2017 Global Retained Blood Syndrome New Product Innovation Award
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Industry Challenges

Physicians use chest tubes to evacuate shed blood around the heart and lungs following all cardiac surgery operations. While considered the gold standard, chest tubes can often become blocked, halting draining and leaving excess blood behind in the chest cavity after the tube’s removal. A patient’s body must try to reabsorb excess unevacuated postoperative blood. However, patients are often unable to completely reabsorb it without an inflammatory response causing retained blood syndrome (RBS) which can lead to numerous complications, including postoperative atrial fibrillation (AFib) occurring in 20% to 60% of patients. Postoperative AFib is a leading cause of hospital readmissions, which increases treatment costs. Patients suffering from associated complications and undergoing additional interventions experience a variety of challenges including extended length of stay, increased occurrence of acute kidney injury, greater infection incidence, higher risk of postoperative AFib, and amplified treatment costs. The average cost of treatment for one or more RBS complications that requires a recurrent surgery is $28,814.

According to a study completed by the Cleveland Clinic, the incidence of patients with chest tube clogging is 36%. Nursing staff or providers try to unblock chest tubes using a balloon catheter or by manually manipulating the outside of the tubes with their fingers in an attempt to loosen the clot in the tube. However, this can require them to break the sterile field of the chest tube, leaving the patient at increased risk for infection. Furthermore, if these strategies do not work, providers must re-operate or re-intervene to wash out the pericardial or pleural spaces and remove the retained blood. Published studies reveal that 13.8% to 22.7% of cardiac surgery patients develop one or more components of retained blood syndrome. Sometimes this requires the insertion of a different drainage tube, insertion of a needle into the chest to drain fluid, or a complete reopening of the surgical incision in the operating room resulting in extended healing times and increased patient pain during early recovery. Additionally, physicians often do not know that a tube is blocked since 86% of chest tube blockages occur within the patient’s body, resulting in inefficient drainage and a high-risk of associated complications.

While there has been ongoing innovation regarding cardiac devices, chest tube design has remained relatively unchanged for decades leaving patients exposed to potential complications from blocked tubes and inefficient unblocking techniques.

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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).
New Product Attributes and Customer Impact

Founded in partnership by Drs. Edward Boyle and Marc Gillinov in 2007, ClearFlow is pioneering the reduction of retained blood syndrome (RBS) with its unique PleuraFlow® Active Clearance Technology® (ACT®) System. The system offers patients, doctors, nurses, and the healthcare system increased value, both in terms of improved patient outcomes and reduced treatment costs. These benefits are derived from both shorter recovery times and reduced treatment costs of RBS associated complications. ClearFlow’s advanced technology marks a disruptive and transformational force that significantly improves upon existing post-operative cardiothoracic surgery protocols.

PleuraFlow® Active Clearance Technology®

PleuraFlow (ACT) fits include a tube clearance apparatus that is inserted outside the body between the patient’s chest tube and the drainage canister, allowing cardiac ICU staff to proactively prevent or minimize the drainage tube from clogging at the bedside in the ICU. As the system connects easily to a conventional chest tube, physicians can place the chest tube as normal and merely cut and attach the PleuraFlow ACT to the chest tube before connecting it to the drainage canister. The system is magnetically coupled with the clearance tube which runs through the length of the chest tube preserving the sterile field within the tube. During initial placement, the clearance loop is extended inside the tube into the section within the body cavity; ensuring that clots are cleared towards the drainage canister. Cardiac ICU staff members periodically pull the shuttle guide toward the drainage canister—preventing build-up within the tube—and push it back toward the patient—placing it for subsequent use. ClearFlow provides the chest tubes for use with the PleuraFlow ACT system; the company chose to use silicon for its chest tubes since the softer material is much more comfortable for the patient and causes less pain during removal than conventional hard plastic tubes.

I regard the maintenance of chest drain patency as absolutely vital. PleuraFlow performs consistently and reliably in keeping chest tubes clear and preventing clogging – something I was unable to safeguard prior to adopting the use of this device. The peace of mind that this system has provided my team has been significant.

- Patrick McConnell, MD at the Department Cardiothoracic Surgery at Nationwide Children’s Hospital in Ohio
Continuing Innovation

ClearFlow offers four standard French (FR) configurations—20-FR, 24-FR, 28-FR, and 32-FR—allowing physicians to choose a tube size that best fits the patient. The company recently released a pediatric edition of its 20-FR System, with a shorter effective drainage length (SEDL) which offers fewer drainage holes on the chest tube to allow for use in a smaller chest cavity. The 20-FR SEDL can be used in about two thirds of pediatric applications; the company is also developing additional smaller tube configurations to fit the remaining one-third of pediatric applications.

While 36-FR and 40-FR tubes are still sometimes used by physicians, these tubes which are as large as a garden hose are extremely painful while inserted and upon removal. The PleuraFlow ACT System’s superior drainage capabilities make it unnecessary to use such large-bore tubes today.

