

For Immediate Release

Biosense Webster Launches HELIOSTAR™ in Europe, the First Radiofrequency Balloon Ablation Catheter, Enabling Physicians to Perform More Efficient Cardiac Ablations

The HELIOSTAR™ Balloon Ablation Catheter's unique one-shot balloon technology enables pulmonary vein isolation in 12 seconds, with customized energy delivery and one integrated 3D mapping solution¹

IRVINE, CA – October 13, 2022 – Biosense Webster, Inc., part of Johnson & Johnson MedTech[†], today announced the European launch of the HELIOSTAR™ Balloon Ablation Catheter – the first radiofrequency balloon ablation catheter. The HELIOSTAR™ Balloon Ablation Catheter is indicated for use in catheter-based cardiac electrophysiological mapping (stimulating and recording) of the atria and, when used with a compatible multi-channel RF generator, for cardiac ablation.

Europe is home to more than 11 million people living with atrial fibrillation (AF);² by 2030, the number of people with AF is expected to increase by up to 70%.³ In Europe, catheter ablation is a recommended first-line treatment option^{‡4} and is associated with a significant improvement in quality of life and significant reductions in AF burden and AF-related complications.^{5,6,7}

The HELIOSTAR™ Balloon Ablation Catheter is fully integrated with the CARTO™ 3 System, a 3D mapping solution. The HELIOSTAR™ Balloon Ablation Catheter has a compliant balloon that can conform to varied pulmonary vein anatomy^{8,§} and provides the ability to achieve single-shot pulmonary vein isolation (PVI) in 12 seconds.¹ Use of the HELIOSTAR™ Balloon Ablation Catheter, with the LASSOSTAR™ Catheter and CARTO™ 3 System, may reduce fluoroscopy time and exposure,^{9,10,11,**} potentially benefitting both the patient and physician. Shorter procedure time may require less anesthesia and radiation and may result in less facility time. These time savings may also enable more procedures per day, facilitating patient access.^{12,13} The HELIOSTAR™ Balloon Ablation Catheter is not commercially available in the United States.

“The HELIOSTAR™ catheter is an effective and efficient technology, enabling great results in less procedure time, which has many benefits to both my patients, myself and my staff,” said Prof. Gian Battista Chierchia, Full Professor in Cardiology, HRMC, Brussels, Belgium, CMO Electrophysiology Frontiers.* “The high single-shot isolation success rate is particularly valuable when it comes to procedural efficiency, and at my institution we’ve been able to reproducibly perform procedures in 15 - 20 minutes.”

[†]The Johnson & Johnson MedTech Companies comprise the surgery, orthopaedics, vision and interventional solutions businesses within Johnson & Johnson’s MedTech segment.

*Drs. Chierchia and Dahme are compensated by and presenting on behalf of Biosense Webster, and must present information in accordance with applicable regulatory requirements.

[‡]Recommended first-line treatment for patients with symptomatic Paroxysmal AF episodes or persistent AF without major risk factors for AF recurrence, of as an alternative to AAD class I or III, considering patient choice, benefit, and risk.

[§]In a multicenter, single-arm study SHINE (n = 95), 100% of the targeted PVs were electrically isolated and no additional ablation with a focal ablation catheter was necessary.

**In a multicenter single-arm study, SHINE (n=95), fluoroscopy time was 10.9 ± 9.1 minutes in per-protocol population while in a multicenter single-arm study RADIANCE (n=40), fluoroscopy time was 17.4 ± 10.1 minutes without using LASSOSTAR™ Diagnostic Catheter.

