Acutus Medical® Receives FDA Clearance for AcQGuide™ Steerable Sheath

- Company will also present clinical data at the Heart Rhythm Society’s 38th Annual Scientific Sessions-

CARLSBAD, CA – May 3, 2017 – Acutus Medical®, a company committed to transforming the lives of millions of patients with complex arrhythmias, today announced the FDA clearance of the AcQGuide™ Steerable Sheath. The company will also feature several international presentations highlighting the AcQMap® High Resolution Imaging and Mapping System at the Heart Rhythm Society’s 38th Annual Scientific Sessions from May 10-12 in Chicago, IL.

FDA Clearance
The clearance of AcQGuide marks the first U.S. regulatory milestone for the company. The AcQGuide Steerable Sheath is a percutaneous catheter introducer designed to provide additional maneuverability to catheters that are advanced through the sheath and into the right or left chambers of the heart.

Acutus is currently pursuing FDA clearance for the AcQMap High Resolution Imaging and Mapping System, including the AcQMap 3D Imaging and Mapping Catheter. Both products received CE Mark in May of 2016.

Heart Rhythm Society Meeting Participation
Dr. Stephan Willems of University Heart Center, Hamburg, Germany will present initial results of the international DDRAMATIC SVT study evaluating the AcQMap system in patients with supraventricular tachycardia on May 12 at 2:00pm CT. A total of six additional presentations will be featured at the meeting highlighting the use of ElectroFunctional™ procedures in patients with both atrial fibrillation and supraventricular tachycardia.

“Acutus has seen incredible momentum over the past twelve months with significant clinical and regulatory milestones under our belt,” said Randy Werneth, President and Chief Executive Officer of Acutus. “As we build our differentiated portfolio of products, we are thrilled to have had data accepted for several presentations that underscore the positive impact of our technology. We believe these data and case studies will shed more light on the unmet need AcQMap can fill by offering patient-specific therapy guidance for people with complex arrhythmias.”

Details of Acutus’ oral and poster presentations are as follows:

Date: May 11, 2017
Time: 9:30 AM CT – 12:00 PM CT
Title: “New Insights Into Persistent Atrial Fibrillation with the AcQMap® Dipole Density Mapping System”
Poster Number: C-PO02-68
Presenter: Arian Sultan, M.D., University Heart Center Cologne, Dept. of Electrophysiology, Cologne, Germany
Location: EPicenter, Exhibit Hall

Date: May 11, 2017  
Time: 9:30 AM CT – 12:00 PM CT  
Title: “Feasibility of Using An Intracardiac Mapping and Ultrasound Imaging Catheter to Estimate Left Atrial Volume”  
Poster Number: C-PO02-73  
Presenter: Derrick Chou, PhD., Acutus Medical Inc.  
Location: EPicenter, Exhibit Hall

Date: May 11, 2017  
Time: 2:00 PM CT – 5:00 PM CT  
Title: “First-in-Man Biatrial Dipole Density Mapping of AT Arising during Ablation of Persistent AF: An Iterative Strategy of Electrofunctional Mapping and Ablation”  
Poster Number: C-PO03-70  
Presenter: Rui Shi, M.D., Ph.D., Royal Brompton and Harefield NHS Foundation Trust, London, United Kingdom  
Location: EPicenter, Exhibit Hall

Date: May 12, 2017  
Time: 2:00 PM CT – 5:00 PM CT  
Title: “Electro-Functional Ablation Procedures: Initial Results from DDRAMATIC SVT”  
Poster Number: C-PO05-71  
Presenter: Stephan Willems, M.D., Ph.D., University Heart Center, Hamburg, Germany  
Location: EPicenter, Exhibit Hall

Date: May 12, 2017  
Time: 2:00 PM CT – 5:00 PM CT  
Title: “Dipole Density Versus Voltage-Based Mapping in Atrial Fibrillation: What Can Be Uncovered?”  
Poster Number: C-PO05-85  
Presenter: Atul Verma, M.D., F.R.H.S., Southlake Regional Health Centre, Newmarket, Ontario, Canada  
Location: EPicenter, Exhibit Hall

Date: May 12, 2017  
Time: 2:45PM CT – 3:00PM CT  
Title: “Use of Novel Global Ultrasound Imaging and Continuous Dipole Density Mapping to Guide Ablation in Macro-Reentrant Tachycardias”  
Session Number: C-AB32-06  
Presenter: Claire Martin, Ph.D., M.R.C.P., Barts Heart Centre, London, United Kingdom  
Location: Room 181
Acus will also be hosting in-booth presentations from management and academic collaborators during the meeting (Booth 1733).

**About AcQMap High Resolution Imaging and Mapping System**
The Acus AcQMap High Resolution Imaging and Mapping System, our diagnostic platform, is a technology that reveals the electrical conduction of the whole heart chamber along with the heart wall motion (functional structure). The AcQMap System utilizes the unique combination of ultrasound to create a CT quality anatomy and non-contact, dipole density propagation maps to visualize previously unmappable complex arrhythmias (AF, Atypical Flutter) without the confounding effects of far field signals. This allows physicians for the first time to see real-time electrical activity within the heart chamber, with the ability to remap in seconds to confirm successful substrate modification via ablation therapy.

Additionally, the company is developing a significantly differentiated ablation technology designed to provide functionality that will further advance and support an electrophysiologist’s desire to produce improved, durable, patient-specific benefits.

**About Acus Medical**
Acus Medical is a company committed to transforming the lives of millions of patients by providing electrophysiologists a highly unique, dual-platform portfolio of breakthrough products that image, diagnose and treat complex arrhythmias. Acus is pioneering ElectroFunctional™ procedures, that provide electrophysiologists a unique ability to establish and execute highly informed, patient-specific treatment strategies for complex cardiac arrhythmias.

Acus Medical is a privately held company located in Carlsbad, CA. To learn more, visit [http://www.acusmedical.com](http://www.acusmedical.com)

The AcQMap High Resolution Imaging and Mapping System is not available for sale in the United States.

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