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Medtronic's Next-Gen Evolut™ FX TAVR System Shows Significant Improvement in Commissure Alignment in Real World Setting

London Valves 2022: Latest Transcatheter Aortic Valve Replacement Data for Treatment of Aortic Stenosis and Prosthetic Aortic Valve Degeneration

Medtronic's newest generation self-expanding, transcatheter aortic valve replacement (TAVR) system, Evolut™ FX, significantly improved commissure alignment during TAVR procedures compared to earlier generation Evolut systems. A late breaker presentation at PCR London Valves 2022 summarized the early limited market release experience with the Evolut FX system in 168 patients from six US centers. Additionally, these data were compared to 378 Evolut PRO+ patients from a single center.

Commissure alignment during TAVR procedures is a key factor for easier future coronary access, improved coronary blood flow and valve hemodynamic performance, and may facilitate redo-TAVR in the future.[i] The next-generation Evolut FX system is refined with key enhancements including gold markers built into the frame to facilitate visualization of implant depth and valve commissure location during TAVR procedures. The system also employs a redesigned delivery system for greater trackability and flexibility during valve deployment.

"In this early experience the Evolut FX system provided several enhancements over the PRO+ system not only because of its easier trackability, but more importantly achieving a more symmetric deployment on release and improved commissural alignment with reduced coronary overlap. These features resulting in better procedural predictability and consistency in TAVR may be critical in low risk patients and broaden the adoption of TAVR to a wider population" said Gilbert Tang, MD, MSc, MBA., Surgical Director of the Structural Heart Program at Mount Sinai Health System, Professor in the Department of Cardiovascular Surgery at the Icahn School of Medicine at Mount Sinai and Principal Investigator. "By looking closely at data across multiple centers, we're able to demonstrate the procedural improvements of the FX system over its predecessors."

In the multicenter retrospective analysis of 168 patients across six U.S. centers (89% treated for symptomatic, severe native aortic stenosis and 11% for prosthetic valve degeneration), commissural alignment was achieved in 95.8% of Evolut FX cases. The 30-day rates of death and stroke were 1.2% and 1.8%, respectively. Preliminary data of the Evolut FX system also showed low rates of mild (13.2%) and no moderate or severe paravalvular leak (PVL) 30 days after the procedure, with excellent hemodynamic performance similar to earlier generation CoreValve and Evolut devices.

