FRANKFURT, Germany- SentreHEART, Inc., the manufacturer of the LARIAT Suture Delivery Device will be presenting recent data on the use and benefits of the LARIAT as a therapeutic and prophylactic solution for patients with atrial fibrillation (AFib) at the LAA conference hosted by Horst Sievert, MD in Frankfurt, Germany on November 20th and 21st.

AFib is an irregular heartbeat, a rapid heartbeat, or a quivering of the upper chambers of the heart, called the atria, due to a malfunction in the heart’s electrical system. Current estimates indicate that approximately 33.5 million individuals have AF worldwide, with close to 5 million new cases occurring each year. By not getting enough oxygen to the body, AFib can lead to heart and valve diseases, sleep apnea, and chronic fatigue. In addition, atrial fibrillation can lead to two potentially life-threatening conditions: stroke and congestive heart failure.

PVI Catheter ablation is the standard of care in the management of drug-refractory symptomatic AFib. However, the success rates of PVI ablation are less than ideal, especially in patients with persistent AFib. Current data suggests that a single ablation procedure of the pulmonary veins (PV) for treating AFib results in success rates of only 20%-40%.

The left atrial appendage (LAA) has been shown to play a role in the initiation and maintenance of atrial arrhythmias and is the source of most stroke-causing blood clots (thrombus) in AFib patients. A recent study by Di Biase, et al showed that nearly 30% of AFib patients returning for repeat ablation procedures had abnormal electrical activity that included the LAA as its source.

Studies have demonstrated the LARIAT device not only closes the LAA mechanically but may also isolate electrical activity within the LAA. SentreHEART has received FDA approval for and has begun enrolling patients in the aMAZE study, which is intended to demonstrate a LARIAT procedure for LAA closure, plus a subsequent PVI ablation will lead to a reduced incidence of recurrent AFib compared to PVI alone; with a high safety profile. study plans to enroll a maximum of 600 persistent or longstanding persistent patients who are candidates for PVI catheter ablation at up to 50 centers across the United States. The first stage of the AMAZE trial is to establish safety and will enroll up to 100 patients at 15 centers.

Having a non-implant option that may both electrically and mechanically isolate the LAA is a potentially important addition to the treatment armamentarium for clinicians treating patients with persistent or longstanding persistent AFib. The LARIAT has the potential to eliminate the LAA as a source of AFib and remove it as a nidus for thrombus.

The LAA conference in Frankfurt is intended to explore device options for Left Atrial Appendage closure as an alternative to drug therapy. Physician thought leaders in this field will be relating their experience and presenting data, which will include transpericardial LAA closure with the LARIAT, identifying when and where to close the LAA, and a comparison of leak rates between the LARIAT and Watchman devices.

ABOUT THE LARIAT SUTURE DELIVERY DEVICE
The LARIAT Suture Delivery Device is indicated for suture placement and knot tying in surgical procedures where soft tissues are being approximated and/or ligated with a pre-tied polyester suture. SentreHEART received FDA 510(k) clearances for the LARIAT in 2006, 2009 and 2014. The LARIAT device also has CE Mark approval in Europe.

The LARIAT Suture Delivery Device received approval for an Investigational Device Exemption (IDE) from the U.S. Food and Drug Administration (FDA) to begin enrollment in a randomized, controlled clinical study, known as the AMAZE Trial, which will evaluate the use of the LARIAT device for the ligation, or closure, of the left atrial appendage (LAA) as an adjunctive treatment to ablation in patients with persistent or longstanding persistent atrial fibrillation (AFib). The LARIAT device is investigational for this purpose.

ABOUT SENTREHEART

SentreHEART is a privately owned medical device company based in Redwood City, CA. Founded in 2005, SentreHEART has developed technology for remote delivery of suture for closure of anatomic structures.

2. Lakkareddy D, et al. Left Atrial Appendage Ligation and Ablation for Persistent Atrial Fibrillation, JACC: Clinical Electrophysiology 2015; VOL. 1, NO. 3,

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