Aquedeon Medical Announces First Patient Enrolled in the IDE Study of Duett(TM) Vascular Graft System

SUNNYVALE, Calif., March 18, 2024 /PRNewswire/ -- Aquedeon Medical, Inc., a Silicon Valley pioneering medical device company specializing in novel cardiothoracic solutions, is pleased to announce a significant milestone with initiation of its investigational device exemption (IDE) clinical trial to study for the Duett(TM) Vascular Graft System. This February, the first enrolled patient underwent open surgical aortic arch reconstruction at the University of Pennsylvania, Presbyterian Medical Center, Philadelphia, PA. During the surgery, the Duett Vascular Graft System was successfully deployed to connect the native left common carotid artery to the surgical graft.

Aortic arch surgical reconstruction involves removal of the diseased aortic segment and replacement with a synthetic (e.g., polyester) surgical aortic vascular graft. Typically, the three vessels, which provide blood flow to the brain and the left arm, are resected from the diseased aortic arch and reattached to the surgical aortic graft with a series of hand sewn, circumferential surgical anastomoses by suturing. A sutured surgical anastomosis can take upwards of 15 minutes per vessel to complete, while the Duett Vascular Graft System may enable surgeons to connect vessels in substantially less time.

"This procedure is done under hypothermic circulatory arrest (HCA), in which the body temperature of the patient is brought down from 37°C to 28°C with the heart stopped and the body supported with a cardiopulmonary bypass machine. During this period of HCA, the brain and the lower body are subjected to temporary periods of decrease blood flow, and therefore, the longer the patient is subjected to HCA, the greater the risk for neurological complications" said Dr. Wilson Szeto, Chief of Cardiovascular Surgery at Penn Presbyterian Medical Center, and Professor of Surgery who is serving as the Principal Investigator for the clinical trial. Adding "I'm very excited about this technology...suturing vessels by hand adds time to the procedure, as these vessels are often deep within the thoracic cavity and difficult to access. The Duett enables us to significantly reduce the surgical time associated with creating an anastomosis."

"The patented Duett Vascular Graft System has been developed in collaboration with leading cardiothoracic surgeons and the device is aimed at helping to address the complexities and intricacies of thoracic aortic surgeries. Reducing anastomosis time is one major step in addressing this long and complex procedure."

"This is a significant milestone for our team, and we look forward to continued patient enrollment and use of the device at our other clinical sites", said Tom Palermo, Chief Operations Officer and General Manager of Aquedeon Medical.

For more information about Aquedeon Medical and its pioneering cardiothoracic solutions, please visit www.aquedeonmedical.com.

CAUTION ---- Investigational device. Limited by Federal (United States) law to investigational use.

About Aquedeon Medical

Aquedeon Medical, Inc. was founded and supported by Medeon Biodesign in 2018. Headquartered in Sunnyvale, California, Aquedeon Medical is at the forefront of designing and developing patented technologies tailored to advance cardiothoracic surgical procedures.
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