5.1
1. Obstructions Form In The Chest Tube

6.1
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 Shuttle Guide Fully Withdrawn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
1. Clearance Loop Is Advanced to the Tip When Not in Use
2. Shuttle Guide Is in the Parked Position

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)

ENGLISH
1. Must Cut On Cut-Line

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

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

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)
DESCRIPTION:
The PleuraFlow System with FlowGlide technology is an active chest drainage system that proactively removes clots formed inside the chest tube to prevent or minimize chest complications. The PleuraFlow System with FlowGlide technology is a sterile, single-use disposable system designed to be connected to any pleural effusion drainage system. It features an external, magnetic-controlled Clearance Wire and Loop that can be positioned at any point along the chest tube. The system is indicated for adults and pediatric patients with a history of intolerance to implantable silicone material.

INDICATIONS:
- To drain pleural effusion
- To remove clots formed inside the chest tube
- To prevent or minimize chest complications

CONTRAINDICATIONS:
- Skin irritation or infection
- Chest tube erosion through skin
- Empyema
- Chest tube malposition
- Pneumothorax
- Re-expansion pulmonary edema
- If decoupling occurs when the Clearance Wire and Loop are in proximity to the Parked Position, the PleuraFlow System with FlowGlide technology should be disconnected from the PleuraFlow Chest Tube and left in the Guide Tube. (FIG. 8)

HOW SUPPLIED:
- The PleuraFlow System with FlowGlide technology is supplied as a single-use, disposable system.

HOW TO USE:
1. Open the Pouch and deliver the contents to the sterile field using aseptic technique.
2. Check the package for damage before opening.
3. Confirm tip position of the PleuraFlow Chest Tube according to institution protocol. Although the PleuraFlow Chest Tube should not be clamped when the Clearance Wire and Loop is advanced in the chest tube. (FIG. 4)
4. Once the PleuraFlow Clearance Apparatus is connected to the PleuraFlow Chest Tube, advance the external Clearance Wire and Loop extending beyond the tip of the Chest Tube, which could potentially damage internal structures. (FIG. 6)
5. Connect the drain barb adapter of the Clearance Apparatus to the drainage tubing that goes to the drainage canister in the standard fashion. (FIG. 3)
6. The PleuraFlow Chest Tube should not be clamped when the Clearance Wire and Loop is advanced in the chest tube. (FIG. 4)
7. The PleuraFlow Chest Tube should not be clamped when the Clearance Wire and Loop is advanced in the chest tube. (FIG. 4)
8. The Clearing Exit Site: Maintain according to institution protocol.
9. The PleuraFlow System with FlowGlide technology is a single-use, disposable system.

DURATION OF USE:
- The PleuraFlow System with FlowGlide technology is a single-use, disposable system.

COMPLICATIONS:
- Pneumothorax
- Empyema
- Chest tube malposition
- Pneumothorax
- Re-expansion pulmonary edema

STORAGE:
- If the device is not used in the expiration date, it shall be disposed of per institutional policy. It should be stored upright and in a stable position.

NEW SUPPLIES:
- The PleuraFlow System with FlowGlide technology is provided sterile and will remain so as long as the packaging is unopened and undamaged. Do not store.

CAUTION:
- It is critical that the device be used only by trained personnel.

The Instructions for Use do not describe all possible adverse effects or complications associated with the use of this product. All registered medical professionals should be familiar with the potential adverse effects and complications associated with the use of this product. The manufacturer recommends following the specific protocol for the insertion and management of the PleuraFlow System with FlowGlide technology.