THE ZIP
Accessory Shuttle for PleuraFlow® System
CLINICAL TRAINING MODULE

TN107-A
THE ZIP - GENERAL DESCRIPTION

• A removable magnetic shuttle that is used to actuate the Clearance Wire and Loop of the PleuraFlow System.
  – Consists of a plastic housing containing shielded magnets.

• Designed to snap onto the Shuttle Guide Tube of the PleuraFlow System and couple to the Internal Magnets contained within.

• Once coupled, THE ZIP can be used to actuate the Clearance Wire and Loop within the PleuraFlow Chest Tube to proactively prevent and break up and clear any tube obstructions or clogging to keep the tube patent.
• THE ZIP is an accessory of the PleuraFlow System family of products that is indicated for use during cardiothoracic surgical procedures and chest trauma.

• The PleuraFlow System’s 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.
INDICATIONS

• THE ZIP accessory is a non-sterile reusable hand-held external magnetic shuttle that can be used to couple to and move the Clearance Wire of the PleuraFlow System in place of the integral shuttle when the user determines that additional magnetic coupling strength is needed.

• Possible scenarios when user may determine that the use of THE ZIP is warranted:
  – Excessive bleeding
  – Hypercoagulation
  – Inadequate frequency of actuation
  – Etc.
THE ZIP is meant to be utilized to **Retract** the Clearance Wire.
Step 1. Decouple the PleuraFlow (PF) ACT Shuttle from the Internal Magnet and attach THE ZIP onto the Clearance Apparatus over the Internal Magnet.
Step 2. Ensure that THE ZIP is fully engaged on the Internal Magnet of the Clearance Apparatus and that the patient symbol is aligned with the patient (head pointing towards head). Actuate by using THE ZIP to retract the Clearance Wire.
Step 3. Once the Clearance Wire has been successfully retracted, THE ZIP can now be removed. Clean THE ZIP in accordance with the Instructions For Cleaning on the reverse side of this card and return to its storage case.
### INSTRUCTIONS

Step 4. Refer to troubleshooting protocols in the PF product IFU to ensure actuation schedule can be resumed. **Once the troubleshooting is completed, recouple the PF ACT shuttle and continue the actuation schedule.**

<table>
<thead>
<tr>
<th>Location</th>
<th>Phase</th>
<th>Recommended Timing</th>
<th>ACT Frequency</th>
<th>Cycles/hour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating Room (OR)</td>
<td>Chest Closure</td>
<td>1 time when PleuraFlow System is connected</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Prep for transfer to ICU</td>
<td>1 time upon transfer from OR table to bed</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Every 15 minutes (if there is a delay in transfer)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intensive Care Unit (ICU)</td>
<td>Early Bleeding</td>
<td>0-8 Hours</td>
<td>Every 15 minutes*</td>
<td>4 per hour</td>
</tr>
<tr>
<td></td>
<td>Slowed Bleeding</td>
<td>8-24 Hours</td>
<td>Every 30 minutes*</td>
<td>2 per hour</td>
</tr>
<tr>
<td></td>
<td>Serosanguineous Drainage</td>
<td>&gt; 24 Hours</td>
<td>Every hour*</td>
<td>1 per hour</td>
</tr>
</tbody>
</table>
WARNINGS / CONTRAINDICATIONS

• Do not place THE ZIP within 6 inches of a medical device with conductive and/or magnetic parts.
  • Some examples include:
    – An implanted pulse generator
    – Pacemakers
    – Implantable defibrillators

• Do not use if in proximity to an MRI.

• THE ZIP is designed for use with the PleuraFlow System only.
INSTRUCTIONS FOR CLEANING

THE ZIP is supplied non-sterile and must not be sterilized by any sterilization method since it is not to be used sterile.

1. THE ZIP is supplied “non-sterile” and must be cleaned prior to initial use and after each use.

2. Remove THE ZIP from the storage case and visually inspect the device before use. Do not use if the device is damage.

3. The ZIP should be cleaned before initial use and between uses as follow:
   a. Wipe down all surfaces using 70% Isopropyl alcohol wipes.
   b. After use, wipe down all surfaces of THE ZIP using 70% Isopropyl alcohol wipes. Visually inspect the device for any debris and visible soil and repeat cleaning as necessary.
   c. Metal brushes and scouring pads must not be used during manual cleaning. These materials will damage the surface and finish of THE ZIP. If necessary, use only soft bristle nylon brushes to aid with manual cleaning.
   d. Allow the device to air dry then store the ZIP in the supplied storage case when no longer is use.

Disposal:
Dispose per institutional protocol for medical devices.
THANK YOU!