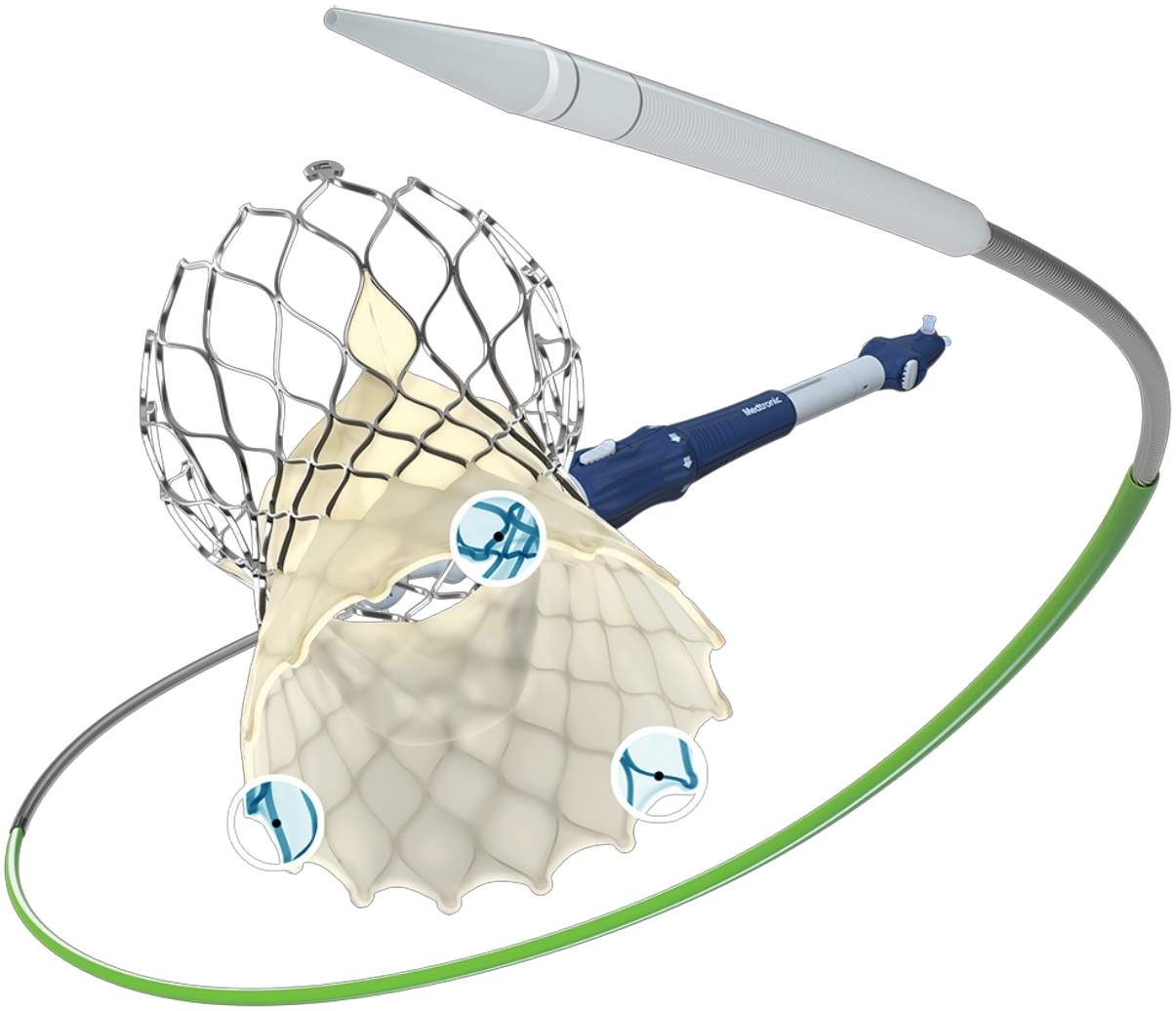
In addition to improved commissural alignment with the Evolut FX system, the findings demonstrated reduced device recapture rates and more symmetric implant depths upon release, making the TAVR procedure with the FX platform simpler and more predictable than earlier generation systems in this early experience.

"This is an exciting milestone in the treatment of aortic stenosis," said Jeffrey Popma, M.D., vice president and chief medical officer for the Structural Heart & Aortic business, which is part of the Cardiovascular Portfolio at Medtronic. "These continued innovations will provide physicians with the key enhancements needed to improve precision and clinical experience. The preliminary real-world results from the Evolut FX system deliver on our goal to further enhance our TAVR platform to improve physician experience and optimize outcomes for patients."

Aortic stenosis is a heart condition that occurs when the aortic valve narrows, preventing it from properly opening and closing, and causing the heart to work harder to pump blood to the rest of the body. This increased pressure within the heart causes the heart to weaken and function poorly. Severe aortic stenosis is a life-threatening condition that affects 3.4% of elderly people worldwide.[ii] As many as 50% of aortic stenosis patients with severe symptoms may die within one year without appropriate treatment.[iii]

About Evolut™ FX

The Evolut FX system, the fourth generation of the Medtronic's TAVR platform, received FDA approval in 2021 and further refines the trusted Evolut platform with key enhancements that make the self-expanding system easier to use. The system is equipped with gold markers built into the frame to provide implanters with direct visualization of depth and commissure alignment during the implant. Additionally, the newest iteration of the device incorporates a redesigned catheter tip for a smoother insertion profile, a more flexible delivery system allowing for 360-degree freedom of motion with stable, predictable deployment.



About Medtronic

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https://news.medtronic.com/Medtronics-Next-Gen-Evolut-TM-FX-TAVR-System-Shows-Significant-Improvement-in-Commissure-Alignment-in-Real-World-Setting