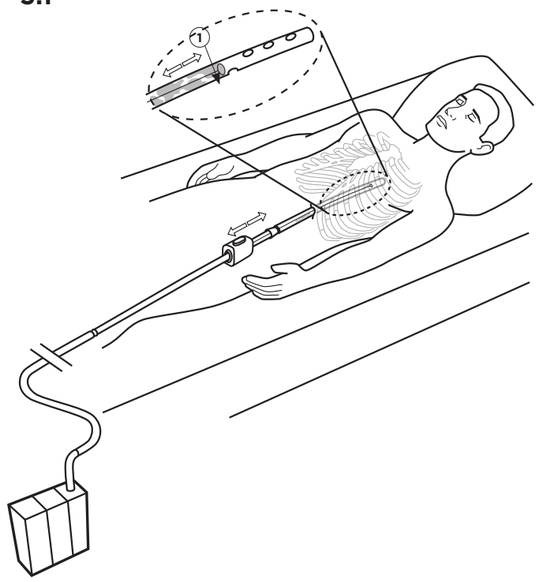
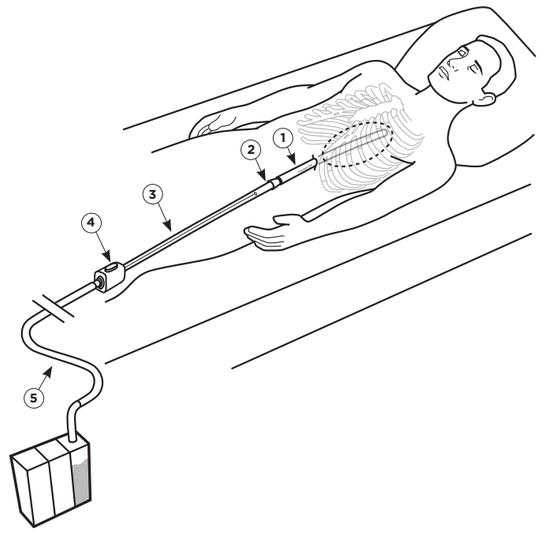
5.1



ENGLISH

1. Obstructions Form In The Chest Tube

6.1



ENGLISH

1. Chest Tube Free Of Obstructions
2. Proximal End
3. When Finished, Return Shuttle Guide To Proximal End And “Click” Into Position
4. Shuttle Guide Fully Withdrawn
5. Drainage Material Flows To Drainage Canister

Do not reuse

Use by

LOT Batch code

STERILE EO Sterilization using ethylene oxide

Do not resterilize

Manufacturer

Consult Instructions for Use

REF Catalog number

MR unsafe

Contents

Do not use if package is damaged

℞ ONLY **CAUTION**
Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

The PleuraFlow® System with FlowGlide®
For Single Use Only. Made in the U.S.A.

PLEURAFLOW
ACTIVE CLEARANCE TECHNOLOGY

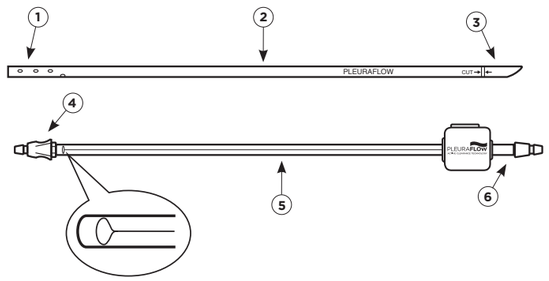
ENGLISH

The PleuraFlow® System with FlowGlide®
For Single Use Only. Made in the U.S.A.

Manufactured for:
ClearFlow, Inc.
140 Technology, Suite 100
Irvine, CA 92618, USA
US Toll Free: (844) CLR-FLOW (257-3569)
Support@clearflow.com
www.clearflow.com

