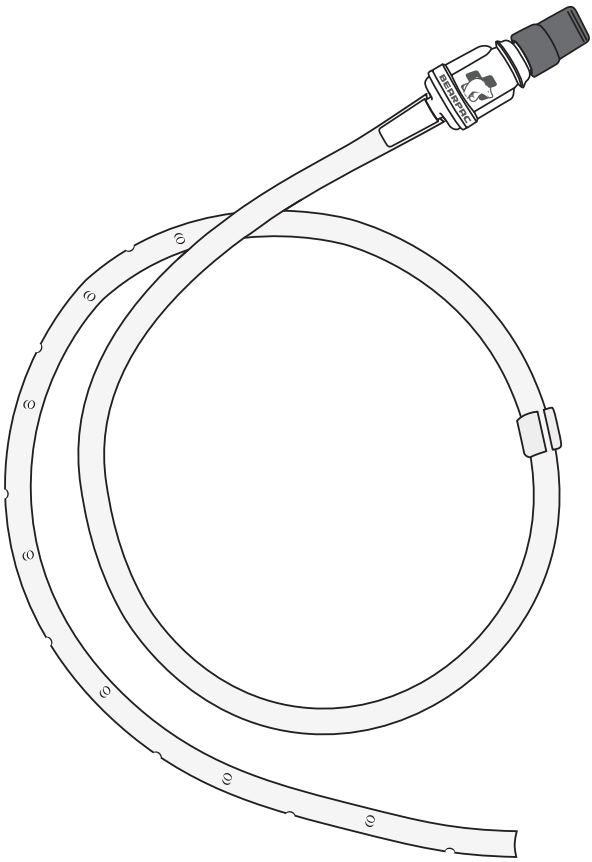
# passio

## Pleural Catheter Insertion Kit

**Instructions for Use**



## Product Description:

The Passio Pleural Catheter Insertion Kit contains a Passio Pleural Catheter and the components necessary to implant the catheter in a patient. The Passio Pleural Catheter is a silicone catheter with a polyester cuff and eyelets to drain accumulated fluid from the pleural cavity. This cuffed catheter is implanted to allow for intermittent external draining of excess fluid in the pleural cavity. There is a valve on the catheter that prevents air and/or fluid from being evacuated from the pleural space until drainage is activated with the Handheld Control Unit. The Passio Pleural Catheter Insertion Kit is exclusively designed for use with the Passio collection system but can be connected to a water seal chest drain or vacuum pump at the discretion of a physician.

## Indication for Use:

The Passio Pump Drainage System is indicated for intermittent drainage of recurrent and symptomatic pleural effusions. The Passio Pleural Catheter is intended for long-term access of the pleural cavity in order to relieve symptoms such as dyspnea and chest discomfort associated with malignant pleural effusions and other recurrent effusions.

## Contraindications:

Use of the Passio Pleural Catheter with the Passio Pump Drainage System is contraindicated under the following conditions:

- If there is known or suspected pleural cavity infection or sepsis.
- If there is known or suspected coagulopathy.
- If the pleural cavity is multi-loculated, and the drainage of a single loculation would not be expected to provide relief of dyspnea.
- If the patient's anatomy is insufficient to accommodate an indwelling drainage catheter.
- If the patient is known or suspected to be allergic to materials contained in the catheter.

## Warnings:

- The Passio Pleural Catheter Kit is intended as a single patient use kit (Do not reuse). Reuse and repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device which may lead to device failure and/or lead to injury, illness or death of the patient.
- Do not use excessive force on the valve or catheter. Excessive force or incorrect usage may damage the device.
- Accessing the catheter valve with anything other than an approved Passio Pump Drainage System adaptor may damage the valve.
- Dispose of used product in accordance with accepted medical practice and applicable local, state and federal regulations. Used product may present a potential biohazard.
- Do not reuse on another patient, reprocess or resterilize. Reuse, reprocessing or resterilizing may compromise the device and/or lead to device failure.
- Do not use if package is damaged.

