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50-0071, 50-7700, 50-9900**

PleurX Drainage Procedure

- en** PleurX Drainage Procedure
- fr** Procédure de drainage PleurX
- de** PleurX-Drainagverfahren
- it** Procedura di drenaggio con dispositivo PleurX
- es** Procedimiento de drenaje con PleurX
- pt** Procedimento de drenagem PleurX
- nl** PleurX-drainageprocedure
- sv** PleurX tömningsprocedur
- fi** PleurX-dreneeraus
- no** Prosedyre for PleurX-drenasje
- da** Procedure for dræning med PleurX
- el** Διαδικασία παροχέτευσης PleurX
- tr** PleurX Drenaj Prosedürü

USA Rx Only



For Single
Use Only



Not made with
natural rubber
latex.



Do not use
if package
is damaged.



DEHP
Contains phthalates

STERILE **EO**

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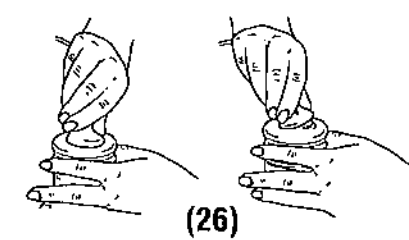
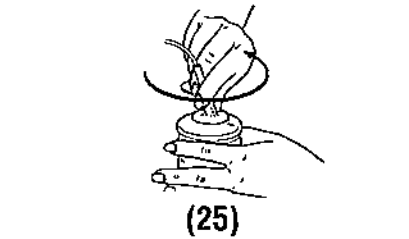
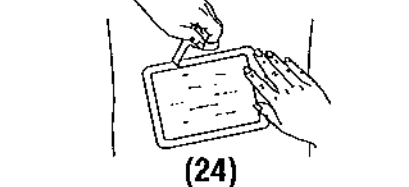
