



## **FIRST-IN-HUMAN EXPERIENCE WITH REAL-TIME 4D HOLOGRAPHIC THERAPY GUIDANCE AS AN INTRAPROCEDURAL TOOL FOR STRUCTURAL HEART INTERVENTIONS**

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### **Introduction:**

Standard of care for left atrial appendage occlusion (LAAO) with the Watchman™ FLX (Boston Scientific, Marlborough, MA) relies on 2D imaging modalities such as fluoroscopy and echocardiography. These imaging modalities have limitations in accurately depicting the spatial relationships of devices and cardiac structures, imaging complex anatomies, and analyzing device apposition and performance post deployment. EchoPixel (EchoPixel, Inc., Santa Clara, CA) Holographic Therapy Guidance (4D EP-HTG) is a novel imaging tool that attempts to resolve these limitations by providing interactive and real-time 4D holographic images of cardiac anatomy and devices. Here we describe the first-in-human experience with 4D EP-HTG (EchoPixel, Inc., Santa Clara, CA) for the intraprocedural guidance of a Watchman™ FLX implant.

### **Methods:**

This is an observational, single center, feasibility study conducted at one investigational center. A patient with persistent atrial fibrillation underwent LAAO with Watchman™ FLX utilizing 4D EP-HTG in addition to standard of care imaging. Throughout the LAAO procedure, 4D Transesophageal echocardiography (TEE) images were acquired by a Vivid E95 Cardiac Ultrasound (General Electric Company, Boston, MA) and streamed to the 4D EP-HTG system and displayed in real-time. 4D EP-HTG was the primary imaging modality used in multiple steps of the procedure including transeptal crossing, advancement of catheters into the left atrial appendage (LAA), device deployment, device interrogation, and device release. Baseline patient characteristics, procedural details, and procedural outcomes were recorded and analyzed.

### **Results:**

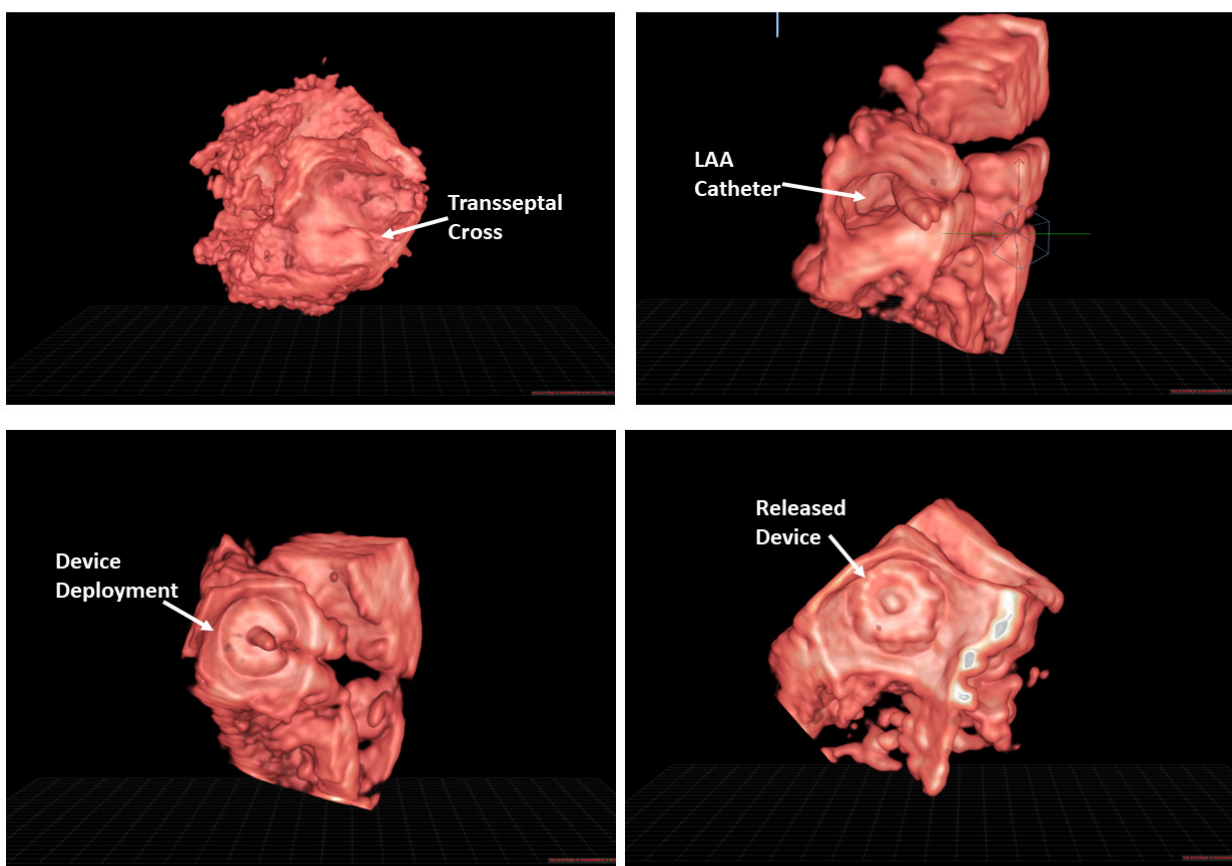
4D EP-HTG was successfully used to guide a Watchman™ FLX implant. The procedure was performed with conscious sedation. Total length of the procedure was 26 minutes with the use of only 15mL of contrast dye and 198 mGy of radiation. There were no procedural complications and the patient was discharged from the hospital 6 hours post procedure. 4D EP-HTG was



utilized during transeptal crossing, LAA access, device deployment and in the final assessment of the device post implant (see image 1). At 45 days post LAAO, CT imaging identified the device to be well seated without evidence of thrombus or leak. Anticoagulation was discontinued and the patient was placed on dual antiplatelet therapy, as per standard of care. At the time of this abstract, there have been no reported complications.

**Conclusions:**

In this first-in-human experience, 4D EP-HTG demonstrated technical success and was used safely to image and interact with intracardiac structures to guide a Watchman™ FLX implant. The 4D EP-HTG system was used throughout the procedure to guide key steps including transeptal crossing, LAA access, device deployment, and the final assessment of the device prior to- and post-release. In conclusion, 4D EP-HTG imaging provides enhanced, real-time, 4D holographic imaging of cardiac structures and devices, which may ultimately improve outcomes in structural heart interventions.



**Image 1:** Example of 4D EP-HTG images acquired during the procedure