## Precautions:

- Do not drain more than 1000 ml from the pleural cavity in any one drainage session.
- Follow a clean procedure when accessing the catheter.
- Check the packages for damage before opening them. Use of the device if package is damaged could result in patient injury, illness or death.
- Inspect kit to ensure all components are included.
- Ensure the expiration date for the kit has not passed.
- Ensure the drainage system is securely connected to the valve before initiating drainage.
- Do not drain fluid through a damaged catheter.
- Do not use scissors or any sharp instruments on the catheter as that may damage the catheter.
- If damage to the catheter occurs during use,

place the supplied slide clamp between the catheter damage and exit site and contact the patient's physician.
- Access the catheter valve using only the Passio Pump Drainage System.
- Potential complications of draining the pleural space include, but not limited to:
  - Pneumothorax; failure of lung to re-expand
  - Re-expansion pulmonary edema (swelling or fluid build-up in the lung due to rapid re-expansion of the lung)
  - Hypotension (low blood pressure)
  - Circulatory collapse
  - Infection
- The patient should be instructed to contact their physician if:
  - Patient develops a fever (body temperature above 100.5°F (38°C), redness, swelling, oozing, drainage or discomfort around catheter exit site. These may be signs of infection that may require treatment.
  - Shortness of breath isn't relieved after draining 1000 ml from the chest at one time.
  - The patient continues to experience symptoms, but little or no fluid drains from the catheter.
  - Less than 50 ml drains in 3 drainage procedures in a row.
  - The appearance of fluid (color, thickness, etc.) changes significantly between drainages.

## Possible Complications:

Inserting the catheter and pleural fluid drainage may result in any of the following complications:

- Accidental catheter dislodgement or removal
- Catheter malposition
- Catheter or cuff erosion through skin
- Empyema (pleural space infection)
- Skin and/or soft tissue infection
- Exposure to bodily fluids
- Discomfort during fluid removal
- Skin irritation
- Hypotension subsequent to drainage
- Accidental catheter dislodgement, breakage or removal
- Leakage around catheter
- Occlusion around catheter
- Fluid path blockage
- Low flow rate/prolonged drainage
- Re-expansion pulmonary edema
- Splenic or hepatic laceration
- Tumor seeding

## Passio Pleural Catheter Insertion Kit components:

Refer to product label

## Storage:

Normal warehouse conditions.

## MRI Safety Information:

Non-clinical testing demonstrated that the Passio Pleural Catheter is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla or 3-Tesla, only
- Maximum spatial gradient magnetic field of 4,000-Gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, the Passio Pleural Catheter is expected to produce a maximum temperature rise of 1.4°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the Passio Pleural Catheter extends approximately 10 mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

*Note: The Passio Pleural Catheter does not contain DEHP and is not made with natural rubber latex.*

## Insertion Instructions:

Before beginning this procedure, read the "Contraindications", "Warnings", "Precautions" and "Possible Complications" sections of these instructions for use.

1. Select insertion site for catheter.
2. Position patient to access the insertion site.
3. Identify location of guidewire placement and catheter exit site (approximately 5 cm apart) to conform to patient anatomy and comfort and adequately access pleural fluid.
4. Prepare sterile field and open insertion kit.
5. Prepare the patient for procedure and apply drape over the insertion and catheter exit site.
6. Inject adequate Lidocaine HCL 1% into procedural area.
7. Attach guidewire introducer with needle to syringe. Insert into desired location for guidewire placement. (Figure 1)

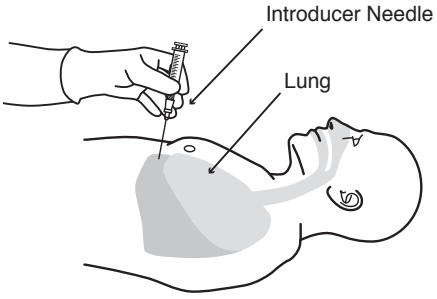



Fig. 1

8. Ensure proper placement by aspiration of pleural fluid. Remove needle and syringe, leaving guidewire introducer in place. *Care must be taken during guidewire insertion to prevent puncturing or damaging lung or liver.*
9. Insert guidewire through the introducer advancing it into the pleural space, while still leaving adequate extracorporeal guidewire length for control of guidewire.
10. Remove guidewire introducer, leaving the guidewire in place. (Figure 2)

