REDUCING COMPLICATIONS AND COSTS FOR YOUR CARDIOThorACIC SURGERY PATIENTS

With the PleuraFlow® ACT® System
Pericardial drainage* is associated with:

- 90% reduction in tamponade
- 80% reduction in pericardial effusions
- 58% reduction POAF
- 50% lower risk of mortality
- 1-day shorter length of stay (LOS)

THE PROBLEM

Retained Blood Syndrome
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.
CLOGGED CHEST TUBES: A ROOT CAUSE OF POST OPERATIVE COMPLICATIONS

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

CURRENT PRACTICES DON’T WORK

“Milking” and “stripping” are reactive measures to an already clogged chest tube. They are ineffective and can harm/damage vital tissue and organs.

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

AHA GUIDELINES
CURRENT PRACTICES: LEVEL 3B

I
Intervention is useful and effective

IIa
Weight of evidence/opinion is in favor of usefulness/efficacy

IIb
Usefulness/efficacy is less well established by evidence/opinion

III
Intervention is not useful/effective and may be harmful

Level A
Data from many large RCTs

Level B
Data from fewer, smaller RCTs, analysis of nonrandomized studies, observational registries

Level C
Expert consensus

Benefit >>> Risk
Benefit > Risk
Benefit ≥ Risk
Risk > Benefit

Reactive
Current Practices

Milking & Stripping
Retained Blood Syndrome (RBS):

The composite of drainage related complications that are detrimental to outcomes and costs after cardio-thoracic surgery and that may require early or late intervention to remediate.

RBS can occur at any stage of recovery:
- Acute: Pericardial tamponade or hemothorax
- Sub-Acute: Bloody pleural or pericardial effusions
- Chronic: Fibrothorax, constrictive pericarditis
Retained Blood Syndrome (RBS) can occur in any cardio-thoracic procedure and all patients are at risk.

>17% of adult cardiac surgery patients have one or more complications due to retained blood

*(based on ICD9/10 codes)*
Retained Blood Syndrome (RBS) delays patient recovery, drives readmissions and negatively affects patient outcomes.
$28,814

average unreimbursed cost of care per patient with RBS complications

Based on over 313,000 US adult heart surgery patients. Data extracted using ICD-9 codes from the 2010 Nationwide Inpatient Sample (NIS), from the DHHS Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project (HCUP).
ECONOMIC CONSEQUENCES OF RBS

<table>
<thead>
<tr>
<th>Complication</th>
<th>Incidence</th>
<th>Cost/Episode</th>
<th>Cost/100 CV Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tamponade</td>
<td>2%</td>
<td>$56,547</td>
<td>$113,094</td>
</tr>
<tr>
<td>RBS effusions</td>
<td>10%</td>
<td>$11,786</td>
<td>$117,860</td>
</tr>
<tr>
<td>Post-Op Atrial Fibrillation (POAF)</td>
<td>30%</td>
<td>$9,000</td>
<td>$270,000</td>
</tr>
</tbody>
</table>

Estimated cost for every 100 CV surgical cases $500,954

Cardiac tamponade was the most costly complication, resulting in a median net increase in hospital costs of $56,547, p < .001 (Iribarne*)
Pleural Interventions (greater than 25% of hemothorax) – (Light, Patel*)
30% reported rate of POAF in a meta-analysis of 24 studies of CABG patients. (Rostagno, LaPar*)
HOSPITALS WILL PAY FOR MORBIDITIES

- New MediCare/MIPS/MACRA reimbursement rules

<table>
<thead>
<tr>
<th>Year</th>
<th>Performance Period (Jan-Dec)</th>
<th>Reporting and Data Collection</th>
<th>MIPS Adjustments in Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2019</td>
<td></td>
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<td></td>
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<tr>
<td>2020</td>
<td></td>
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<tr>
<td>2021</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2022</td>
<td></td>
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</tr>
</tbody>
</table>

- 98 metropolitan areas – 1,120 hospitals
- Applicable procedures:
  - Coronary artery bypass surgery (CABG)
  - Medically treated heart attacks
  - Heart attacks receiving PCI
  - Hospitalization + 90 days post-discharge
  - Target price + quality standard performance
- Starts July 1st 2017
THE SOLUTION

Active Clearance Technology
ACTIVE CLEARANCE TECHNOLOGY® (ACT®)

PleuraFlow ACT is the only 510K cleared device indicated for the removal of retained blood.