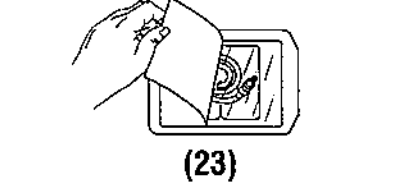
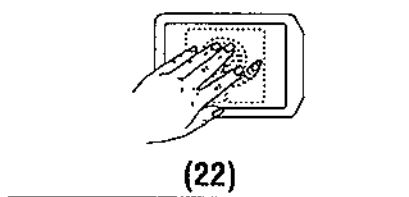
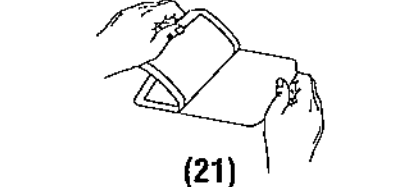
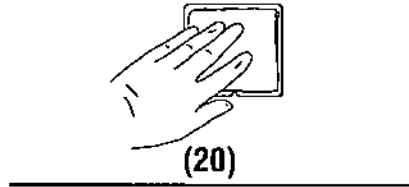
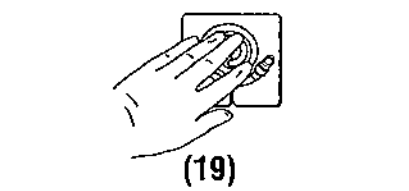
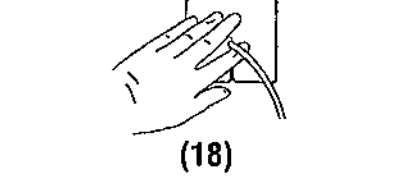
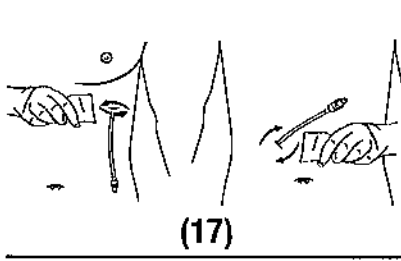
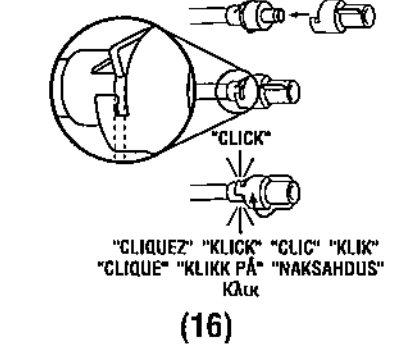
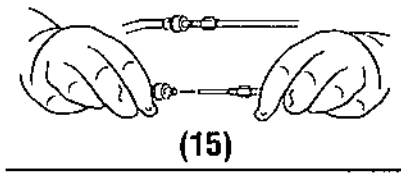
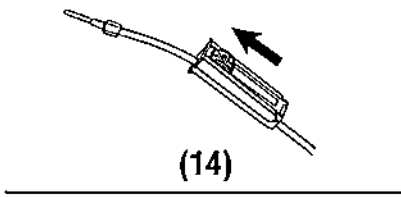
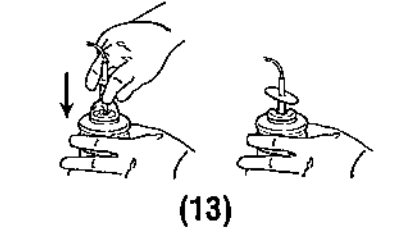
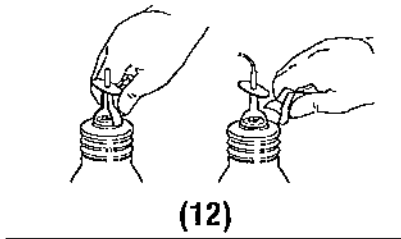
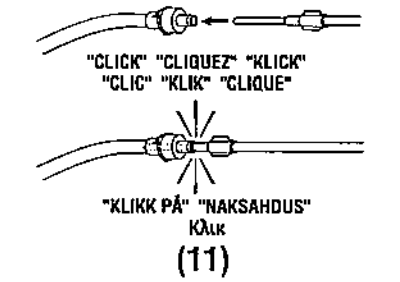
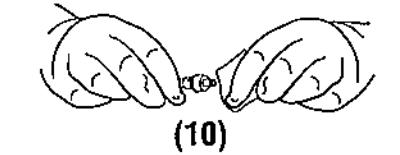
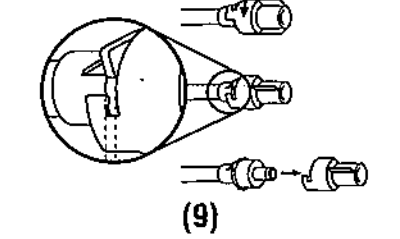
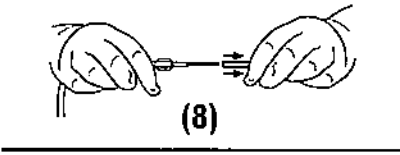
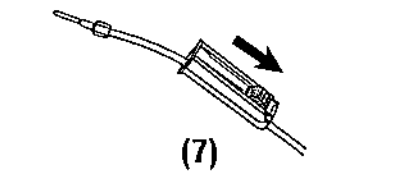
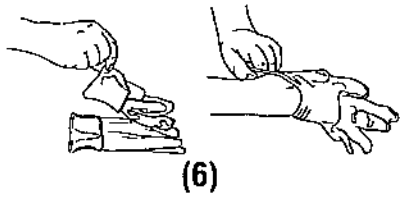
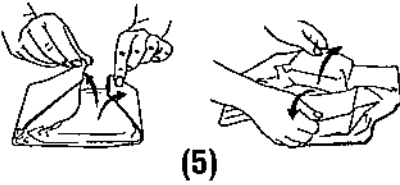
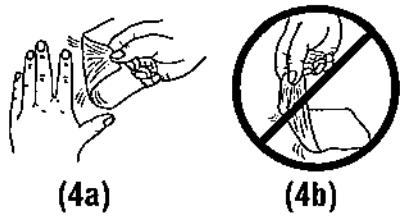
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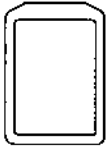