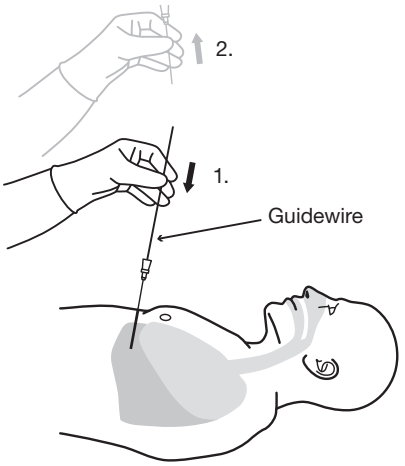



Fig. 2

11. Make a 1 cm incision at the guidewire insertion site.
12. Make an additional 1 cm incision approximately 5 cm inferior and either lateral or medial to the guidewire insertion site. This will be the catheter exit location. (Figure 3)

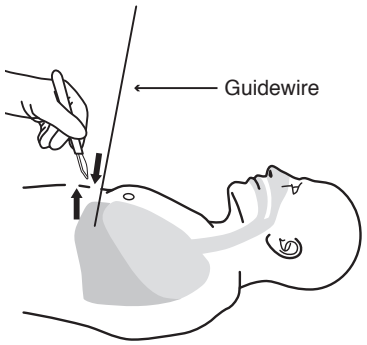



Fig. 3

13. Create a tunnel between the 2 incision sites. *Ensure that the area where catheter will be tunneled has proper anesthesia.*
14. Confirm length of catheter is appropriate for patient anatomy. Catheter can be cut on end with eyelets if needed to adjust intracorporeal length to fit patient anatomy.

15. Attach proximal end of catheter to tunneler.
16. Thread tunneler and catheter from catheter exit location to the guidewire site. Continue to advance catheter until the cuff is approximately 1cm under the skin before catheter exit location.
17. Disconnect the catheter from the tunneler.
18. Dilate the insertion site over the guidewire using the 12Fr dilator. (Figure 4)

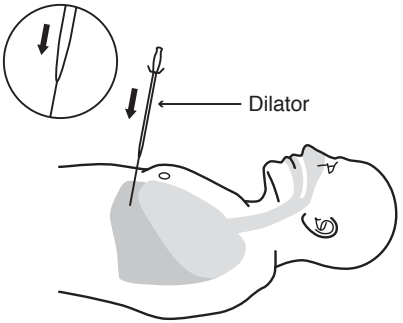



Fig. 4

19. Thread the 16Fr tearaway introducer over the guidewire into the pleural space.
20. Remove guidewire and dilator as one from tearaway introducer, leaving introducer in place. *Place thumb over end of introducer to prevent air from entering pleural space.* (Figure 5)

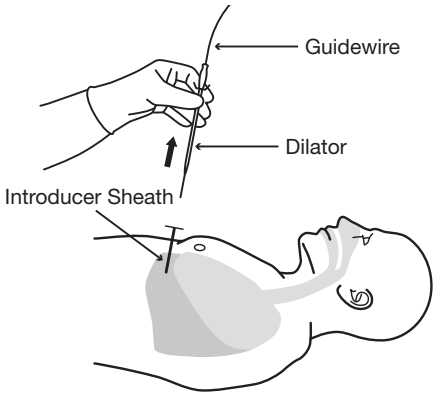



Fig. 5

21. Insert proximal end of catheter into introducer, advancing until all eyelets are located in the pleural space. Separate tearaway sheath to allow catheter to advance if needed. (Figure 6)

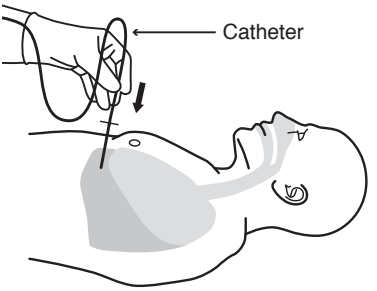



Fig. 6

22. Separate the introducer and remove at the same time ensuring the catheter remains in the pleural space.
23. Adjust catheter to ensure it is placed properly and flat.
24. Close the guidewire incision site.
25. Close the catheter exit location and secure the catheter to the skin.
26. Cover site(s) with dry sterile gauze and occlusive dressing (provided).

