

# HERE'S THE EVIDENCE!

Published clinical data demonstrates the negative impact of Retained Blood Syndrome (RBS) on patient outcomes.

**BETWEEN 13.8% AND 22.7% OF CARDIAC SURGERY PATIENTS REQUIRE A POST-SURGICAL INTERVENTION FOR RETAINED BLOOD WHEN DRAINAGE SYSTEMS FAIL TO ADEQUATELY EVACUATE BLOOD**

Boyle, E.M., Gillinov, A.M., Cohn, W.E., Ley, S.J., Fischlein, T., Perrault, L.P. Retained Blood Syndrome After Cardiac Surgery: A new look at an old problem. *Innovations in cardiovascular and thoracic surgery*. 2015 Sept/Oct;10(5):296-303.

**PATIENTS THAT REQUIRE INTERVENTION(S) FOR RBS HAVE INCREASED MORTALITY, INCREASED LENGTH OF STAY, AND OTHER POSTOPERATIVE COMPLICATIONS**

Balzer, F., von Heymann, C., Boyle, E.M., Wernecke, K.D., Grubitzsch, H., Sander, M. Impact of Retained Blood Requiring Reintervention on Outcomes after Cardiac Surgery. *J Thorac Cardiovasc Surg*. 2016. 152(2):595-601.e4

**PEER REVIEWED AND PUBLISHED CLINICAL TRIAL DEMONSTRATES A SIGNIFICANT REDUCTION IN POST-SURGICAL INTERVENTIONS FOR RETAINED BLOOD AND POAF USING THE PLEURAFLOW SYSTEM**

Sirch, J., Ledwon, M., Puski, T., Boyle, E.M., Pfeiffer, S., Fischlein, T. Active clearance of chest drainage catheters reduces retained blood. *J Thorac Cardiovasc Surg*. 2016. Mar; 151(3):832-838.

**10% OF ALL PATIENTS HAVE A UNILATERAL PLEURAL EFFUSION INVOLVING MORE THAN 25% OF THE LUNG AT 30 DAYS FOLLOWING CARDIAC SURGERY**

Light, R.W., Rogers, J.T., Moyers, J.P., et al. Prevalence and clinical course of pleural effusions at 30 days after coronary artery and cardiac surgery. *Am J Respir Crit Care Med*. 2002 Dec 15;166:1567-71.

**PATIENTS THAT REQUIRE INTERVENTION(S) FOR RBS ARE MORE LIKELY TO DEVELOP POSTOPERATIVE INFECTIONS**

Balzer, F., Mezger, V., Grubitzsch, H., von Heymann, C., Treskatsch, S., Boyle, E.M., Sander, M. Postoperative Infections Are Associated With Retained Blood After Cardiac Surgery: An Observational, Cross-sectional Analysis. Presented at the Society of Cardiovascular Anesthesiologists (SCA) 38th Annual Meeting in San Diego, CA on April 5, 2016

**RETAINED BLOOD LEADS TO AN INTENSE PRO-OXIDANT LOCAL INFLAMMATORY RESPONSE THAT MAY TRIGGER POAF AFTER CARDIAC SURGERY**

Kramer, P.A., Melby, S.J., et al. Hemoglobin-associated oxidative stress in the pericardial compartment of postoperative cardiac surgery patients. *Lab Invest*. 2015;95(2):132-41.

**MONTREAL HEART INSTITUTE STUDY SHOWS A SIGNIFICANT REDUCTION IN POST-OPERATIVE ATRIAL FIBRILLATION (POAF) FROM 35% TO 23% WHEN USING THE PLEURAFLOW SYSTEM**

St-Onge, S., Ben Ali, W., Bouhout, I., Bouchard, D., Lamarche, Y., Perrault, L.P., Demers, P. Examining the impact of active clearance of chest drainage catheters on postoperative atrial fibrillation. *J Thorac Cardiovasc Surg*. 2017. In press. Society of Cardiovascular Anesthesiologists (SCA) 38th Annual Meeting in San Diego, CA on April 5, 2016. In Press.

