your chest and has several holes that allow fluid to enter 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

Always use the Pleurx Drainage Kit for draining fluid from your chest 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. The items in the kit are:

- 1 - Plastic vacuum bottle (500 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 (70% isopropyl alcohol)

Sterility

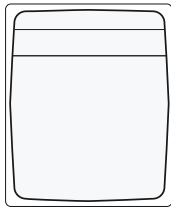
The Procedure Pack and Vacuum Bottle (with drainage line) in this kit have been sterilized. As long as the packaging is not damaged or opened, the contents within each package are sterile. These products are for single use only and are not to be reused.

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

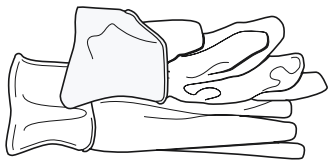
Procedure Pack

Self-Adhesive Dressing

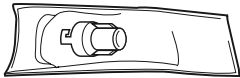


Blue Wrapping around the following

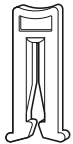
Gloves



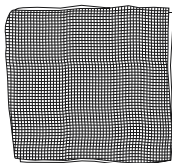
Catheter Valve Cap



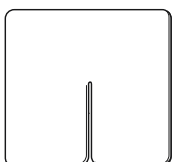
Blue Emergency Slide Clamp



Gauze Pads



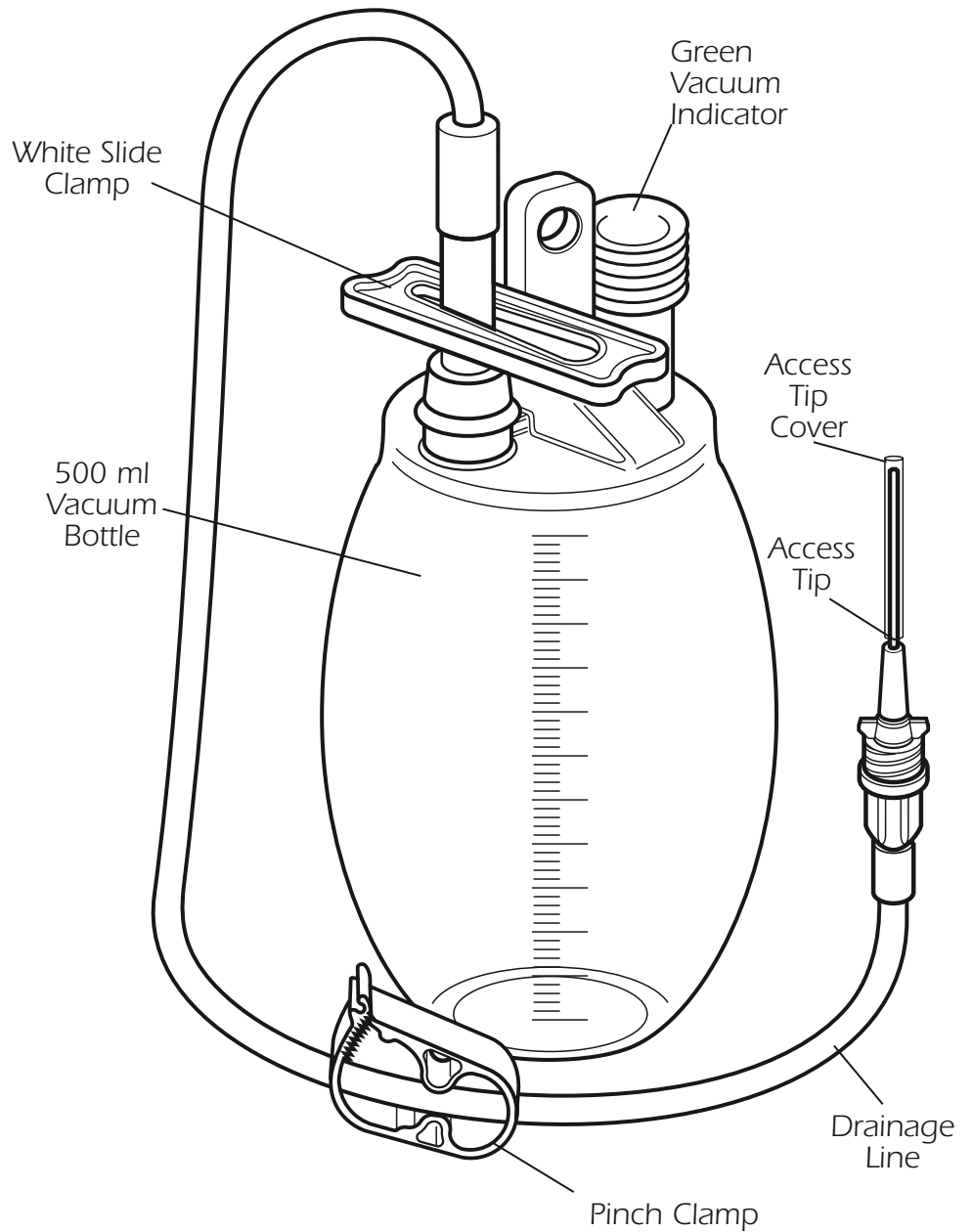
Foam Catheter Pad



Alcohol Pads



Plastic Vacuum Bottle

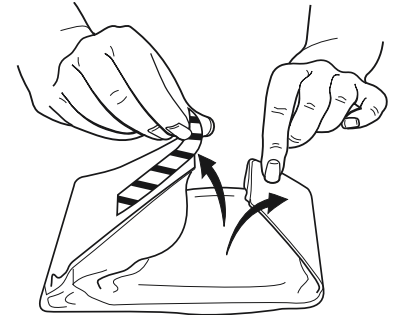


How to drain using the Pleurx Drainage Kit

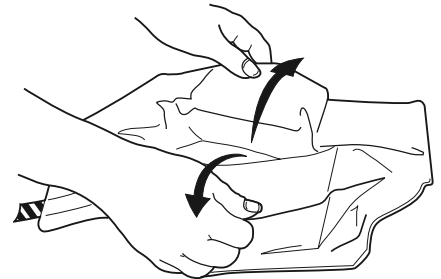
Now that your doctor or nurse has trained you on the drainage procedure, you should find it easy to follow these step-by-step directions. You should drain the fluid from your chest every one to two days or as directed by your doctor.

Getting started

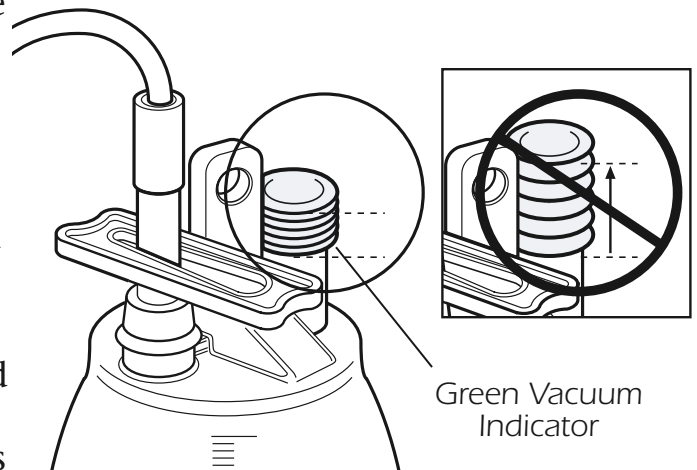
1. Set up a clean, clear workspace on a table or counter.
2. **Thoroughly** wash your hands with soap and water for at least 1 minute.
3. Remove the dressing from over your catheter.
If you see any redness, swelling or fluid around the catheter, finish this drainage procedure and contact your doctor 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.

