Johnson&Johnson MedTech | Cardiovascular

Media Contacts:

Erin Farley
efarley1@its.jnj.com

Majo Echeverria
Mechever@its.jnj.com

Investor Relations:
Tracy Menkowski
Investor-relations@its.jnj.com

FOR IMMEDIATE RELEASE

Johnson & Johnson MedTech Launches SOUNDSTAR CRYSTAL™ in the US, Redefining Image Clarity in 2D Intracardiac Imaging[i]

New ultrasound catheter delivers superior image quality,[i,ii] peak maneuverability and seamless CARTO™ 3 System integration[i], giving physicians improved visualization[ii] for added confidence during cardiac ablation procedures

Irvine, CA – May 21, 2025 – Johnson & Johnson MedTech, a global leader in cardiac arrhythmia treatment, announced the U.S. launch of the SOUNDSTAR CRYSTAL™ Ultrasound Catheter for intracardiac echocardiography (ICE) imaging in cardiac ablation procedures.

The device provides clearer, enhanced image quality compared to other ICE catheters[ii], representing an advanced 2D ICE catheter. Integrated with CARTO™ 3 Mapping System[i], including the CARTOSOUND™ FAM module for enhanced mapping capabilities powered by AI[1,iii], SOUNDSTAR CRYSTAL™ provides an efficient workflow[i]. CARTOSOUND™ FAM enables automatic generation of the left atrial anatomy by a novel artificial intelligence algorithm using images collected from a rotation of the ultrasound catheter in the right atrium, simplifying the integrated workflow[i] for electrophysiologists performing cardiac ablation procedures for patients[1].

“We are proud to advance our legacy in integrated ultrasound catheters with this latest innovation that equips electrophysiologists with the tools they need to promote patient safety[ii] and drive effective[iv] results,” said Jasmina Brooks, President, Electrophysiology, Johnson & Johnson MedTech. “The superior image quality[i,ii] , improved catheter maneuverability[ii] and stability of the SOUNDSTAR CRYSTAL™ Ultrasound Catheter, along with seamless CARTO™ 3 System integration[i] can help enable a zero fluoroscopy workflow[iv,v,iv†,2,3,4,vi], enhancing procedure effectiveness and safety for both healthcare professionals and patients they treat.”

ICE is broadly used in catheter ablation procedures to visualize the heart in high resolution to monitor catheter-tissue contact and ablation in real-time and quickly detect procedural complications. When real-time imaging is

---

[i] Based on Siemens' internal report CRF data responses as of 8/9/2024. CRF Data PN 11291187-EPT-021.
[ii] When compared to [ACUSON AcuNav™ Ultrasound Catheter] [SOUNDSTAR™ Ultrasound Catheter]
[iii] CARTOSOUND™ FAM Module uses Deep Learning, which is a subset of AI
[iv] Safety profile refers to complication and primary adverse event rates
†Efficacy profile refers to acute success (pulmonary vein isolation) and long-term success.
[v] Based on a survey of 31 physicians.
[vi] Johnson & Johnson and its affiliates' portfolio of products with FDA approved/cleared instructions for use to support fluoro alternative workflows when used with the CARTO™ 3 System include the following: THERMOCOOL SMARTTOUCH™ SF Catheter, THERMOCOOL SMARTTOUCH™ Catheter, CARTO™ VIZIGO™ Bi-Directional Guiding Sheath, PENTARAY™ NAV ECO High Density Mapping Catheter, OCTARAY™ Mapping Catheter with TRUEref™ Technology, OPTRELL™ Mapping Catheter with TRUEref™ Technology, DECANAV™ Mapping Catheters, and Webster™ CS Catheter.

integrated with a 3D electroanatomical mapping system, such as the CARTO™ 3 System, ICE can help reconstruct cardiac anatomy and enable zero-fluoroscopy procedures[v†,2,3,4]. ICE-guided electrophysiology procedures can be performed under conscious sedation, without requiring esophageal intubation and additional anesthesia[vii,5].

“During the cases I performed with the SOUNDSTAR CRYSTAL™ Ultrasound Catheter, I was impressed by the clear visualization, tissue definition and enhanced far field imaging[i], and full integration with other platforms. Integration with the CARTO™ 3 System provides clear, high-resolution images[i,viii] which simplify the anatomical mapping process[ix] and procedure workflow[v],” said Amin Al-Ahmad, MD[x], St. David’s HealthCare, Austin, TX.

The SOUNDSTAR CRYSTAL™ Ultrasound Catheter is the latest addition to a comprehensive portfolio of ultrasound solutions at Johnson & Johnson MedTech. The company recently brought forward the NUVISION™ Catheter, which harnesses advanced 4D imaging to assist physicians performing cardiac procedures, such as Left Atrial Appendage Closure (LAAC).