**LEVEL 1A EVIDENCE THAT IMPROVING DRAINAGE OF FLUID FROM THE PERICARDIUM FOLLOWING CARDIAC SURGERY REDUCES THE INCIDENCE OF POAF, EFFUSIONS, AND TAMPONADE**

Gozdek, M., Pawliszak, W., Hagner, W., et al. Systematic review and meta-analysis of randomized controlled trials assessing safety and efficacy of posterior pericardial drainage in patients undergoing heart surgery. *J Thorac Cardiovasc Surg*. 2016. Oct;

**PATIENTS WHO HAD CLOGGED CHEST TUBES HAD STATISTICALLY SIGNIFICANT HIGHER RATES OF POAF AND RENAL FAILURE, PLUS TRENDS TOWARDS CARDIAC ARREST AND STROKE COMPARED TO THOSE THAT DIDN'T HAVE CLOGGED CHEST TUBES**

Karimov, J.H., Gillinov, A.M., Schenck, L., et al. Incidence of chest tube clogging after cardiac surgery: a single-centre prospective observational study. *Eur J Cardiothorac Surg*. 2013 Dec;44(6):1029-36.

2. 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).

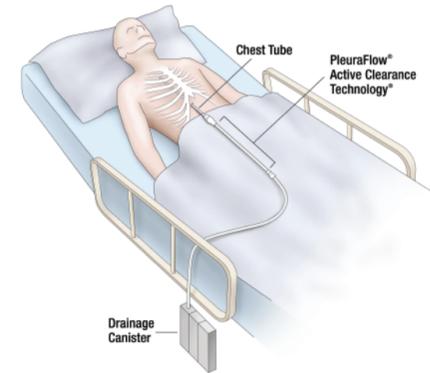
# ACT NOW

Improve Outcomes, Lower Costs

## Ordering Information

### PleuraFlow® ACT® Systems

All Systems include a straight silicone chest tube and a clearance apparatus.



CODE	SIZE	EFFECTIVE-DRAINAGE LENGTH (EDL)	NUMBER OF EYELETS
PF-20	20FR	4" (10.2 cm)	6
PF-24	24FR	4" (10.2 cm)	6
PF-28	28FR	4" (10.2 cm)	6
PF-32	32FR	4" (10.2 cm)	6
PF-20 SEDL <sup>1</sup>	20FR	2" (5.1 cm)	4
PFFG-20	20FR	4" (10.2 cm)	6
PFFG-24	24FR	4" (10.2 cm)	6
PFFG-28	28FR	4" (10.2 cm)	6
PFFG-32	32FR	4" (10.2 cm)	6

<sup>1</sup> Chest tube includes Shorter Effective Drainage Length (SEDL)

DON'T LET RETAINED BLOOD SYNDROME BLOCK YOUR PATIENT'S RECOVERY

# FLOW BETTER

WITH PLEURAFLOW® ACTIVE CLEARANCE TECHNOLOGY® SYSTEM WITH FLOWGLIDE™



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US Patents 7,854,728, 7,951,243, 8,048,233, 8,246,752, 8,388,759, 8,702,662, and 8,951,355. International Patents AU 2004235782; CA 2,565,303. Other US and international patents pending.

US FDA 510(k): K150042; K153681; K163139; Health Canada License Number 92263; ARTG Identifier 218317; CE Marking Registration Number: 252.1078

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#### References

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2. 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).

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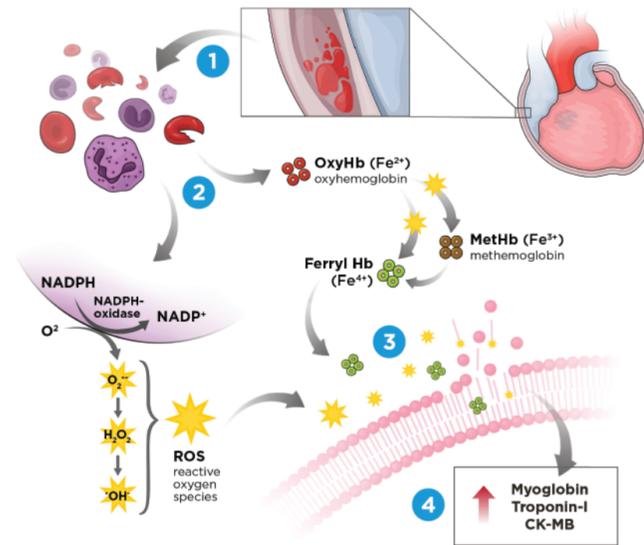
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# EVEN A SMALL AMOUNT OF RETAINED BLOOD CAN CAUSE DAMAGE

Retained blood around the heart causes mechanical and inflammatory damage<sup>1,3,4,12</sup>

Retained blood left behind in the pericardial space can lead to a cascade of events resulting in the **release of free radicals and reactive oxygen species (ROS)**. These inflammatory agents cause lipid peroxidation and the breakdown of myocardial cell membrane – heart muscle damage indicated by an increase in local biomarkers.



