

Estech Launches Next Generation Technology, the COBRA Fusion™ System for Cardiac Ablation

The Associated Press

SAN RAMON, Calif.--(BUSINESS WIRE)--Sep 6, 2012--Estech, a leading provider of minimally invasive cardiac ablation devices, today announced the market release of its COBRA Fusion™ ablation system. This revolutionary technology is the first of its kind to use a unique suction application and innovative electrode configuration to gently pull the tissue targeted for ablation into the device and out of the path of circulating blood. The COBRA Fusion™ ablation system overcomes the most significant challenge faced in minimally invasive epicardial ablation, the cooling effect of the circulating blood inside the heart, and reproducibly creates transmural (full-thickness) lesions on a beating heart. This bipolar clamping technology in the form of an epicardial catheter is thus capable of creating linear lesions anywhere on a beating heart with unprecedented performance and ease of use.

The COBRA Fusion ablation system incorporates proprietary Versapolar™ technology — an exclusive innovation that delivers both bipolar and monopolar radiofrequency (RF) energy to the targeted cardiac tissue, enabling transmural lesion formation in thin and thick cardiac tissue. As with all COBRA® ablation systems, the new device is powered by Estech's patented temperature controlled radiofrequency (TCRF) energy which continuously monitors and maintains tissue temperature at target levels throughout the procedure. TCRF avoids the need for multiple applications that other technologies often require and ensures that tissue temperatures remain within a safe and effective range.

James L. Cox, M.D., the pioneer and creator of the Cox-Maze procedure stated: "I have had the recent opportunity to observe the clinical use of this new device in several patients. The historical problem of attaining atrial wall transmural reliability in a beating, working heart by applying ablative energy from the epicardium only, appears to have been solved with this new device." Dr. Cox added: "The ability to involute the atrial wall into the ablation device itself using suction allows for the application of radiofrequency energy to both sides of the involuted tissue, thereby creating reproducible transmural and contiguous linear lesions for the first time off-pump. Moreover, the device is small enough to fit through a standard port, using an endoscopic port-access approach. I believe that this device represents a significant addition to the surgeon's armamentarium in the field of cardiac ablation." Dr. Cox is the Evarts A. Graham Professor of Surgery Emeritus, Chief, Division of Cardiothoracic Surgery Emeritus, Washington University School of Medicine, Barnes-Jewish Hospital, St. Louis, Missouri, USA.

The COBRA Fusion is the result of several years of research and development and has been extensively tested in several labs including the prestigious research lab at Washington University in St. Louis. Ralph J. Damiano, M.D. stated: "We have evaluated this new device in our animal lab and were very impressed with the

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results. It is an innovative device that has the potential to facilitate minimally invasive surgical ablation. It is likely to advance the field by improving lesion formation on the beating heart.” Dr. Damiano is the John M. Shoenberg Professor of Surgery, Chief of Cardiac Surgery, Washington University School of Medicine, St. Louis, Missouri, USA.

The COBRA Fusion™ ablation system received FDA clearance in April, CE mark in May and has been in extensive clinical evaluations in the US and EU since then. One of the health care institutions that have used this new technology in a clinical setting is the UNC Center for Heart and Vascular Care, Chapel Hill, North Carolina, USA, where professor and cardiothoracic surgeon Andy C. Kiser, M.D., and professor and electrophysiologist J. Paul Mounsey, B.M. B.Ch., have performed numerous hybrid ablation procedures. Dr. Mounsey stated: “The electrical isolation we have obtained with the COBRA Fusion system is superior to any other epicardial ablation technology we have used. The ablation lines have been consistent and complete in the immediate postoperative period and long lasting as judged by follow-up a few weeks later.” About Estech Estech develops and markets a 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 company’s COBRA line comprises a number of first-ever ablation technologies invented, developed, and brought exclusively to market by Estech. These include temperature-controlled RF energy delivery, Versapolar™ devices that provide both bipolar and monopolar energy, suction-applied tissue contact, and internally-cooled devices which provide superior ablation performance compared to other ablation systems. For more information, please visit www.estech.com.

COBRA Fusion Ablation System: Regulatory Disclaimer In the U.S. the Estech Cobra Fusion is intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy when connected directly to the Estech Electrosurgical unit (ESU). The Estech Cobra Fusion may be used for temporary cardiac pacing, sensing, recording, and stimulation during the evaluation of cardiac arrhythmias during surgery when connected to a temporary external cardiac pacemaker or recording device. The Estech ablation products are not approved for the treatment of Atrial Fibrillation in the U.S. Estech has received Investigational Device Exemption (IDE) approval from FDA to begin enrollment in a clinical trial to support a PMA submission to obtain a specific atrial fibrillation indication in the U.S. for several products. In Europe, the Estech COBRA ablation products are CE marked with an indication for the treatment of atrial fibrillation.

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