Cardiac arrhythmias are a growing epidemic. AFib alone is the most common type of cardiac arrhythmia and impacts more than 50 million people worldwide, and 8 million people in the U.S[6]. 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[7,8]. Catheter ablation is a safe and effective procedure to restore the heart’s incorrect electrical signals, which causes an abnormal heart rhythm[9].

About SOUNDSTAR CRYSTAL™
SOUNDSTAR CRYSTAL™ is an ultrasound catheter that features an 88-element phased linear array to deliver outstanding image quality and detailed visualization of intricate anatomical structures inside the heart[i]. SOUNDSTAR CRYSTAL™ is integrated with the CARTO™ 3 System for a cohesive and efficient workflow during catheter ablation procedures. The catheter also is designed with optimal balance of stiffness and flexibility, ensuring precision in maneuverability[i].

Cardiovascular Solutions from Johnson & Johnson MedTech
Across Johnson & Johnson, we are tackling the world’s most complex and pervasive health challenges. Through a cardiovascular portfolio that provides healthcare professionals with advanced mapping and navigation, miniaturized tech, and precise ablation we are addressing conditions with significant unmet needs such as heart failure, coronary artery disease, stroke, and atrial fibrillation. We are the global leaders in heart recovery, circulatory restoration and the treatment of heart rhythm disorders, as well as an emerging leader in neurovascular care, committed to taking on two of the leading causes of death worldwide in heart failure and stroke. For more, visit biosensewebster.com and connect on LinkedIn and X, formerly Twitter.

About Johnson & Johnson
At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity. Learn more about our MedTech sector’s global scale and deep expertise in surgery, orthopaedics, vision and cardiovascular solutions at https://thenext.jnjmedtech.com. Follow us at @JNJMedTech and on LinkedIn. Biosense Webster, Inc. is a Johnson & Johnson MedTech company.

Cautions Concerning Forward-Looking Statements
This press release contains “forward-looking statements” as defined in the Private Securities Litigation Reform Act of 1995 regarding SOUNDSTAR CRYSTAL™. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual

[vii] Based on a meta analysis of ICE applications in EP
[viii] When compared to SOUNDSTAR™ Catheter
[ix] Based on 96 surveys, by 31 EPs with an average score of 5.0 or higher on 7-point Likert scale with 5=Satisfied 6/7=Completely Satisfied
[x] Dr. Al-Ahmad serves as a consultant for Johnson & Johnson but was not compensated for this announcement.

results could vary materially from the expectations and projections of 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 healthcare products and services; and trends toward healthcare cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's most recent Annual Report on Form 10-K, 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 , jnj.com or on request from Johnson & Johnson. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.sec.gov, jnj.com or on request from Johnson & Johnson.

[1] CARTOSOUND™ FAM Module Instructions for Use. UG_5462-018H P02. November 2023.
[2] Debreceni D, Janosi K, Bocz B, et al. (2023). Zero fluoroscopy catheter ablation for atrial fibrillation: a systematic review and meta-analysis. Front Cardiovasc Med;10:1178783. doi: 10.3389/fcvm.2023.1178783.
[3] Rajendra A, Hunter TD, Morales GX, et al. (2023). Steerable sheath visualizable under 3D electroanatomical mapping facilitates paroxysmal atrial fibrillation ablation with minimal fluoroscopy. J Interv Card Electrophysiol;66(2):381-388. doi: 10.1007/s10840-022-01332-8.
[4] Tahin T, Riba A, Nemeth B, et al. (2021). Implementation of a zero fluoroscopic workflow using a simplified intracardiac echocardiography guided method for catheter ablation of atrial fibrillation, including repeat procedures. BMC Cardiovasc Disord;21(1):407. doi: 10.1186/s12872-021-02219-8.
[5] Tong Hu, Tongshuai Chen, Kellina Maduray, Wenqiang Han, Jingquan Zhong. Intracardiac Echocardiography: An Invaluable Tool in Electrophysiological Interventions for Atrial Fibrillation and Supraventricular Tachycardia. Rev. Cardiovasc. Med. 2024, 25(6), 191. https://doi.org/10.31083/j.rcm2506191.
[6] Mensah, G, Fuster, V, Murray, C. et al. Global Burden of Cardiovascular Diseases and Risks, 1990-2022. J Am Coll Cardiol. 2023 Dec, 82 (25) 2350–2473.
[7] Calkins, H., et al (2017). 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation. Heart rhythm, 14(10), e275–e444.
[8] Odutayo, A. et al (2016). Atrial fibrillation and risks of cardiovascular disease, renal disease, and death: systematic review and meta-analysis. BMJ (Clinical research ed.), 354, i4482.
[9] Natale, A. et al (2014). Paroxysmal AF catheter ablation with a contact force sensing catheter: results of the prospective, multicenter SMART-AF trial. Journal of the American College of Cardiology, 64(7), 647–656.