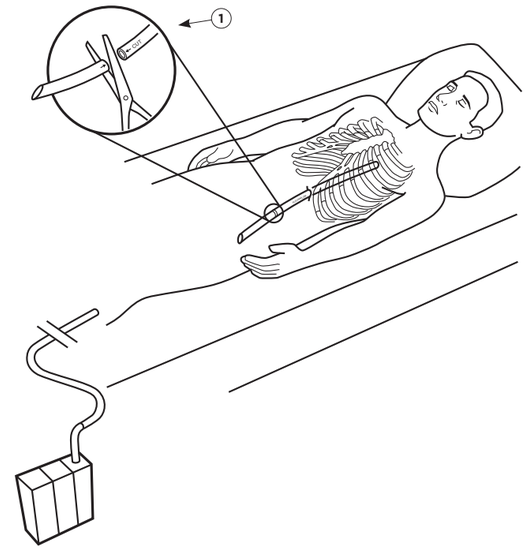
℞ **ONLY**

1.1



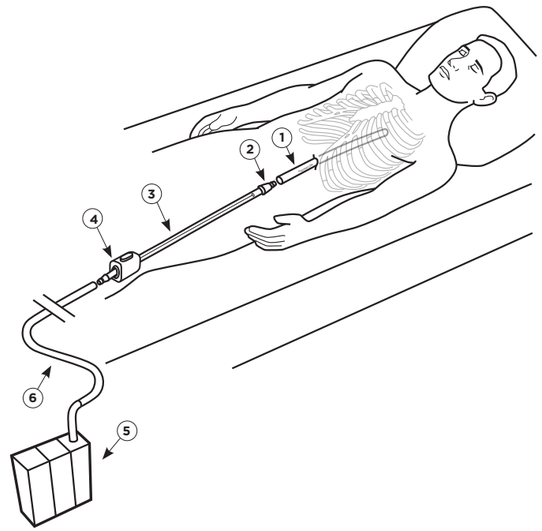
ENGLISH
1. Proximal
2. PleuraFlow Chest Tube
3. Distal
4. Proximal End (Connects To PleuraFlow Chest Tube)
5. PleuraFlow Guide Tube
6. Distal End (Away From Patient)

2.1



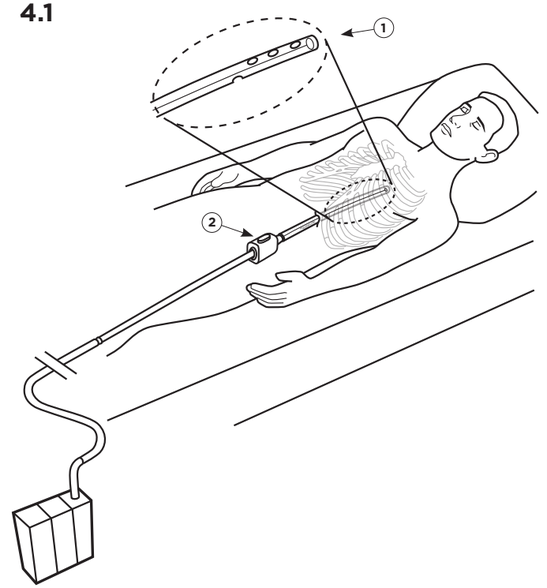
ENGLISH
1. Must Cut On Cut-Line

3.1



ENGLISH
1. PleuraFlow Chest Tube
2. Proximal End
3. PleuraFlow Clearance Apparatus
4. Distal End
5. Drainage Canister
6. Drainage Tubing

4.1



ENGLISH
1. Clearance Loop Is Advanced To The Tip When Not In Use
2. Shuttle Guide Is In The Parked Position

ENGLISH Instructions for Use

DESCRIPTION:
The PleuraFlow® System with FlowGlide® incorporates a Clearance Apparatus intended to prevent clogging and occlusion of PleuraFlow Chest Tubes used for pleural and mediastinal drainage after cardiothoracic surgery and trauma.

The primary components of the System are the PleuraFlow Chest Tube and the PleuraFlow Clearance Apparatus. (FIG. 1) The PleuraFlow Chest Tube is a silicone chest tube coated with FlowGlide®. It is connected to a Clearance Apparatus, which is connected to the tubing from the drainage canister. (FIG. 3) The PleuraFlow Clearance Apparatus consists of a Guide Tube with a Clearance Wire and Loop that is advanced into the PleuraFlow Chest Tube using a magnetic Shuttle Guide. The Shuttle Guide includes the Magnet Strength Button that, when depressed, enables greater magnetic force when needed. When indicated, the Clearance Wire and Loop is advanced and retracted within the PleuraFlow Chest Tube to proactively prevent or break up and clear any tube obstructions or clogging to keep the tube patent. Components of the PleuraFlow System are not made with natural rubber latex.

The device is inserted through the skin adjacent to open surgical incision. The proximal end of the drain is positioned within the operative site prior to repair of the incision. The device's distal end is attached to an appropriate suction source in order to allow efflux of bloody, serosanguinous, chylous, purulent fluid, and/or other fluids from the operative site that could impair surgical wound healing. The device is indicated for use in cardiothoracic surgical procedures.

