



Medtronic

Harmony™  
Transcatheter Pulmonary Valve System

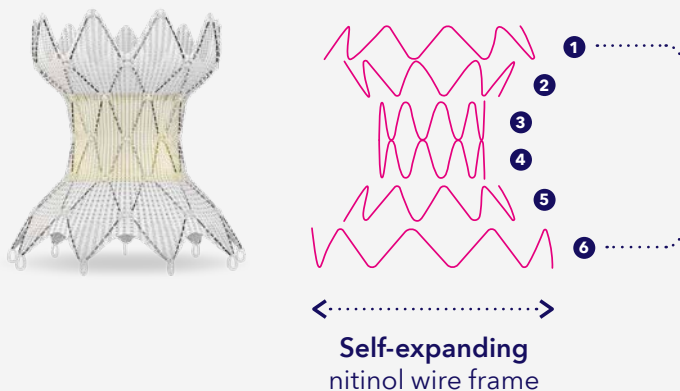
Right valve.  
Right heart.  
**Right choice.**

# Designed for the RVOT. Made to conform.

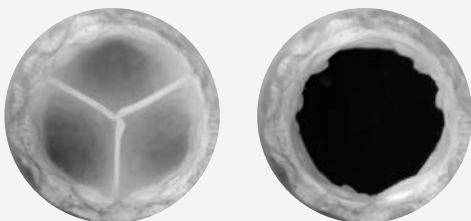
The Harmony transcatheter pulmonary valve (TPV) is designed to treat a wide range of anatomies in patients with severe pulmonary regurgitation who have a native or surgically repaired RVOT.

## Valve and system overview

- 1 One step, 25 Fr fully sheathed delivery system is **highly trackable** through the vasculature.<sup>1</sup>
- 2 The Harmony TPV is constructed of a self-expanding nitinol frame made up of six **individual** wire struts, designed to **conform** to the native RVOT anatomy.<sup>†,‡,2-6</sup>



- 3 Porcine pericardial leaflets provide **excellent kinematics** across the full range of pressures of the right heart. The leaflets have been treated with the alpha-amino oleic acid (AOA™) to mitigate calcification.<sup>§,3,4</sup>



<sup>†</sup> Bench testing may not be indicative of clinical performance.

<sup>‡</sup> N = 89. In those whom an implant was attempted.

<sup>§</sup> The benefits of AOA tissue treatment have been demonstrated through animal testing. No direct clinical evaluation of the benefits of AOA treatment in humans has been conducted. Medtronic data on file (10035596DOC).



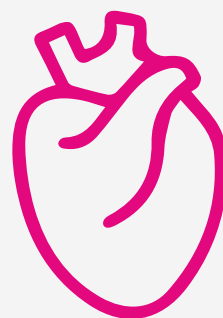
# Easy loading. Easy deployment.

Thanks to its innovative coil system and highly trackable delivery system, the pre-procedure steps are simple.<sup>1</sup>

- A single deployment system delivers both valve sizes Harmony TPV 22 and Harmony TPV 25.
- The coil system facilitates loading and maintains the valve prosthesis during deployment until final release.

Over time,  
**Harmony TPV**  
demonstrates positive  
right ventricle (RV)  
remodeling and  
sustains improvement  
of quality of life.<sup>7</sup>

View Harmony TPV  
midterm data.



Harmony TPV risks may include, but are not limited to, nonsustained ventricular tachycardia, premature ventricular contraction, minor paravalvular leak, stenosis, and migration of the TPV.



1. Medtronic data on file. Harmony System Human Factors Engineering Master Report - D00244206. Bench testing may not be representative of clinical performance. Bench testing performed in simulated anatomical fixture.
2. Medtronic data on file. DV COF reports: D00053571 (TPV 25) and D00260135 (TPV 22). Bench testing performed in simulated anatomical fixture.
3. Medtronic data on file. Design Verification Test Report for Hydrodynamic Performance of Harmony Modified TPV 25 – D00064319. Bench testing performed in a non-anatomical test fixture.
4. Medtronic data on file. Design Verification Test Report for Harmony TPV 22 Hydrodynamic Performance – D00266155. Bench testing performed in a non-anatomical test fixture.
5. Medtronic data on file. PVL reports: 10790377DOC (TPV 25) and D00169229 (TPV 22). Bench testing performed in simulated anatomical fixture.
6. Medtronic data on file. Migration report for both sizes: D00999234. Bench testing performed in simulated anatomical fixture.
7. Morray BH. Midterm Outcomes in an Expanded Cohort of Harmony Transcatheter Pulmonary Valve Recipients. Presented at: SCAI 2024 Scientific Sessions, May 2-4, Long Beach, CA.

