

passioTM

Pump Drainage System

Patient Guide



BEARPAC
MEDICAL

Table of Contents

Indication for Use	2
General Information About Passio Pump Drainage System.....	2
Precautions	3
Passio Pump Drainage System Supplies.....	4
Battery Replacement.....	4
Drainage Instructions:	
Prepare the Workspace.....	5
Prepare to Begin Therapy	5
Begin Drainage Therapy.....	6
End Drainage Therapy.....	7
Dressing the Site	8
Complete Drainage Therapy	9
Cleaning and Storage	10
Glossary	11
Frequently Asked Questions	12
Drainage Log.....	13-14

You have had a drainage catheter placed by your doctor to drain your fluid build-up. You should have been given personal step-by-step instructions on the correct way to drain and care for your catheter using clean technique with sterile supplies by your doctor or nurse. The information in this booklet is for reference only. Please call your doctor or nurse if you still have questions after reading this guide.

Before beginning the therapy, ensure that a Passio Catheter has been placed in the patient. Read the Instructions for Use that come with Passio kits for more detailed instructions. These instructions are to be used only as a supplemental reference.

Indication for Use:

The Passio Pump Drainage System is indicated for intermittent drainage of recurrent and symptomatic pleural effusions and malignant

ascites. The Passio Catheter is intended for long-term access of the pleural or peritoneal cavity in order to relieve symptoms such as dyspnea and chest discomfort associated with malignant pleural effusions, malignant ascites and other recurrent effusions.

General Information about the Passio Pump Drainage System:

Why do I need a Passio Catheter?

A catheter has been placed in your chest or abdomen to drain excess fluid. Removing the excess fluid will help relieve symptoms such as discomfort or shortness of breath.

How do the Passio Catheter and Passio Pump Drainage System work together?

The Passio Catheter is a silicone tube with holes in the section that is inside your body. The valve, which is on the end that is outside of your body, connects to the Passio Pump Drainage System. When the Passio Handheld Control Unit is activated, the pump gently draws fluid out of your chest or abdomen into a collection bag.

Precautions:

- Check the package for damage before opening. Use of the device if package is damaged could result in injury, illness or death.
- Follow a clean procedure as described in this guide when accessing the catheter.
- Inspect kit to ensure all components are included.
- Ensure the drainage system is securely connected to the valve before initiating drainage.
- Do not use scissors or any sharp instruments on the catheter as that may damage the catheter.
- Access the catheter valve using only the Passio Pump Drainage system or an approved Passio Pump Drainage System adapter.

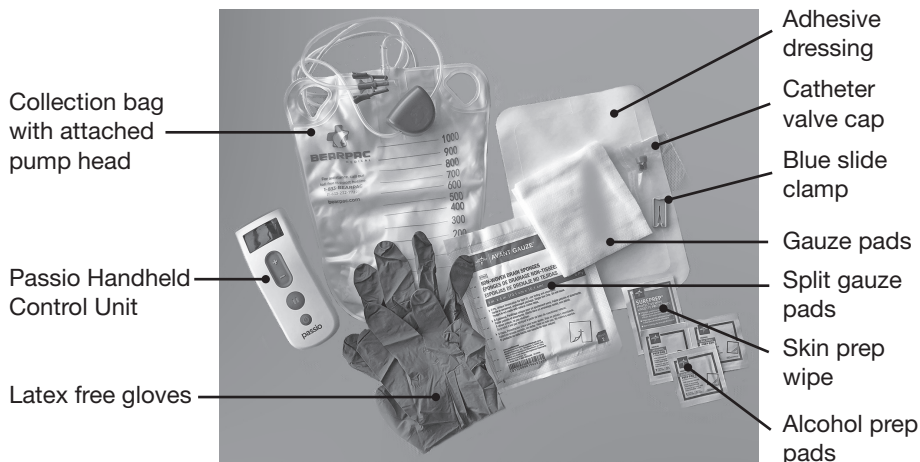
Passio Pump Drainage System supplies required to complete a drainage session:

- 1 Passio Handheld Control Unit (pump)
- 1 Passio Disposable Collection Kit containing:
 - 1 Collection bag with attached pump head
 - 1 Redressing Kit containing:
 - 1 pair latex free gloves
 - 3 ea. alcohol prep pads
 - 1 ea. catheter valve cap
 - 4 ea. 4" x 4" gauze pads
 - 2 ea. split gauze pads
 - 1 ea. adhesive dressing
 - 1 ea. removable blue slide clamp
 - 1 ea. skin prep wipe
- 2 AA batteries

Battery Replacement:

Two (2) AA batteries are included in the Passio Pump Drainage System Starter Pac and the Passio Disposable Collection Kit 10 pack. Remove the battery compartment cover on the back of the pump. Place the new batteries in the position indicated in the compartment and replace the battery compartment cover. Replace the 2 batteries in the Passio Handheld Control Unit prior to using the Passio Disposable Collection Kits in the 10 pack.

