CLINICAL TRAINING MODULE (ICU)

PleuraFlow® Active Clearance Technology® (ACT®) System
OBJECTIVES

• Understand the value of the PleuraFlow® Active Clearance Technology® (ACT®) System

• Know the PleuraFlow System components

• Understand how to use the System

• Understand the indications, contraindications, and warnings

• Actuation and Troubleshooting
ALL PATIENTS BLEED POST SURGERY

Chest drainage systems are utilized in every cardiac surgery case.

The goal is complete evacuation of blood & fluids from around the heart and lungs.

Typical occluded chest drainage tube
POSTOPERATIVE BLEEDING PATHWAY

ADEQUATE BLOOD EVACUATION

Recovery

INADEQUATE BLOOD EVACUATION

Clinically Large Volume of Retained Blood/Clot

Subclinical Volume of Retained Blood/Clot

Clot causes Inflammation/VEGF Production and Fluid

Pericardial Effusion

Pleural Effusion

Subclinical Volume of Retained Blood/Clot

Pericardial Tamponade

Hemothorax

ACUTE RBS

Pericardial Effusion

Pleural Effusion

Inflammation Transitions to Fibrosis

Postoperative Constrictive Pericarditis

Fibrothorax

CHRONIC RBS
36% of patients have chest tubes with complete occlusions

86% of the time, occlusion is below the skin where it can’t be seen by nursing staff

In the patient group (36%) with one or more completely occluded chest tubes:

- POAF was significantly higher
- Renal failure was significantly higher
- Trends for cardiac arrest and stroke were higher

“...stripping chest tubes may significantly increase negative intrathoracic pressures that could cause harm (eg, tissue entrapment, increased bleeding, left ventricular dysfunction), thereby further impairing patients’ postoperative recovery.”

Halm, American Journal of Critical Care, 2007
PLEURAFLOW SYSTEM

Inserted between the chest tube and the drainage canister tubing

**Proximal End**
Closet to the Patient

**Distal End**
Farthest from the patient
PleuraFlow Systems

- Available in various sizes and configurations, such as:
  - Straight: 20, 24, 28, 32 FR
  - Pediatric: 20 FR SEDL (Short Effective Drainage Length)
  - XDL: 20, 24 FR (Extended Drainage Length)
  - RA: 24, 28, 32 FR (Right Angle)

- System consists of PleuraFlow Chest Tube and Clearance Apparatus

- Use only the supplied PleuraFlow Chest Tube (Clearance Wire is calibrated to match the inner diameter and length of the Chest Tube)
Anterior Mediastinum is area of maximal bleeding due to:
- Bone/Periostium
- Mediastinal fat
- Cannulation sites
- Bypass grafts

Additional Conventional Chest Tubes can be placed as needed
PLEURAFLOW CLEARANCE APPARATUS

Consists of:

- Guide Tube
- Proximal Connector (blue)
- Distal Connector (white)
- Shuttle Guide with magnets
- Clearance Wire and Loop
CONNECTING THE CHEST TUBE TO THE CLEARANCE APPARATUS

• **Ensure clearance apparatus matches the chest tube French size and configuration** (for e.g. Right Angle “RA” or “XDL”).

• **When connecting, check that component labeling (printing) on proximal (chest tube) barb matches.** Note: Right Angle chest tube and clearance apparatus are labeled “RA”.

• Once the appropriate chest tube has been connected to the proximal barb of the clearance apparatus, Do not detach the chest tube until the chest tube has been discontinued.

• The utilization of zip ties as an additional securement method may be considered in accordance with internal practice/facility protocols.
HOW TO ACTUATE

1. **Squeeze**
   Initiate shuttle activation by depressing finger pads

2. **Actuate**
   Slowly slide the Shuttle Guide toward the distal connector then advance Clearance Wire back into the Chest Tube

3. **Park**
   Click the Shuttle Guide into the proximal connector during use
### Recommended 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>
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<tr>
<td></td>
<td></td>
<td>Every 15 minutes (if there is a delay in transfer)*</td>
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<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(^5)</td>
<td>Every hour*</td>
<td>1 per hour</td>
</tr>
</tbody>
</table>

- Actuation schedule must be initiated in the OR (every 15 mins.) and continued in the ICU
- Actuation frequency can be increased as necessary to keep the tube patent and free of any occlusions
- Clot should also be cleared from the wire as necessary in the OR / ICU
WHAT TO EXPECT DURING USAGE

• “Goop on the Loop” and clot on the Clearance Wire is NORMAL

• Clot on Wire will usually stay attached to the wire and should not interfere with suction or drainage

• Clot on the wire is confirmation that the chest tube is being cleared

• Loose clot within the tubing can be manipulated to facilitate movement into the drainage canister
CLOT AROUND THE LOOP

- This image confirms that clot is being removed from the Chest Tube

- Clot should be cleared from the wire using the technique described in the IFU

- Perform routine checks and confirm:
  - Actuation is still possible
  - Fresh blood can be seen below and above clot
  - Wall suction and canister are functioning properly

- In this image the clot on wire is not occluding CT drainage holes. The device is still functional. Fresh blood can be seen above and below loop.
EXCESSIVE BLOOD & CLOT

- Image shows excessive build up of clot. If the patient is still actively bleeding, this device will need to be exchanged.

- Possible courses of action to prevent excessive build up of clot:
  - Increasing actuation frequency to every 5-10 mins. until resolved
  - Clearing the clot from the wire regularly
  - Checking that wall suction and canister are functioning properly

- Please contact your local representative if a PleuraFlow System was replaced.
CLEARING THROMBUSBUS RESIDUE

1. **Squeeze** the Clearance Wire gently through the Chest Tube with your thumb and forefinger.
   - Do not bend or crush Loop
   - Do not use a clamp (to prevent damage to Loop)

2. **Slide** the Clearance Wire through the squeezed Chest Tube several times in order to dislodge the clot. Again be sure not to damage the loop.