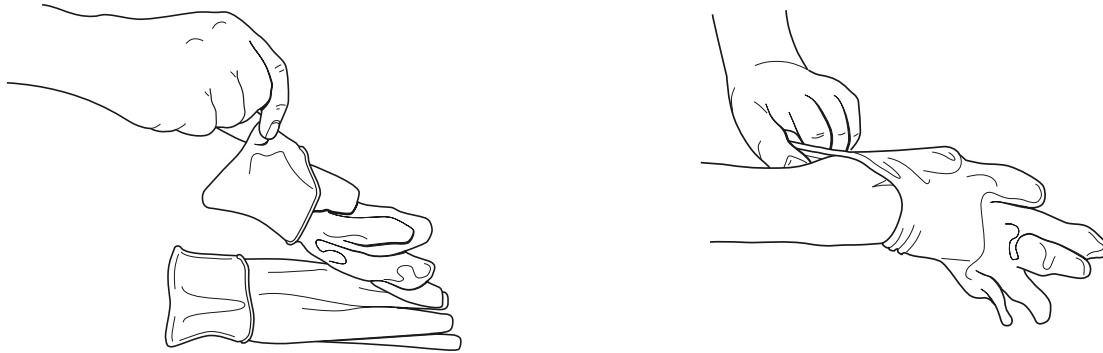


7. Pick up the bag that contains the Vacuum Bottle. Look at the green vacuum indicator on the top of the bottle. This indicator tells you if there is vacuum in the bottle. The indicator should be down, not up. If the indicator is up discard the bottle and use another.

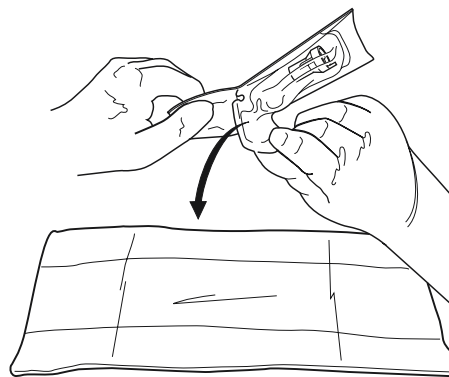


8. Open the Vacuum Bottle bag and remove the bottle with the attached drainage line. The items in the bag are sterile. It is especially important that the access tip remain sterile. If the cover has fallen off of the access tip, make sure that you do not touch the tip with your hand or anything non-sterile. Set the bottle near the blue wrapping and place the access tip on the wrapping near the other sterile items.

9. Tear open the three alcohol pads, but do not remove the pads from the pouches. Place them on the blue wrapping, a short distance from the sterile items.
10. 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.