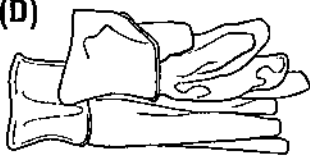

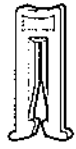
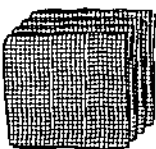
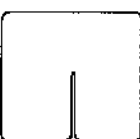


Procedure Pack
 Trousse de procédure
 Verfahrensset
 Pacco procedurale
 Paquete para procedimientos
 Pacote de procedimento
 Procedurepak
 Procedurpaket
 Toimenpidepakkaus
 Prosedyrepakke
 Procedurepakke
 Πακέτο εξαρτημάτων διαδικασίας
 Prosedür Paketi

Plastic Vacuum Bottle
 Bouteille sous vide en plastique
 Plastik-Vakuumflasche
 Flacone sottovuoto in plastica
 Botella de vacío de plástico
 Frasco de vácuo em plástico
 Plastic vacuümfles
 Vakuumflaska i plast
 Muovinen tyhjiöpullo
 Vakuumflaske av plast
 Vakuumflaske af plast
 Πλαστική φιάλη κενού
 Plastik Vakum Şişesi

Figure, Image, Abbildung, Figura, Afbeelding, Kuva, Figur, Eικόνα, Şekil (1)

Self-Adhesive Dressing

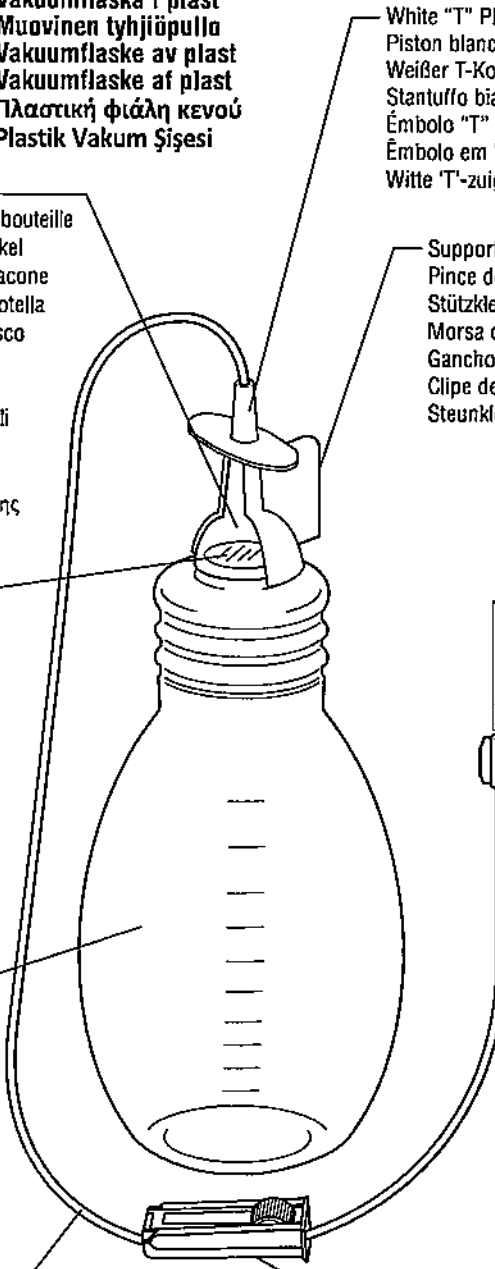
- (A) 
- (B) Blue Wrap around the following:
Alcohol Pads
- (C) 
- (D) 
- (E) 
- (F) 
- (G) 
- (H) 

Flexible Bottle Cap
 Bouchon souple de la bouteille
 Flexibler Flaschendeckel
 Tappo flessibile del flacone
 Tapón flexible de la botella
 Tampa flexível do frasco
 Flexibele flesdop
 Bøjligt flaskelock
 Taipuisa pullon kapseli
 Fleksibel flaskehette
 Fleksibelt flaskelåg
 Εύκαμπτο πώμα φιάλης
 Esnek Şişe Kapağı

