

Acutus Medical Announces FDA Clearance of Second-Generation AcQMap 3D Imaging & Mapping Catheter

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Design Features Improve Handling and Deliverability to Enhance Efficiency

CARLSBAD, Calif., Sept. 17, 2020 (GLOBE NEWSWIRE) -- <u>Acutus Medical</u> (Nasdaq: AFIB) today announces FDA 510(k) clearance of the second-generation AcQMap® 3D imaging and mapping catheter which builds on its predecessor, improving handling and deliverability. This flagship 3D mapping and navigation catheter combines 48 ultrasound transducers responsible for creating the anatomical geometry and 48 engineered electrodes which enable electrical activation patterns to be displayed along the inner surface of the heart. Compatible with an 0.035" guidewire, the AcQMap catheter is designed to be inserted into the left and right atrium.

The AcQMap catheter is the cornerstone of Acutus' innovative mapping platform. It is the world's only integrated high-resolution ultrasound-based imaging and non-contact mapping catheter capable of capturing cardiac imaging information in addition to cardiac activation mapping. This second-generation catheter carries additional benefits such as improved anatomy reconstruction, faster acquisition times and the potential for enhanced procedural efficiencies. The catheter also comes with a reusable and sterilizable cable that can be used up to 10 times, resulting in greater cost savings for health care systems.

Customer feedback during development suggested that users perceived anatomy reconstruction to be faster than our generation one catheter*. Dr. Anil Rajendra from Grandview Medical Center in Birmingham, Alabama commented, "the new ergonomic handle and catheter deployment mechanism has the potential to allow me to maneuver the catheter with greater speed, ease and control."

The versatility of the AcQMap System allows physicians to map all types of atrial arrhythmias – simple and complex, spontaneous, repetitive and chaotic. The high definition maps provided by the AcQMap catheter allow physicians to identify ablation targets outside the pulmonary veins and strategically plan a patient-specific ablation strategy. Physicians can efficiently map any arrythmia in under 3 minutes, ablate and then remap again to evaluate therapy effectiveness.

"At Acutus, we pride ourselves on our continued and rapid cadence of bringing innovative, differentiated technologies to the market," said Vince Burgess, President & CEO of Acutus Medical, Inc. "We are committed to partnering with physicians to continually provide products and solutions to address physicians unmet needs."

*Acutus Medical data on file.

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 in each of its geographic markets. Founded in 2011, Acutus is based in Carlsbad, California.

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