ACT Registry Summary
PleuraFlow® Active Clearance Technology® System

The ACT Registry – Prevention of Retained-Blood Outcomes with Active Clearance Technology® is a multinational registry of cardiothoracic surgery patients. There are two track options for participation: ALL-ACT is for sites enrolling a consecutive cohort of all cardiac surgery patients, and VAD-ACT is for sites enrolling only patients post ventricular assist device (VAD) surgery. The purposes of the ACT Registry are:

1) To evaluate the effectiveness of the PleuraFlow® Active Clearance Technology® (ACT) System in the management of blood evacuation after cardiac surgery (Figure 1);

2) To educate about the incidence of complications and post-surgical interventions consistent with Retained Blood Syndrome (RBS). (Figure 2)

3) To collect post-market surveillance data on the PleuraFlow® ACT System.

Participation Phases: There are three distinct phases.

• **Phase 0: Establishes baseline incidence of RBS.** Historical data (12-24 months) is collected to establish the baseline information for the purpose of comparative analyses with the prospective data sets.

• **Phase 1: Roll-in phase for training.** Precedes prospective enrollment phase. This phase is to familiarize users with the product use and with ACT; plus to implement and demonstrate consistency and compliance with Clinical Use Protocols provided by ClearFlow, Inc. (~2 months). No data is collected.

• **Phase 2: Prospective Data Collection.** Once training is completed and compliance with the protocols has been verified, data is collected prospectively (6 months for ALL-ACT track and 12 months for VAD-ACT track).

**NOTE:** Phase 0 and Phase 1 can be executed in parallel. Participating sites may start prospective enrollment (Phase 2) after completion of Phases 0 and 1. (Figure 3)
Independent Data Management: Data will be collected and managed by Vanderbilt University through their secure, web-based REDCap (Research Electronic Data Capture) system.

Data Coordinating Center: Vanderbilt University, Nashville, TN, USA

Trial Data Coordinator: Mary Beth Davis MSc, CTP, CCRP, Program Manager, Advanced Heart Failure Research, (615) 343-6189, mary.beth.davis@vanderbilt.edu

Coordinating Principal Investigators:
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- Louis Perrault, MD, Ph.D. Chief of Cardiac Surgery, Montreal Heart Institute, Professor of Surgery and Pharmacology, Université de Montréal, Quebec, Canada.

Outcomes Measured: The primary outcome measure is the incidence of RBS. This endpoint will be measured for a historical baseline group (Phase 0) and compared to a prospective group treated with PleuraFlow ACT (Phase 2). Secondary outcomes will consist of subject demographics and relevant pre- and post-operative outcome measures.

Preliminary Data:
In a preliminary study with this same protocol, 1,849 patients in phase 0 were compared with 256 patients from Phase 2 at Klinikum Nürnberg, Germany. There was a 42% reduction in RBS and a 30% reduction in Post Operative Atrial Fibrillation (POAF). Data were presented at the FACTS-Care Cardiovascular-Thoracic (CVT) Critical Care Meeting in Washington D.C. on October 10, 2014.

Publication Opportunities: Participating sites will have the opportunity to publish data from this Registry.

Ethical and regulatory considerations: Registry sites will obtain their institutions’ approval to participate. Patient privacy and data confidentiality will be maintained. All data entered into the Vanderbilt REDCap database is anonymized. Personal Health information (PHI) will not be collected. The user interface with REDCap is password protected. Site personnel who have been trained on the use of REDCap will have password-protected access for the purpose of data entry.