Foil Seal
 Opercule
 Foliensiegel
 Sigillo laminato
 Sello de aluminio
 Vedante laminado
 Folieafdichting
 Folieförslutning
 Lehtimetallikalvo
 Folięforsegling
 Φύλλο σφράγισης
 Folyo Kapak

Vacuum Bottle
 Bouteille sous vide
 Vakuumflasche
 Flacone sottovuoto
 Botella de vacío
 Frasco de vácuo
 Vacuümfles
 Vakuumflaska
 Tyhjiöpullo
 Vakuumflaske
 Φιάλη κενού
 Vakum Şişesi

Drainage Line
 Ligne de drainage
 Verbindungsschlauch
 Tubo di drenaggio
 Tubo de drenaje
 Linha de drenagem
 Drainagelijin
Dränageslang
 Łaskuputki
 Drenasjeslange
 Drænslange
 Γραμμή παραχέτευσης
 Drenaj Hattı



White "T" Plunger
 Piston blanc en « T »
 Weißer T-Kolben
 Stantuffo bianco a "T"
 Êmbolo "T"
 Êmbolo em "T" branco
 Witte 'T'-zuiger

Vit "T"-kolv
 Valkoinen T-mäntä
 Hvidt T-stempel
 Hvidt "T"-stempel
 Λευκό έμβολο σχήματος "T"
 Beyaz "T" Pistonu

Support Clip
 Pince de soutien
 Stützklemme
 Morsa di supporto
 Gancho de soporte
 Clipe de apoio
 Steunklem

Stödklämma
 Tukikliipsi
 Støtteklemme
 Støtteclips
 Κλιπ στήριξης
 Destek Klipsi

Access Tip Cover
 Capuchon de l'embout d'accès
 Hülle des Spezialansatzes
 Copertura punta di accesso
 Tapa de la punta de acceso
 Tampa da ponta de acesso
 Toegangstipdop
 Ätkomstspetsens hölje
 Liitinkärjen suojus
 Deksel for tilgangsspiss
 Beskyttelse til adgangsspids
 Κάλυμμα άκρου πρόσβασης
 Giriş Ucu Kapağı

Access Tip
 Embout d'accès
 Spezialansatz
 Punta di accesso
 Punta de acceso
 Ponta de acesso
 Toegangstip
 Ätkomstspets
 Liitinkärki
 Tilgangsspiss
 Adgangsspids
 Άκρο πρόσβασης
 Giriş Ucu

Roller Clamp
 Régulateur de débit à roulette
 Rollklemme
 Modulatore di flusso con rotellina
 Pinza reguladora
 Grampo regulador

Rollklem
 Rullklämma
 Rullasuljin
 Rulleklemme
 Κυλιόμενος σφικτήρας
 Makara Klempe

PleurX Drainage Procedure

Instructions for Use

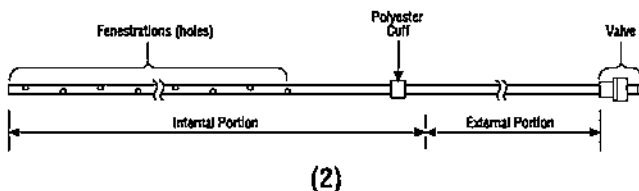
You should have been trained by a doctor or nurse in the correct way to use the items in this kit. If you have any problems or questions about draining the fluid, contact your doctor or nurse.

Read this entire pamphlet carefully before draining fluid.

Product Information

The PleurX Catheter (**Figure 2**) 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 the 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. To provide the best performance and to avoid damage to the catheter, always use the PleurX Drainage Supplies for draining fluid through the PleurX Catheter.

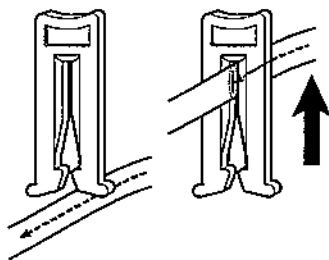
Indications for Use

The PleurX Drainage Kits are indicated for use only with the PleurX Catheter for intermittent drainage.

Warnings

If you accidentally cut the catheter or the valve is leaking, 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. (**Figure 3**)
- Notify your doctor immediately.



