

Siemens Healthineers Receives CE Mark for the ACUSON AcuNav Volume ICE Catheter

- **Siemens Healthineers AcuNav Volume ICE Catheter is the first 4D ICE catheter to receive a CE Mark.**
- **AcuNav Volume ICE Catheter improves procedural efficiency for Structural Heart procedures due to the potential reduction of general anesthesia as well as scheduling effort, staffing needs, procedural time, and cost.**
- **AcuNav Volume ICE Catheter transforms care delivery by enabling access to Structural Heart procedures for patients with tricuspid regurgitation and other pathologies.**

Siemens Healthineers, a global leader in medical technology, announced today that it has received CE Mark for the AcuNav Volume ICE (Intracardiac Echocardiography) catheter, which is a therapy-enabling imaging guide that provides real-time, wide-angle visualization of heart anatomy during Structural Heart and Electrophysiology procedures. AcuNav Volume ICE is the market's first Volume ICE catheter, developed based on 20 years of innovation history in ICE.

Due to the growth of the world population over the age 65 the number of Structural Heart Disease procedures within this population is rapidly expanding. Serving these patients better and faster requires advanced imaging tools to increase procedural efficiency and image quality. With these challenges in mind, Siemens Healthineers developed 4D Volume ICE catheter technology.

“The AcuNav Volume ICE catheter is a pioneering innovation in Structural Heart Disease. It is a result of Siemens Healthineers’ focus on designing catheters that meet the needs of interventional cardiologists and electrophysiologists for clinical efficiency with reduced scheduling efforts, staffing needs, procedure time and costs”, said Jim Gilmore, Head of Intracardiac Imaging, Siemens Healthineers.

The AcuNav Volume ICE catheter further transforms care delivery by enabling treatment of patients who were not able to previously receive access to Structural Heart procedures. This group includes patients with TOE (transoesophageal echo) or general anesthesia contraindications, as well as some patients suffering from tricuspid regurgitation.

The tricuspid valve can be sufficiently visualized with TOE imaging in only 11% of cases¹. Less than 0.5% of 1.6 Million of patients with moderate or severe tricuspid regurgitation are treated annually².

“Today, we see an increasing focus on the so called “forgotten valve” – the tricuspid valve. Due to the increasing number of repair and replacement devices for the tricuspid valve, imaging guidance for these procedures is getting more important than ever. With the AcuNav Volume ICE catheter, we are able to clearly visualize the tricuspid valve anatomy from the right heart atrium”, said Dr. von Bardeleben, Head of the Center of Structural Heart Disease Interventions and the Heart Valve Center in Mainz, Germany.

“The interest in using 4D Volume ICE came through a patient need”, said Dr. Carlos Sanchez, Ohio Health Riverside Methodist Hospital, USA. “For patients not able to undergo TOE or general anesthesia, we started using 4D ICE for LAAC (Left Atrial Appendage Closure). With 4D Volume ICE you only need one view, and from that view you can reconstruct the whole LAA. Once the device is deployed, you can do all the required measurements to comply with the PASS criteria, which is very important to make this procedure successful”.

Additionally, AcuNav Volume ICE catheter offers potential cost reduction due to reduced cath lab turnaround time and shorter hospital stay, increasing procedural efficiency. Eliminating general anesthesia can cut LAAC procedure and recovery time by 57% compared to TOE³, with potential cost savings of 33%⁴.

The AcuNav Volume ICE catheter is offered exclusively on the ACUSON SC2000 PRIME ultrasound system, a complete Structural Heart Disease solution delivering advanced visualization and AI-powered quantification with 2D and 4D TTE, TOE, ICE and TrueFusion.

**Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

TrueFusion represents a workflow consisting of syngo® TrueFusion (syngo X Workplace) and TrueFusion echo-fluoro guidance (ACUSON SC2000 PRIME).

¹ Rodés-Cabau J, et al. J Am Coll Cardiol. 2016;67:1829-45

² Sugeng L, et al. J Am Coll Cardiol. 2008 Aug 5;52(6):446-9

³ JACC: Cardiovascular Interventions Vol. 10, No.21, 2017

⁴ November 13, 2017:2198-206 3. Amin, A. et al. Heart Rhythm, Vol. 16, No. 5, May Supplement 2019

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Siemens Healthineers AG (listed in Frankfurt, Germany: SHL) is shaping the future of healthcare. As a leading medical technology company headquartered in Erlangen, Germany, Siemens Healthineers enables healthcare providers worldwide through its regional companies to increase value by empowering them on their journey towards expanding precision medicine, transforming care delivery, improving the patient experience, and digitalizing healthcare. Siemens Healthineers is continuously developing its product and service portfolio, with AI-supported applications and digital offerings that play an increasingly important role in the next generation of medical technology. These new applications will enhance the company's foundation in in-vitro diagnostics, image-guided therapy, in-vivo diagnostics, and innovative cancer care. Siemens Healthineers also provides a range of services and solutions to enhance healthcare providers' ability to provide high-quality, efficient care to patients. In fiscal 2020, which ended on September 30, 2020, Siemens Healthineers generated revenue of €14.5 billion and adjusted EBIT of €2.2 billion. Following the acquisition of Varian Medical Systems, Inc. the company has approximately 66,000 employees worldwide. Further information is available at www.siemens-healthineers.com.