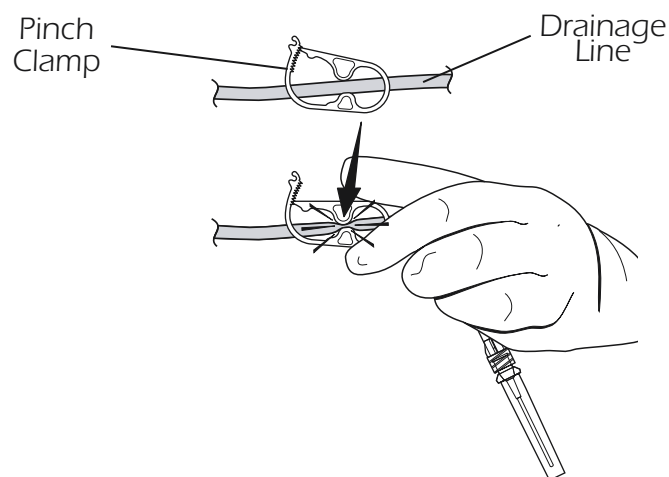


11. Peel open the pouch containing the valve cap and let the cap fall onto the sterile blue wrapping.

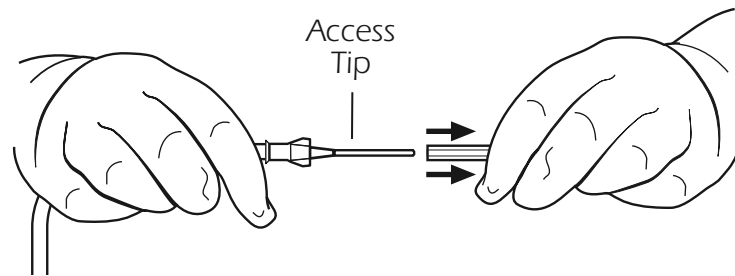


Connecting the drainage bottle

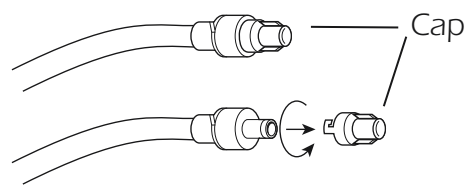
1. Squeeze the clamp on the drainage line **completely closed**.



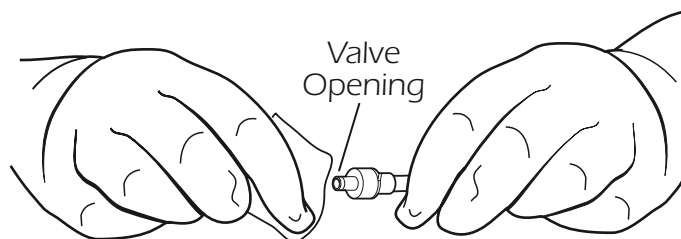
2. Hold the drainage line near the access tip and remove the cover from the access tip with your other hand. Set the access tip back on the sterile blue wrapping.



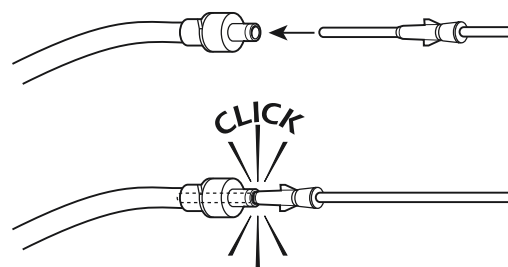
3. Hold the base of the catheter valve and remove the cap by twisting it counterclockwise and pulling gently. Discard the cap.



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.

