



FOR IMMEDIATE RELEASE

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**FIRST PATIENT TREATED IN BIOSENSE WEBSTER U.S. IDE STUDY
EVALUATING NEXT GENERATION BALLOON ABLATION CATHETER
FOR ATRIAL FIBRILLATION**

IRVINE, CA – Nov. 29, 2018 – Johnson & Johnson Medical Devices Companies* announced today that Biosense Webster, Inc., a worldwide leader in the diagnosis and treatment of heart arrhythmias, has enrolled and treated the first patient in its STELLAR** U.S. Investigational Device Exemption (IDE) study. The study will evaluate the safety and effectiveness of HELIOSTAR Multi-electrode Radiofrequency (RF) Balloon Ablation Catheter in treating symptomatic drug refractory recurrent paroxysmal (intermittent) atrial fibrillation (AF). Up to 640 patients will be enrolled in as many as 40 clinical sites worldwide.

“This new balloon catheter is unique because it conforms to any pulmonary vein anatomy and allows me to control electrodes individually to deliver tailored energy when ablating around pulmonary veins,” said cardiac electrophysiologist Rodney Horton, M.D., who treated the first patient in the study with Dr. Andrea Natale at the Texas Cardiac Arrhythmia Institute at St. David’s Medical Center†.

“The HELIOSTAR catheter design has the potential to overcome the limitations of current balloon ablation catheters, result in fewer catheter exchanges and, most importantly, shorter procedure times. HELIOSTAR is an exciting technology and we look forward to seeing the final study results,” said Andrea Natale, M.D., F.H.R.S., F.A.C.C., F.E.S.C., cardiac electrophysiologist and Executive Medical Director, Texas Cardiac Arrhythmia Institute at St. David’s Medical Center†.

The HELIOSTAR RF Balloon Ablation Catheter has 10 electrodes, which allows electrophysiologists to deliver different levels of energy depending on the tissue during lesion creation. In addition, the balloon design makes it possible to achieve pulmonary vein isolation with a single application of RF energy. The device is compatible with the Biosense Webster CARTO 3 Mapping System, an advanced imaging technology that enables creation of real-time 3D maps of a patient’s cardiac structures. The use of the CARTO 3 System during an ablation procedure can reduce exposure to radiation from fluoroscopy.

It is estimated that 33 million people worldwide are living with AF, or an irregular heartbeat, which can lead to blood clots, stroke, heart failure and other heart-related complications.¹



“The STELLAR study is an important step forward in expanding treatment options for atrial fibrillation patients in the United States,” said Uri Yaron, Worldwide President, Biosense Webster, Inc. “The burden of atrial fibrillation on quality of life, morbidity and mortality is significant and we are committed to developing innovative and life-enhancing technologies that fill important clinical needs, improve care and reduce this burden.”

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, orthopaedics, vision and interventional 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.

About Biosense Webster, Inc.

Biosense Webster, Inc., part of Johnson & Johnson Medical Devices Companies, is a global leader in the science of diagnosing and treating heart rhythm disorders. The company partners with clinicians to develop innovative technologies that improve the quality of care for arrhythmia patients worldwide. For more information, visit www.biosensewebster.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 the HELIOSTAR, Multi-electrode Radiofrequency (RF) Balloon 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 regulatory approvals; uncertainty of commercial success; challenges to patents; competition, including technological advances, new products and patents attained by competitors; manufacturing difficulties and delays; product efficacy or safety concerns resulting in product recalls or regulatory action; 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 31, 2017, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," in the company's most recently filed Quarterly Report on Form 10-Q, and in the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of Biosense Webster, Inc., the Johnson & Johnson Medical Devices Companies, or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

**Comprising the surgery, orthopaedics, vision and interventional solutions within the Johnson & Johnson's Medical Devices segment*

**** Safety and Effectiveness Evaluation of the Multi-Electrode Radiofrequency Balloon Catheter for the Treatment of Symptomatic Paroxysmal Atrial Fibrillation (STELLAR)**

+Dr. Rodney Horton and Dr. Andrea Natale performed the first HELIOSTAR procedure and are two of the study clinical investigators.



The device is approved for investigational use only. It is not approved or available for sale.

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¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4151302/>