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# Medtronic relaunches first-of-its-kind transcatheter pulmonary valve replacement system for congenital heart disease

Harmony™ Transcatheter Pulmonary Valve System is the first FDA-approved minimally invasive valve designed for the right side of the heart





Medtronic today announced the relaunch of its Harmony™ Transcatheter Pulmonary Valve (TPV) System, a minimally invasive alternative to open-heart surgery for congenital heart disease patients with native or surgically repaired right ventricular outflow tract (RVOT).

Congenital heart disease (CHD) is the most common type of birth defect in the United States, affecting an estimated 40,000 infants each year<sup>[1]</sup> and 1.6 million who live with the disease<sup>[2]</sup>. Approximately one in five patients born with CHD have structural malformations that disrupt the connection between the heart and the lungs<sup>[3]</sup>, or the RVOT. The current standard of care is open-heart surgery or other interventions early in life to address these malformations. For the 80% of CHD patients who require a native or surgically repaired RVOT at birth, many will need a pulmonary valve replacement later in life, which often requires another open-heart surgery.

Harmony TPV was designed to treat patients with RVOT anomalies who develop severe pulmonary valve regurgitation, a condition where blood leaks back into the right lower chamber of the heart after being pumped into the lungs. The Harmony TPV provides these patients with a minimally invasive alternative.

“For congenital heart disease patients with severe pulmonary valve regurgitation, utilizing a valve that works with their anatomy is key to preventing risks such as right-sided heart failure, and optimizing outcomes while minimizing the disruption to their lives,” said Matthew J. Gillespie, M.D., Director of Interventional Cardiology and Co-Director of the Valve Center at Children’s Hospital of Philadelphia. “I am pleased to be able to once again offer Harmony TPV as an option to patients who require pulmonary valve replacement.

The Harmony TPV System received U.S. FDA approval in 2021 based on the Harmony TPV clinical study that demonstrated safety and effectiveness up to 6 months with no significant reinterventions.

Medtronic initiated a voluntary recall of the Harmony Delivery Catheter System (DCS) in March 2022 due to six reported cases of the bond holding the capsule at the end of the delivery catheter breaking. Medtronic worked collaboratively with the FDA to remediate the issue and earn FDA approval to return the device to market.

“The relaunch of Harmony TPV underscores our continued commitment to advancing solutions for all people who experience heart disease, and we are proud to be driving innovation forward by offering the first non-surgical solution designed for congenital heart disease patients with severe pulmonary valve regurgitation,” said Nina Goodheart, SVP and President of the Structural Heart & Aortic business at Medtronic. “

The Harmony TPV device is now commercially available for use in the United States and has received regulatory approval in Japan.

#### **About Medtronic**

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, 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 90,000+ 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 (NYSE:MDT), visit [www.Medtronic.com](http://www.Medtronic.com) and follow [@Medtronic](https://twitter.com/Medtronic) on Twitter and [Linkedln](https://www.linkedin.com/company/medtronic).

**Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.**

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[1] Hoffman JL, Kaplan S. The incidence of congenital heart disease. *J Am Coll Cardiol.* 2002;39(12):1890-1900.

<sup>[2]</sup> Adult Congenital Heart Association (ACHA).

<sup>[3]</sup> McElhinney DB, Hennesen JT. The Melody<sup>®</sup> valve and Ensemble<sup>®</sup> delivery system for transcatheter pulmonary valve replacement. *Ann NY Acad Sci.* 2013; 1291: 77-85.

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