INDICATIONS:
The PleuraFlow System is indicated for use during cardiothoracic surgical procedures and chest trauma. Its active clearance technology proactively removes clots formed inside the chest tube to prevent or minimize chest tube occlusion with clot. A patent chest tube enables evacuation of blood and fluid from the operative site after closure of the surgical wound and reduces retained blood.

The product is indicated for adult and pediatric patients including infant, preadolescent and adolescent patients under clinical settings.

CONTRAINDICATIONS:
The PleuraFlow System is contraindicated for patients with a history of intolerance to implantable silicone materials.

This device should not be used in proximity to an MRI.

SET UP INSTRUCTIONS
Prior to Placement:
• Check the package for damage before opening.

To open the package:

• Open the Pouch and deliver the contents to the sterile field using aseptic technique.

• Inspect thoroughly, assuring that it is not kinked or otherwise damaged. If there is any damage, replace with a new device.

• Engage the Shuttle Guide with the internal magnets by withdrawing the Shuttle Guide distally against the drain barb.

Inserting the PleuraFlow System
• Insert the PleuraFlow Chest Tube into the pleural or mediastinal space according to standard methods.

When a median sternotomy approach is used it is recommended that at least one PleuraFlow System is used in the anterior mediastinum as the majority of postoperative bleeding occurs in this location.

WARNING: The Chest Tube is not intended for direct contact with the central circulatory system.

Care should be taken to ensure the path of the PleuraFlow Chest Tube is as straight as possible to minimize the resistance of the Clearance Wire and Loop inside the Chest Tube. In some instances, excessive curvature and tortuosity may result in activating the Magnetic Safety Release.

• Secure the PleuraFlow Chest Tube according to standard methods.

• Take care not to constrict the PleuraFlow Chest Tube when securing in place, which may restrict the movement of the Clearance Wire and Loop.

• After insertion, when trimming the PleuraFlow Chest Tube, cut the Chest Tube precisely where indicated by the labeling that indicates "CUT". The proximal end of the Chest Tube (with eyelets) shall never be cut. (FIG. 2)

• WARNING: Do not attempt to cut the PleuraFlow Chest Tube shorter than indicated by the "CUT" indicator close to the distal end. Never cut the proximal end of the PleuraFlow Chest Tube. This could result in the Clearance Wire and Loop extending beyond the tip of the Chest Tube, which could potentially damage internal structures.

Connect the Clearance Apparatus between the PleuraFlow Chest Tube and the drainage tubing (FIG. 3)
• Connect the chest tube to the chest barb, advance tubing all the way onto barb.

• Ensure clearance apparatus matches chest tube French size and configuration (for e.g. Right Angle "RA"). When connecting, check that component labeling (printing) matches. Note: Right Angle chest tube and clearance apparatus are labeled "RA."

• Once the PleuraFlow Clearance Apparatus is connected to the PleuraFlow Chest Tube, advance the external Shuttle Guide toward the proximal barb and Chest Tube. This will advance the Clearance Wire and Loop into the proximal end of the Chest Tube. (FIG. 4)

• Click the Shuttle Guide into the proximal barb housing to park the Clearance Wire and Loop in the proximal end of the Chest Tube.

• Connect the drain barb adapter of the Clearance Apparatus to the drainage tubing that goes to the drainage canister, advance tubing all the way onto barb.

• Secure all connections per hospital protocol.

• Connect the drainage canister to the suction source.

- Maximum vacuum: -40 cmH_2O

• If a Y-connection is indicated, ensure the Y-junction is placed distal to the Clearance Apparatus. Additional drainage tubing may be used to compensate for length discrepancies.

POST INSERTION INSTRUCTIONS
• Confirm tip position of the PleuraFlow Chest Tube according to institution protocol. Although the PleuraFlow Chest Tube material contains a radiopaque stripe to aid in the radiographic visualization of the PleuraFlow Chest Tube, the Clearance Wire and Loop may be left in place to improve radiographic visualization.

USE OF THE CLEARANCE APPARATUS
• Only a qualified healthcare practitioner should operate the device.

• When it is indicated to clear the PleuraFlow Chest Tube, the Shuttle Guide is disengaged from the proximal connector, and moved down the Clearance Apparatus, away from the patient and toward the drainage canister tubing. (FIG. 5)

• The Clearance Apparatus should be actuated often in the setting of thick output, such as clotting blood, to ensure the chest tube is patent.

