Cleveland Clinic Innovations

Hands Free Cardiac De-Airing System

Inventors: Jamshid Karimov, MD, PhD, Mark Gillinov, MD, Kiyotaka Fukamachi, MD, PhD

PRODUCT
Method and device for effective air removal from cardiac chambers during cardiac surgical procedures

INDICATION
Cardiac surgery, open-heart, minimally invasive cardiac surgery, air embolism, de-airing

VALUE PROPOSITION
- Placement through minimally invasive working ports or conventional surgical incisions.
- Tunable control parameters for active de-airing.
- Reduces unnecessary OR cost of passive “wait and watch” approach.
- Reduces cross clamp, CPB surgery, OR and anesthesia times.

DEVELOPMENT STAGE
- Prototype available.
- Human study using prototype.

INTELLECTUAL PROPERTY
US: 10,842,631
EP: 18710952.5

PARTNERING OPPORTUNITY
Development and commercialization partnership

CONTACT INFORMATION
Partha Paul, PhD, MBA
Director, Business Development & Licensing
Paulp2@ccf.org
216-672-1664

Ref: IDF 2015-226

UNMET NEED
In all current open-heart surgeries, air that is induced into the heart is removed through manual manipulation of the heart via application of compression and other subtle movement. In minimally invasive surgical procedures such as a mitral valve replacement active de-airing is not possible. In published studies, the presence of pooled air has been significantly associated with the occurrence of cardiac events such as regional wall motion abnormalities, ST elevation, and heart block. Cerebral and coronary air emboli are still a hazard when the left side of the heart is opened during intracardiac surgeries. Post-op neurologic dysfunction range between 1-5%. Standard of practice is to wait between 5-25 minutes and visually confirm with echocardiograph that the bubbles have dissipated. Despite the widespread use of carbon dioxide insufflation (CDI) in cardiac surgery and recent innovation, the present meta-analysis did not find any significant protective effect from the use of CDI when compared with manual de-airing maneuvers in terms of clinical outcomes. No current device enables the surgeons to actively de-air the heart.

SOLUTION
This device will mechanically dislodge air bubbles through rapid inflation/deflation of a small air bladder introduced under the heart. It is a single-use catheter with balloon with a minimally invasive delivery tool and is powered by operating room pressure and vacuum that is manipulated by a controller operated by the surgeon.