**36%** of patients have one or more **COMPLETELY** occluded chest tubes<sup>1</sup>

A recent prospective study found that **36%** of patients suffer from **completely blocked chest tubes**. Worse yet, **86%** of those occlusions were **intra-thoracic** and therefore invisible to the bedside caregivers.<sup>1</sup> The crucial post-surgery hours, when the patient is still bleeding, are vitally important. Why risk patient outcomes by relying on a conventional chest tube?



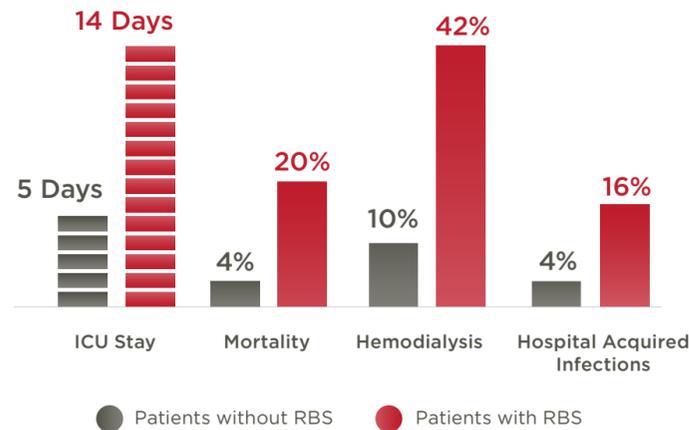
# RETAINED BLOOD SYNDROME (RBS) IS SERIOUS & COSTLY

**17-20%** of patients require one or more interventions due to retained blood<sup>2,3,4,11</sup>

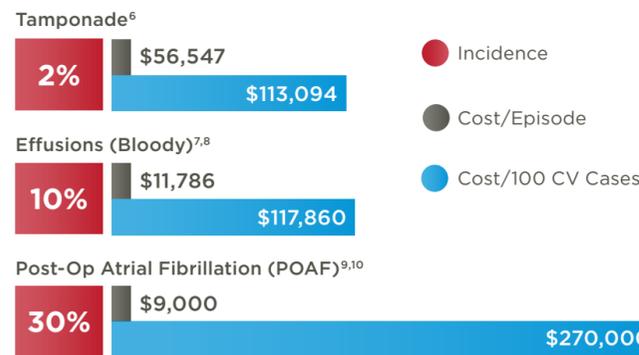
RBS negatively impacts patient outcomes

**Retained Blood Syndrome (RBS)** – the composite of drainage-related post-cardiothoracic surgery complications - is detrimental to patient outcomes and may include **hemothorax, pericardial tamponade** and **bloody pleural or pericardial effusions**<sup>3</sup>. RBS can affect anyone at any stage of recovery.

Retained Blood Syndrome (RBS) delays patient recovery, drives readmissions and negatively affects patient outcomes.<sup>4,5</sup>



**\$28,814** – average unreimbursed cost of care per RBS episode<sup>2</sup>



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

# PROTECT PATIENTS FROM RBS

with PleuraFlow® Active Clearance Technology® (ACT®) System with FlowGlide™

- Developed by cardiothoracic surgeons, PleuraFlow ACT is a unique system that pro-actively prevents or minimizes the occlusions of chest tubes. Now available with new FlowGlide™ treatment for smoother clearance and lower surface drag.
- It is the **only 510K cleared device indicated for the removal of retained blood**. The PleuraFlow ACT System meets **AHA Level 1B evidence** and should be used after cardiothoracic surgery in all patients to reduce the incidence of RBS.<sup>11,13,14</sup>



Clearance Loop enables proactive clearance of thrombus obstruction from the chest tube and provides real-time patency feedback.

## Clinical Benefits

PleuraFlow ACT System was reported to reduce the incidence of both Retained Blood Syndrome (RBS) and Post-operative Atrial Fibrillation.<sup>11</sup>

**43%**

Reduction in RBS with PleuraFlow ACT (p=0.0087)

**33%**

Reduction in POAF with PleuraFlow ACT (p=0.013)

## Economic Benefits

Cardiothoracic surgery centers can immediately reduce their costs by implementing PleuraFlow ACT System in all their patients.<sup>2,11</sup>

**100**

cardiothoracic surgery patients

**\$171K**

Savings with PleuraFlow ACT