The Clearance Loop is manipulated inside the chest tube to **proactively clear thrombus obstructions** and prevent the retention of blood in the chest cavity.
### AHA GUIDELINES

**PLEURAFLOW = LEVEL 1B**

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level A</strong></td>
<td>Data from many large, RCTs</td>
<td>Benefit &gt;&gt;&gt; Risk</td>
</tr>
<tr>
<td><strong>Level B</strong></td>
<td>Data from fewer, smaller RCTs, analysis of nonrandomized studies, observational registries</td>
<td>Benefit &gt; Risk</td>
</tr>
<tr>
<td><strong>Level C</strong></td>
<td>Expert consensus</td>
<td>Benefit ≥ Risk</td>
</tr>
</tbody>
</table>

**I**
- Intervention is useful and effective

**IIa**
- Weight of evidence/opinion is in favor of usefulness/efficacy

**IIb**
- Usefulness/efficacy is less well established by evidence/opinion

**III**
- Intervention is not useful/effective and may be harmful

**Proactive**
- PleuraFlow ACT

**Reactive**
- Current Practices

**Milking & Stripping**
PleuraFlow ACT was reported to reduce the incidence of both Retained Blood Syndrome (RBS) and Post-operative Atrial Fibrillation (POAF).

43% Reduction in RBS with PleuraFlow ACT (p=0.0087)

33% Reduction in POAF with PleuraFlow ACT (p=0.013)

Patients with PleuraFlow ACT showed a markedly lower rate of Retained Blood Syndrome complications.

<table>
<thead>
<tr>
<th>Baseline Cardiothoracic Patients</th>
<th>Prospective Cardiothoracic Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>256 with conventional drains</td>
<td>256 with PleuraFlow ACT</td>
</tr>
<tr>
<td>20% RBS Interventions (51 total)</td>
<td>11% RBS Interventions (29 total)</td>
</tr>
</tbody>
</table>

Reduction in RBS with PleuraFlow ACT (p=0.0087)

RBS interventions rebounds back to baseline upon withdrawal of PleuraFlow ACT.

Patients receiving PleuraFlow in a **Prospective Registry** arm showed a markedly lower rate of Atrial Fibrillation.

<table>
<thead>
<tr>
<th>Baseline Cardiothoracic Patients</th>
<th>Prospective Cardiothoracic Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>256 with conventional drains</td>
<td>256 with PleuraFlow ACT</td>
</tr>
<tr>
<td>30% POAF (77 total)</td>
<td>20% POAF (52 total)</td>
</tr>
</tbody>
</table>

**Reduction in POAF with PleuraFlow ACT (p=0.013)**

PleuraFlow ACT can lead to substantial hospital savings.

<table>
<thead>
<tr>
<th>Baseline Total RBS Cost</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Cardiothoracic Surgeries per Year</td>
<td>1,200</td>
</tr>
<tr>
<td>Baseline Patients with RBS (17%) Complications</td>
<td>204</td>
</tr>
<tr>
<td>Baseline Total Cost of RBS Complications (^1,^2)</td>
<td>$5,878,056</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Projected Total RBS Savings</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Projected Reduction in RBS Complications Cost</td>
<td>$2,468,784</td>
</tr>
<tr>
<td>Total Cost of PleuraFlow ACT (^4) (one/patient)</td>
<td>$474,000</td>
</tr>
<tr>
<td><strong>Projected Total Hospital Savings</strong></td>
<td><strong>$1,994,784</strong></td>
</tr>
</tbody>
</table>

\(^1\) 17% RBS rate based on over 313,000 US adult heart surgery patients from the 2010 Nationwide Inpatient Sample (NIS)/(AHRQ)/(HCUP).

