ACTIVE CLEARANCE TECHNOLOGY

PleuraFlow is a unique system that proactively clears chest tubes and prevents the retention of blood in the chest cavity.
EASY INTEGRATION INTO WORKFLOW

- Reduces time required for nurses to manage blocked tubes (up to 2 hours per patient per day)

Cook, et al., Cleveland Clinic Foundation, Presented at AATS 2014 Poster session
ACT MAINTAINS CHEST TUBE PATENCY

Clogged conventional tubes and clear PleuraFlow ACT tubes removed from the same patients 24-48 hours post-surgery.

Top: PleuraFlow ACT
Bottom: Conventional

Top: Conventional
Bottom: PleuraFlow ACT

Left & Right: PleuraFlow ACT
Middle: Conventional
Patients with Retained Blood Syndrome incurred significantly higher reinterventions, length of stay, readmissions & total cost of care.

20% required one or more 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>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>

Historic data (2011-2012 incl. n= 1,869)

Independent German Data
Presented at 2014 EACTS (Milan) and 2014 FACTS-CARE (Washington DC)
Patients receiving PleuraFlow in a **Prospective Registry** arm showed a markedly lower rate of Retained Blood Syndrome.

**Retrospective data 2011-2012**

- 1,869 patients with regular drains
- 20% RBS Interventions (374 total)

**Prospective Same-site data 2014**

- 256 patients with PleuraFlow
- 11% RBS Interventions (29 total)

**42%** Reduction in RBS with PleuraFlow (p=0.025)

Independent German Data
Presented at 2014 EACTS (Milan) and 2014 FACTS-CARE (Washington DC)
Patients receiving PleuraFlow in a **Prospective Registry** arm showed a markedly lower rate of Atrial Fibrillation.

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<tr>
<th>Retrospective data 2011-2012</th>
<th>Prospective same-site data 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,869 With regular drains</td>
<td>256 with PleuraFlow</td>
</tr>
<tr>
<td>29% A-Fib. (543 total)</td>
<td>20% A-Fib. (52 total)</td>
</tr>
</tbody>
</table>

**30% Reduction in A-Fib. with PleuraFlow** *(p,=0.0055)*

Independent German Data
Presented at 2014 EACTS (Milan) and 2014 FACTS-CARE (Washington DC)
RBS RETURNED TO BASELINE AFTER!

- **Phase 1 (n=1,869)**: 20% RBS Interventions
- **Phase 2 (n=256)**: 11% RBS Interventions, 42% reduction, p=0.0021
- **Phase 3 (n=222)**: 18% RBS Interventions

No ACT compared to ACT shows a significant reduction in the percentage of RBS interventions, with a p-value of 0.0021. The comparison of No ACT before and after ACT intervention is not significant, with a p-value of 0.54.
PREVENTING EVEN A FRACTION OF RBS LEADS TO SUBSTANTIAL HOSPITAL SAVINGS

All cardiothoracic hospitals can immediately reduce their total cost of care by adopting PleuraFlow ACT.

<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><strong>Cost of RBS Complications¹,²</strong></td>
<td><strong>$5,878,056</strong></td>
<td><strong>$3,918,704</strong></td>
<td><strong>$1,959,352</strong></td>
</tr>
<tr>
<td>42% Reduction³</td>
<td>$2,468,784</td>
<td>$1,645,856</td>
<td>$822,928</td>
</tr>
<tr>
<td>Cost of ACT⁴</td>
<td>$474,000</td>
<td>$316,000</td>
<td>$158,000</td>
</tr>
<tr>
<td><strong>Projected Hospital Savings</strong></td>
<td><strong>$1,994,784</strong></td>
<td><strong>$1,329,856</strong></td>
<td><strong>$664,928</strong></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.
The documented cost savings may represent only the “tip of the iceberg” for actual costs to treat patients with retained blood.

- POAF management (in ~30% of patients)\(^1,2\)
- ICU Nursing time (if tubes clogged ~2 hrs/pt)\(^3\)
- Opportunity Costs for ICU bed occupancy
- Hospital and general ward workflow impact
- P4P Penalties under Affordable Healthcare Act
- Medical/legal liability for death or injury

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1 American Association for Thoracic Surgery (AATS) evidence-based guidelines for the prevention and treatment of perioperative and postoperative atrial fibrillation states: “POAF is associated with longer intensive care unit and hospital stays, increased morbidity, including strokes and new central neurologic events, as well as use of more resources. Patients who develop POAF tend to stay two to four days longer in the hospital.” [http://www.eurekalert.org/pub_releases/2014-09/aaf-tisi092214.php](http://www.eurekalert.org/pub_releases/2014-09/aaf-tisi092214.php)


SUMMARY OF CLINICAL IMPACT

- **36%** of chest tubes become completely clogged and in **86%** of these cases it *cannot be seen by the nursing staff*.¹

- There is a Class III recommendation against current practice which states milking and stripping:

  "*May be harmful; no benefit documented*."²

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SUMMARY OF FINANCIAL IMPACT

- Clogged chest tubes lead to **expensive and avoidable** additional re-operations and interventions in **16-23%** of all cardiac surgery patients.¹,²,³

- A conservative estimate of the average cost to treat only those complications that require interventions is **$489,838 for every 100 cardiac surgeries** performed.²

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¹ Karimov, Eur J Cardiothorac Surg. 2013
² Based on over 313,000 US adult heart surgery patients from the 2010 Nationwide Inpatient Sample (NIS)/(AHRQ)/(HCUP).
³ Additional references from published literature available upon request
SUMMARY OF SOLUTION

PleuraFlow is the only FDA approved System with \textbf{Active Clearance Technology\textsuperscript{®}}.