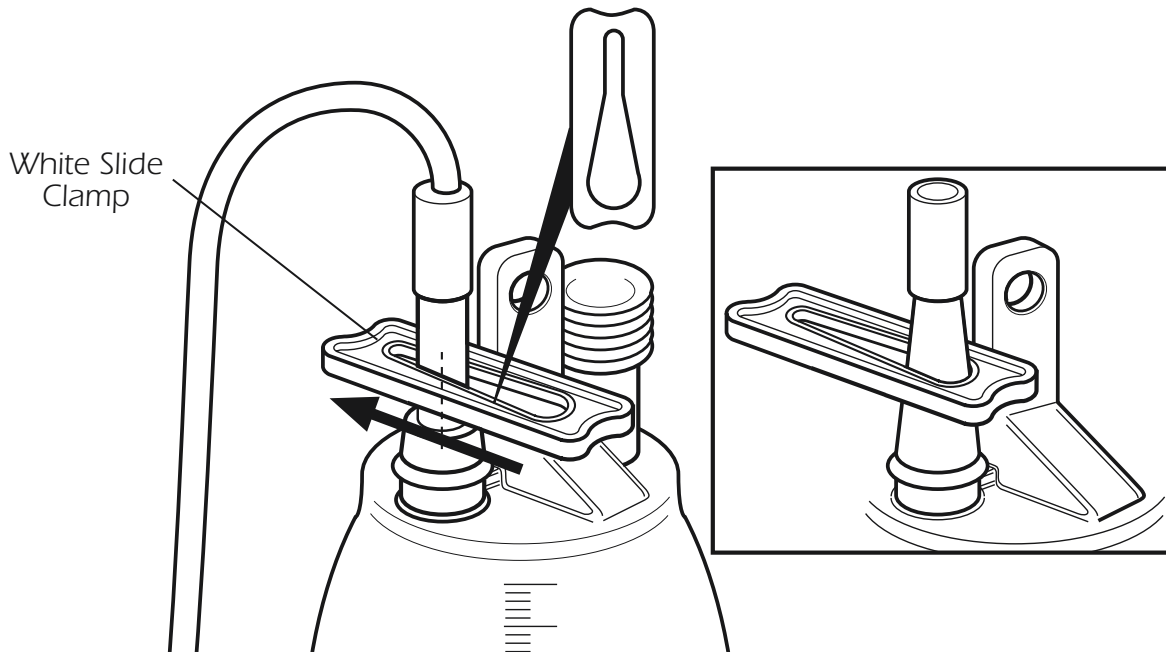


Warning: Keep the valve on your Pleurx Pleural Catheter and the access tip on the drainage line clean. Keep them away from other objects to help avoid contamination.

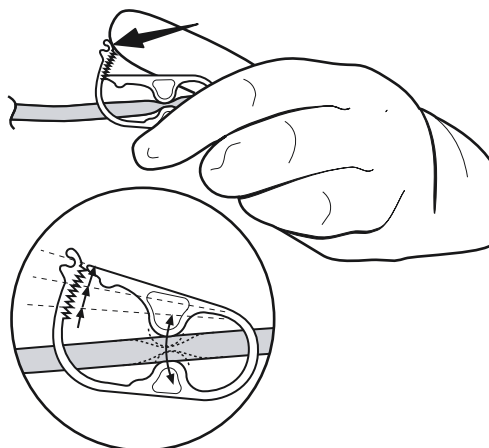
Warning: Do not put anything except the access tip of the drainage line into the Pleurx Pleural Catheter valve, since this could damage the valve. A damaged valve might let air be pulled into your chest cavity or let fluid leak out through the valve.

Draining fluid

1. Push the white slide clamp on the green rubber tube at the top of the vacuum bottle until it no longer pinches the tube closed.



2. 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.



3. The flow into the bottle may slow down when the fluid is almost completely drained from your chest. When the flow stops or the 500 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 in your chest 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, contact your nurse or doctor.

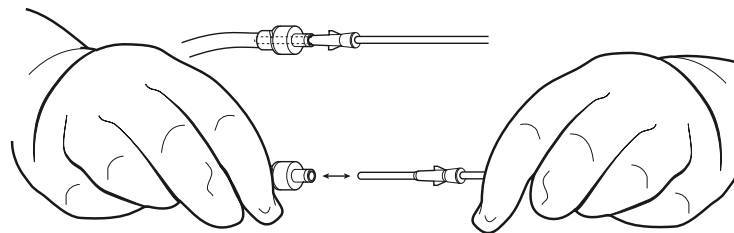
Warning: Do not drain more than 1000 ml of fluid from your chest at any one time.

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

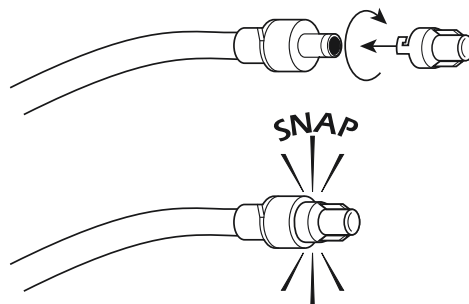
Note: The blue slide clamp should be used if you accidentally cut the catheter. See Warnings and Cautions on page 3.

Final steps

1. 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.

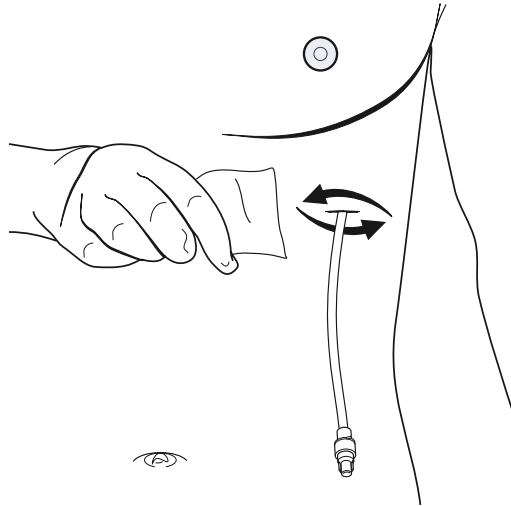


2. Clean the valve with an alcohol pad.
3. Place the new cap over the catheter valve and twist it clockwise until it snaps into its locked position.