Supplies you will need for a therapy session:



Drainage Instructions:

NOTE: These instructions are for reference only. For more detailed instructions, read the Instructions for Use that came with the package.

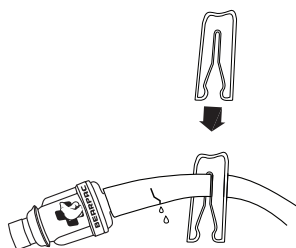
Prepare the Workspace

1. Prepare a clean working area:
 - a. Clear space on a table or countertop for the drainage supplies.
 - b. Clean the surface thoroughly with a disinfecting wipe or with a paper towel moistened with rubbing alcohol. **NOTE: Wipes or rubbing alcohol may damage some surfaces.**
 - c. Allow the area to air dry or wipe the surface dry with a clean paper towel.
 - d. Thoroughly wash your hands with warm soapy water for one minute. Dry using a clean towel or paper towels.
2. Open the pouch containing the collection bag with attached pump head and redressing kit. Remove and separate the redressing kit (blue wrapped pouch) from the collection bag and

pump head.

3. Remove the clear dressing and gauze from your catheter site. Do not pull on the catheter.

CAUTION: Do not drain fluid through a damaged catheter. If the catheter is damaged, place the supplied slide clamp between the catheter damage and exit site as shown below and contact your physician.



4. Open the redressing kit to create a clean working area using the blue wrap. Leave all of the contents of the redressing kit on the blue wrap. **CAUTION: Do not touch any of the contents without gloves on.**

Prepare to Begin Therapy

5. Thoroughly wash and dry your hands again with warm soapy water for one minute.
6. Pick up the gloves by the cuffed fold and put them on. Do not touch any unclean surfaces with your gloves.

7. Tear open the 3 alcohol pads without removing them from the pouch and put them back on the blue wrap.
8. Remove blue valve cap and throw it away. (Figure 1)

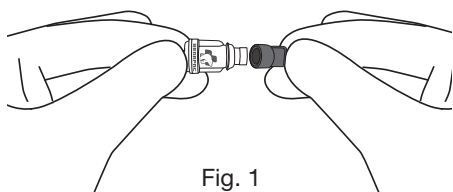


Fig. 1

CAUTION: The white tip of the valve is not intended to be removed and attempting to do so may cause damage to the valve.

9. Wipe the catheter valve with an alcohol pad. (Figure 2)

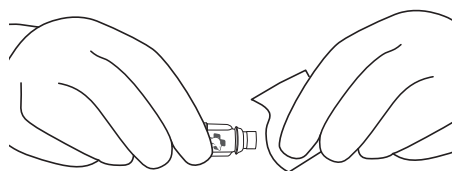


Fig. 2

10. Remove the clear cover from the catheter connector
 - Insert connector into the catheter valve. You should hear or feel a click.
 - Gently pull back on the drainage line to confirm the connection is secure. (Figure 3)

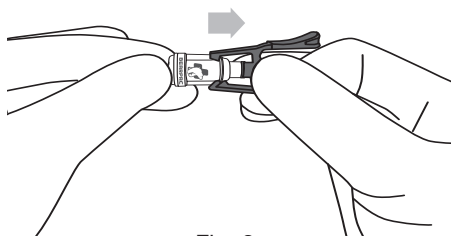


Fig. 3

11. Attach the pump head to the Passio Handheld Control Unit. (Figure 4) Place the Passio Handheld Control Unit and collection bag on a flat surface below the level of the catheter.

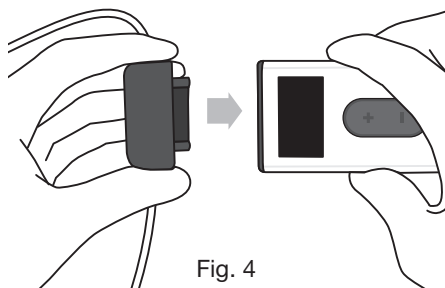


Fig. 4

Begin Drainage Therapy


12. Press the Power button  on the Control Unit to turn it on. The following screens will appear: (Figures 5a, 5b, 5c).



Fig. 5a



Fig. 5b

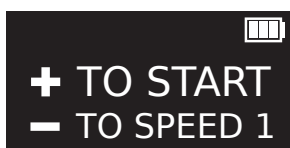


Fig. 5c

13. Press the "+" button once to start drainage.
- The Passio Handheld Control Unit will begin filling the tubing with fluid and then shift to SPEED 1 to continue flow of fluid. (Figures 6a, 6b)



Fig. 6a

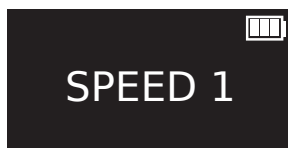


Fig. 6b

NOTE: If the system does not begin filling the tubing with fluid, remove the pump head and restart the Passio Hand-held Control Unit.

