



## Acutus Medical Announces FDA Clearance of AcQCross™, a Full Suite of Universal Transseptal Crossing Devices

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### Product Family Targets Over 300,000 Annual US Electrophysiology and Structural Heart Procedures

CARLSBAD, Calif., April 13, 2021 (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 the FDA clearance of the AcQCross™ family of universal transseptal crossing devices. This is the first and only transseptal puncture system specifically engineered to pair and mate seamlessly with Acutus' own suite of sheaths and with sheaths sold by other manufacturers. In the United States, there are over 300,000 electrophysiology (EP) and structural heart procedures per year involving the use of transseptal crossing devices<sup>1,2,3</sup>. The company will initiate its full US commercial launch of AcQCross in the coming weeks.

Crossing the septum to gain access to the left atrium of the heart is a critical and required step in any atrial fibrillation or left sided tachycardia ablation procedures as well as in many left sided structural heart procedures (such as left atrial appendage closure device implants or percutaneous mitral valve repair). Achieving the proper crossing angle and location of septal crossing can significantly impact the efficiency of the entire procedure.

The new and expanded family of AcQCross catheters include versions that are length-, diameter- and tip-matched and designed to lock into the hub of sheaths now used in the vast majority of left heart procedures, including those provided by Acutus and by other vendors. This unique compatibility allows physicians to utilize AcQCross with their sheath of choice during virtually any left heart procedure.

AcQCross enables mechanical septal crossing with a spring-loaded needle that can also be enhanced with concurrent delivery of radiofrequency (RF) energy. AcQCross further streamlines procedural workflow by eliminating the need for wire and needle exchanges, as it incorporates a retained .032 guidewire within the hollow crossing needle.

"The elimination of guidewire and needle exchanges is an important step in facilitating transseptal crossing procedures," said Dr Peter Weiss MD, MSC, Director of Ventricular Arrhythmia Management and Robotics, Assistant Professor of Medicine, Banner University of Arizona Medical Center Phoenix. "The optimal septal crossing location and angle differs depending on the procedure – be it Cryoablation, RF ablation, non-contact mapping or left atrial appendage implant – so the unique ability to easily reposition without cumbersome catheter withdrawals and exchanges are benefits that cannot be overstated. As physicians, we rely on meaningful device innovation that fits into our existing procedural workflow and provides improvement. Acutus is delivering that with AcQCross."

"This product is absolutely unique in the industry. We are giving physicians an immensely adaptable and versatile product family developed to provide an enhanced and more precise transseptal approach – and still allow them to continue to use their sheath of choice for the remainder of the procedure," said Vince Burgess, President and CEO of Acutus Medical. "We expect that this product will be quickly and widely adopted by electrophysiologists and interventional cardiologists."

AcQCross is now commercially available in the United States. For more information, visit [www.acutusmedical.com/us/](http://www.acutusmedical.com/us/).

### References

<sup>1</sup>2019 Millennium Research Group: Electrophysiology Mapping and Ablation Devices | Market Analysis |US | 2019

<sup>2</sup>American College of Cardiology – The NCDR Left Atrial Appendage Occlusion Registry

<sup>3</sup>Transcatheter Cardiology Therapeutics (TCTMD), American Heart Association Database

### 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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### AcQCross Transseptal Crossing Device



Versatility to be utilized with top sheaths currently used in left atrium electrophysiology and structural heart procedures

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