Biosense Webster Receives FDA Approval for Multiple Atrial Fibrillation Ablation Products to be Used in a Workflow Without Fluoroscopy

First and only AFib ablation products to receive approval for use in a workflow without fluoroscopy from the U.S. Food and Drug Administration

Enables workflows with zero fluoroscopy during catheter ablation procedures

Approval based on data from REAL AF Registry, demonstrating value of real-world evidence

IRVINE, CA – August 4, 2023 – Biosense Webster, Inc., a global leader in cardiac arrhythmia treatment and part of Johnson & Johnson MedTech, today announced that several products in its market-leading cardiac ablation portfolio have received approval for a zero fluoroscopy workflow from the U.S. Food and Drug Administration (FDA). The products that can be used in this workflow include: THERMOCOOL SMARTTOUCH™ SF catheter -- the most commonly used ablation catheter in the world for RF ablation, THERMOCOOL SMARTTOUCH™ Catheter, CARTO® VIZIGO® Bi-Directional Guiding Sheath, PENTARAY® NAV ECO High Density Mapping Catheter, DECANAV® Mapping Catheters, and Webster® CS Catheter. The updated workflow indicates that direct imaging guidance, such as ultrasound, may be used as an alternative to fluoroscopy.

Fluoroscopy is a type of medical imaging that shows a continuous X-ray image on a monitor, and is used in a variety of examinations and procedures to diagnose or treat patients. Fluoroscopy can result in relatively high radiation doses, especially for complex interventional procedures which require fluoroscopy be administered for a long period of time. Reducing fluoroscopy lowers radiation exposure, which may minimize long-term cancer risk, and can reduce the risk of musculoskeletal pain due to extensive wear of heavy personal protective equipment, such as lead aprons.

“Cardiac ablation procedures for the treatment of atrial fibrillation (AFib) usually require fluoroscopy to guide the advancement and positioning of intracardiac catheters, resulting in considerable radiation exposure for patients, operators, and support medical staff as well as a high orthopedic burden from protective equipment such as lead aprons,” explained Jose Osorio, MD, FHRS, President of Heart Rhythm Clinical and Research Solutions. “Eliminating or reducing radiation exposure is beneficial to patients as well as physicians and staff working every day in the electrophysiology lab.”

“The label change approved by the FDA underscores that the Biosense Webster integrated ecosystem, anchored by the CARTO® 3 mapping and navigation together with our diagnostic and treatment catheters, enables workflows with zero fluoroscopy, which improves safety, and
efficiency of cardiac ablation procedures,” said Jasmina Brooks, President, Biosense Webster. “As a result of this update, our teams can now proactively discuss the fluoroscopy alternative workflow with our customers to reinforce the benefits of the Biosense Webster portfolio of products.”

The company received the label change based on an observational, prospective, multicenter registry that assesses real-world catheter ablation clinical outcomes, including procedural efficiency, safety, and long-term effectiveness in a broad group of patient populations with novel radiofrequency (RF) technologies in paroxysmal AFib patients. The REAL AF Registry is a first-of-its kind real-world evidence registry in the electrophysiology field, led by physicians and supported by Biosense Webster since 2019.

“At Biosense Webster, we are committed to advancing innovative technologies that enable safe, effective, and efficient cardiac ablation procedures, as well as expanding the body of evidence supporting how our technologies are used to improve patient lives,” said Anthony Hong, Vice President, Preclinical & Clinical Research and Medical Affairs, Cardiovascular & Specialty Solutions, Johnson & Johnson. “Our novel approach to evidence generation, utilizing real-world evidence from the REAL AF Registry, has helped us secure regulatory approval for our fluoroscopy alternative workflow, and I’m looking forward to utilizing this approach in the future to lower study costs and achieve faster regulatory milestones.”

Cardiac arrhythmias are a growing epidemic. AFib alone is the most common type of cardiac arrhythmia and impacts nearly 37.5 million people worldwide, and 6 million people in the U.S.\(^3\),\(^4\) AFib is a progressive disease, and if left untreated can get worse over time or lead to other serious complications like heart disease or stroke.\(^5\),\(^6\) Catheter ablation is a safe and effective procedure to restore the heart’s incorrect electrical signals, which causes an abnormal heart rhythm.\(^7\)

About Biosense Webster
Biosense Webster is the global market leader in the science and technology behind the diagnosis and treatment of cardiac arrhythmias. Part of Johnson & Johnson MedTech, the specialized medical-technology company is headquartered in Irvine, California, 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](https://www.linkedin.com/) and [Twitter](https://twitter.com/).

About Johnson & Johnson MedTech\(^1\)
At Johnson & Johnson MedTech,\(^1\) we unleash diverse healthcare expertise, purposeful technology, and a passion for people to transform the future of medical intervention and empower everyone to live their best life possible. For more than a century, we have driven breakthrough scientific innovation to address unmet needs and reimagine health. In surgery, orthopaedics, vision, and interventional solutions, we continue to help save lives and create a future where healthcare solutions are smarter, less invasive, and more personalized. For more information, visit [https://www.jnjmedtech.com](https://www.jnjmedtech.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 FDA Approval for Multiple Atrial Fibrillation Ablation Products to be Used Without Fluoroscopy. 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 MedTech 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; 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 January 1, 2023, including in the sections captioned “Cautionary Note Regarding Forward-Looking Statements” and “Item 1A. Risk Factors,” and in Johnson & Johnson’s subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at sec.gov, jnj.com or on request from Johnson & Johnson. None of Biosense Webster, Inc., Johnson & Johnson MedTech nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

Important Information: For product details such as indications, contraindications, warnings and precautions please consult the IFU. Johnson & Johnson MedTech bears no responsibility for the accuracy, legality or content of the external site.

The THERMOCOOL SMARTTOUCH® SF Catheter is indicated for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation (AF) and for drug refractory recurrent symptomatic persistent 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® 3 System.

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