



## Acutus Medical Initiates CE Mark Study for Focal Pulsed Field Ablation Therapy to Treat Atrial Fibrillation

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### Acutus' Catheter-Based Therapy Platform, AcQBlate Force, Will Integrate Multiple Ablation Modalities Guided by Novel Noncontact Mapping Technology to Treat Complex Atrial Arrhythmias

CARLSBAD, Calif., Nov. 11, 2021 (GLOBE NEWSWIRE) -- [Acutus Medical, Inc.](https://www.acutusmedical.com) (Nasdaq: AFIB) ("Acutus"), an arrhythmia management company focused on improving the way cardiac arrhythmias are diagnosed and treated, today announced the initiation of AcQForce PFA-CE, a new clinical study that will evaluate the safety and performance of the company's focal force sensing Pulsed Field Ablation (PFA) catheter and system in combination with its novel noncontact 3D mapping system in treating patients with atrial fibrillation. The first patients were successfully treated at Na Homolce Hospital in the Czech Republic by Dr. Petr Neuzil, the Primary Investigator and Head of the Department of Cardiology, along with his colleague Dr. Jan Petru, and Drs. Vivek Reddy and Jacob Koruth from Mount Sinai Health System. Dr. Doug Gibson of Scripps Memorial Hospital is serving as the site's primary technology advisor.

The inception of this study highlights Acutus' unique therapeutic position offering the first and only force sensing gold-tip ablation catheter, AcQBlate Force, designed to deliver either radiofrequency (RF) or PFA therapy – with the added benefit of fully integrating with therapy guidance provided by the novel AcQMap 3D Imaging and Mapping System.

"The vision for pioneering Pulsed Field Ablation treatment was primarily due to PFA's ability to have high-impact treatment while preserving healthy tissue. As physicians, we know that the majority of our patients that come back for re-treatment following ablation for atrial fibrillation have triggers in various locations beyond the standard course of care, and it's imperative for us to research beyond pulmonary vein isolation-only utilizations," said Dr. Steven Mickelsen, Acutus' Chief Translational Science Officer and founder of PFA pioneer Farapulse, Inc. "PFA lesion volume and contours follow well-defined and predictable electromagnetic rules, and the technology lends itself well to integration into 3D mapping systems like AcQMap. This paves the way for a higher degree of certainty and efficacy when ablating specific areas of the heart inclusive of and outside the pulmonary veins. We're working towards a future where we can quickly create a 3D electroanatomic map of a complex arrhythmia like atrial fibrillation, and deliver precise, individualized and durable therapy with dramatically improved safety, reliability and workflow."

"Pulsed Field Ablation as applied to the field of cardiac electrophysiology has enormous potential, given the expected improvements in safety, efficacy and speed over current therapies," said Vince Burgess, President and CEO of Acutus Medical. "Our vision for the future of this new energy source is to deliver it via a force sensing focal point ablation catheter and to guide that delivery with advanced 3D cardiac mapping, rather than fluoroscopy. This approach is different from many others entering this field, in that it will allow precise applications of PFA in highly targeted tissue across the full range of arrhythmias, including atrial fibrillation and flutter and atrial and ventricular tachycardias – while preserving as much fully functional cardiac tissue as possible. Competing multi-electrode, large format catheters guided by fluoroscopy will have inherently limited precision upon delivery."

#### About Acutus' RF Ablation System for Electrophysiology Procedures

Acutus' therapeutic radiofrequency ablation system and force sensing catheter is currently approved and commercially available for use in Europe\*. It can operate in a standalone manner or in conjunction with compatible 3D mapping systems to provide consistent, effective therapy during cardiac ablation procedures. This system can also be fully integrated into Acutus' mapping system to provide real-time displays of ablation bioparameters and contact force data.

#### About Pulsed Field Ablation

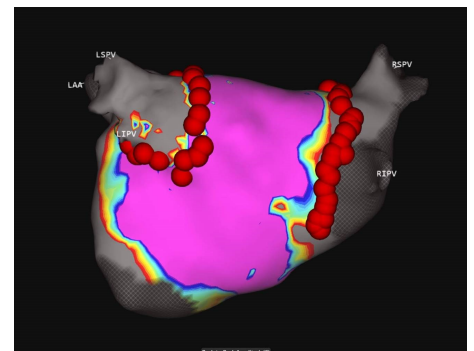
Contemporary Pulsed Field Ablation technologies utilize short bursts of high voltage microsecond or nanosecond electrical pulses to selectively isolate areas of cardiac tissue that are thought to contribute to triggering or sustaining cardiac arrhythmias. PFA is currently being investigated as an alternative to cryo and radiofrequency ablations, which ablate tissue by either extreme cold or extreme heat. When designed and applied appropriately, the therapeutic treatment effect of pulsed field ablation energy is almost exclusively confined to the targeted cardiac tissue

### Acutus Medical's Electrophysiology System



AcQForce PFA-CE study is designed to demonstrate the safety and performance of the Acutus focal PFA system utilizing the AcQBlate Force Sensing Ablation Catheter (pictured) and system (not shown) and AcQMap 3D mapping system (pictured) in patients undergoing ablation therapy for atrial fibrillation.

### Acute Pulmonary Vein Isolation Confirmed Utilizing Acutus Technology with SuperMap



Acutus SuperMap image shows acute pulmonary vein isolation in the first patient enrolled in the AcQForce PFA-CE clinical study. Circumferential ablation lesions were delivered with Acutus Pulsed Field Ablation using Acutus' gold-tip contact force sensing ablation catheter, AcQBlate Force. Imaging and confirmation of the acute pulmonary vein isolation were performed with the AcQMap non-contact mapping system.

without raising or lowering tissue temperature. Focal PFA may allow for more precise demarcated lesions, promoting rapid tissue healing and facilitating practical safety margins for nearby tissue structures outside the heart.

#### **AcQForce PFA-CE Study**

AcQForce PFA-CE is a prospective, non-randomized European clinical study designed to demonstrate the safety and performance of the Acutus Pulsed Field Ablation system in up to 60 patients undergoing ablation therapy for AF.

Site recruitment and patient enrollment for AcQForce PFA-CE is ongoing. For more information, please visit <https://www.clinicaltrials.gov> reference NCT05113056.

\*The AcQBlate Force Sensing System is CE marked for RF energy delivery. The AcQBlate Force Sensing System is an investigational device and is limited by United States law to investigational use. Acutus' PFA technology is under premarket study in Europe and is not approved for sale in the U.S.

#### **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.

To learn more about Acutus Medical's complete portfolio of diagnostic, access and therapy products, please visit <https://acutusmedical.com>.

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