

Boston Scientific

Boston Scientific Comments on Positive Results with the FLEX™ Microwave Ablation System

New data provide support for minimally invasive treatment of atrial fibrillation (AF)

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NATICK, Mass., May 10 [/PRNewswire-FirstCall/](#) -- Boston Scientific Corporation (NYSE: BSX) today commented on data released on May 9th at the American Association for Thoracic Surgery (AATS) conference in Washington, D.C. Dudley A. Hudspeth, M.D., of Desert Cardiothoracic Surgeons in Mesa, Arizona, reported positive results from his single-center clinical investigation of 79 patients treated with the FLEX 10® and FLEX 10® XE Microwave Ablation Probes. Patients in the study achieved greater than 95 percent conversion to sinus rhythm based on electrocardiograms and 30-day event monitoring. Significantly, 82 percent of patients at one-year follow-up were off anti-arrhythmic medications and 68 percent of patients at one-year follow-up were off anti-coagulant medications.

Following the presentation, Dr. Hudspeth stated, "Standard medical therapy often fails to treat AF patients' symptoms. These data look promising for a minimally invasive ablation procedure for appropriate AF patients." Most procedures in the series were performed through a few small incisions (<1 cm) on one side of the patients' chest.

"We're very encouraged by Dr. Hudspeth's clinical findings," said Lisa Earnhardt, President, Boston Scientific Cardiac Surgery. "Dr. Hudspeth conducted extensive patient follow-up and shares our commitment to generating rigorous clinical science to determine if microwave surgical ablation may be used safely and effectively for the treatment of AF. His patient population and procedural characteristics are very similar to those targeted in our RESOLVE-AF 2 clinical study, which is currently in progress, and we look forward to sharing those results as they become available."

Atrial fibrillation is a condition in which the heart quivers, or fibrillates, instead of beating normally. As many as 5.1 million people suffer from AF in the U.S. alone, and many either receive inadequate treatment or suffer from numerous side effects associated with standard medical therapy.

The FLEX 10 and FLEX 10 XE Microwave Ablation Probes are indicated for the surgical ablation of soft tissue and striated, cardiac, and smooth muscles under direct visualization, including minimally invasive cardiac surgery procedures. The FLEX Microwave Ablation System is uniquely designed to facilitate a unilateral, or one-sided, ablation procedure. The FLEX 10 and FLEX 10 Microwave Ablation Probes have not been proven safe and effective for the treatment of atrial fibrillation.

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. For more information, please visit: <http://www.bostonscientific.com/>.

This press release contains forward-looking statements. Boston Scientific wishes to caution the reader of this press release that actual results may differ from those discussed in the forward-looking statements and may be adversely affected by, among other things, risks associated with product development and commercialization, clinical trials, intellectual property, regulatory approvals, competitive offerings, integration of acquired companies, Boston Scientific's overall business strategy, and other factors described in Boston Scientific's filings with the Securities and Exchange Commission.

(1) The use of the FLEX 10 and FLEX 10 XE Microwave Ablation Probes for the treatment of atrial fibrillation is considered investigational in the United States.

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