Protocol for Active Clearance of Anterior Mediastinal Chest Tubes to Maintain Tube Patency After Cardiac Surgery

Clinical Use Protocol 001

Manual: Surgical and Post Operative Procedures
Procedure No.: 
Approved By: 

Subject: Anterior Mediastinal Chest Tube management with PleuraFlow® Active Clearance Technology™ (ACT) 
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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:
Chest tubes are used to collect shed blood in the mediastinum and pleural spaces after cardiac surgery. Bleeding primarily occurs in the first 12 to 16 hours after cardiac surgery. Adequate evacuation of all of the shed blood in the early hours after cardiac surgery is critical to prevent retained blood complications. Over one third of all chest tubes occlude, which can contribute to complications (such as tamponade and bloody effusions) and increased costs. The PleuraFlow® System with Active Clearance Technology™ (ACT) has been shown to reduce retained blood by preventing chest tube clogging. 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 initial hours after cardiac 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).

This manual is intended for users who have already read and studied the Instructions For Use. Always refer to the Instructions for Use for detailed information.

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

2. For this protocol, a single PleuraFlow ACT System is placed intraoperatively prior to closing after cardiac surgery.

3. In most cardiac surgery cases, a majority of the bleeding comes from the anterior mediastinum (bone, peristium, mediastinal fat, thymus, cannulation sites and aortotomy sites). For this protocol, a single PleuraFlow System is placed intra-operatively in the area of maximal bleeding prior to chest closing after cardiac surgery. The rationale of a single PleuraFlow System in this location is to maximize blood evacuation while minimizing potential for chest tube clogging during the early hours of surgery until bleeding ceases.
a. In the case of partial or full sternotomy, the Chest Tube is placed in the anterior mediastinum (Figure 3).

b. When alternative access approaches are used (i.e., thoracotomy or mini thoracotomy), the Chest Tube is placed in the main surgical wound site.

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 1 & 2).

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

6. In addition to the PleuraFlow System, additional conventional chest tubes or channel drains (i.e. Blake Drains) of any size can be placed in any location at the discretion of the surgeon (mediastinal, pleural, etc).

7. Additional PleuraFlow systems can be placed at the discretion of the surgeon, but for this protocol, only one ACT system is placed in the anterior mediastinum. (Figure 3)

8. The PF-CA is actuated primarily in the early hours after cardiac surgery, and then is discontinued when the bleeding ceases or the drainage becomes serous.
EQUIPMENT LIST:
  i. PleuraFlow System (32 Fr, 28 Fr, 24 Fr, 20 Fr).
  ii. Additional conventional chest tubes optional and used as needed.

<table>
<thead>
<tr>
<th>INTRAOPERATIVE PROCEDURE</th>
<th>KEY POINTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Surgeon shall select and insert appropriate sized PF-CT (32 Fr, 28 Fr, 24 Fr, or 20 Fr).</td>
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</tbody>
</table>
  - PF-CT is inserted in the anterior mediastinum. (Figure 3) |
  - Cut PF-CT precisely on cut line. (Figure 4) |
  - 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). |
  - Attach PF-CT to proximal (blue) end of PF-CA. (Figure 1) |
  - Remove ~ 50cm (20”) of drain tubing to minimize dependent loops. |
  - Attach white distal (away from the patient) end of PF-CA to drain tubing to the drainage canister. (Figure 2) |
  - Make sure Clearance Loop passes without obstruction from tube kinking. |
  - “Park” PF-CA by clicking the external shuttle into the proximal connector. |

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

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

1. 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)

   - 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)

   - Recommended Actuation Schedule. (Figure 7)

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

   (See larger chart on following page.)

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

   - Wire Withdraw – 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 8: Clamping the PF-CT before disconnecting the PF-CA](image)

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 PleuraFlow System.
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:
  - The entire Chest Tube and PF-CA can be removed and discarded in one piece.
  - The PF-CA only can be removed and the PF-CT can be connected to the drainage tubing using sterile technique.
  - 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 (OR)</td>
<td>Chest Closure</td>
<td>1 time when PleuraFlow System is connected</td>
<td></td>
<td></td>
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<tr>
<td></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 (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>

Figure 8: 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:


