References:
Alan Tremblay, MD, FCCP; and Gaëtane Michaud, MD, FCCP. Single-Center Experience with 250 Tunneled Pleural Catheter insertions for Malignant Pleural Effusion (Chest 2006; 129:362-368)

ASEPT™ is a trademark of PFM Medical, Inc.
Product Description:
The ASEPT™ Pleural Drainage System is a tunneled, long term catheter used to drain accumulated fluid from the pleural cavity to relieve symptoms associated with pleural effusions. The catheter is being placed in the pleural cavity enabling the patient to perform intermittent pleural effusion drainage at home or hospital. The primary components of the system are the ASEPT™ indwelling Pleural Catheter and the ASEPT™ Pleural Drainage Kit. The end of the indwelling catheter has a valve attached that will allow flow of fluid only when accessed. The valve should only be connected to the ASEPT™ Drainage line connected to the drainage bottle kit. Although the ASEPT™ drain line, which is part of the Pleural Drainage System as well as available separately, may be connected to other fluid collection equipment we strongly recommend using the ASEPT™ Drainage Kit only. The ASEPT™ Pleural Drainage System provides patients with a convenient way to relieve pleural effusion symptoms at home.

Indications For Use:
The ASEPT™ Pleural Drainage System is intended for long term, intermittent drainage of symptomatic, recurrent, pleural effusions, including malignant pleural effusions and other pleural effusions that do not respond to treatment.

Contraindication, Warnings and Precautions:
Contraindications to catheter placement:
This device is contraindicated under the following conditions:
- Known or suspected pleural cavity infections or sepsis.
- Known or suspected coagulopathy or other hemorrhagic tendency.
- Pleural cavity is multi-loculated in a way that drainage from a single location is not expected to effectively relieve symptoms, such as dyspnea and chest discomfort.
- Patient medical condition including their anatomy is insufficient to accommodate an indwelling catheter.
- Dyspnea developed by other medical conditions is irrelevant to pleural effusion.
- Patient is known or suspected to be allergic to materials contained in the device.
- Patient has a medical history or symptom palliation failure by pleural drainage.
- The effusion is known to be chylous.
- There is a shift of greater than or equal to 2 cm in the mediastinum towards the ipsilateral side of the effusion.

Warnings:
- Do not reuse. Intended for single patient use.
- Accessing the catheter with anything other than the ASEPT™ drainage line connector may damage the valve.
- Dispose of the used product in accordance with applicable local, state and federal regulations. Used product may present a potential biohazard.
- When using the ASEPT™ drain line to access the catheter for drainage with equipment other than the ASEPT™ Drainage Kit, the adapter that is included in the kit may be utilized.
- When using the ASEPT™ drain line to access the catheter, ensure that the pinch clamp is fully closed prior to connecting.
- Use caution when using wall suction or drainage equipment other than the ASEPT™ Drainage Kit. It is strongly recommended to use the ASEPT™ Drainage Kit only.
- Do not pass a wire, needle or other device through the valve.
- Do not flush or attempt to clear an occluded catheter with a syringe smaller than 10 ml.
- This product and its packaging have been sterilized with ethylene oxide. Ethylene Oxide is a chemical known to the State of California to cause cancer, birth defects, or reproductive harm.

Precautions:
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Carefully read and follow instructions prior to using this device.
- Insertion or removal of this device is only to be done by qualified health professionals.
- Sterile technique should be used when placing and draining the catheter.
- Sterilized by Ethylene Oxide. Do not resterilize.
- Exercise care when placing the catheter to prevent it from coming into contact with surfaces such as drapes or towels. Silicone rubber is highly electrostatic and attracts airborne particles and surface contaminants.
- Care must be taken when inserting the guidewire needle (commonly referred to as Seldinger needle) to avoid puncturing or lacerating organs.
- Exercise care when placing ligatures to avoid cutting or occluding the catheter.
- Use rubber-shod instruments when handling the catheter. Possible cuts or tears can occur if rubber-shod instruments are not used.
- Re-expansion pulmonary edema may occur if too much fluid is removed too rapidly. Therefore, it is recommended to limit drainage to no more than 1000 – 1500 ml. The volume of pleural fluid removed should be based on the patient’s individual status.
Suggested Catheter Placement Procedure

Before beginning this procedure, read the "Contraindication, Warning and Precautions" sections of this manual. Proper procedures are the responsibility of the physician. The appropriateness of any procedure must be based upon good medical judgment and the needs of the patient. The following placement procedure should be used as general guideline only; actual procedures may differ and are the responsibility of the physician. Figure 1 illustrates the placement of the ASEPT™ Pleural Drainage catheter, as described in the following procedure.