14. To increase fluid flow, press the "+" button. You can increase flow up to SPEED 4. Dots at the bottom of the screen display the speed. (Figure 7)



Fig. 7

15. Press the "-" button to slow the fluid flow.
16. At any time during therapy or to stop drainage, press the pause (II) button. The system will stop automatically when 1000 ml has been drained.

CAUTION: A kink or loop in the tubing can stop flow early. If this occurs, remove the kink or loop and restart the Passio Handheld Control Unit to restart flow.

CAUTION: Do not drain more than 1000 ml from the chest or 2000 ml from the abdomen in any one drainage session.

CAUTION: You should be contact your physician if:

- You develop a fever above 100.5°F (38°C), or notice redness, swelling, oozing, drainage or discomfort around catheter exit site. These may be signs of infection that may require treatment.
- Shortness of breath is not relieved after draining 1000 ml from the chest or 2000 ml from the abdomen at one time.
- If you continue to experience symptoms, but little or no fluid drains from the chest or abdominal cavity.
- Less than 50 ml drains in 3 drainage procedures in a row.
- The appearance of fluid (color, thickness, etc.) changes significantly between drainages.

End Drainage Therapy

17. Disconnect the drainage line by squeezing both sides of the blue catheter connector and pull apart. (Figure 8)

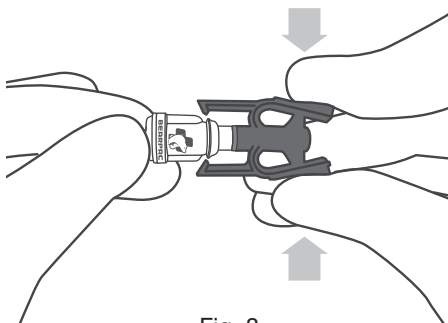


Fig. 8

18. Wipe the catheter valve with a new alcohol pad (Figure 9a) and place a new blue valve cap onto the catheter valve. (Figure 9b)

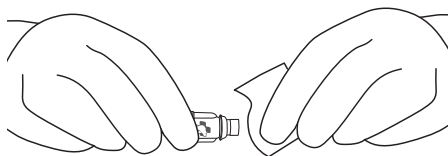


Fig. 9a

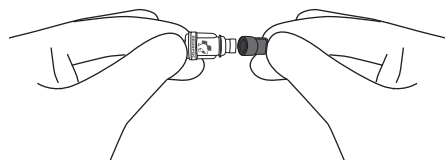


Fig. 9b

Dressing the Site

CAUTION: In order to help prevent infection, replace the clear dressing and gauze over the catheter site after each therapy session.

19. Open the skin prep wipe and wipe the area where you will place clear dressing and gauze over the catheter site after each therapy session.

- Place split gauze pad around catheter up against skin and coil catheter on top of gauze. (Figures 10a, 10b)
- Cover coiled catheter with gauze pads. (Figure 10c)

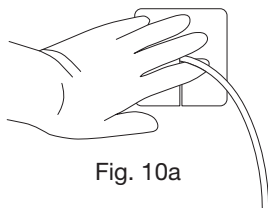


Fig. 10a

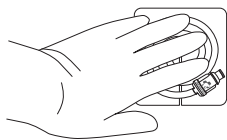


Fig. 10b

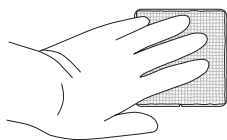


Fig. 10c

- Remove gloves
- Remove the paper backing from the adhesive dressing to expose the sticky side. (Figure 11a)

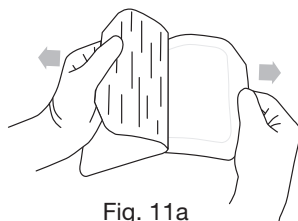


Fig. 11a

- Remove the center panel to view the site through the film. (Figure 11b)

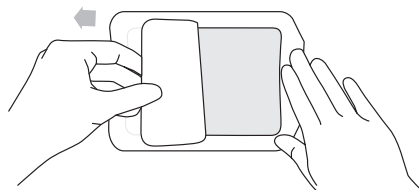


Fig. 11b

NOTE: Do not remove the outer frame until after the dressing is applied to the site.