**NOTICE: If a serious incident occurs during use of this device, please report to the manufacturer.**

## Drainage Instructions:

*Refer to the Passio Pump Drainage System Instructions for Use for Warnings, Precautions, Indications, Complications and complete instructions for using the Passio Handheld Control Unit.*

1. Remove and discard catheter valve cap from catheter valve. (Figure 1)


Fig. 1

2. Wipe the catheter valve with an alcohol pad.
3. Remove the plastic sheath from the catheter connector. While holding the catheter firmly, insert the (blue) male catheter connector on the end of the drainage line into the catheter valve until you hear or feel a connection (click). Gently pull back on drainage line to confirm the connection is secure. (Figure 2)

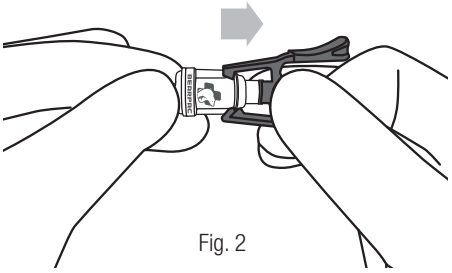


Fig. 2

4. Attach the pump head to the Passio Handheld Control Unit. (Figure 3) Place the Passio Handheld Control Unit and collection bag at or below the level of the chest for draining.

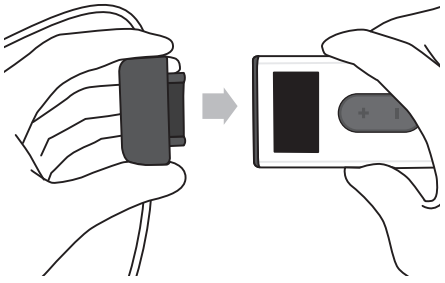


Fig. 3

5. Press the Power button ⏻ on the Passio Handheld Control Unit to activate the system.
6. Press the "+" button to prime the Handheld Control Unit and for fluid flow to begin.
7. Continue to press "+" button to increase fluid flow as can be tolerated by patient.
8. Press the "–" button to slow the fluid flow rate.
9. When the collection bag is full or fluid flow has stopped, press the pause ("II") button to complete therapy. The system will automatically pause/stop when the volume indicator reaches 1000 ml.
10. Clamp off the collection bag tubing with the blue clamp to prevent fluid leakage.
11. Disconnect the drainage line by holding the catheter firmly and squeezing both sides of the catheter's connector allowing for the catheter connector to be pulled back from the catheter. (Figure 4)

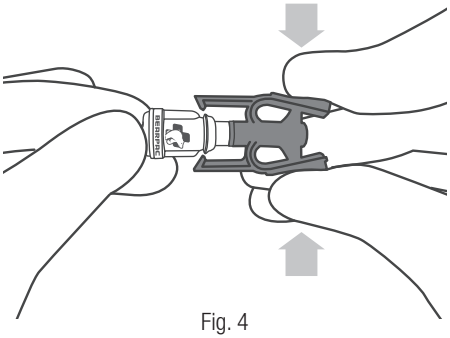


Fig. 4

12. Wipe the catheter valve with a new alcohol pad and place a new valve protector cap onto the catheter valve.
13. Coil catheter and redress the catheter insertion site.

*Maximum Pressure: Maximum negative pressure generated is less than 49 kPa (500 $cmH_2O$).*

## Catheter Removal Procedure

It may be appropriate and/or necessary at a later date to remove the Passio Pleural Catheter. Three successive attempts to drain fluid that result in less than 50 ml of fluid removed may indicate one of the following:

- Pleurodesis has been achieved
- The catheter is loculated away from the fluid
- The catheter is occluded

1. Place the patient appropriately to access the catheter insertion site.
2. Aseptically clean the patient's chest around the catheter insertion site.
3. Anesthetize the site.
4. Remove any remaining sutures securing the catheter.
5. Using forceps or other small clamp (e.g. hemostat), 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. Dress the exit site as appropriate.
8. Dispose of the catheter in accordance with all applicable regulations.

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


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