## Indications

The Harmony™ transcatheter pulmonary valve (TPV) system is indicated for use in the management of pediatric and adult patients with severe pulmonary regurgitation (i.e., severe pulmonary regurgitation as determined by echocardiography and/or pulmonary regurgitant fraction  $\geq 30\%$  as determined by cardiac magnetic resonance imaging) who have a native or surgically-repaired right ventricular outflow tract and are clinically indicated for surgical pulmonary valve replacement.

## Contraindications

The following are contraindications for the use of this device: active bacterial endocarditis or other active infections, known intolerance to Nitinol (titanium or nickel), or an anticoagulation/antiplatelet regimen.

## Warnings

**General:** Implantation of the Harmony TPV system should be performed only by physicians who have received Harmony TPV system training. The transcatheter pulmonary valve (TPV) is to be used only in conjunction with the Harmony delivery catheter system (DCS). This procedure should only be performed where emergency pulmonary valve surgery can be performed promptly. Do not use any of the Harmony TPV system components if any of the following has occurred: it has been dropped, damaged, or mishandled in any way, or if the use-by date has elapsed.

**Transcatheter pulmonary valve (TPV):** This device was designed for single use only.

Do not reuse, reprocess, or resterilize the TPV. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death. Do not resterilize the TPV by any method. Exposure of the device and container to irradiation, steam, ethylene oxide, or other chemical sterilants renders the device unfit for use. The device is packaged with a temperature sensor. Do not freeze the device. Do not expose the device to extreme temperatures. Do not use the device if the arrow on the sensor points to the symbol that indicates that the temperature limit has been exceeded. Do not use the device if any of the following have occurred: the tamper-evident seal is broken, the serial number tag does not match the container label, the arrow on the sensor points to the symbol that indicates that the temperature limit has been exceeded, or the device is not completely covered by the storage solution. Do not contact any of the Harmony TPV system components with cotton or cotton swabs. Do not expose any of the Harmony TPV system components to organic solvents, such as alcohol. Do not introduce air into the catheter. Do not expose the device to solutions other than the storage and rinse solutions. Do not add or apply antibiotics to the device, the storage solution, or the rinse solution. Do not allow the device to dry. Maintain tissue moisture with irrigation or immersion. Do not attempt to repair a damaged device. Do not handle the valve leaflet tissue or use forceps to manipulate the valve leaflet tissue. Do not attempt to recapture the device once deployment has begun. Do not attempt to retrieve the TPV if any one of the outflow TPV struts is protruding from the capsule. If any one of the outflow TPV struts has deployed from the capsule, the TPV must be released from the catheter before the catheter can be withdrawn. Do not attempt post-implant balloon dilatation (PID) of the TPV during the procedure, which may cause damage to or failure of the TPV leading to injury to the patient resulting in reintervention.

**Delivery catheter system (DCS):** This device was designed for single use only. Do not reuse, reprocess, or resterilize the DCS. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death. Do not reuse or resterilize the DCS. If resistance is met, do not advance the guidewire, DCS, or any other component without first determining the cause and taking remedial action. Do not remove the guidewire from the DCS at any time during the procedure.

## Precautions

**General:** Clinical long-term durability has not been established for the Harmony TPV. Evaluate the TPV performance as needed during patient follow-up. The safety and effectiveness of Harmony TPV implantation in patients with pre-existing prosthetic heart valve or prosthetic ring in any position has not been demonstrated. The Harmony TPV system has not been studied in female patients of child-bearing potential with positive pregnancy.

**Before use:** Exposure to glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to the chemical vapor. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water (for a minimum of 15 minutes) and seek medical attention immediately. The TPV and the glutaraldehyde storage solution are sterile. The outside of the TPV container is nonsterile and must not be placed in the sterile field. The TPV and DCS should be used only in a sterile catheterization laboratory (cath lab) environment. Ensure that sterile technique is used at all times. Strictly follow the TPV rinsing procedure. For TPV 25: Ensure that all green sutures have been removed from the attachment suture loops on the TPV before loading onto the DCS. Prevent contamination of the TPV, its storage solution, and the DCS with glove

powder. Verify the orientation of the TPV before loading it onto the DCS. The inflow end of the TPV with attachment suture loops must be loaded first. Do not place excessive pressure on the TPV during loading. Inspect the sealed DCS packaging before opening. If the seal is broken or the packaging has been damaged, sterility cannot be assured. Proper functioning of the DCS depends on its integrity. Use caution when handling the DCS. Damage may result from kinking, stretching, or forceful wiping of the DCS. This DCS is not recommended to be used for pressure measurement or delivery of fluids. Carefully flush the DCS and maintain tight DCS connections to avoid the introduction of air bubbles.

