CLEARFLOW
ACTIVE CLEARANCE TECHNOLOGY

FDA Expands Label Indication for PleuraFlow to Reduce Retained Blood

Anaheim, CA – June 03, 2015— ClearFlow, Inc., a medical device company based in Anaheim, California, announced today that the United States Food & Drug Administration (FDA) has granted expanded *Indications for Use* of the company's patented PleuraFlow® Active Clearance Technology® System. The PleuraFlow System is a patented medical device that prevents chest drains from occluding with clot, which can lead to retained blood around the heart and lungs.
The composite of drainage related complications that are detrimental to outcomes after cardiothoracic surgery and that may require early or late intervention to remediate are known as Retained Blood Syndrome (RBS). These clinical complications have significant economic consequences, namely higher costs of care for patients, hospitals, and society at large.

"A recently published study showed chest drains completely occlude at a rate of 36%," commented ClearFlow CEO Paul Molloy. "Physicians are forced to gamble that the chest drains will stay open during the critical first hours after heart surgery. Retained Blood Syndrome leads to high rates of post-surgical complications that drive increased costs and 30-day hospital readmissions. The PleuraFlow Active Clearance Technology System is the first FDA cleared device indicated to maintain chest drain patency and to reduce retained blood. Retained Blood Syndrome (RBS) is associated with higher rates of mortality, post operative atrial fibrillation (POAF), renal dialysis, stroke, infection and extended ICU and total hospital length of stay after cardiothoracic surgery. The PleuraFlow System has been shown to reduce the incidence of retained blood as well as other complications such as postoperative atrial fibrillation (POAF) by keeping chest tubes free of occlusion during early recovery."

The FDA's expanded *Indications for Use* also allow the PleuraFlow System to be used in all cardiothoracic surgery and chest trauma procedures for adult and pediatric patients.

"For decades, surgeons have worked to reduce the complication rates associated with inadequate drainage of blood around the heart and lungs after surgery," remarked cardiothoracic surgeon and ClearFlow co-founder Ed Boyle, M.D. "This unevacuated blood can be mechanically detrimental to heart and lung function and causes both local and systemic inflammation that impact recovery. Studies have now linked both chest tube clogging and retained pericardial blood with POAF. We are delighted that the US FDA has evaluated data demonstrating that PleuraFlow reduces retained blood and has granted these expanded *Indications for Use*. This is an additional step forward towards the establishment of new *Standard of Care* for post-surgical chest tube patency in the ICU."

About ClearFlow, Inc.

ClearFlow, Inc. is an Anaheim, CA based medical device company that has developed a patented active blood and fluid evacuation system to speed recovery, reduce complications and lower healthcare costs related to medical tube obstruction. The company has been awarded several prestigious awards, including the *European Association of Cardiothoracic Surgeons Techno-College Innovation Award* for worldwide innovation that has the potential to change the standard of care in heart and lung surgery, and the *Innovations in Cardiovascular Interventions Award*, among others.

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