



Acutus Medical Announces Approval of its AcQMap System and AcQMap 3D Imaging and Mapping Catheter in Japan

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Approval ushers in a new era of arrhythmia management in Japan through revolutionary non-contact imaging and diagnosis technology

CARLSBAD, Calif., July 27, 2022 (GLOBE NEWSWIRE) -- Acutus Medical, Inc. ("Acutus") (Nasdaq: AFIB), an arrhythmia management company focused on improving the way cardiac arrhythmias are diagnosed and treated, today announced approval of its AcQMap High Resolution Imaging and Mapping System and the AcQMap 3D Imaging and Mapping Catheter in Japan. Japan is the 2nd largest medical device market in the world and the EP Mapping and Ablation market is estimated to exceed \$1.4 billion in 2022 with more than 150,000 procedures performed and grow to an estimated \$1.8 billion by 2025¹. Acutus' International Alliance partner BIOTRONIK has commenced training and early market development activities in collaboration with Acutus Medical in preparation for more significant activities in 2023.

"The AcQMap System and Catheter clearance represents a major advancement in the tools available to EPs in Japan," said David Roman, President & CEO of Acutus Medical. "This approval uniquely enables electrophysiologists in Japan to employ a fully non-contact system to aid in the personalized diagnosis and treatment of patients suffering from cardiac arrhythmias. We view Japan as one of several key growth drivers to accelerate long-term performance. We look forward to entering Japan with BIOTRONIK given its established and respected position in the market."

"We are excited to bring this innovative technology to Japan," said Dr. Hans-Jürgen Wildau, Segment Head EP & Sensors, BIOTRONIK SE & Co. KG. "These approvals represent another successful milestone in the market readiness work we've done with Acutus over the past 24 months. We believe Japanese physicians specifically will appreciate the innovation the Acutus platform brings to the diagnosis of complex arrhythmias especially in mapping non-pulmonary vein triggers which is a significant unmet need in the treatment for atrial fibrillation."

The AcQMap 3D Imaging and Mapping Catheter are the cornerstones of Acutus' innovative mapping platform as the world's only integrated ultrasound-based imaging and non-contact mapping catheter capable of capturing cardiac imaging information and cardiac activation mapping, all without touching the heart. The AcQMap System can uniquely map the electrical conduction of each heartbeat to characterize the most complex arrhythmias across the entire atrial chamber.

The ability to map every beat allows the physician to visualize global chamber activity of irregular rhythms like atrial fibrillation, complex flutters and tachycardias, and clinically relevant, fleeting rhythms such as non-sustained tachycardia which are all burdensome with conventional contact-based systems that rely on probing the heart sequentially over many heartbeats to create diagnostic maps. The unique capability of AcQMap to understand these complex arrhythmias helps physicians to personalize a diagnosis and treatment strategy for each individual patient leading to superior outcomes.^{2,3,4}

For more information, visit www.acutusmedical.com/us/.

References

¹ Millennium Research Group: 2021 Electrophysiology Mapping and Ablation Devices | Market Insights | Japan | 2021

² Shi R, et al, An Individualised Ablation Strategy to Treat Persistent Atrial Fibrillation: Core-to-Boundary Approach Guided by Charge-Density Mapping, *Heart Rhythm* 2021

³ Shi R, et al. Novel aggregated multiposition noncontact mapping of atrial tachycardia in humans: From computational modeling to clinical validation. *Heart Rhythm*. 2022

⁴ Gagyi R, et al. New Possibilities in the Treatment of Brief Episodes of Highly Symptomatic Atrial Tachycardia: The Usefulness of Single-Position Single-Beat Charge Density Mapping. *Circulation: Arrhythmia and Electrophysiology* 2021

About Acutus Medical

Acutus Medical is an arrhythmia management company focused on improving the way cardiac arrhythmias are diagnosed and treated. Acutus is committed to advancing the field of electrophysiology with a unique array of products and technologies which will enable more physicians to treat more patients more efficiently and effectively. Through internal product development, acquisitions, and global partnerships, Acutus has established a global sales presence delivering a broad portfolio of highly differentiated electrophysiology products that provide its customers with a complete solution for catheter-based treatment of cardiac arrhythmias. Founded in 2011, Acutus is based in Carlsbad, California.

BIOTRONIK/Acutus Alliance for Electrophysiology

In May 2020, BIOTRONIK and Acutus Medical announced a new alliance to provide a comprehensive line of electrophysiology, mapping, ablation, and accessory products across select markets in the world including Europe and Asia. At the center of the *BIOTRONIK/Acutus Alliance for Electrophysiology* lies the groundbreaking AcQMap High Resolution Imaging and Mapping System. Under terms of the agreement, Acutus and BIOTRONIK will jointly introduce and market, under respective private labels, their complete line of electrophysiology products to most major international markets, providing a complete suite of state-of-the-art technologies for the electrophysiologist to diagnose and treat arrhythmias.

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