- It is recommended that the device is actuated to clear the PleuraFlow Chest Tube every 15 minutes during the first 8 hours after placement when bleeding is typically more common, then every 30 minutes for the next 16 hours, then every hour thereafter.
- The device should be actuated as needed in addition to these baseline requirements.
- This should be repeated as often as necessary to keep the tube patent and free of any occlusions.
- During actuation, if additional magnetic strength is needed, depress and hold the Shuttle Guide Magnet Strength Button.

• Each time the Clearance Apparatus is actuated to clear the PleuraFlow Chest Tube, the Clearance Apparatus should be inspected for any clot or occluding material accumulating on the Clearance Wire and Loop.

- If obstructive clot is forming on the Clearance Wire and Loop, steps should be taken to dislodge the clot or fibrinous material stuck to the wire.
- If this cannot be cleared from the wire and is obstructing drainage, the Clearance Wire and Loop should be parked outside the PleuraFlow Chest Tube, in the Clearance Apparatus, by moving the Shuttle Guide to the distal portion of the Clearance Apparatus and leaving it outside of the Chest Tube.

• Traditional methods of chest tube clearance can be carried out at any time, as long as the Clearance Wire and Loop is fully retracted outside of the PleuraFlow Chest Tube.

• When not in use, the Shuttle Guide should be parked by clicking it to the proximal barb, thereby parking the Clearance Wire and Loop in the proximal end of the PleuraFlow Chest Tube. (FIG. 6)

• The Clearance Apparatus should be removed within 5 days or once the bleeding and clotting have ceased, whichever is sooner. This can be done by retracting the Clearance Wire into the Guide Tube and removing the PleuraFlow Chest Tube and the Clearance Apparatus together, if clinically indicated. Alternatively, the Clearance Wire can be retracted into the Guide Tube and the Clearance Apparatus removed, leaving the Chest Tube connected directly to the drainage tubing. The chest tube can then be left in place until removal is clinically indicated up to two weeks from insertion.

TROUBLE SHOOTING
• If obstructive clot appears on the Clearance Wire and Loop, steps should be taken to dislodge the clot into the larger diameter Guide Tube.

- Gently squeeze the wire through the PleuraFlow Chest Tube or Guide Tube while advancing the Clearance Wire and Loop to clear off clots.
- Rapidly run the wire back and forth to dislodge any clot while taking care not to squeeze the Clearance Loop.
- Flick or tap the PleuraFlow Chest Tube and Guide Tube.
- Gently tap the Shuttle Guide against the distal connector.
- If clot remains adherent to the Clearance Wire and Loop, withdraw it from the PleuraFlow Chest Tube and leave in the Guide Tube.
- If further tube clearance is needed, you may attach a new Clearance Apparatus into the existing PleuraFlow Chest Tube using standard techniques.
- If necessary, the Clearance Apparatus can be removed and the PleuraFlow Chest Tube can be connected to the drainage tubing in the standard fashion.
- Never move Clearance Wire and Loop against resistance without careful assessment of cause.
- If cause cannot be determined, move the Clearance Wire and Loop out of the PleuraFlow Chest Tube and leave it in the Guide Tube.
- Movement against resistance may result in damage to the PleuraFlow Chest Tube, which could allow the Clearance Wire and Loop to extend outside the Chest Tube.
- If the internal and external magnets become uncoupled, advance or retract the Shuttle Guide over the internal magnet to recouple. Retaining elements set on the internal magnets will keep the internal magnets and wire from exiting the Guide Tube, thus encouraging recoupling of the magnets.
- If decoupling occurs when the Clearance Wire and Loop are in proximity to the Parked Position, the Clearance Wire and Loop can continue to be used even if the Shuttle Guide does not fully click into the Parked Position.
- If after several attempts the magnets remain uncoupled, the PleuraFlow Clearance Apparatus may be disconnected from the PleuraFlow Chest Tube. The Chest Tube may then be connected to the drainage tubing and canister in the standard fashion.
- If decoupling occurs when the Clearance Wire and Loop are in proximity to the parked position continue using the device if:
  - it is not possible to click the Shuttle Guide into the proximal barb housing to park the Clearance Wire and Loop in the proximal end of the Chest Tube, and;
  - There is no resistance to wire movement inside the chest tube distally to the point of decoupling.