3. **Retract** wire to pull clot into the guide tube so it can be suctioned out of the system. Sometimes flicking is required to loosen the clot.

*If this fails to remove the thrombus, and the device is not functioning as expected, then remove or replace Clearance Apparatus (see slides 29 & 30)*
MAGNETIC SAFETY RELEASE ALGORITHM

PleuraFlow® Active Clearance Technology® (ACT®) System
ICU Troubleshooting Algorithm

Step 1
Is the PleuraFlow System actuating?

YES
Continue with Recommended Actuation Schedule
Q 15 min for 8 hours
Q 30 min for 16 hours
Q 1 hr until discontinued

When mobilizing patient
Before removing the chest tube
Before moving patient, retract Clearance Wire and Loop into Guide Tube (out of chest)

NO
Decoupling/Magnetic Safety Release (MSR) with Actuation

MSR occurs close to the parked position, cannot completely park shuttle

Most eyelets are being cleared, proceed with actuation schedule

Step 2
Actuating?

YES

NO

Step 3
MSR/Decoupling Causes

Cause: Actuation is too rapid
Solution: Move shuttle over magnet to recouple → slow actuation

Cause: Patient position
Solution: Reposition patient

Cause: Excessive thrombus on Clearance Wire and Loop causing possible obstruction
Solution: Clear thrombus as per IFU, consider increasing actuation frequency

Additional considerations for persistent Magnetic Safety Release/Decoupling

Less than 24 hours post-op:
Notify MD/PA/NP and consider replacing ACT per IFU

More than 24 hours post-op:
Consider removing chest tube if no further drainage is necessary

Call your Clinical Specialist directly or 714-916-5010
MAGNETIC SAFETY RELEASE – 4 CAUSES

1. Suture is too tight on chest tube
   • Remind surgeon to check this when placing the tube
   • Skin incision too small and impinging the Chest Tube

2. Not following the recommended actuation schedule
   • The actuation process helps minimize complete clot obstruction
   • If no ACT actuation, performance equals standard chest tube

3. Actuating too quickly (most common cause)
   • Rapid movement will cause magnet to disengage
   • Go slow! Slow and steady movement should prevent MSR

4. Sharp angle or bend of Clearance Wire
   • When patient is moved or sitting up, Clearance Wire should be in the Wire Withdraw position (outside chest tube/patient)
   • Adjust patient position or recline patient to minimize potential for compression
   • If you are unable to actuate, put patient back in original position
ENCOUNTERING RESISTANCE

- Never advance Clearance Wire against resistance without careful assessment of cause.

- If cause cannot be determined, move the Clearance Wire out of the Chest Tube and leave it in the Guide Tube.

- Movement against resistance may result in damage to the Chest Tube, which could allow the Clearance Wire to extend outside the Chest Tube.
DURATION OF USE AND STORAGE

Maximum for Clearance Apparatus: 5 days

Maximum for PF Chest Tube: 2 weeks

Shelf life of system: 32 Months

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 confirm expiration date before use. Do not use after expiration date.
- 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.
ADDITIONAL CONSIDERATIONS

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

• The PleuraFlow Clearance Apparatus is **NOT** MRI Compatible.

• Do not place the Shuttle Guide within 15 cm (6 inches) of an implanted pulse generator such as pacemakers or implanted defibrillators.

• The PleuraFlow System is Latex Free.
ADDITIONAL NOTES
ADDITIONAL NOTES

• The PleuraFlow System is sterile and will remain so as long as the package is unopened and undamaged. Do not reuse. Do not resterilize.

• Confirm tip position of the PleuraFlow Chest Tube post-insertion according to institution protocol.
  - Chest Tube material contains a radiopaque stripe to aid in radiographic visualization
  - The Clearance Wire may be left in place to improve radiographic visualization

• Maintain the Chest Tube in accordance with standard institutional protocols. Assess the dressing in the first 24 hours for accumulation of blood, fluid, or moisture beneath the dressing. Clean exit site according to institution protocol.
PLEURAFLOW REMOVAL AND DISPOSAL

**To remove** the PleuraFlow:
- **Withdraw the Clearance Wire from the Chest Tube**
- Remove old dressing, sutures and/or tape
- Grasp the Chest Tube near the insertion site; using a slow, steady motion, remove the chest tube from the incision
- Apply occlusive dressing after removal

**Dispose** of the used product in accordance with accepted medical practice and applicable local, state and federal regulations. Used product presents a potential biohazard.
WARNINGS

- **Caution:** The characteristics of this device have been verified for single-use ONLY. Reprocessing of this device is prohibited. 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.

- The PleuraFlow Chest Tube should not be clamped when Clearance Wire and Loop is advanced in the Chest Tube, as this could damage the Clearance Wire.

- Do not strip or milk the PleuraFlow Chest Tube when the Clearance Wire and Loop are advanced inside the Chest Tube.
EXCHANGING THE PLEURAFLOW
CLEARANCE APPARATUS REMOVAL OR REPLACEMENT

1. **Withdraw** the Clearance Wire

2. **Clamp** the Chest Tube

3. **Disconnect** the Clearance Apparatus

**DO NOT CUT THE CHEST TUBE**
1. **Attach** the Clearance Apparatus to Chest Tube and drainage tube

Check security of connections. The utilization of zip ties as an additional securement method may be considered in accordance with internal practice/facility protocols.

2. **Unclamp** the Chest Tube

3. **Park** - Actuate and park the Clearance Wire and Loop inside the Chest Tube
THANK YOU

Questions & Discussion