



## Acutus Medical Receives FDA Approval to Initiate US Atrial Fibrillation IDE Trial with the AcQBlate® FORCE Sensing Ablation System

May 27, 2021

CARLSBAD, Calif., May 27, 2021 (GLOBE NEWSWIRE) -- Acutus Medical (Nasdaq: AFIB), an arrhythmia management company focused on improving the way cardiac arrhythmias are diagnosed and treated, today announced FDA approval for the company to initiate its Atrial Fibrillation ("AF") Investigational Device Exemption (IDE) clinical trial for the AcQBlate Force Sensing Ablation Catheter and System. In the US, AF ablation procedures total approximately 190,000 per year and are projected to reach 375,000 annually by 2025<sup>1</sup>. This trial is expected to enroll 350 subjects in leading centers globally and will evaluate the safety and efficacy of the system in the treatment of both paroxysmal and persistent atrial fibrillation.

Designed specifically to provide consistent, effective therapeutic solutions during cardiac ablation procedures, the AcQBlate Force gold-tipped catheter and system shows physicians, in real-time, how much contact force is being applied to the heart during ablations. Studies have shown the utility of real-time contact force information in helping physicians guide safe and effective therapy, which may improve patient outcomes<sup>2</sup>.

In contrast to most contemporary ablation systems, the AcQBlate Force Catheter and System can operate both in a stand-alone manner or in conjunction with compatible 3D mapping systems. The new ablation system is comprised of Acutus' AcQBlate Force Catheter and Qubic Force module and seamlessly integrates with the Qubic RF generator and Qiona irrigation pump. This state-of-the-art system received a key CE Mark in late 2020 and is now commercially available in Europe. In addition to ongoing US IDE and European commercial activities, the AcQBlate Force Catheter and System is planned to serve as the work-horse delivery platform for the company's Pulsed Field Ablation (PFA) program.

"The AF IDE trial will expand on our entry into the US with a therapeutic technology for the treatment of the most common of arrhythmias, atrial fibrillation," said Vince Burgess, President & CEO of Acutus Medical. "In April, we kicked off our efforts to add therapy to our US portfolio with our right atrial flutter IDE trial, and that trial is enrolling on plan. Pursuing an atrial fibrillation indication represents a critical step forward in our strategy to become a comprehensive partner to electrophysiologists in the treatment of complex arrhythmias. We look forward to offering the benefits of a force sensing ablation system to electrophysiologists and patients in the United States once we complete clinical trials and gain regulatory approval."

Enrollment for the AcQBlate Force AF trial is expected to begin in the second half of 2021, once participating sites gain necessary institutional review board (IRB) approvals.

More information on the AcQBlate AF trial is available at <https://www.clinicaltrials.gov> under NCT04904354. The AcQForce Flutter trial is ongoing, and the company is actively working with selected sites to initiate cases under the IDE (reference: NCT04658940 on <https://www.clinicaltrials.gov>). AcQBlate Force Sensing Catheter and System is limited by US Federal Law to investigational use.

### References

1. Erik J. Bracciodieta, Electrophysiology Mapping and Ablation Devices, Market Insights, US. Decision Resources Group M360EP0059, June 2019.
2. Ariyaratna N. et al., Role of Contact Force Sensing in Catheter Ablation of Cardiac Arrhythmias: Evolution or History Repeating Itself? JACC: Clinical Electrophysiology (2018); 707-723

### 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.

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### AcQBlate Force System



A complete ablation system which includes the smallest footprint of any RF Generator and is comprised of four components: Qubic RF controller, Qubic Force Module, Qubic RF Generator and Qiona Irrigation pump. Qubic RF and Qiona are trademarks of BIOTRONIK SE & Co. KG.

### AcQBlate Force Sensing Ablation Catheter



AcQBlate FORCE: the first and only force sensing ablation catheter with a gold-tip electrode.

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**Media Contact**

Holly Windler  
619-929-1275  
holly.windler@acutus.com

**Investor Contact**

Caroline Corner  
415-202-5678  
caroline.corner@westwicke.com

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