- Place the dressing over the site, and press gently to adhere to skin. (Figure 11c)

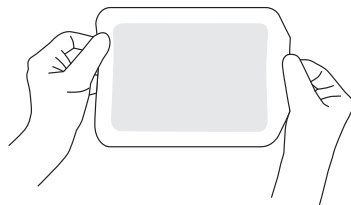


Fig. 11c

- Remove the outer frame and press down the edges of the dressing as the frame is being removed to stick firmly to the skin. (Figure 11d)

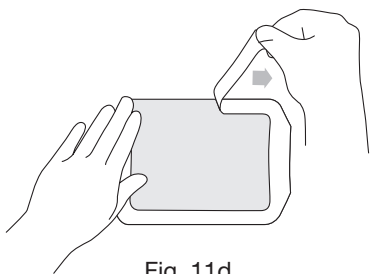


Fig. 11d

Complete Drainage Therapy

20. Record the amount of drainage displayed on the screen in the log on pages 13-14.
21. Press and hold the Power button for 2 seconds to turn off the power.
22. Remove pump head from Passio Handheld Control Unit. (Figure 12)

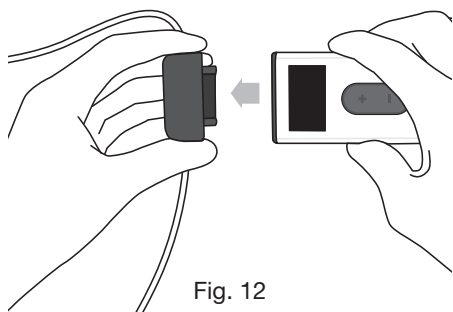


Fig. 12

23. Dispose of collection bag and pump head in the trash.

Cleaning and Storage

If the Passio Handheld Control Unit is dirty, wash with mild soap and water and wipe dry immediately. Do not put the Passio Handheld Control Unit in water.

Store the Passio Handheld Control Unit in a cool, dry place until the next therapy session.

NOTICE: If a serious incident occurs during use of this device, please report it immediately to your physician or nurse.

Glossary

Ascites

Accumulation of fluid in the abdominal space.

Catheter

Soft silicone tube that is placed inside the body to help remove fluid.

Cuff

Small piece of woven felt around the catheter that helps the catheter stay in place while it's inside the body.

Dyspnea

Difficult or labored breathing which can be caused by excess fluid in the abdominal cavity.

Exit Site

Small cut where the catheter comes out of the body.

Insertion Site

Small cut where the catheter is inserted by the doctor.

Peritoneal Space

Space surrounding the abdominal organs where fluid may build up.

Pleural Effusion

Fluid that builds up in the pleural space.

Pleural Space

The area between the lungs and chest wall where fluid may build up.

Frequently Asked Questions

How often will I have to drain fluid?

Your doctor will direct you on how often to drain fluid depending on your symptoms. It may vary from every day to twice a week.

What if I have pain while draining?

The Passio Pump Drainage System allows for precise control of the flow of fluid. Simply press the + or – button on the Handheld Control Unit to adjust the flow based on your comfort level.

Can I take a shower with the catheter in place?

As long as a watertight covering (such as Tegaderm) is placed over the catheter, it is permissible to shower. Do not bathe or allow the catheter to soak under water. If the area becomes wet, remove the dressing, dry and redress the site.

What if I'm only draining a small amount of fluid?

If the amount of fluid you have been draining gradually declines, your chest or abdominal space may be drying up and it is possible that your doctor will remove the catheter.

If the amount of fluid drained suddenly stops or declines rapidly, it is possible that the catheter may be clogged. By gently squeezing the drainage line and the catheter near the valve, the flow of fluid may restart. If the catheter continues to be clogged, contact your doctor.

When will the catheter be removed?

Your doctor will leave the catheter in place until fluid stops draining. The amount of time will vary from patient to patient.

Drainage Log

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Drainage Log

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Bearpac Medical, LLC

1-833-BEARPAC

(1-833-232-7722)


bearpac.com



Bearpac Medical, LLC
124 West Point Road
Moultonborough, NH 03254 USA
Tel. 1-833-232-7722

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

UK Responsible Person: Advena Ltd. Pure Offices, Plato Close, Warwick, CV34 6WE United Kingdom

 Arazy Group GmbH, The Squire 12, Am Flughafen, 60549 Frankfurt am Main, Germany

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