

**EMBARGOED FOR RELEASE UNTIL FRIDAY, JULY 30, 2021, 1:45 P.M.**

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**LATE-BREAKING CLINICAL TRIAL RESULTS ANNOUNCED  
AT HEART RHYTHM 2021:**

**FIRST IN-HUMAN RESULTS REVEAL NOVEL ICE CATHETER PROVIDES ENHANCED  
VISUALIZATION DURING ATRIAL FIBRILLATION PROCEDURES**

*4-Dimension Imaging Helps Operators Better Understand Patient Anatomy*

**BOSTON, MA., July 30, 2021** – Findings from a new, multi-center clinical trial reveal a novel 4-Dimension (4D) ICE catheter provides a simple, intuitive field of view during catheter ablation and left atrial appendage closure procedures. The results from the first in-human clinical study were presented as a late-breaking clinical trial as part of Heart Rhythm 2021.

Atrial fibrillation increases the risk of stroke, as it can cause blood to pool in the heart and clot – specifically in the upper left chamber. For eligible patients with blood clots in their left atrial appendage (LAA), left atrial procedures are conducted to close off the appendage when medications are ineffective. Currently, most of these procedures are guided by 2-dimensional ultrasound to view the patient’s anatomy. The new 4D catheter (NuVision, Biosense Webster Inc.) is designed to allow multiplanar visualization of target cardiac structures with intuitive, minimal catheter manipulation.

The prospective, non-randomized, multicenter study evaluated the diagnostic value of the 4D ICE catheter during left atrial procedures in 28 patients. Nine operators at two European clinical sites used the 4D ICE catheter to guide either LAA closure (2 patients; one each - Watchman-Flx and Amulet) or catheter ablation of AF (8 cryoballoon patients; 12 radiofrequency ablation patients) or other arrhythmias (6 patients). Patients enrolled were aged 44-74 and 75% were male. The primary and secondary safety endpoints were absent of unanticipated adverse events (AE) or ICE-procedure/device related AEs, and all device-related AEs. Primary and secondary performance endpoints included the device’s ability to provide adequate imaging to complete the procedure.

The findings show the 4D ICE catheter met all safety and performance endpoints in all patients – suggesting the device is a safe and effective visualization tool for a variety of electrophysiology procedures using multiplanar imaging. The catheter effectively guided transeptal puncture to create a small transeptal passage in all attempts. In the majority of patients (82%), operators rated image quality and catheter performance as very good.

“Our data support a growing shift in the electrophysiology field toward multiplanar imaging catheters that can offer operators a clearer look at a patient’s heart and enhance their field of view when performing life-saving procedures,” said Vivek Y. Reddy, MD, Director of Cardiac Arrhythmia Services for The Mount Sinai Hospital and lead author of the study. “For patients, this technology provides the most comprehensive look at their heart, helping to ensure their physician can provide optimal outcomes.”

The authors note that the 4D ICE catheter is FDA approved and further studies are necessary to understand the optimal way to use the device.

**Sessions Details:**

“Late-Breaking Clinical Trials 4: *First-in-human Clinical Experience With A Novel 4d Ice Catheter During Catheter Ablation And LAA Closure Procedures*” [Friday, July 30, 2021 at 2:30 p.m. EST]

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About Heart Rhythm 2021

The Heart Rhythm Society's annual meeting attracts thousands of the world's finest clinicians, scientists, researchers, and innovators in the field of cardiac pacing and electrophysiology. Heart Rhythm 2021 attendees were able to determine how to participate - virtually or in-person. More than 600 international experts in the field will serve as faculty for programming that includes Daily Plenary Sessions, Late-Breaking Clinical Trials, Recorded Cases, Debates, Rhythm Theater Presentations and more, while over 100 exhibitors will showcase innovative products and services.

About the Heart Rhythm Society

The Heart Rhythm Society is the international leader in science, education, and advocacy for cardiac arrhythmia professionals and patients and is the primary information resource on heart rhythm disorders. Its mission is to improve the care of patients by promoting research, education, and optimal health care policies and standards. Incorporated in 1979 and based in Washington, D.C., it has a membership of more than 7,000 heart rhythm professionals in more than 90 countries around the world. For more information, visit [www.HRSONline.org](http://www.HRSONline.org).