1. Place the patient appropriately to access the desired catheter insertion site.
2. Identify the appropriate interspace through which to place the catheter. The catheter is typically placed in the mid axillary line.
3. ASEPTically clean all around the planned insertion site.
4. Place the fenestrated drape with the opening located over the planned insertion and tunneling site.
5. Proceed with local anesthesia. Aspirate Lidocaine HCl 1% into a small syringe with a 25 Ga needle and raise a skin wheal. Attach the 22 Ga needle to the large syringe aspirating additional Lidocaine to complete infiltration of the access site and tunnel track.
6. Insert the guidewire needle (Commonly referred to as "Seldinger Needle") attached to a small syringe through the desired interspace and just over the lower rib. Ensure free aspiration of pleural fluid. Figure 2 Remove the syringe, leaving the guidewire needle in place. Figure 3

Caution: Care must be taken when inserting the needle to avoid puncturing the heart, lung, liver or abdominal organs.

Figure 1: ASEPT™ Pleural Drainage Catheter Placement

- Incision Site for Pleural Space
- Catheter
- Incision Exit Site

Figure 2: Guidewire needle with attached syringe
7. Leaving the guidewire needle in place, insert the guidewire through the needle, advancing it into the pleural cavity. Figure 4. Ensure that no resistance is encountered.

8. Remove the guidewire needle. Leave the guidewire in place. Figure 5

9. Make a 1 cm incision through the guidewire insertion site.
10. Make a 1-2 cm incision approximately 5 cm away from the first incision site. Figure 6
11. Attach the fenestrated end of the catheter onto the tunneler.

Caution: Exercise care when placing the catheter to prevent the catheter from coming into contact with non-sterile surfaces or particles. Silicone rubber is highly electrostatic and attracts airborne particles and surface contaminants.

Caution: Use rubber-shod instruments when handling the catheter. Possible cuts or tears can occur if rubber-shod instruments are not used.

12. Pass the tunneler and a catheter subcutaneously from second incision through and out through the incision at the guidewire insertion site. The lower incision up to and out through the incision at the guidewire insertion site. Figure 7a
Continue to draw the catheter through the tunnel until the polyester cuff passes about 1 cm beyond the lower incision. Figure 7b. Remove the tunneler from the catheter.

13. Pass the 16 Fr. dilator with sheath over the guidewire and into the pleural space. Figure 8

Note: If the cuff is advanced further into the tunnel, it can make later removal of the catheter difficult.

14. Remove the guidewire and dilator from the sheath.
15. Insert the fenestrated end of the catheter into the sheath advancing it until all the fenestrations are within the pleural space. This can be verified under fluoroscopy as fenestrations are located along the barium stripe. Figure 9a.

![Figure 9a: Catheter insertion](image)

16. Peel away the sheath, taking care to keep the catheter in place within the pleural space. Adjust the catheter so that it lies flat in the tunnel and has no kinks as it passes into and through the interspace. Figure 9b

![Figure 9b: Peel away sheath](image)

Caution: Do not use forceps on the introducer to break its handle and/or peel the sheath.

17. Close the skin incision at the insertion site.

18. Close the second incision site and suture the catheter to the skin without restricting the diameter of the catheter. 

**Caution:** Exercise care when placing ligatures to avoid cutting or occluding the catheter.

**Caution:** The ASEPT™ catheter valve is for drainage only! Care should be taken to ensure its proper use.

**Drainage Procedure**

**Caution:** Re-expansion pulmonary edema may occur if too much fluid is removed too rapidly. Therefore, it is recommended to limit drainage to no more than 1000 – 1500 ml for each drainage procedure. The volume of pleural fluid removed should be based on the patient’s individual status. Do not use wall suction directly.

The drainage procedure can be done using ASEPT™ Drainage Kit or standard hospital drainage equipment. An adapter is included in the kit that can be attached to the drain line. It is strongly recommended to drain with the ASEPT™ Drainage Kit. If pleural drainage is practiced using devices other than the ASEPT™ Drainage Kit follow procedures or refer to the Manufacturer’s Instructions for Use. The ASEPT™ Drainage Kit (Catalog #622287) has a drain line attached that can only be used with the ASEPT™ Drainage Catheter. The following procedure is recommended when draining fluid with the ASEPT drainage kit.

1. Clamp the drainage line completely closed using the clamp found on the tubing.

**Caution:** The clamp must be fully closed. If complete occlusion is not achieved, it is possible for some or the entire vacuum in the bottle to be lost.

The illustration below represents all the components involved in connecting to the Drainage line. Figure 10
Caution: Make sure there is no fluid leaking around the valve/hub connection. If they become disconnected or are accidentally separated, a new drainage set should be used under sterile conditions.

4. Push the white slide clamp until it no longer pinches the green tube on the drainage bottle.

5. Release the pinch clamp on the drainage line to begin draining fluid. The fluid will flow into the vacuum bottle. Note: If there is no or very little fluid flow, check and ensure that the connection between the ASEPT™ connector and the valve is tight.