\(^2\) $28,814 average cost per patient who had 1 or more RBS complications that required re-operation or intervention.

\(^3\) 42% RBS reduction – based on clinical trial results from Paracelsus Medical University Klinikum Nürnberg Germany, 2014.

\(^4\) $395 per PleuraFlow ACT System.
COST NEUTRALITY IS 14.1 FEWER RBS EVENTS

Hospital Wide Use

1000 Patient Pilot:

- RBS rate = 17% at $28k/event (rounded for the calculation)
- 1000 cases would cause an expected 170 RBS events @ $28K each = $4,760,000
- Cost of using 1000 PleuraFlow at $395 ea is $395K
- Number of RBS events needed to be avoided to save $395K = $395K/$28K = 14.1 events
- Projected RBS reduction = 42% while, Cost Neutrality is achieved at 8.2% RBS reduction (14/170).

COST OF RETAINED BLOOD SYNDROME INTERVENTIONS CALCULATOR

<table>
<thead>
<tr>
<th>Current Status</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Name</td>
<td></td>
</tr>
<tr>
<td>Cardiac Surgery Procedures per Year</td>
<td>1,000</td>
</tr>
<tr>
<td>Rate of Interventions for RBS Complications [1]</td>
<td>17.0%</td>
</tr>
<tr>
<td>Number of Patients with RBS Interventions</td>
<td>170</td>
</tr>
<tr>
<td>Cost of Interventions for RBS Complications [2]</td>
<td>$ 4,760,000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Impact of Reduction of RBS Interventions</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of PleuraFlow Active Clearance Technology® Systems per patient</td>
<td>1.0</td>
</tr>
<tr>
<td>Price Per PleuraFlow System</td>
<td>$ 395.00</td>
</tr>
<tr>
<td>Cost of PleuraFlow Systems for use on all procedures</td>
<td>$ 395,000</td>
</tr>
<tr>
<td>Percent Reduction in RBS[3]</td>
<td>42%</td>
</tr>
<tr>
<td>Projected Cost Savings</td>
<td>$ 1,999,200</td>
</tr>
<tr>
<td>Projected Hospital Savings</td>
<td>$1,604,200</td>
</tr>
</tbody>
</table>

[1] Based on over 313,000 US adult heart surgery patients from the 2010 Nationwide Inpatient Sample (NIS)/(AHRQ)/(HCUP).
[2] $28,814 average cost per patient who had 1 or more RBS complications that required re-operation or intervention.
20% OF PATIENTS REQUIRE ONE OR MORE INTERVENTIONS DUE TO RETAINED BLOOD

Retained blood is associated with clinical and economic costs

<table>
<thead>
<tr>
<th>Clinical Costs</th>
<th>Economic Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality rate – up from 4% to 20%</td>
<td>Cost per patient – €20,376*</td>
</tr>
<tr>
<td>Ventilation time – up from 20 to 80 hours</td>
<td>Length of stay – up by 15 days</td>
</tr>
<tr>
<td>Post-op dialysis – up from 10% to 42%</td>
<td>ICU length of stay – up by 9 days</td>
</tr>
</tbody>
</table>

*Average incremental cost per patient that had one or more interventions associated with retained blood.


### Study Conclusions

- The use of the PleuraFlow ACT System is clinically beneficial to cardiothoracic surgery patients.

- There is a significant economic benefit for hospitals using the PleuraFlow ACT System on their patients.

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By implementing PleuraFlow ACT, the time required for nurses to manage blocked tubes is reduced by up to 2 hours per patient per day.
SUMMARY OF PLEURAFAFLOW ACT

• The only FDA cleared and CE marked device that is indicated to **proactively maintains chest tube patency** to prevent or minimize occlusions and reduce retained blood.