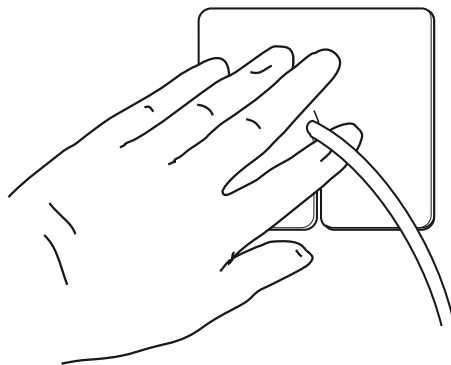


Placing a new dressing

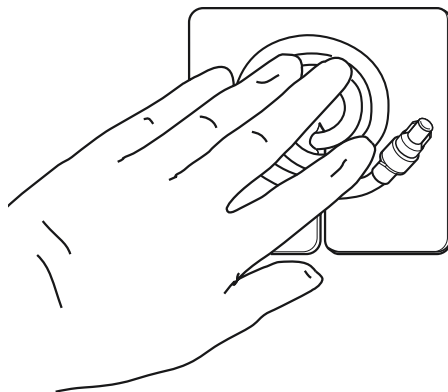
1. Clean around the catheter site with an alcohol pad.



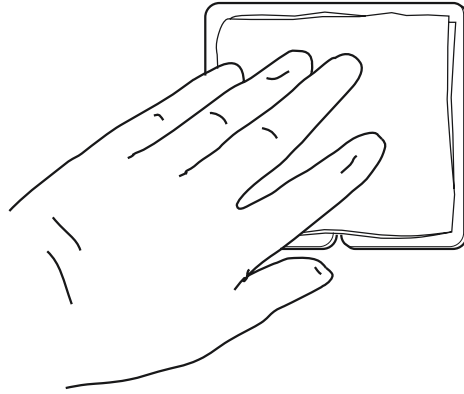
2. Place the foam catheter pad around the catheter.



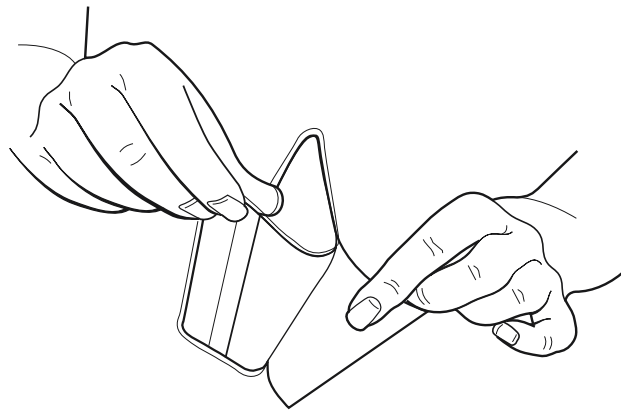
3. Wind the catheter into loops and place it over the foam pad.



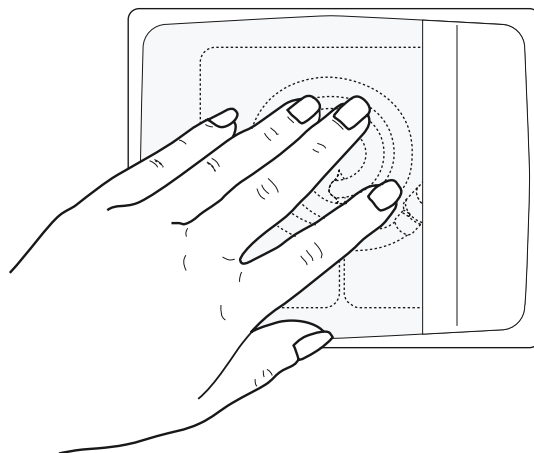
4. Cover the catheter with the gauze pads.