Fluid removal rate may be regulated by adjusting the drainage line clamp. The clamp can be used to slow the rate of fluid removal down if the patient experiences pain associated with drainage.

6. Clamp the drainage set fully closed when drainage stops or the desired amount of fluid has been removed.

7. Grasp the catheter valve and the ASEPT™ connector and twist to disconnect the drainage set. Make sure the catheter is tightly secured to the valve.

8. Disinfect the end of the valve. Do not push the swab through the valve as damage to the valve may occur.

9. Place the soft, foam catheter pad around the catheter, on the patient's abdomen.

10. Wind the catheter into loops, cover with gauze pads, and secure to the patient with self-adhesive dressing.

11. Dispose of the drainage set and bottle container appropriately.

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Figure 10: Drain line and Catheter

2. Remove the protective cap from the drain line and align the ASEPT™ Connector in the center of the silicone valve surface. Figure 11a

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Figure 11a: Centering ASEPT™ Connector

3. Push the ASEPT™ Connector into the silicone valve surface while turning the spin collar on to the valve. Figure 11b, 11c

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Figure 11b: Pushing ASEPT Connector into valve

Figure 11c: Turning spin collar

WARNING: Make sure the connectors are tight and that end of the valve is pressed against the “O” ring and sealed.

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Figure 12: Drainage Line and Catheter to Patient’s Body
Catheter Valve Replacement
In case the catheter valve becomes blocked it is necessary to replace the valve.

Make sure you have a new valve replacement kit opened and ready before changing the valve. Follow sterile technique procedures.

1. Clamp the ASEPT™ catheter to prevent air from entering the catheter.
   Use rubber shods in between the forceps to prevent damage to the catheter and cut the ASEPT™ catheter between the forceps and the connector.
2. Using proper ASEPTic technique, wipe the surface of the replacement connector that will be inserted into the catheter with an alcohol pad.
3. Insert the catheter tubing all the way into the valve connector.

Subsequent Drainage Procedures
Subsequent drainage procedures are to be performed using the ASEPT™ Drainage Kit (Catalog # 622287). Each drainage kit contains the necessary drainage line, vacuum bottle, and other necessary items to perform the drainage procedure.

It is vital that patients and/or caregivers are carefully instructed on how to use the kit to drain the pleural space. The person(s) responsible for drainage must be able to demonstrate they are capable of performing the procedure.

If the patient/caregiver is not able or willing to drain the effusion at home, a medical professional should drain the effusion.

Catheter Removal Procedure
It may be appropriate and/or necessary to remove the ASEPT™ Pleural Drainage catheter. Three successive attempts to drain fluid that result in less than 50 ml of fluid removed may indicate one of the following:
1) pleurodesis has been achieved, 2) the catheter is loculated away from the fluid, or 3) the catheter is occluded.

1. Place the patient in an appropriate position.
2. ASEPTically clean the patient’s chest around the catheter incision site.
3. Anesthetize the site.
4. Remove the sutures.
5. Using forceps, dissect around the cuff to free it from the ingrowth. Ensure that the cuff is completely free within the tunnel.
6. Grasp the catheter in one hand and pull with a firm constant pressure.
7. Cover the site as appropriate.

ASEPT™ Drainage Parts and Accessories
(Provided separately, see package label for contents.)

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Catalog #</th>
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<tbody>
<tr>
<td>ASEPT™ Pleural Drainage System</td>
<td>622289</td>
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<tr>
<td>(includes ASEPT™ drainage catheter and insertion kit)</td>
<td>(1 each)</td>
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<tr>
<td>ASEPT™ Peritoneal Drainage System</td>
<td>622284</td>
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<td>(box of 5 each)</td>
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<tr>
<td>ASEPT™ Two Bottle Drainage Set</td>
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<tr>
<td>(Two Bottle Kit for Peritoneal Drainage)</td>
<td>(box of 5 each)</td>
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<tr>
<td>ASEPT™ Drainage Kit</td>
<td>622287</td>
</tr>
<tr>
<td>(includes vacuum bottle, drainage line and procedure kit)</td>
<td>(box of 10 each)</td>
</tr>
<tr>
<td>ASEPT™ Replacement Valve</td>
<td>622288</td>
</tr>
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<td>(box of 5 each)</td>
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<tr>
<td>ASEPT™ Drainage Line Set</td>
<td>622286</td>
</tr>
<tr>
<td>(includes drainage line with end caps,</td>
<td>(box of 10 each)</td>
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<tr>
<td>ASEPT™ connector, 5-in-1 adapter and pinch clamp)</td>
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Warranty
B. Braun Interventional Systems 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 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 the user. B. Braun Interventional Systems Inc. shall not be liable for incidental or consequential damages of any kind.

Warning: This product and its packaging have been sterilized with ethylene oxide. Ethylene Oxide is a chemical known to the State of California to cause cancer, birth defects, or reproductive harm.