PLEURAFLOW SYSTEM (CHEST TUBE AND CLEARANCE APPARATUS) REMOVAL
• Retract the Clearance Wire into the Guide Tube.
• Remove old dressing, sutures and/or tape.
• Grasp the PleuraFlow Chest Tube near the insertion site; using a slow, steady motion, remove the Chest Tube from the incision.
• Apply occlusive dressing after removal.
• CAUTION: Care should be taken during chest tube removal from the patient to avoid damaging the Chest Tube. Withdrawal against excessive resistance may result in Chest Tube damage and patient injury.

SUGGESTED PLEURAFLOW CHEST TUBE MAINTENANCE
• The PleuraFlow Chest Tube should be maintained in accordance with standard institutional protocols. Suggested PleuraFlow Chest Tube maintenance is as follows:

- Dressing Changes: Assess the dressing in the first 24 hours for accumulation of blood, fluid, or moisture beneath the dressing.
- Cleaning Exit Site: Maintain according to institution protocol.

COMPATIBILITY
• The PleuraFlow System with FlowGlide® is only compatible with PleuraFlow Chest Tubes. Compatibility with other drainage tubes has not been established.
• The PleuraFlow System is compatible with any drainage canister system.
• Refer to product label for device dimensions.

DURATION OF USE
- Maximum for PleuraFlow Chest Tube Use is 2 weeks.
- Maximum for Clearance Apparatus is 5 days.
- If the PleuraFlow Chest Tube is still needed, but the Clearance Apparatus is not, the Clearance Apparatus can be removed and discarded, and the Chest Tube left in place. Always retract the Clearance Wire and Loop into the Guide Tube prior to removing the Clearance Apparatus. The Chest Tube may then be connected to the drainage tubing and canister in the standard fashion.

WARNINGS
• Do not reuse. Discard after one use. **Caution:** The characteristics of this device have been verified for single-use ONLY. Any attempt to re-process this device for subsequent re-use may adversely affect the integrity of the device or lead to deterioration in performance.
• PleuraFlow Chest Tubes should not be clamped except when changing the drainage canister or removing the Clearance Apparatus. Withdraw the Clearance Wire and Loop prior to clamping.
• The PleuraFlow Chest Tube should not be clamped when the Clearance Wire and Loop is advanced in the Chest Tube, as this could result in damage.
• Use only the supplied PleuraFlow Chest Tube.
• Cut the PleuraFlow Chest Tube only as indicated by the "CUT" mark on the distal end. Cutting it shorter can result in the Clearance Wire and Loop extending beyond the tip of the Chest Tube. (FIG. 2). Do not cut the proximal end of the PleuraFlow Chest Tube.
• Never advance the Clearance Wire and Loop against resistance without careful assessment of cause. If cause cannot be determined, withdraw the Clearance Wire and Loop into the Guide Tube or replace the PleuraFlow Chest Tube. Movement against resistance may result in damage to the PleuraFlow Chest Tube, which could allow the Clearance Wire and Loop to extend outside the PleuraFlow Chest Tube.
• Dispose of the used product in accordance with accepted medical practice and applicable local, state and federal regulations. Used product presents a potential biohazard.
• Do not place the Shuttle Guide within 6 inches of an implanted pulse generator, such as pacemakers or implantable defibrillators.
• The PleuraFlow Clearance Apparatus should be removed if in proximity to an MRI.

PRECAUTIONS
• 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.
• Follow aseptic techniques when inserting or removing the PleuraFlow System.
• The device must be used prior to the expiration date.

COMPLICATIONS
Inserting the PleuraFlow Chest Tube and utilizing the Clearance Apparatus may result in any of the following complications:

- Pneumothorax
- Pericardial tamponade
- Infection
- Exposure to body fluids
- Empyema
- Leakage
- Hypotension subsequent to drainage
- Skin irritation or infection
- Splenic or hepatic laceration
- Re-expansion pulmonary edema
- Occlusion
- Pain
- Hemothorax
- Chest tube malposition
- Accidental Chest Tube dislodgement or removal
- Tumor seeding
- Chest tube erosion through skin

HOW SUPPLIED
The PleuraFlow System is provided sterile and will remain so as long as the package is unopened and undamaged. Do not resterilize.

STORAGE
Handle with care. The System should be stored in an area with good ventilation under good conditions that protect it from extremes of temperature and humidity and ultraviolet light.

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

The Instructions for Use do not override clinical practice by qualified individuals.