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New Medtronic Mosaic Neo™ mitral bioprosthesis sees rapid adoption with successful implants across major US hospitals following FDA approval

Next generation mitral valve, designed to facilitate patient lifetime management and setting new benchmark for ease of use in small incision surgery1-3 reports first uses in sternotomy, Minimally Invasive Cardiac Surgery (MICS) and robotic cases

Medtronic plc, a global leader in healthcare technology, received U.S. Food and Drug Administration (FDA) approval for its Mosaic Neo™ mitral bioprosthesis and has launched the valve in the U.S. This approval marks an important milestone for patients and clinicians.

The Mosaic Neo mitral bioprosthesis is thoughtfully designed to be implanted through sternotomy, Minimally Invasive Cardiac Surgery (MICS), and robotic access, all of which were recently used when initial implants were performed at numerous prominent centers across the United States, including The Mount Sinai Hospital New York, where David H. Adams, M.D., implanted the first Mosaic Neo mitral valves worldwide.

Simultaneously, the first concomitant use of the Mosaic Neo mitral valve and the recently introduced Penditure™ Left Atrial Appendage (LAA) Exclusion System was performed by Gorav Ailawadi, M.D., Director, University of Michigan Health Frankel Cardiovascular Center, Helen F. and Marvin M. Kirsh Professor of Cardiac Surgery, University of Michigan, Ann Arbor, Michigan.

The first robotic implantation of the Mosaic Neo mitral valve was performed by Vinay Badhwar, M.D., and Executive Chair of the West Virginia University (WVU) Heart and Vascular Institute. The Mosaic Neo mitral valve will be officially launched at the American Association for Thoracic Surgeons (AATS) 106th Annual Meeting in Chicago on May 2-5, 2026.

“The Mosaic Neo mitral valve builds on the prior Mosaic platform, and the new intuitive sizers, strut suspension system, valve holder, and sewing cuff are all noticeable improvements,” said David H. Adams, M.D., Marie-Josée and Henry R. Kravis Professor and System Chairman of the Department of Cardiovascular Surgery, Icahn School of Medicine at Mount Sinai Hospital.

The Mosaic Neo mitral valve uniquely combines enhanced user experience, excellent hemodynamics, and unsurpassed, industry-leading durability as demonstrated by the Mosaic mitral valve.[4-8] To facilitate patient

lifetime management, the Mosaic Neo mitral valve combines a reduced left ventricular stent post protrusion, a unique wide anterior distance between the stent posts, intuitive orientation markers and improved visualization under fluoroscopy to enable Left Ventricular Outflow Tract (LVOT) clearance and preservation of the neo-LVOT.[†2,3,9-13]

"I was very pleased with the implantation of the Mosaic Neo valve," said Douglas R. Johnston, M.D., Chief of Cardiac Surgery at Northwestern Medicine Bluhm Cardiovascular Institute. "The reduced stent post protrusion and the wide distance between the anterior stent posts, combined with a very conformable sewing cuff, make the Mosaic Neo a favorable choice for the often challenging annular and LVOT anatomy we see currently in mitral valve replacement patients. With the proven durability of the Mosaic Mitral platform, the design enhancements of Mosaic Neo bring a much-needed option to the landscape of mitral valve replacement surgery." With new features such as a low-profile valve holder and first-to-market small incision sizers, this next-generation device features innovative, surgeon-inspired enhancements specifically designed to improve ease-of-use both during open and minimally invasive surgery.[2]

"Not all valves are user-friendly for MICS cases, but our initial experience with the Mosaic Neo valve was very positive," said Joseph Lamelas, M.D., Director of Center for Minimally Invasive Heart Surgery at NCH Rooney Heart Institute. "It has a very low implant profile for minimally-invasive surgery and features the Cinch mechanism for full stent post deflection. As a minimally-invasive surgeon, I am pleased that we can now offer the Mosaic Neo mitral valve to our patients."

By providing a best-in-class implant profile, the Mosaic Neo mitral valve helps facilitate the MICS procedures patients are actively requesting.[‡,14-16] Almost 20,000 patients undergo surgical mitral valve replacement in the U.S. every year. Many of those also undergo concomitant procedures such as Left Atrial Appendage (LAA) Exclusion, a procedure for which Medtronic has launched the Penditure™ LAA Exclusion System in 2024. With these latest innovations, in addition to a comprehensive valve repair portfolio, Medtronic offers a broad range of solutions for patients with mitral valve disease.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic, visit www.Medtronic.com and follow Medtronic on LinkedIn.

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Contacts:
Becky Dvorak
Communications
becky.j.dvorak@medtronic.com

Ingrid Goldberg
Investor Relations
Ingrid.goldberg@medtronic.com

Disclaimer: Dr. David Adams, Dr. Gorav Ailawadi, Dr. Vinay Badhwar, Dr. Douglas Johnston, and Dr. Joseph Lamelas were not compensated for their quotes or input in this media alert.

Disclosures: Dr. Gorav Ailawadi has a paid relationship with Medtronic.

Dr. Adams is the inventor of the Medtronic Tri-Ad™ Adams Tricuspid Annuloplasty Ring, National Co-Principal Investigator of the FDA Medtronic-CoreValve Pivotal Trial and National Co-Principal Investigator of the FDA Medtronic APOLLO Pivotal Trial.

References:
† The benefits of the Mosaic Neo valve atrialized design have been demonstrated through bench testing. No direct clinical evaluation in humans has been conducted.
‡ Dimensional measurements taken with Mosaic Neo valve size 29, Epic™* Plus size 29, MITRIS™* size 27 based on OD comparability.

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