(3)

Cautions

For single use only. Re-use may result in a non-functional product or contribute to cross contamination.

Contains Phthalates. The benefit of treatment outweighs the remote possibility of exposure to phthalates.

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.

Contact your physician if:

- You believe your catheter is infected. Pain, redness (erythema), warmth to touch, swelling (edema), fever, or fluid around the catheter site may indicate your catheter is infected. Some discomfort and redness after insertion is expected but should not persist or worsen.
- Shortness of breath is not relieved after draining 1000 ml from your chest or 2000 ml of fluid from the abdomen at one time.
- You continue to experience symptoms, but little or no fluid drains from the catheter.
- Less than 50 ml of fluid drains in 3 drainage procedures in a row.
- The appearance (color, thickness, etc.) changes significantly between drainages.

Sterility

The Procedure Pack and Vacuum Bottle (with drainage line) have been sterilized. The inside of the bottle and bottle connections are not exposed to sterilant. Samples should not be taken from the bottles. These products are for single use only. Do not re-sterilize.

Do not use if package is damaged.

CareFusion 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.

PleurX Drainage Supplies

The following supplies are required to complete a drainage procedure: (**Figure 1**)

- 1 Plastic Vacuum Bottle with attached Drainage Line
- 1 Procedure Pack containing the following sterile items:
 - 1 Self-Adhesive Dressing (**A**)
 - Blue Wrap (Wrapped around the following Items) (**B**)
 - 3 Alcohol Pads (**C**)
 - 1 Pair of Gloves (**D**)
 - 1 Valve Cap (**E**)
 - 1 Blue Emergency Slide Clamp (**F**)
 - 4 Gauze Pads 4" x 4" (10 cm x 10 cm) (**G**)
 - 1 Foam Catheter Pad (**H**)

How to Drain Using the PleurX Vaccum Bottle

Now that your doctor or nurse has trained you on the drainage procedure, you should find it easy to follow these step-by-step instructions. 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.

Prepare to Drain

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

Note: The blue emergency slide clamp should be used if you accidentally cut the catheter. See Warnings (Figure 3)

1. Set up a clean, clear workspace on a table or counter. Be sure to be near a sink and have a garbage can nearby.
2. Place the number of bottles that you plan on using near your workspace.
3. Thoroughly wash your hands with soap and water for at least 1 minute.
4. Remove the self-adhesive dressing from over your catheter and discard. Be sure not to tug on the catheter: support the skin while removing the self-adhesive dressing, gently grasp one edge and slowly peel the self-adhesive dressing from the skin. (Figure 4a) **Note:** Avoid skin trauma by peeling the self-adhesive dressing back, rather than pulling it from the skin. (Figure 4b)

Caution: Pain, redness (erythema), warmth to touch, swelling (edema), fever, or fluid around the catheter site may indicate your catheter is infected. Some discomfort and redness after insertion is expected but should not persist or worsen. If you see signs of infection, finish the drainage procedure and consult your doctor or nurse.

5. Thoroughly wash your hands again with soap and water for at least 1 minute.
6. Open the Drainage Kit bag and remove the Procedure Pack pouch.
7. Open the Procedure Pack pouch. Set the self-adhesive dressing aside.
8. Set packet with blue wrap on your workspace with the flap side up. Carefully unfold the blue wrap by pulling on the outside of the wrap. Leave the enclosed items on the wrap. The items and the inside of the wrap are sterile. Do not touch them with your ungloved hands or other non-sterile items. (Figure 5)
9. Remove the bottle with the drainage line from the outer pouch. Set the bottle near the blue wrap and place the access tip on the blue wrap. If the cover has fallen off of the access tip, make sure you do not touch the tip with your hands or anything non-sterile. It is especially important that the access tip remain sterile.
10. Remove the paper tape from the drainage line and uncoil the drainage line. Place the access tip back on the blue wrap.
11. Pick up the gloves by the folded cuff and put on as shown. (Figure 6) 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.

12. Tear open the three alcohol pads, but do not remove the pads from their pouches. Place them on the blue wrap.

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

Connect the Drainage Bottle

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 any other device could damage the valve. A damaged valve may allow air into your body or let fluid leak out through the valve when you are not draining.