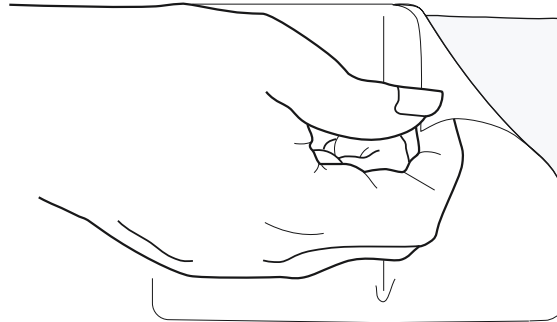
5. Remove the gloves from both hands.
6. Take the self-adhesive dressing and peel away the larger of the two pieces of paper backing from the dressing.



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



- 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.



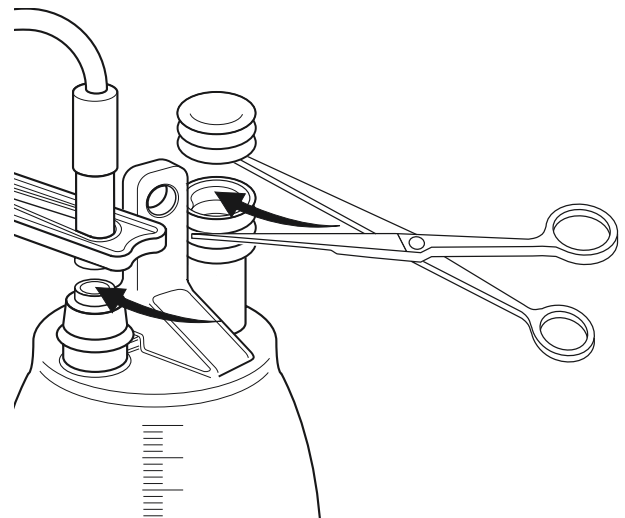
- Remove the remaining paper backing from the dressing and press it down.

Changing the drainage bottle

If you still feel short of breath, or if the bottle contains more than 450 ml of fluid, all the fluid may not have drained from your chest. Use a second bottle to make sure that all the fluid is drained. Open a second bottle. To remove the first bottle, grasp the drainage line in one hand and the catheter valve in the other hand. Pull the access tip out of the valve in a firm, smooth motion. To attach a second bottle, repeat the steps for connecting the bottle to the catheter on pages 7-10. You do not need to clean the valve between bottles.

Emptying the vacuum bottle

- With a pair of scissors, cut off the green vacuum indicator tube and the green rubber tube connected to the drainage line.
- Empty the bottle into the toilet or sink.
- Discard the bottle.



Frequently Asked Questions

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

A: You should drain fluid every one to two days. 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. Consult your doctor if you want to drain more or less frequently.

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

A: You should not drain more than 1000 ml per drainage. Therefore, you should use no more than two 500 ml bottles. Notify your doctor if you continue to feel short of breath after draining two bottles. (Note: The bottle loses a small amount of vacuum over time. The bottle usually contains 450-500 ml when it is “full”.)

Q: What if the drainage bottle won't drain fluid?

A: Due to the composition of pleural fluid, it is possible for fibrous material (clumps) to be drawn into the catheter or drainage line causing it to become plugged or blocked, preventing flow into the bottle. This occurs most often at the tip of the drainage line once it has been inserted into the catheter valve. Should this occur, gently squeeze the catheter where it joins the catheter valve, then gently squeeze the drainage line near the access tip. This may loosen the material lodged at the connection. If this does not cause immediate flow into the bottle, disconnect this drainage line and bottle and try a second bottle. If use of a second bottle does not permit drainage, notify your doctor.

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

A: 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.

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

A: When you try to drain fluid from your chest 3 times in a row, and each time less than 25–50 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.

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 inside my chest?

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.

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.

