Protocol for Active Clearance of Anterior Mediastinal and Pleural Chest Tubes to Maintain Tube Patency After VAD Surgery

Clinical Use Protocol 003

| Manual: Surgical and Post Operative Procedures |
| Procedure No.: |
| Approved By: |
| **Subject:** Anterior Mediastinal and Pleural and Pleural Chest Tube management with PleuraFlow® Active Clearance Technology ™ (ACT) | **Effective Date:** |
| | **Revised Date:** |
| | **Reviewed Date:** |

| **Key Words:** | Chest tube, mediastinal drainage, PleuraFlow Active Clearance Technology, tamponade, pleural effusion, pericardial effusion. |
| **Cross References:** | Active Chest Tube Clearance Protocol. |

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INTRODUCTION:
Bleeding is a frequent complication after Ventricular Assist Device Surgery. Chest tubes are used to collect shed blood in the mediastinum and pleural spaces after cardiac surgery. Bleeding primarily occurs in the first 72 hours after VAD surgery (Acute Phase). During the acute phase, which can last up to 72 hours, volumes are high, and the blood is thick and prone to clotting and obstructing the chest tubes. Generally, by 72 hours after a VAD implant the volume of drainage is less, and the fluid is thinner, and less prone to clot in the chest tubes (Chronic Phase). Adequate evacuation of all of the shed blood after VAD surgery is critical to prevent retained blood complications such, especially in this acute phase, Over one third of all chest tubes occlude, which can contribute to complications (such as tamponade and bloody effusions) and increased costs. This is especially a high risk in the acute phase, for the first 72 hours. The PleuraFlow® System with Active Clearance Technology™ (ACT) has been shown to reduce retained blood by preventing chest tube clogging with shed blood. This clinical use protocol is a suggested use protocol for implementing PleuraFlow® System with Active Clearance Technology™ with the goal of maximizing evacuation of shed blood in the first 72 hours after VAD surgery. This protocol is intended as a guideline for use by clinical staff responsible for patient management in the operating room and in the Intensive Care Unit (ICU).

Figure 1: Average Volumes of Chest Tube Output After VAD Implants. Adapted from Haglund N, Davis ME, Tricarico NM, Ahmad RM, DiSalvo TG, Keebler ME, Schlendorf KH, Wigger MA, Stulak JM, Maltais S: Perioperative Blood Product Utilization: A Comparison between HeartWare and HeartMate-II Devices. (Annals of Thoracic Surgery, In press)
CRITICAL ELEMENTS:

1. The PleuraFlow® System is made up of two parts (Figure 2):
   a. PleuraFlow Chest Tube (PF-CT); and
   b. PleuraFlow Clearance Apparatus (PF-CA)

   ![Figure 2: PF-CT, PF-CA, and Drainage Canister](image)

2. For this protocol, three to four PleuraFlow ACT Systems are placed intraoperatively prior to closing after VAD surgery.

3. One to two PleuraFlow Systems are placed intra-operatively in the anterior mediastinum and at least one PleuraFlow System in each open pleural space prior to chest closure after VAD surgery. The rationale of multiple PleuraFlow Systems in this Protocol is to maximize blood evacuation during the early hours of surgery until bleeding ceases.

4. Once the PF-CT is inserted, the PF-CA is connected to the PF-CT and connected to the drainage canister in the O.R. (Figures 2 & 3).

   ![Figure 3: Connecting (PF-CT and PF-CA)](image)

5. Surgeon shall select appropriate sized PleuraFlow System (32 Fr, 28 Fr, 24 Fr, 20 Fr).

6. The PF-CA is actuated primarily in the first 72 hours after VAD surgery, and then is discontinued when the bleeding ceases or the drainage becomes serous.
**EQUIPMENT LIST:**

1. PleuraFlow System (32 Fr, 28 Fr, 24 Fr, 20 Fr).
2. Additional conventional chest tubes optional and used as needed.

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**INTRAOPERATIVE PROCEDURE**