• Clinical data shows that patients threatened with PleuraFlow ACT have:
  - **43% reduction** in RBS complications such as bloody pleural and pericardial effusions
  - **33% reduction** in post-operative atrial fibrillation (POAF)

• ClearFlow expects hospitals to benefit approximately $1,600/patient of **net economic gain*** vs. traditional chest-drain systems
  (* **after deduction of device cost**)

*after deduction of device cost*
Peer Reviewed, Published


Submitted or In Progress


2. Pleural Effusions are Associated with Adverse Outcomes and Increased Costs after Cardiac Surgery. Prepared for submission to Journal of Thoracic and Cardiovascular Surgery.


5. Active Clearance of Chest Drainage Catheters Reduces Postoperative Atrial Fibrillation. In Progress, plan to submit to Innovations (Phila)

Peer reviewed & published benefits of using PleuraFlow ACT

- **43%** reduction in **RBS** (Sirch, et al, *JTCVS*, 2016)
- **33%** reduction in **POAF** (Sirch, et al, *JTCVS*, 2016)
- **39%** reduction in **RBS in VAD Pts.** (Maltais, *ASAIO*, 2016)
- **65%** reduction in **re-explorations in VAD Pts.** (Maltais, *ASAIO*, 2016)
- **50%** reduction in the odds for **POAF** (St. Onge, in review, *JTCVS*)
THANK YOU

Questions & Discussion
ADDITIONAL SLIDES

Not Edited / Needs to be Paired Down
50% LESS DIAMETER = 94% LESS FLOW

10% = 10%
Restriction = Less Flow

25% = 50%
Restriction = Less Flow

50% = 94%
Restriction = Less Flow

75% = 98%
Restriction = Less Flow
ACT MAINTAINS CHEST TUBE PATENCY

Each photo shows clogged conventional tubes and clear ACT tubes removed from the same patients 24-48 hours post-surgery.

ACT on top
Conventional on bottom

Conventional tube on top
ACT on bottom

ACT on right and left;
Larger conventional tube in middle
RBS DRIVES READMISSIONS

Causes of 30d readmissions post cardiac surgery

20% of cardiac patients readmitted at 30 days

- Infection - 25%
- Pleural-Pericardial Effusion - 21%
- Arrythmia (POAF) - 17%
- Other - 15%
- CHF - 11%
- Angina Pectoris - 7%
- GI Event/Bleeding - 4%

1. Magnus, Circulation, 2011
2. Hannan, J AM Coll Cardio Intv, 2011
Patients with Retained Blood Syndrome incurred significantly higher reinterventions, length of stay, readmissions & total cost of care.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Non-RBS</th>
<th>RBS</th>
<th>Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of Stay (Days)</td>
<td>12.6</td>
<td>20.75</td>
<td>+65%</td>
</tr>
<tr>
<td>ICU Stay (Days)</td>
<td>4.1</td>
<td>10.1</td>
<td>+149%</td>
</tr>
<tr>
<td>Ventilation Time (Hrs.)</td>
<td>40.2</td>
<td>111.3</td>
<td>+149%</td>
</tr>
<tr>
<td>Cardiac Arrest (%)</td>
<td>2</td>
<td>5.6</td>
<td>+182%</td>
</tr>
<tr>
<td>Atrial Fibrillation (%)</td>
<td>27.5</td>
<td>36.8</td>
<td>+34%</td>
</tr>
<tr>
<td>Permanent Stroke (%)</td>
<td>0.89</td>
<td>2.3</td>
<td>+163%</td>
</tr>
<tr>
<td>Mortality</td>
<td>6.3</td>
<td>8.5</td>
<td>+34%</td>
</tr>
</tbody>
</table>

20% required one or more reinterventions due to RBS
Retrospective study of 6,909 patients from 2006-2013.

