



Acutus Medical Announces CE Mark Approval for Suite of Next Generation EP Products in Europe

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Expanded and Product Portfolio Strengthens Offering in Access and Therapy Guidance

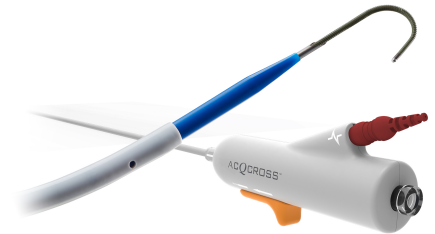
CARLSBAD, Calif., May 12, 2021 (GLOBE NEWSWIRE) -- Acutus Medical, Inc. ("Acutus") (Nasdaq: AFIB), an arrhythmia management company focused on improving the way cardiac arrhythmias are diagnosed and treated, today announced CE Mark Approval for a broad suite of EP products that includes the AcQCross™ family of universal transeptal crossing devices, the next generation AcQGuide® MAX and VUE large bore delivery sheaths and the next generation AcQMap® mapping catheter. These products are designed to streamline procedural workflow in all left heart procedures and further improve ease-of-use of Acutus' proprietary non-contact mapping technology, which allows electrophysiologists to quickly and accurately map the most complex atrial arrhythmias in minutes.

"Our R&D investments are translating into meaningful clinical innovations, as we build a comprehensive portfolio of therapy management solutions that make procedures safer, simpler and more effective," said Vince Burgess, President and CEO of Acutus Medical. "We remain steadfast in our commitment to improve the treatment of complex atrial arrhythmias, and the European launch of our next generation access and diagnostic technologies is another step in that direction."

Today's approvals expand on the company's extensive therapy guidance and ablation product lines already approved in Europe. Newly CE marked products include:

- **AcQCross family of universal transeptal crossing devices.** This is the first and only transeptal puncture system specifically engineered to pair and mate seamlessly with market leading sheaths in addition to Acutus' own offerings. Transeptal crossing devices are used in a range of electrophysiology and structural heart procedures, such as atrial fibrillation ablation, left atrial appendage occlusions, and transcatheter mitral valve repair. The new AcQCross family of 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.
- **AcQGuide MAX and VUE steerable sheaths.** These sheaths provide improved handling and deliverability that are designed to facilitate even faster anatomy reconstruction and mapping acquisition times when used in conjunction with Acutus' AcQMap 3D imaging and mapping system. The VUE sheath, which is expected to be launched later this year, will also include tip electrodes intended to facilitate catheter localization and improved workflow in procedures where physicians desire to limit the use of fluoroscopy.
- **Next-generation AcQMap 3D imaging and mapping catheter.** The only integrated high-resolution ultrasound-based imaging and non-contact mapping catheter capable of capturing cardiac imaging information in addition to cardiac electrical activation mapping is enhanced with improved torque response, handling, and maneuverability. AcQMap Catheter's advanced transducer and electrode design, when partnered with the AcQMap System, allows electrophysiologists to create an anatomical map of the atrial chambers of the heart and map simple and complex electrical patterns of the heart in sinus and complex arrhythmias. Improved visualization of the arrhythmia in cardiac tissue allows physicians to employ new approaches to

AcQCross Transeptal Crossing Device



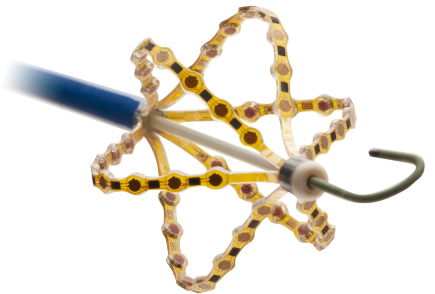
Versatility to be utilized with top sheaths currently used in left atrium electrophysiology and structural heart procedures.

Second Generation AcQGuide MAX Sheath



These sheaths provide improved handling and deliverability to facilitate faster anatomy reconstruction.

AcQMap Next Generation Mapping Catheter



Integrated high-resolution ultrasound-based imaging and non-contact mapping catheter with improved torque response, handling, and maneuverability.

cardiac ablation as evidenced in a recently published article online in the Heart Rhythm Society Journal. Independent investigators found that 87.5% of patients experienced freedom from AF at two years after a single ablation procedure informed by Acutus' AcQMap System ¹.

In Europe, there are approximately 350,000 cardiac ablations annually. This procedure volume is expected to grow to 475,000 by 2025². The increasing prevalence of complex arrhythmias and the associated burden on patients and healthcare providers requires new solutions from access to diagnosis to therapy.

The AcQCross Universal Transseptal Access System and the second-generation AcQMap 3D imaging and mapping catheter are now commercially available in Europe and the United States. The AcQGuide VUE and second generation AcQGuide MAX are approved in Europe but are not cleared for sale in the United States. For more information, visit www.acutusmedical.com/us/.

References

¹ Shi R, et al, An Individualised Ablation Strategy to Treat Persistent Atrial Fibrillation: Core-to-Boundary Approach Guided by Charge-Density Mapping, Heart Rhythm (2021), doi: <https://doi.org/10.1016/j.hrthm.2021.02.014>.

²2019 Millennium Research Group: Electrophysiology Mapping and Ablation Devices | Market Analysis | Europe (Supplemental) | 2019

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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