It is easy to implement and has been shown in a German clinical study to \textit{reduce RBS complications} like bloody pleural and pericardial effusions \textit{by 42\%} and post-operative AFib (POAF) \textit{by 30\%}.\textsuperscript{1}

\textsuperscript{1} Clinical trial results from Paracelsus Medical University Klinikum Nürnberg Germany, 2014
DON’T LET RETAINED BLOOD SYNDROME BLOCK YOUR PATIENT’S RECOVERY


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).
APPENDIX
POSTOPERATIVE BLEEDING PATHWAY

ADEQUATE BLOOD EVACUATION

Recovery

INADEQUATE BLOOD EVACUATION

Clinically Large Volume of Retained Blood/Clot

Pericardial Tamponade  Hemothorax

ACUTE RBS

Subclinical Volume of Retained Blood/Clot

Clot causes Inflammation/VEGF Production and Fluid

Pericardial Effusion  Pleural Effusion

SUB-ACUTE RBS

Inflammation Transitions to Fibrosis

Postoperative Constrictive Pericarditis  Fibrothorax

CHRONIC RBS
EVERYONE IS ON THE BELL CURVE

Rate of reintervention for Retained Blood Syndrome (RBS)

16-23%

Documented complications in the literature

NIS ICD-9 codes
n=313,000

17%

Hospital 1
n=6,909

16%

Hospital 2
n=1,869

20%

Hospital 3
n=77 (VAD)

51%
RBS IS FREQUENT AND SERIOUS

- No RBS - 83.7%
- Thoracentesis - 8.9%
- Re-exploration - 6.7%
- Pericardial Effusion - 1.6%
- Hemothorax - 3.3%
- Tamponade - 1.6%

*Patient may have more than one RBS event

N=6,909 Cardiac Surgery Patients at Charité Hospital
5,784 (83.7%) = No Retained Blood Syndrome (RBS)
1,125 (16.3%) = One or more RBS complications
## RBS IN THE LITERATURE

<table>
<thead>
<tr>
<th>RBS Type</th>
<th>Range</th>
<th>Reference Source</th>
<th>% Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subacute pericardial intervention</td>
<td>1.2 – 2.0%</td>
<td>Ashikhmina 2010 Russo, 1993 Pompilio, 2011</td>
<td>1.2 2.0 2.0</td>
</tr>
<tr>
<td>Subacute pleural intervention</td>
<td>5.9 – 10.0%</td>
<td>Lancey, 2001 Light, 2002</td>
<td>5.9 10.0</td>
</tr>
<tr>
<td>Chronic complications</td>
<td>2 – 3%</td>
<td>Gaudino, 2013</td>
<td>2-3.0</td>
</tr>
</tbody>
</table>

References Available Upon Request
ICD-9 Procedures and Diagnoses that indicate RBS after Heart Surgery

- Pleural Effusions
- Thoracentesis
- Thoracotomy
- Cardiac tamponade
- Thoracoscopic drainage of pleural cavity
- Decortication of lung
- Empyema
- Thoracoscopic decortication of lung
- Transpleural thoracoscopy
- Hemopericardium
- Incision of chest wall
- Incision of pleura
- Pericardiocentesis
- Pericardiotomy
- Thoracoscopic drainage of pleural cavity
- Open chest cardiac massage
- Diagnostic ultrasound of other sites of thorax
- Reopening of recent thoracotomy site
- Decortication of lung
- Empyema
- Transpleural thoracoscopy
- Thoracentesis
- Insertion of intercostal catheter for drainage
- Scarification of pleura

**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).
Approximately 53,000, or 17%, of patients had additional codes consistent with Retained Blood Syndrome (RBS) with the following results:

- Mean LOS increased from 9.2 days to 15 days compared to patients without RBS
- Total charges and costs were about 55% higher ($28,814) than for patients without RBS
- Routine discharges declined to 29% from 39%, with an increase in both assisted discharges and expired patients over average cardiac surgery patients
- Mortality doubled from 3% to 6% over average cardiac surgery patients
50% LESS DIAMETER = 94% LESS FLOW

10% Restriction = 10% Less Flow

25% Restriction = 50% Less Flow

50% Restriction = 94% Less Flow

75% Restriction = 98% Less Flow
READMITTED AFTER NINE MONTHS

The New York Times

“A collection of bloody fluid caused scar tissue to form and squeeze the lower lobe of his left lung, impeding his breathing capacity by more than 25%... 

...doctors removed a large, unspecified amount of bloody fluid...

...(then found) a large thick rind of inflammatory tissue encasing the lower lobe of the lung...some sections were five to eight millimeters (thick).”
SIGNIFICANT AND AVOIDABLE COST

For every 100 cardiac surgery patients, 17 will suffer one or more interventions for Retained Blood Syndrome.

17 x $28,814 = $489,838

Non reimbursable costs

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).
SIGNIFICANT ECONOMIC VALUE

The average RBS intervention costs US hospitals $28,814 per patient, which covers the cost of ~75 PleuraFlow Systems at $395 each.

$28,814
Cost of 1 RBS

$395
Cost of 1 PleuraFlow

~75 PleuraFlow Catheters

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).
### AWARD-WINNING TECHNOLOGY

PleuraFlow has won 7 design & innovation awards including:

<table>
<thead>
<tr>
<th>Best Startup Innovation</th>
<th>Techno-College Innovation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Innovations in Cardiovascular Interventions Award (ICI)</td>
<td>European Association of Cardio-Thoracic Surgery (EACTS)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pro Design Award</th>
<th>Most Technologically Significant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Act as a catalyst, address problems &amp; improves lives</td>
<td>salutes the 100 most significant products introduced into the marketplace over year</td>
</tr>
</tbody>
</table>