



RECOVER AF Study Reports 91% of First Redo Patients Achieved Freedom from AF at One Year After AcQMap-guided Ablation Therapy

April 20, 2023

CARLSBAD, Calif., April 20, 2023 (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 results from the RECOVER AF study. The study, published online in *EP Europace*, found that patients who received AcQMap-guided ablations for retreatment achieved better outcomes compared to those who underwent traditional anatomical retreatment strategies.¹⁻³

Moreover, the study showed patients who had only undergone pulmonary vein isolation (PVI) before enrollment achieved 91% freedom from atrial fibrillation (AF) at one year, while the entire study population, with varying prior procedures, reported 76% freedom from AF at one year.¹ Overall, these findings underscore AcQMap's differentiated offering for retreatment procedures in delivering personalized therapy to yield improved outcomes and fulfill a major unmet need in the market.

"These results are encouraging and add to the growing evidence that mapping AF to guide an individualized treatment plan may be advantageous at the earliest opportunity in patients with persistent AF," says principal investigator Timothy R. Betts, MD, MBChB, FRCP (Oxford University Hospitals, UK). "Furthermore, the particularly high success rates for persistent AF retreatment patients with only a prior PVI, in contrast to those with prior PVI+, suggests that ablation beyond the PVs that is empiric and not informed by AF mapping could be detrimental."

In the RECOVER AF study, AcQMap's unique whole chamber single-beat non-contact mapping was used to map AF and detect Pathological Conduction Patterns (PCPs), which were then targeted for therapy with a core-to-boundary ablation strategy. 76% of patients undergoing retreatment with AcQMap-guided ablations experienced freedom from AF at one year. Furthermore, freedom from AF was particularly high for patients who had only PVI before enrollment compared to those who had PVI plus additional non-PV ablations (91% vs. 63%, $p < 0.05$). The outcomes provide clear evidence that advanced, patient-specific mapping with the AcQMap system leads to superior outcomes over empirical approaches, especially when used earlier in the patient's treatment pathway.

Conventional approaches to retreatment procedures for AF consistently result in unsatisfactory outcomes, with only 60-68% of patients being AF-free after 12 months.²⁻³ There are an estimated 100,000-150,000 AF retreatment procedures annually, which create a significant burden on the healthcare system.⁴ Studies have shown that a mere 1% reduction in redo ablations could save the US healthcare system nearly \$30 million annually.⁵ Outcomes in the RECOVER AF study highlight the pivotal advantage of AcQMap system and the importance of a personalized ablation strategy.

"The RECOVER AF study's findings help advance our strategy to become the system-of-choice for EPs treating complex arrhythmias, including for patients undergoing treatment for persistent AF," said David Roman, President & CEO of Acutus Medical. "Over the past year, we have focused the Company's research and development, commercial, and clinical resources to support customers tackling the most challenging conditions in EP. Through technology innovation and further clinical evidence generation, we believe AcQMap has the potential to become standard-of-care across several arrhythmias, and ultimately, impact over \$3 billion in addressable procedure categories."

Conference Call

The company will host a conference call to discuss results from RECOVER with the study's principal investigator Timothy R. Betts, MD, MBChB, FRCP (Oxford University Hospitals, UK) on **Friday April 21, 2023 at 12:00pm Eastern Time**. Please register in advance using the link: <https://edge.media-server.com/mmc/p/cp5ykbic>.

About the RECOVER AF Study

RECOVER AF was a prospective, nonrandomized trial that enrolled patients scheduled for their first or second ablation retreatment for recurrent AF. PVs were assessed and re-isolated if necessary. AF maps were used to guide the ablation of non-PV targets through the elimination of pathologic conduction patterns (PCPs). The primary endpoint was freedom from AF on or off antiarrhythmic drugs (AADs) at 12 months.

Patients undergoing retreatment with the AcQMap System (n=103) were 76% AF-free at 12 months. Patients who had only received a PVI before the study were 91% AF-free at 12 months after the treatment of non-PV targets with the AcQMap System. No major adverse events were reported.

The article can be viewed here on EP Europace: <https://academic.oup.com/europace/advance-article/doi/10.1093/europace/euad097/7128319>

About Acutus Medical

Acutus Medical ("Acutus" or the "Company") 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 portfolio of technologies and solutions designed to enable physicians to treat more patients more effectively. Through internal product development, acquisitions, and global partnerships, Acutus has established a global sales presence that delivers targeted electrophysiology solutions for the catheter-based treatment of cardiac arrhythmias. Founded in 2011, Acutus is based in Carlsbad, California.

Follow Acutus Medical on: [Twitter](#), [LinkedIn](#), [YouTube](#) and [Facebook](#).

Investor Contact

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

Media Contact

Rhiannon Pickus

442-232-6094

Rhiannon.Pickus@acutus.com

References:

1. Betts et al. Treatment of pathophysiologic propagation outside of the pulmonary veins in retreatment of atrial fibrillation patients: Recover AF study. *Europace*. 2023. doi:10.1093/europace/euad097
2. Goldenberg et al. The incremental benefit of non-pulmonary vein left atrial ablation in patients undergoing a repeat persistent atrial fibrillation ablation procedure. *J Interv Card Electrophysiol*. 2017;48:185–191. doi: 10.1007/s10840-016-0198-8
3. Weng et al. Outcomes of a comprehensive strategy during repeat atrial fibrillation ablation. *J Interv Card Electrophysiol*. 2022;65:391–399. doi: 10.1007/s10840-021-00970-w
4. Acutus data on global AF procedure estimates. [Assumes ~450,000 AF procedures of which 43% are paroxysmal and 57% are persistent and long-standing persistent AF (CABANA trial data). Retreatment AF was calculated using weighted averages and composite first procedure success rates across published trials].
5. Mansour M et al. The impact of first procedure success rate on the economics of Atrial Fibrillation Ablation. *JACC Clin Electrophysiol*. 2017;3(2):129-138. doi: 10.1016/j.jacep.2016.06.002