1. Close the roller clamp completely by rolling the wheel on the roller clamp toward the bottle. (Figure 7)

Caution: The roller clamp on the drainage line must be completely closed when not draining or the vacuum in the bottle may be lost.

2. Remove the cover from the access tip by twisting it and pulling gently. Discard the cover. Set the access tip back on the sterile blue wrap. (Figure 8)
3. Hold the base of the catheter valve and remove the cap by twisting it counterclockwise and pulling gently. (Figure 9) Discard the cap.
4. Clean around the valve opening with an alcohol pad. Discard the alcohol pad. (Figure 10)
5. Insert the access tip securely into the catheter valve. You will feel and hear a click when the access tip and valve are securely connected. (Figure 11)

Caution: Make sure that the valve and the access tip are securely connected when draining. If they are accidentally separated, they may become contaminated. If this occurs, clean the valve with an alcohol pad and use a new drainage line to avoid potential contamination.

Caution: Precautions should be taken to ensure the drainage line is not tugged or pulled.

Drain Fluid

Warnings: It is normal to feel some discomfort or pain when draining fluid. If discomfort or pain is experienced when draining, roll the wheel on the roller clamp toward the bottle 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 doctor or nurse. Pain may be an indication of infection.

Warnings: Do not drain more than 1000 ml of fluid from your chest or 2000 ml of fluid from your abdomen at any one time.

1. The support clip on the vacuum bottle ensures 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. (Figure 12)
2. Hold the bottle steady with one hand and push the white "T" plunger down with the other hand to puncture the foil seal. The vacuum in the bottle will pull the flexible bottle cap down. (Figure 13)

3. Roll the wheel on the roller clamp away from the vacuum bottle to begin drainage. (Figure 14) When fluid begins to flow into the drainage line you may partially close the roller clamp to slow the flow of fluid by rolling the wheel on the roller clamp toward the bottle.
4. The flow into the bottle may slow down when the fluid is almost completely drained. When the flow stops or the bottle is filled, completely close the roller clamp by rolling the wheel on the roller clamp toward the bottle. Drainage will usually take 5–15 minutes.

Changing the Drainage Bottle

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

1. Remove the new bottle with the drainage line from the outer pouch. Set the bottle near the blue wrap and place the access tip on the blue wrap. If the cover has fallen off of the access tip, make sure you do not touch the tip with your hands or anything non-sterile. It is especially important that the access tip remain sterile.
2. Remove the paper tape from the drainage line and uncoil the drainage line. Place the access tip on the blue wrap.
3. Completely close the roller clamp by rolling the wheel on the roller clamp toward the bottle. (Figure 7)
4. Remove the cover from the access tip by twisting it and pulling gently. Discard the cover. Set the access tip back on the sterile blue wrap. (Figure 8)
5. To remove the used bottle, pull the access tip of the used bottle out of the valve in a firm, smooth motion. Set the used drainage line down.
6. Pick up the new drainage line and insert the access tip securely into the catheter valve. You will feel and hear a click when the access tip and valve are securely connected.
7. Resume following these instructions for use beginning with **Draining Fluid**. You do not need to clean the valve between bottles.

Finish Drainage

1. Pull the access tip out of the valve in a firm, smooth motion. (Figure 15) Set the used drainage line down.
2. Clean the catheter valve with a new alcohol pad. Discard the alcohol pad.
3. Place the new cap over the catheter valve and twist it clockwise until it clicks into its locked position. Cap might feel loose until it is locked into place. (Figure 16)

Place a New Self-Adhesive Dressing

1. Clean around the catheter site with a new alcohol pad. (Figure 17)
2. Place the foam catheter pad around the catheter. (Figure 18)
3. Wind the catheter into loops and place it over the foam pad. (Figure 19)
4. Cover the catheter with up to four (4) gauze pads. (Figure 20)
5. Remove gloves from both hands.