The HELIOSTAR™ Balloon Ablation catheter features ten gold-plated, irrigated electrodes and the amount of power delivered to each electrode can be customized based on anatomical location and known tissue thickness.^{8,12,16,††} HELIOSTAR™ is the only multi-electrode single-shot balloon with the flexibility to perform both circumferential and segmental ablation, enabling personalized PV ablation.⁸ The amount of power delivered to each electrode can be controlled independently¹ and the catheter can deliver titrated radiofrequency energy for a customizable workflow.¹⁴

“The HELIOSTAR™ catheter is an exciting addition to my set of tools for delivering customizable, efficient and effective cardiac ablations. I have performed more than 120 cases with this tool at my institution to date, with an average left atrial procedure time of 35 minutes,” said Prof. Tillman Dahme, Ulm University Medical Center – Department of Medicine II (Cardiology, Angiology, Pneumology, Critical Care Medicine), Germany. * “As AF prevalence continues to rise and impact more people in Europe and around the world, I am always looking for novel solutions like this to help me deliver better and more personalized treatments for my patients.”

In a multicenter single-arm study, SHINE, the HELIOSTAR™ Balloon Ablation Catheter was an effective treatment for paroxysmal atrial fibrillation (AF)¹⁰ and isolated targeted pulmonary veins (PV) in 98.8% of patients without the need for focal touch-up.^{10,‡‡} Average time to isolation of each pulmonary vein was 9-12 seconds.^{10,§§} In addition, the RADIANCE study demonstrated 86% freedom from documented atrial arrhythmia at 12 months.^{15,***} In September 2021, the [first post-approval procedures](#) were successfully performed with the HELIOSTAR™ Balloon Ablation Catheter at sites across Europe.

“Our goal at Biosense Webster is to utilize the latest science and technology to help electrophysiologists deliver the best possible outcomes for their patients,” said Michael Bodner, Ph.D., Worldwide President, Biosense Webster, Inc. “The launch of the HELIOSTAR™ Balloon Ablation Catheter in Europe is an exciting milestone as we work together with the EP community to advance safe, effective and efficient treatment solutions for patients suffering from atrial fibrillation.”

The HELIOSTAR™ Balloon Ablation Catheter is CE Mark approved and now available across Europe. For more information on HELIOSTAR™, visit <https://www.injmedtech.com/en-EMEA/product/heliostar-balloon-ablation-catheter>. In addition, a Biosense Webster-hosted webinar titled “Clinical Results and Optimized Workflows with the HELIOSTAR™ Balloon Ablation Catheter” is scheduled to take place on Thursday, November 10, 2022, from 5:00 – 6:00pm CET. Guest speakers include Prof. Gian Battista Chierchia, Prof. Tillman Dahme and Prof. Boris Schmidt, Cardioangiology Center Bethanien, Frankfurt, Germany. To register, visit: <https://cvent.me/Rkzqx0?RefId=Press+Release>.

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 the Johnson & Johnson MedTech 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 and connect on [LinkedIn](#) and [Twitter](#).

About Johnson & Johnson MedTech

At Johnson & Johnson MedTech, 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

†† Tissue thickness is known per anatomical location or measured via intracardiac echocardiography.

‡‡ This data is based on 7 operators. PV isolation is defined as sustained PV entrance block on adenosine/isoproterenol challenge.

§§ In a multi-center single-arm study (SHINE, n=95), pure single shot isolation was achieved by one initial RF application (regardless of the duration of ablation). Time to isolation (mean ± SD, sec) was 9.0 ± 6.46 (LIPV), 12.0 ± 11.58, (LSPV), 9.1 ± 4.95 (RIPV), 8.9 ± 6.22 (RSPV).

*** 86.4% (32/37) includes those both on/off AAD; 75.7% (28/37) off AAD. Based on n=37/39 pts, observational study.

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 HELIOSTAR™ 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, 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; 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 January 2, 2022, 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 www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither the Johnson & Johnson MedTech nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

Always verify catheter tip location using fluoroscopy or IC signals and consult the CARTO® 3 System User Guide regarding recommendations for fluoroscopy use.

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⁷ *Journal of Nursing*: June 2019 - Volume 119 - Issue 6 - p 18 doi:10.1097/01.NAJ.0000559795.09114.0b.

⁸ SHINE Study Clinical Study Report (BWI_2017_01 12M Final Results). December 20, 2019.

⁹ Calkins et al, 2017HRS/EHRA/ECAS/APHS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation, *Europace* (2018) 20, e1–e160.

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225610-220831 US/EMEA

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