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

ASEPT™ Pleural Drainage System  622289 (1 each)
(includes ASEPT™ drainage catheter and insertion kit)

ASEPT™ Peritoneal Drainage System  622284 (1 each)

ASEPT™ Two Bottle Drainage Set  622285 (box of 5 each)
(Two Bottle Kit for Peritoneal Drainage)

ASEPT™ Drainage Kit  622287 (box of 10 each)
(includes vacuum bottle, drainage line and procedure kit)

ASEPT™ Replacement Valve  622288 (box of 5 each)

ASEPT™ Drainage Line Set  622286 (box of 10 each)
(includes drainage line with end caps, ASEPT™ connector, 5-in-1 adapter and pinch clamp)

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.

References:
M.J. O’Neill, Ralph Weissleder, MD, Debra A. Gervais, MD, Peter F. Hahn, MD, Peter Mueller, MD “Tunneled Peritoneal Catheter Placement Under Sonographic and Fluoroscopic Guidance in the Palliative Treatment of Malignant Ascites”, AJR 2001; 177; 615-618

Barnett TD, MD, Rubins J., MD “Placement of a permanent tunneled peritoneal drainage catheter for malignant ascites: a simplified percutaneous approach”

Refer to Drainage System IFU for complete instructions for use including indications, contraindications, warnings, precautions.

ASEPT™ is a trademark of PFM Medical, Inc.
Product Description:
The ASEPT™ Peritoneal Drainage System is a tunneled, indwelling catheter used to drain accumulated fluid from the abdomen. The catheter is placed in the patient's peritoneal cavity enabling the patient to perform periodic peritoneal drainage at home or in the hospital. The primary components of the system are the ASEPT™ indwelling Peritoneal Catheter and the ASEPT™ 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 Peritoneal 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™ Peritoneal Drainage System provides patients with a convenient way to relieve malignant ascites symptoms at home.

Indications For Use:
The ASEPT™ Peritoneal Drainage System is indicated for periodic drainage of recurrent and symptomatic malignant ascites. The catheter is intended for long term drainage of the peritoneal cavity in order to relieve symptoms such as dyspnea.

Contraindications, Warnings and Precautions:
Contraindications:
This device is contraindicated under the following conditions:
• When the peritoneal cavity is infected.
• When there is coagulopathy.
• When the peritoneal cavity is multi-loculated, and drainage of the single loculation may not provide relief of all associated symptoms.

Warnings:
• Do not reuse. Intended for single use.
• Accessing the catheter with anything other than the ASEPT™ drain 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, ensure that the pinch clamp is fully closed prior to connecting.
• When using the ASEPT™ drain line to access the catheter for drainage with equipment other then the ASEPT™ Drainage Kit, the adapter that is included in the kit may be utilized.
• 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 intra-abdominal 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.
• Do not use forceps on the introducer to break its handle and/or peel the sheath.
• In malignant ascites patients, paracentesis-related hypotension is uncommon but has been documented. Use of IV fluid replacement and/or administration of colloidal agents can reduce the risk of hypotension. Additionally, initial drainage should be no more than 6 L during the first 24 hours.
• Potential complications of access and drainage of the peritoneal cavity include, but may not be limited to, the following: laceration of liver or bowel, hypotension/circulatory collapse, electrolyte imbalance, protein depletion, ascites leakage, peritonitis, wound infection, tumor growth in the catheter tunnel, and loculation of the peritoneal space.
• Removal of chylous malignant ascites could exacerbate protein depletion or related nutritional complications.
• Individual patient anatomy, such as thin or weak abdominal wall, may require special care and treatment.
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™ Peritoneal Drainage catheter, as described in the following procedure.

1. Place the patient appropriately to access the desired catheter insertion site.
2. Identify the appropriate insertion site through which to place the catheter.
3. ASEPTically clean around the planned insertion site.
4. Place the fenestrated drape with the opening located over the planned insertion and tunneling sites.
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, obliquely through the abdominal wall at the desired insertion site. Ensure free aspiration of ascitic fluid. Figure 2a. Remove the syringe, leaving the guidewire needle in place. Figure 2b

Caution: Care must be taken when inserting the guidewire needle to avoid puncturing any of the intra-abdominal organs.
7. Leaving the guidewire needle in place, insert the guidewire through the needle, advancing it into the peritoneal cavity. Figure 2c. Ensure that no resistance is encountered.

Figure 2b: Remove the syringe

Figure 2c: Guidewire insertion

8. Remove the guidewire needle. Leave the guidewire in place. Figure 3

Figure 3: Remove Needle

9. Make a 1 cm incision through the guidewire insertion site.

10. Make a 1-2 cm incision approximately 5 cm from the first incision site. Figure 4

Figure 4: Incision

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 the catheter subcutaneously from the second incision site (Image shows as upper incision site) through and out through the incision at the guidewire insertion site. Figure 5a

Continue to draw the catheter through the tunnel until the polyester cuff passes about 1 cm beyond the lower incision Figure 5b. Remove the tunneler from the catheter.

Figure 5a, 5b: Passing the Catheter through Subcutaneous Tunnel

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

13. Pass the 16 Fr. dilator over the guidewire and into the peritoneal space. Figure 6

14. Remove the guidewire and dilator from the sheath.

Figure 6: Dilator with Sheath
15. Insert the fenestrated end of the catheter into the sheath advancing it until all the fenestrations are within the peritoneal space. Figure 7a. This can be verified under fluoroscopy as fenestrations are located along the barium stripe.

16. Peel away the sheath, taking care to keep the catheter in place within the peritoneal space. Figure 7b. Adjust the catheter so that it lies flat in the tunnel and has no kinks as it passes into and through the abdominal wall. Figure 7a, 7b

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

17. Close the 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: In malignant ascites patients, paracentesis-related hypotension is uncommon but has been documented. Use of IV fluid replacement and/or administration of colloidal agents can reduce the risk of hypotension. Initial drainage should be no more than 6 L during the first 24 hours. Drainage procedures thereafter should be limited to no more than 1,500 ml. 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 peritoneal 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 present 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 the Catheter to the Drainage line. Figure 8

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**Figure 7a:** Catheter insertion

**Figure 7b:** Peel away sheath

**Figure 8:** 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 9a

![Figure 9a: Centering ASEPT™ Connector](image)

3. Push the ASEPT™ Connector into the silicone valve surface while turning the spin collar on to the valve. Figure 9b, c

![Figure 9b: Pushing ASEPT™ Connector into valve](image)

![Figure 9c: Turning spin collar](image)

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

Caution: Make sure there is no fluid leaking around the valve/hub connection.

FIG 8. 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.

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 peritoneal 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. Curl the catheter into loops, cover with gauzes pads, and secure to the patient with self-adhesive dressing.
11. Dispose of the drainage set and bottle container appropriately.

**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 malignant ascites. 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 at home, a medical professional should perform the drainage.

It is recommended that the patient is periodically contacted or seen by a clinician to evaluate treatment regimen, assess need for albumin supplementation and evaluate catheter function status.

**Catheter Removal Procedure**

It may be appropriate and/or necessary to remove the ASEPT™ Peritoneal 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) the catheter is located away from the fluid 2) the catheter is occluded 3) the ascites has resolved

1. Place the patient in an appropriate position.
2. Aseptically clean the patient's abdomen around the catheter insertion site.
3. Anesthetize the site.
4. Remove the sutures.
5. 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.

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