ClearFlow is also developing a robotic PleuraFlow ACT system that will dramatically decrease the amount of nurse time to monitor these systems in the future.

Two Pronged Value: Improved Patient Outcomes and Lower Treatment Costs

Hospitals utilizing the PleuraFlow ACT System derive significant value, both in terms of improved patient outcomes and reduced costs of treatment of RBS-associated complications. A clinical study compared the amount of drainage for two hours with a 32-FR tube to the PleuraFlow ACT System with a 20-FR conventional tube; it discovered that despite the smaller tube size, the 20-FR tube with the PleuraFlow ACT System had almost three times the amount of drainage than the 32-FR conventional tube.

The PleuraFlow ACT Systems cost $395 each. The average cost of treatment for one or more RBS complications requiring a reintervention or re-operation is $28,814; therefore, PleuraFlow ACT System users experience a solid return on investment through fewer complications and associated treatment cost reduction. Clinical studies show that the PleuraFlow ACT System achieved a 43% reduction in interventions required to treat RBS and 33% reduction in Post-op A-Fib compared to conventional chest tubes. ACT use was shown to reduce re-explorations for bleeding after ventricular assist device (VAD) placement, showing further benefits for high risk patients.

"We have evaluated the PleuraFlow ACT system in hundreds of patients safely and effectively over three years at our center in Germany. The device is superior to conventional drainage options and in our patients resulted in substantially lower incidence of complications that typically occur when blood is incompletely evacuated from the chest."

- Dr. Med. Theodor Fischlein at the Department of Cardiac Surgery at Paracelsus Medical University in Klinikum Nürnberg, Germany

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6 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).
ClearFlow’s Advanced Customer Support

ClearFlow invests significant resources into education for cardiac surgeons, physician assistants, and nursing staff members within the cardiac surgery suite and ICU. This education is helping caregivers understand the added value—both in terms of cost reduction and improved patient outcomes—that the PleuraFlow ACT enables. To help hospitals calculate these benefits, the company also developed a simple cost calculator application leveraging multiple industry studies and large medical payment records databases that allow hospitals to estimate specific overall cost savings after using the PleuraFlow ACT. Once a hospital understands the positive cost-benefit value, ClearFlow’s team members go onsite to conduct three to five day training sessions with both cardiac surgeons and ICU staff members. Training for physicians focuses on helping them determine the proper cut line for the tube and emphasis on how not to suture the chest tube too tightly. For staff members, training focuses on how to use the PleuraFlow ACT systems and how to identify patients bleeding faster than average requiring more frequent actuation. ClearFlow also uses a “Train the Trainer” program, training a hospital staff member on proper methodology to allow them to train subsequently hired staff. The company also offers a protocol based on trusted Lean and Six Sigma Quality methodologies. ClearFlow’s continuous quality improvement (CQI) program can be utilized by hospitals, to allow them to compare patient results prior to using the PleuraFlow ACT—using ICD-9 and ICD-10 codes for treatment of associated complications of RBS—and after implementing the system, to track return on investment. Furthermore, ClearFlow’s clinical specialist team remains in communication with customers, soliciting feedback, answering clinical questions, and ensuring physician and staff satisfaction.

I have used PleuraFlow on all my cardiac surgery patients since 2013 and regard it as a standard of care in my post-operative care bundle. PleuraFlow actively maintains chest drain patency and reduces the risks associated with the clogging that is frequent and harmful with conventional drainage systems. The device is safe and efficacious and requires no change in clinical practice so I can unreservedly recommend it to other surgeons.

- A. Marc Gillinov, MD at Department of Thoracic & Cardiovascular Surgery at the Cleveland Clinic

Expanding Education Enhances Market Awareness

ClearFlow’s largest market is in the United States (US), and regulatory approval to sell the PleuraFlow ACT has been achieved in many more countries, including the European Union, South America, Australia, and Canada. Additionally, ClearFlow has opened European Headquarters in the Netherlands to service its European and Middle Eastern customers. ClearFlow marketing programs focus on enhancing global awareness of RBS and its effects as well as the value of employing the PleuraFlow ACT System. The company attends relevant congresses, medical conferences and tradeshows, hosts educational symposia, and works with hospitals that gather data to be published in clinical studies to enhance its market awareness and expand education opportunities.
Conclusion

Too often patients are unable to completely reabsorb blood left behind following cardiac surgery, leading to intense inflammation around the heart and lungs leading to retained blood syndrome (RBS). These complications can trigger additional serious and sometimes life-threatening complications such as infection, pleural effusions, kidney injury, and postoperative atrial fibrillation. Physicians attempt to drain the retained blood with chest tubes. However, many times tubes become blocked, resulting in inefficient draining and occurrences of RBS complications. ClearFlow has disrupted the dated field of chest tube design with its unique PleuraFlow® Active Clearance Technology (ACT) System. It has demonstrated its ability to reduce the occurrence of RBS by 43% and postoperative atrial fibrillation by 33%. As a result, hospitals see a considerable return on investment, both in terms of improved patient outcomes and decreased the cost of treatment of RBS associated complications costing cost on average $28,814 per incident. ClearFlow sets a new standard for RBS solutions and is poised for rapid growth as market awareness of RBS and associated complications increases.