16% required one or more RBS reinterventions due to RBS

<table>
<thead>
<tr>
<th>Measure</th>
<th>Non-RBS</th>
<th>RBS</th>
<th>Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>4.9%</td>
<td>17.6%</td>
<td>367%</td>
</tr>
<tr>
<td>LOS</td>
<td>12 days</td>
<td>27 days</td>
<td>225%</td>
</tr>
<tr>
<td>ICU LOS</td>
<td>5 days</td>
<td>14 days</td>
<td>280%</td>
</tr>
<tr>
<td>A Fib</td>
<td>26.2%</td>
<td>47.6%</td>
<td>182%</td>
</tr>
<tr>
<td>Difference in DRG LOS (days)</td>
<td>-0.69</td>
<td>4.22</td>
<td>4.9 days</td>
</tr>
<tr>
<td>Total Costs</td>
<td>22,987 Euro 26,259 USD*</td>
<td>61,508 Euro 70,250 USD*</td>
<td>38,521 Euro 43,995 USD*</td>
</tr>
</tbody>
</table>

* 1.142 Euro-USD exchange rate accessed 2/4/2015
Preventing even a fraction of RBS complications can lead to substantial hospital savings.

<table>
<thead>
<tr>
<th>Cardiac Surgery Procedures/year</th>
<th>1,200</th>
<th>800</th>
<th>400</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate of RBS Complications @ 17%$^{1}$</td>
<td>204</td>
<td>136</td>
<td>68</td>
</tr>
<tr>
<td>Cost of RBS Complications$^{1,2}$</td>
<td>$5,878,056</td>
<td>$3,918,704</td>
<td>$1,959,352</td>
</tr>
<tr>
<td>42% Reduction$^{3}$</td>
<td>$2,468,784</td>
<td>$1,645,856</td>
<td>$822,928</td>
</tr>
<tr>
<td>Cost of PleuraFlow ACT$^{4}$</td>
<td>$474,000</td>
<td>$316,000</td>
<td>$158,000</td>
</tr>
<tr>
<td>Projected Hospital Savings</td>
<td>$1,994,784</td>
<td>$1,329,856</td>
<td>$664,928</td>
</tr>
</tbody>
</table>

$^{1}$ Based on over 313,000 US adult heart surgery patients from the 2010 Nationwide Inpatient Sample (NIS)/(AHRQ)/(HCUP).
$^{2}$ $28,814 average cost per patient who had 1 or more RBS complications that required re-operation or intervention
$^{3}$ Clinical trial results from Paracelsus Medical University Klinikum Nürnberg Germany, 2014
$^{4}$ $395 per PleuraFlow ACT System
EVERYONE IS ON THE BELL CURVE

Rate of reintervention for Retained Blood Syndrome (RBS)

- Hospital 1: 16% (n=6,909)
- Truven Facility Report: 15% (n=89,869)
- MarketScan Database: 14% (n=234,555)
- NIS ICD-9 codes: 17% (n=313,000)
- Hospital 2: 20% (n=1,869)
- Hospital 3: 51% (n=77 (VAD))

Documented complications in the literature: 16-23%
Patients with PleuraFlow showed a markedly lower rate of interventions for retained blood and re-exploration for bleeding\(^1\)

<table>
<thead>
<tr>
<th></th>
<th>No ACT (N=77)</th>
<th>With ACT (N=175)</th>
<th>% of Reduction with PleuraFlow</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retained Blood Interventions</td>
<td>39 (51%)</td>
<td>54 (31%)</td>
<td>-38%</td>
<td>0.0044</td>
</tr>
<tr>
<td>Re-exploration for bleeding</td>
<td>33 (43%)</td>
<td>27 (15%)</td>
<td>-65%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Delayed Sternal Closure (DSC)</td>
<td>26 (34%)</td>
<td>10 (6%)</td>
<td>-82%</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Marked reduction in RBS and Re-exploration following LVAD placement.

Patients with PleuraFlow showed a markedly lower rate of Post-operative Atrial Fibrillation (POAF).

<table>
<thead>
<tr>
<th>Study</th>
<th>POAF % No ACT Used</th>
<th>POAF % With ACT</th>
<th>% of Reduction in POAF with PleuraFlow</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study #1 (Sirch)</td>
<td>30%</td>
<td>20%</td>
<td>-33%</td>
<td>.013</td>
</tr>
<tr>
<td>Study #2 (St-Onge)</td>
<td>35%</td>
<td>23%</td>
<td>-34%</td>
<td>.01</td>
</tr>
</tbody>
</table>

Two independent sites reported a reduction of 33% and 34% respectively.