Media Contacts:
Diane Pressman
Dpressm1@its.jnj.com

Charlene DeBar
Cdebar1@its.jnj.com

IR Contact:
Sarah Wood
SWood15@ITS.JNJ.com

Biosense Webster Launches the OPTRELL™ Mapping Catheter with TRUEref™ Technology for Mapping of Complex Cardiac Arrhythmias

Industry's highest density fixed array mapping catheter, covering the largest area in a fixed matrix format, can help physicians effectively map in a shorter procedure time

IRVINE, CA – **July 24, 2023** – Biosense Webster, Inc., a global leader in cardiac arrhythmia treatment and part of Johnson & Johnson MedTech,[i] today announced the U.S. launch of the OPTRELL™ Mapping Catheter with TRUEref™ Technology powered by the CARTO® 3 System. The OPTRELL™ Mapping Catheter is a high-density diagnostic catheter, with small electrodes arranged in a fixed array formation to provide high-definition electrophysiological mapping of complex cardiac arrhythmia cases like persistent atrial fibrillation (AFib), redo AFib ablation, atrial tachycardia, and ventricular tachycardia.

Cardiac arrhythmias are a growing epidemic. AFib is the most common type of cardiac arrhythmia and impacts nearly 40 million people worldwide, with up to 6 million of these individuals living in the U.S.[1,2] 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.[3,4] Catheter ablation is a safe and effective procedure to restore the heart's incorrect electrical signals, which causes an abnormal heart rhythm.[5]

This new catheter includes 48 electrodes symmetrically distributed across and along six splines and combines with the CARTO® 3 System to deliver intelligent insights and high-resolution directional mapping.[6] Additionally, the OPTRELL™ Mapping Catheter has tight electrode spacing and small electrodes, which produce higher signal resolution, resulting in enhanced maps of the heart.[7,8] With these high-definition maps, clinicians have a better understanding of where the arrhythmia is occurring and can develop a more effective ablation strategy.

"The OPTRELL™ Mapping Catheter has a fixed electrode array structure that provides greater diagnostic insight, which allows physicians to quickly and effectively identify ablation targets," said Pasquale Santangeli, M.D., Ph.D., Cardiovascular Medicine, Cleveland Clinic Main Campus.[ii] "This catheter and the Local Conduction Vectors give me the confidence to quickly and effectively detect ablation lesion gaps and the arrhythmia substrate, even in the most complex cases, including persistent AFib, redo AFib ablation, atrial tachycardia, and ventricular tachycardia."

The OPTRELL™ Mapping Catheter is powered by the CARTO® 3 System, which offers Local Conduction Vectors that display the real-time direction and speed of the electrical impulses traveling through the heart.[9] With these Local Conduction Vectors, clinicians gain enhanced understanding of complex circuits and

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DO NOT use OPTRELL™ Mapping Catheter with TRUEref™ Technology in patients with prosthetic valves.

[i] Johnson & Johnson MedTech comprises the surgery, orthopaedics, vision and interventional solutions businesses within Johnson & Johnson's MedTech segment.
[ii] Dr. Pasquale Santangeli is compensated by and presenting on behalf of BWI and must present information in accordance with applicable regulatory requirements.

mechanisms and can confidently detect gaps in ablation lesions.[7] Together, these technologies can help clinicians quickly identify areas that need ablation and apply more effective therapy in a shorter time.

“The OPTRELL™ Mapping Catheter rounds out the Biosense Webster diagnostic mapping portfolio, providing physicians with a comprehensive set of tools, integrated with our CARTO® 3 mapping system, to diagnose and treat arrhythmias,” said Jasmina Brooks, President, Biosense Webster, Inc. “This is the latest example of the continued commitment of Biosense Webster to providing clinicians with innovative tools to improve efficiency and effectiveness of procedures and quality of care for patients.”

The OPTRELL™ Mapping Catheter with TRUEref™ Technology received U.S. Food and Drug Administration (FDA) 510(k) clearance in 2022 and is now available in the U.S.

The OPTRELL™ Mapping Catheter with TRUEref™ Technology will be commercially available in Japan later this year.

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 and connect on LinkedIn and Twitter.

About Johnson & Johnson MedTech[i]
At Johnson & Johnson MedTech,[i] 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.

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 OPTRELL™ Mapping Catheter with TRUEref™ technology. 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.

Important information: Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, side effects, warnings and precautions.
Caution: US law restricts this device to sale by or on the order of a physician.

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