**During use:** The TPV segment is rigid and may make navigation through vessels difficult. Do not advance any portion of the DCS under resistance. Identify the cause of resistance using fluoroscopy and take appropriate action to remedy the problem before continuing to advance the DCS. Careful management of the guidewire is recommended to avoid dislodgement of the TPV during DCS removal. Once deployment is initiated, retrieval of the TPV from the patient is not recommended. Retrieval of a partially deployed valve may cause mechanical failure of the delivery catheter system or may cause injury to the patient. Refer to the section below for a list of potential adverse events associated with Harmony TPV implantation. During deployment, the DCS can be advanced or withdrawn prior to the outflow struts protruding from the capsule. Once the TPV struts contact the anatomy during deployment, it is not recommended to reposition the device. Advancing the catheter forward once the TPV struts make contact with the anatomy may lead to an undesired deployment or may cause damage to or failure of the TPV and injury to the patient. Refer to the section below for a list of potential adverse events associated with the Harmony TPV implantation. Physicians should use judgment when considering repositioning of the TPV (for example, using a snare or forceps) once deployment is complete. Repositioning the bioprosthesis is not recommended, except in cases where imminent serious harm or death is possible (for example, occlusion of the main, left, or right pulmonary artery). Repositioning of a deployed valve may cause damage to or failure of the TPV and injury to the patient. Refer to the section below for a list of potential adverse events associated with the Harmony TPV implantation. Ensure the capsule is closed before DCS removal. If increased resistance is encountered when removing the DCS through the introducer sheath, do not force passage. Increased resistance may indicate a problem and forced passage may result in damage to the device and harm to the patient. If the cause of resistance cannot be determined or corrected, remove the DCS and introducer sheath as a single unit over the guidewire, and inspect the DCS and confirm that it is complete. If there is a risk of coronary artery compression, assess the risk and take the necessary precautions. Endocarditis is a potential adverse event associated with all bioprosthetic valves. Patients should make their healthcare providers aware that they have a bioprosthetic valve before any procedure. Post-procedure, administer appropriate antibiotic prophylaxis as needed for patients at risk for prosthetic valve infection and endocarditis. Prophylactic antibiotic therapy is recommended for patients receiving a TPV before undergoing dental procedures. Post-procedure, administer anticoagulation and/or antiplatelet therapy per physician/clinical judgment and/or institutional protocol. Excessive contrast media may cause renal failure. Preprocedure, measure the patient's creatinine level. During the procedure, monitor contrast media usage. Conduct the procedure under fluoroscopy. Fluoroscopic procedures are associated with the risk of radiation damage to the skin, which may be painful, disfiguring, and long term.

## Potential Adverse Events

Potential risks associated with the implantation of the Harmony TPV may include, but are not limited to, the following: • death • valve dysfunction • tissue deterioration • hematoma • heart failure • cerebrovascular incident • perforation • rupture of the right ventricular outflow tract (RVOT) • compression of the aortic root • compression of the coronary arteries • sepsis • pseudoaneurysm • erosion • stent fracture • arrhythmias • device embolization or migration • pulmonary embolism • occlusion of a pulmonary artery • laceration or rupture of blood vessels • device misorientation or misplacement • valve deterioration • regurgitation through an incompetent valve • physical or chemical implant deterioration • paravalvular leak • valve dysfunction leading to hemodynamic compromise • residual or increasing transvalvular gradients • progressive stenosis and obstruction of the implant • hemorrhage • endocarditis • thromboembolism • thrombosis • thrombus • intrinsic and extrinsic calcification • bleeding • bleeding diathesis due to anticoagulant use • fever • pain at the catheterization site • allergic reaction to contrast agents • infection • progressive pulmonary hypertension • progressive neointimal thickening and peeling • leaflet thickening • hemolysis. General surgical risks applicable to transcatheter pulmonary valve implantation: • abnormal lab values (including electrolyte imbalance and elevated creatinine) • allergic reaction to antiplatelet agents, contrast medium, or anesthesia • exposure to radiation through fluoroscopy and angiography • permanent disability.

Please reference the Harmony TPV system instructions for use for more information regarding indications, warnings, precautions, and potential adverse events.

**Caution:** Federal law (USA) restricts these devices to the sale by or on the order of a physician.

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