Significance of New Product Innovation

Ultimately, growth in any organization depends upon continually introducing new products to the market and successfully commercializing those products. For these dual goals to occur, a company must be best-in-class in three key areas: understanding demand, nurturing the brand, and differentiating from the competition.

Understanding New Product Innovation

Innovation is about finding a productive outlet for creativity—for consistently translating ideas into high-quality products that have a profound impact on the customer.
Key Benchmarking Criteria

For the New Product Innovation Award, Frost & Sullivan analysts independently evaluated two key factors—New Product Attributes and Customer Impact—according to the criteria identified below.

**New Product Attributes**
- Criterion 1: Match to Needs
- Criterion 2: Reliability
- Criterion 3: Quality
- Criterion 4: Positioning
- Criterion 5: Design

**Customer Impact**
- Criterion 1: Price/Performance Value
- Criterion 2: Customer Purchase Experience
- Criterion 3: Customer Ownership Experience
- Criterion 4: Customer Service Experience
- Criterion 5: Brand Equity
Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices

Frost & Sullivan analysts follow a 10-step process to evaluate Award candidates and assess their fit with select best practice criteria. The reputation and integrity of the Awards are based on close adherence to this process.

<table>
<thead>
<tr>
<th>STEP</th>
<th>OBJECTIVE</th>
<th>KEY ACTIVITIES</th>
<th>OUTPUT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Monitor, target, and screen</td>
<td>Identify Award recipient candidates from around the globe</td>
<td>Pipeline of candidates who potentially meet all best-practice criteria</td>
</tr>
<tr>
<td>2</td>
<td>Perform 360-degree research</td>
<td>Perform comprehensive, 360-degree research on all candidates in the pipeline</td>
<td>Matrix positioning of all candidates’ performance relative to one another</td>
</tr>
<tr>
<td>3</td>
<td>Invite thought leadership in best practices</td>
<td>Perform in-depth examination of all candidates</td>
<td>Detailed profiles of all ranked candidates</td>
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<tr>
<td>4</td>
<td>Initiate research director review</td>
<td>Conduct an unbiased evaluation of all candidate profiles</td>
<td>Final prioritization of all eligible candidates and companion best-practice positioning paper</td>
</tr>
<tr>
<td>5</td>
<td>Assemble panel of industry experts</td>
<td>Present findings to an expert panel of industry thought leaders</td>
<td>Refined list of prioritized Award candidates</td>
</tr>
<tr>
<td>6</td>
<td>Conduct global industry review</td>
<td>Build consensus on Award candidates’ eligibility</td>
<td>Final list of eligible Award candidates, representing success stories worldwide</td>
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<tr>
<td>7</td>
<td>Perform quality check</td>
<td>Develop official Award consideration materials</td>
<td>High-quality, accurate, and creative presentation of nominees’ successes</td>
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<tr>
<td>8</td>
<td>Reconnect with panel of industry experts</td>
<td>Finalize the selection of the best-practice Award recipient</td>
<td>Decision on which company performs best against all best-practice criteria</td>
</tr>
<tr>
<td>9</td>
<td>Communicate recognition</td>
<td>Inform Award recipient of Award recognition</td>
<td>Announcement of Award and plan for how recipient can use the Award to enhance the brand</td>
</tr>
<tr>
<td>10</td>
<td>Take strategic action</td>
<td>Upon licensing, company is able to share Award news with stakeholders and customers</td>
<td>Widespread awareness of recipient’s Award status among investors, media personnel, and employees</td>
</tr>
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</table>
The Intersection between 360-Degree Research and Best Practices Awards

Research Methodology

Frost & Sullivan’s 360-degree research methodology represents the analytical rigor of our research process. It offers a 360-degree-view of industry challenges, trends, and issues by integrating all 7 of Frost & Sullivan’s research methodologies. Too often companies make important growth decisions based on a narrow understanding of their environment, leading to errors of both omission and commission. Successful growth strategies are founded on a thorough understanding of market, technical, economic, financial, customer, best practices, and demographic analyses. The integration of these research disciplines into the 360-degree research methodology provides an evaluation platform for benchmarking industry participants and for identifying those performing at best-in-class levels.

About Frost & Sullivan

Frost & Sullivan, the Growth Partnership Company, enables clients to accelerate growth and achieve best-in-class positions in growth, innovation and leadership. The company's Growth Partnership Service provides the CEO and the CEO's Growth Team with disciplined research and best practice models to drive the generation, evaluation, and implementation of powerful growth strategies. Frost & Sullivan leverages more than 50 years of experience in partnering with Global 1000 companies, emerging businesses, and the investment community from 45 offices on six continents. To join our Growth Partnership, please visit http://www.frost.com.