<table>
<thead>
<tr>
<th>1. Surgeon shall select and insert appropriate sized PF-CT (32 Fr, 28 Fr, 24 Fr, or 20 Fr).</th>
</tr>
</thead>
<tbody>
<tr>
<td>• PF-CT is inserted in the anterior mediastinum and in each open pleural space. Surgeon shall ensure that PF-CT are placed with minimal tortuosity.</td>
</tr>
<tr>
<td>• Cut PF-CT precisely on cut line. (Figure 4)</td>
</tr>
<tr>
<td>• Secure using standard technique, ensuring the sutures do not constrict the PF-CT lumen and limit passage of the Clearance Loop, (which will result in Magnetic Safety Release, MSR).</td>
</tr>
<tr>
<td>• Attach PF-CT to proximal (blue) end of PF-CA. (Figure 2)</td>
</tr>
<tr>
<td>• Attach white distal (away from the patient) end of PF-CA to drain tubing to the drainage canister. (Figure 3)</td>
</tr>
<tr>
<td>• Make sure Clearance Loop passes without obstruction from tube kinking.</td>
</tr>
<tr>
<td>• “Park” PF-CA by clicking the external shuttle into the proximal connector.</td>
</tr>
</tbody>
</table>

**KEY POINTS**

- Precise length is required to enable proper use of the Clearance Apparatus.

Figure 4: Cutting the PF-CT precisely on cut line
1. **POSTOPERATIVE PROCEDURES**

   Monitor all chest tubes for bleeding and/or clots and record assessments as per local protocol.

2. **Use of PF-CA:**
   - Initiate shuttle activation by depressing finger pads. (Figure 5)

   ![Figure 5: Finger Pads](image)

   **Figure 5: Finger Pads**

   - Actuate - Slowly slide the Shuttle Guide toward the distal connector (connects to drainage canister tubing) then advance Clearance Wire back into the Chest Tube. Repeat as necessary. (Figure 6)

   ![Figure 6: Shuttle Guide](image)

   **Figure 6: Shuttle Guide**

   - Recommended Actuation Schedule. (Figure 7)

   ![Figure 7: Recommended Actuation Schedule](image)

   **Figure 7: Recommended Actuation Schedule**

   - Park – Click the Shuttle Guide into the proximal connector during use (Clearance Wire and Loop are inside the PF-CT).

   ![Figure 8: Clamping the PF-CT before disconnecting the PF-CA](image)

   **Figure 8: Clamping the PF-CT before disconnecting the PF-CA**

3. **KEY POINTS**

   - The PleuraFlow System can only be used with PleuraFlow Chest Tubes (Do not add PleuraFlow Clearance Apparatus to non PleuraFlow Chest Tube).

   - Size of PleuraFlow Clearance Loop varies based on PleuraFlow Chest Tube size. (If adding a PleuraFlow Clearance Apparatus to an existing PleuraFlow Chest Tube, make sure the French sizes are an exact match).

   - Slow actuation is sometimes more effective than rapid actuation.

   - The Magnetic Safety Release (MSR) is a safety feature to avoid forcing the Clearance Loop against a fixed obstruction; it is sensitive to patient position, tube angle or kinking, drain character, and speed of actuation.

   - Promote clot drainage into canister; if clot remains adherent to the Clearance Wire or the Clearance Loop, either withdraw the Clearance Wire (if no longer needed) or replace Clearance Apparatus using sterile technique. (Figure 8)

   - Do not strip or milk the PleuraFlow System.
• Wire Withdraw – Slide the Shuttle Guide toward the distal connector (connects to drainage canister tubing) and leave it when the patient is moved or sitting up.

• Only actuate when patient is supine. Do not actuate PF-CA until patient is supine to minimize potential for compression, which may activate the Magnetic Safety Release (MSR).

• Remove the PF-CA within 5 days. The PF-CA can be removed in one of 2 ways:
  o The entire Chest Tube and PF-CA can be removed and discarded in one piece.
  o The PF-CA only can removed and the PF-CT can be connected to the drainage tubing using sterile technique.
  o Remove PF-CT within 2 weeks.

<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</td>
<td>Chest Closure</td>
<td>1 time when PleuraFlow System is connected</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(OR)</td>
<td>Prep for transfer to ICU</td>
<td>1 time upon transfer from OR table to bed</td>
<td>Every 15 minutes (if there is a delay in transfer)*</td>
<td></td>
</tr>
<tr>
<td>Intensive Care Unit</td>
<td>Early Bleeding</td>
<td>0-8 Hours</td>
<td>Every 15 minutes*</td>
<td>4 per hour</td>
</tr>
<tr>
<td>(ICU)</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>

Figure 7: Recommended Actuation Schedule

* This should be repeated as necessary to keep the tube patent and free of any occlusions.
§ Remove the PleuraFlow Clearance Apparatus within 5 days. Remove the PleuraFlow Chest Tube within 2 weeks.

**DOCUMENTATION:**
1. Assess and document CT output with vital signs assessments per local protocol.
2. Document addition and use of the PF-CA.

Author: __________________________
Reviewed by: _________________________
REFERENCES:


