

**For Immediate Release**

## **Biosense Webster Receives FDA Approval for THERMOCOOL SMARTTOUCH<sup>®</sup> SF Ablation Catheter for the Treatment of Persistent Atrial Fibrillation**

*The CARTO<sup>®</sup> 3 System and THERMOCOOL SMARTTOUCH<sup>®</sup> SF Catheter allow for a patient-tailored ablation approach, resulting in high long-term effectiveness in persistent atrial fibrillation patients\**

**IRVINE, CA** – October 6, 2020 – Johnson & Johnson Medical Devices Companies\*\* today announced the United States Food and Drug Administration (FDA) approval of Biosense Webster, Inc.'s THERMOCOOL SMARTTOUCH<sup>®</sup> SF Ablation Catheter for the treatment of persistent atrial fibrillation (persistent AF).<sup>†</sup> The approval is based on results of a prospective, multi-center study (PRECEPT) which met primary safety and effectiveness endpoints and demonstrated 80 percent of persistent AF patients experienced clinical success at 15 months after ablation therapy using the THERMOCOOL SMARTTOUCH SF Catheter with the CARTO VISITAG<sup>™</sup> Module.<sup>‡1,2</sup> In addition, patients experienced clinically meaningful improvement in quality of life and the study showed significant reduction in healthcare resource utilization post-ablation.<sup>1,2</sup>

Atrial fibrillation (AF) is a significant public health issue affecting the health of millions of people and placing a critical burden on healthcare systems. Persistent AF is defined as continuous AF that lasts for more than seven days and up to one year. The management of persistent AF aims to prevent AF recurrence and associated disabilities while reducing side effects from treatment.

"Every patient and every arrhythmia are unique," said Dr. Francis Marchlinski\*\*\*, Director of Electrophysiology, University of Pennsylvania Health System. "This approval and the PRECEPT data provide evidence to support a tailored approach using the CARTO<sup>®</sup> 3 System and THERMOCOOL SMARTTOUCH SF Catheter to treat persistent AF patients, who are more at risk for stroke and other complications from their AF."

The PRECEPT study is the first prospective, multicenter investigational device exemption study designed to evaluate the safety and effectiveness of radiofrequency (RF) catheter ablation in patients with persistent AF, and was conducted using the THERMOCOOL SMARTTOUCH SF Catheter. Results of the PRECEPT study demonstrated 80 percent of persistent AF patients experienced clinical success at 15 months after ablation therapy and 86 percent experienced freedom from repeat procedures at 15 months.<sup>3</sup> The CARTO 3 System and THERMOCOOL SMARTTOUCH SF Catheter allow for a patient-tailored ablation approach, resulting in high long-term effectiveness in a more advanced persistent AF patient group (continuous AF > 7 days < 1 year).<sup>2</sup>

\*In a prospective, multicenter study (PRECEPT, n=333) protocol defined primary effectiveness was the freedom from documented AF/AT/AFL recurrence  $\geq 30$  s.

† The THERMOCOOL SMARTTOUCH<sup>®</sup> SF Catheter is indicated for drug refractory recurrent symptomatic persistent atrial fibrillation (AF) (continuous AF > 7 days but < 1 year), refractory or intolerant to at least 1 Class I or III AAD, when used with the CARTO<sup>®</sup> 3 System.

‡ In a prospective, multicenter study (PRECEPT, n=333) where clinical success is defined as freedom from documented symptomatic AF/AT/AFL recurrence.

Radiofrequency ablation with the THERMOCOOL SMARTTOUCH SF Catheter led to a clinically meaningful improvement in Quality of Life (QOL), as well as a reduction in antiarrhythmic drug (AAD) use, cardioversion and hospitalization in persistent AF patients.<sup>§3</sup>

“Persistent AF patients face a higher risk of complications such as stroke, heart failure, and death,” said Uri Yaron, Worldwide President of Biosense Webster, Inc. “This approval and data from the PRECEPT study help to further our commitment to advancing AF treatment, providing electrophysiologists with state-of-the-art options for their patients.”

The PRECEPT study enrolled a total of 381 patients with documented symptomatic persistent AF who did not respond or were intolerant of one or more AADs (Class I or III). The study was conducted at 27 sites across the United States and Canada.<sup>1</sup> The primary effectiveness endpoint was freedom from documented recurrence of atrial flutter/atrial tachycardia episodes of 30 seconds or longer and freedom from additional five failure modes: acute procedural failure, use of a non-study catheter, repeat procedures, use of new/higher dose antiarrhythmic drugs, surgical AF ablation.<sup>1</sup> A tailored ablation strategy was used, allowing for pulmonary vein isolation (PVI) and additional left atrial ablations (PVI+) at the operator’s discretion based on the patient’s disease state.<sup>1</sup> The study resulted in a 4.7 percent primary adverse event (PAE) rate which is comparable to PAE rates reported in paroxysmal AF studies using CF-sensing RF catheters.<sup>4,5,6</sup>

### **About Atrial Fibrillation**

Atrial fibrillation (AF) is the most common type of cardiac arrhythmia (abnormal heart rhythm) and affects nearly one percent of the population.<sup>7</sup> During AF, the upper chambers of the heart, the atria, beat rapidly or in an uncontrolled manner, which can feel like a flutter. When the heart beats erratically, it does not pump blood as efficiently as it should. When oxygen is not being properly delivered to all parts of the body, the patient may feel ill or experience other AF symptoms. Atrial fibrillation may not be life-threatening; however, it is important to seek treatment to control the symptoms, as AF can lead to stroke.

As with any medical treatment, individual results may vary. Only a cardiologist or electrophysiologist can determine whether ablation is an appropriate course of treatment. There are potential risks including bleeding, swelling or bruising at the catheter insertion site, and infection. More serious complications are rare, which can include damage to the heart or blood vessels; blood clots (which may lead to stroke); heart attack; or death. These risks need to be discussed with your doctor and recovery takes time. The success of this procedure depends on many factors, including your physical condition and your body’s ability to tolerate the procedure. Use care in the selection of your doctors and hospital, based on their skill and experience.

### **About Biosense Webster, Inc.**

Biosense Webster, Inc. is the global market leader in the science and technology behind the diagnosis and treatment of cardiac arrhythmias. Part of the Johnson & Johnson Family of Companies, the specialized medical-technology company is headquartered in Irvine, Calif., and works across the world to advance the tools and solutions that help electrophysiologists identify, treat, and deliver care. Learn more at [www.biosensewebster.com](http://www.biosensewebster.com) and connect on [LinkedIn](#) and [Twitter](#).

### **About Johnson & Johnson Medical Devices Companies**

As the world’s most comprehensive medical devices business, we are building on a century of experience, merging science and technology, to shape the future of health and benefit even more people around the world. With our unparalleled breadth, depth and reach across surgery, orthopedics, vision and interventional

---

<sup>§</sup> In a prospective, multicenter study (PRECEPT, n=333), improvements based on mean AFEQT composite and subscores seen from 6- 15 months, exceeding Clinically Important Difference ( $\pm 5$  points). Class I/III AAD use was reduced from 97% to 25%, incidence of cardioversion decreased from 62% to 10%, and the 15-month Kaplan-Meier estimate of freedom from hospitalization was 84%.

solutions, we're working to profoundly change the way care is delivered. We are in this for life. For more information, visit [www.jnjmedicaldevices.com](http://www.jnjmedicaldevices.com).

### Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding THERMOCOOL SMARTTOUCH® SF Ablation Catheter. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Biosense Webster, Inc., any of the other Johnson & Johnson Medical Devices Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: uncertainty of commercial success; challenges to patents; competition, including technological advances, new products and patents attained by competitors; changes to applicable laws and regulations, including global health care reforms; changes in behavior and spending patterns of purchasers of health care products and services; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2019, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at [www.sec.gov](http://www.sec.gov), [www.jnj.com](http://www.jnj.com) or on request from Johnson & Johnson. Neither Biosense Webster, Inc., the Johnson & Johnson Medical Devices Companies, nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

© Biosense Webster, Inc. 2020 151997-200904

---

<sup>1</sup> Mansour M, Calkins H, Osorio J, et al. Persistent atrial fibrillation ablation with a contact force sensing catheter: the prospective multicenter PRECEPT trial. Presented at: Heart Rhythm Society Scientific Session Virtual Meeting; May 2020.

<sup>2</sup> Mansour M, Calkins H, Osorio J, et al. Persistent Atrial Fibrillation Ablation with Contact Force–Sensing Catheter. *J Am Coll Cardiol EP*. 2020 Aug, 6 (8) 958-969.

<sup>3</sup> Natale A, Calkins H, Osorio J, et al. (2020). Positive Clinical Benefit on Patient Care, Quality of Life and Symptoms After Radiofrequency Ablation with Contact Force in Persistent Atrial Fibrillation: Analyses from PRECEPT. Poster presentation at the European Society of Cardiology Scientific Session, August 29 - September 2, 2020.

<sup>4</sup> PRECEPT IDE G140102.

<sup>5</sup> Natale A, Reddy VY, Monir G, et al. Paroxysmal AF catheter ablation with a contact force sensing catheter: results of the prospective, multicenter SMART-AF trial. *J Am Coll Cardiol*. 2014;64(7):647-656.

<sup>6</sup> Chinitz LA, Melby DP, Marchlinski FE, et al. Safety and efficiency of porous-tip contact-force catheter for drug-refractory symptomatic paroxysmal atrial fibrillation ablation: results from the SMART SF trial. *Europace*. 2018;20(FI\_3):f392-f400.

<sup>7</sup> Johan E.P. Waktare, MB, ChB, MRCP, Atrial Fibrillation, AHA Journals.org.