6. The self-adhesive dressing has three (3) layers:
 - a. printed liner
 - b. clear wound dressing
 - c. center panel and frame backing
7. Peel the printed liner from the self-adhesive dressing, exposing the adhesive surface. (Figure 21)
8. Center the self-adhesive dressing over the gauze pads and press it down. (Figure 22) **Note:** Do not stretch the self-adhesive dressing during application.
9. Remove and discard the center panel from the backing of the self-adhesive dressing. (Figure 23)
10. Slowly remove the frame while smoothing down the self-adhesive dressing edges. (Figure 24)
11. Smooth the entire self-adhesive dressing from the center toward the edges using firm pressure to enhance adhesion.

Dispose of the PleurX Drainage Bottle(s)

1. Record the volume of drained fluid on drainage chart.

Note: Dispose of the drained liquid and the used drainage bottle per applicable local regulations. Used product may present a potential biohazard. Do not reuse.

If the applicable local regulations instruct you to empty the drainage bottle, follow steps 2-6 below.

2. 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. (Figure 25)
3. Roll the wheel on the roller clamp away from the bottle to release any vacuum that may be left in the bottle then completely close the roller clamp by rolling the wheel on the roller clamp toward the bottle.
4. 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 bottle to remove the drainage line. (Figure 26)
5. Empty the bottle into the toilet or sink.
6. Place the drainage line and bottle in a plastic bag, seal tightly, and discard.

Caution: If fluid spills, use soap and water to clean skin and use appropriate cleaning agent for all other surfaces.

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.
- Q: What if I still feel short of breath or experience discomfort after I have finished draining?
- A: Notify your doctor if you continue to feel short of breath or experience discomfort. Do not drain more than 1000 ml of fluid from your chest or 2000 ml of fluid from your abdomen at any one time.

- 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 fluid I drain decreases or if I do not drain any fluid?
 A: If the fluid goes away suddenly or if the amount of drainage gradually declines, it is possible that the catheter or drainage line may be clogged. 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. If the amount of drainage gradually declines, the fluid may be drying up and it may be time for the catheter to be removed. Refer to question "When will I know that the catheter can be removed?"
- Q: How long will the catheter be in my chest or abdomen?
 A: The catheter will be in until fluid stops draining. The amount of time will vary from patient to patient. Fluid build-up is not likely to stop in the abdomen but may stop in the chest. The catheter may remain 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 or bath with the catheter in place?
 A: **Shower:** You can take a shower or sponge bath if a self-adhesive dressing like the one in the Procedure Pack is securely attached to your skin. The self-adhesive dressing is designed to keep fluid out. Be sure the self-adhesive 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 self-adhesive dressing immediately, clean and dry the area, and apply a new self-adhesive dressing as instructed under section "Place a New Self-Adhesive Dressing".
- A: **Bath:** Do not allow the catheter to soak underwater in a tub, bath, pool, etc.
- Q: What happens if the PleurX Catheter is accidentally pulled out?
 A: In the unlikely event that the catheter is pulled out or the cuff becomes exposed, cover the exit site with a sterile self-adhesive dressing and seek immediate medical attention. The PleurX Catheter has a polyester cuff that is normally under the skin where the catheter is inserted. The cuff and the sutures help keep the catheter in place.
- Q: How will I know if my catheter is infected?
 A: You should contact your doctor immediately if you believe your catheter is infected. Pain, redness (erythema), warmth to touch, swelling (edema), fever or fluid from around the catheter site may indicate your catheter is infected. Some discomfort and redness after insertion is expected but should not persist or worsen.

Glossary of Terms

Ascites: liquid that builds up in the abdomen

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

Circulatory collapse: sudden drop in blood pressure: shock

Erythema: redness of the skin

Edema: swelling due to excessive fluid

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

Hypotension: low blood pressure

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

Peritonitis: infection of the peritoneum

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

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

PleurX Accessories

PleurX Lockable Drainage Line REF 50-7245

PleurX Valve Cap REF 50-7235

Contact your doctor, home health care company, or CareFusion about how to obtain supplies.

Warranty

CareFusion 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 expressed 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 a qualified medical professional. CareFusion shall not be liable for incidental or consequential damages of any kind.

Note: Not made with natural rubber latex.