

## Estech Announces Start of Patient Enrollment in HISTORIC-AF European Multi-center Staged Hybrid Ablation Study

San Ramon, California. --- December 5th --- Estech, a leader in minimally invasive cardiac surgery, announced today that the first three patients have been enrolled in the HISTORICAF European multi-center staged hybrid ablation clinical study. Ten centers will participate in the study which is expected to enroll over 100 patients in Italy, Germany, the United Kingdom, France, and Poland.

The HISTORIC-AF staged hybrid ablation study will enroll persistent and long-standing persistent atrial fibrillation (AF) patients – who represent over 50% of all AF patients – in a two-step procedure. The first stage is a true minimally invasive endoscopic epicardial ablation utilizing the COBRA® Adhere XL™ device to isolate the posterior left atrium via the highly efficacious box lesion. This unilateral procedure usually lasts less than two hours and is concluded with rigorous electrophysiological confirmation of conduction block in the operating or hybrid suite. A continuous loop monitor is implanted to continuously monitor the electrical activity of the heart. Four to six weeks later, the second stage is performed in the electrophysiology lab utilizing electrophysiological mapping and, if necessary, additional endocardial catheter ablation.

The HISTORIC-AF clinical study follows the extensive experience with this staged hybrid approach accumulated by Professor Claudio Muneretto, MD, (cardiac surgeon) and Antonio Curnis, MD, (electrophysiologist) at the Civil Hospital of the University of Brescia Medical School, Italy. “We now have experience with almost 50 patients using this technology in a staged hybrid approach, and are very pleased with the safety and the results,” stated Professor Muneretto. “Teamwork between cardiac surgery and electrophysiology will be the key for successful treatment of this challenging disease. Our data indicate that even for the most difficult long-standing persistent AF patients, we have better than 85% freedom from AF throughout more than two years’ follow-up, confirmed by implanted continuous loop recorder data. We have found that the staged approach provides superior clinical success and more efficient workflow. Our patients are very happy with their clinical outcomes and with this treatment,” Professor Muneretto concluded. Professor Curnis added: “We are excited about the staged hybrid solution with the Estech platform which offers us many potential advantages, including a more comprehensive lesion set, better lesion assessment, shorter procedure times for each discipline, fewer complications, and ultimately better outcomes. This will allow us to treat a large population of AF patients previously thought unsuitable for catheter or surgical ablation alone.” Estech will be presenting at the upcoming Canaccord Genuity 6th Annual Cardiovascular, Aesthetics & Metabolic Disorders Medical Devices Conference in San Francisco on December 6th 2011.

### **About Estech**

Estech develops and markets a broad portfolio of innovative medical devices that enable cardiac surgeons to perform a variety of surgical procedures, while specializing in minimally invasive and hybrid ablation. The COBRA line comprises the first technology invented, developed and brought exclusively to the surgical ablation market. Temperature-controlled RF energy delivery, suction-assisted tissue contact and internally-cooled devices provide superior ablation performance compared to other ablation systems. For more information, please visit [www.estech.com](http://www.estech.com).

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**COBRA® Surgical System: Disclaimer**

In the US, the Estech COBRA Revolution and COBRA Bipolar Inserts have been cleared for ablation of soft tissues. The COBRA Adhere XL, COBRA Cooled and COBRA Surgical probes have been cleared for cardiac ablation. The AFfirm Pacing Probe has been cleared to be used upon completion of the cardiac ablation procedure to assess the adequacy of cardiac lesions created in surgically treating the patient's arrhythmia. Estech does not promote off-label use of its products and their use is at the discretion of the cardiac surgeon. Estech is undertaking an Investigational Device Exemption (IDE) clinical trial and subsequent Premarket Approval Application (PMA) submission in the US to obtain a specific atrial fibrillation indication. In Europe, the Estech COBRA RF ablation products are CE marked with an indication for the treatment of atrial fibrillation by ablating cardiac tissue during surgery.