

Medtronic

Harmony™

Transcatheter Pulmonary Valve System

Harmony in every beat

Right valve.
Right heart.
Right choice.



In tune with your patients' needs

Every CHD patient is anatomically unique so matching them to the right treatment is key.

Harmony™ is the transcatheter valve system that treats severe pulmonary regurgitation. It offers a minimally invasive option for your patients, reducing complications.

Adaptable care, amplifying life

This innovative device – with a one-step delivery system – conforms to the native RVOT, minimising force and ensuring a stable seal. It works in harmony with your patient's heart in three ways:

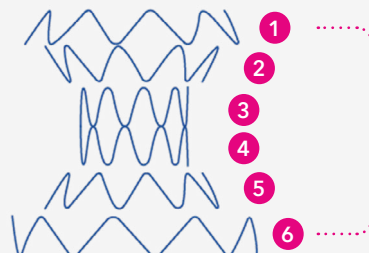
1

Fully sheathed delivery system is highly trackable through the vasculature.¹

2

Each row **conforms** to the dynamic anatomy while minimising impact to other struts^{†2,4} and surrounding structures.^{††2,5}

Maintains **stability** and seal^{††2,5,6} while minimising force to varying sized anatomies.^{††2,6}



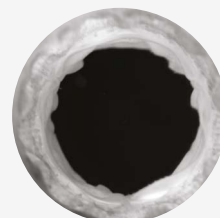
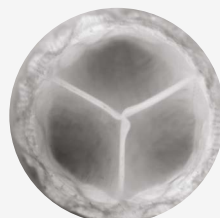
Six **independent** wire struts with sutures hand sewn to polyester fabric



Self-expanding
nitinol wire frame

3

AOA-treated porcine pericardial valve provides excellent leaflet kinematics across the full range (particularly under the low pressure and low flow) of conditions of the right heart.^{3,4}

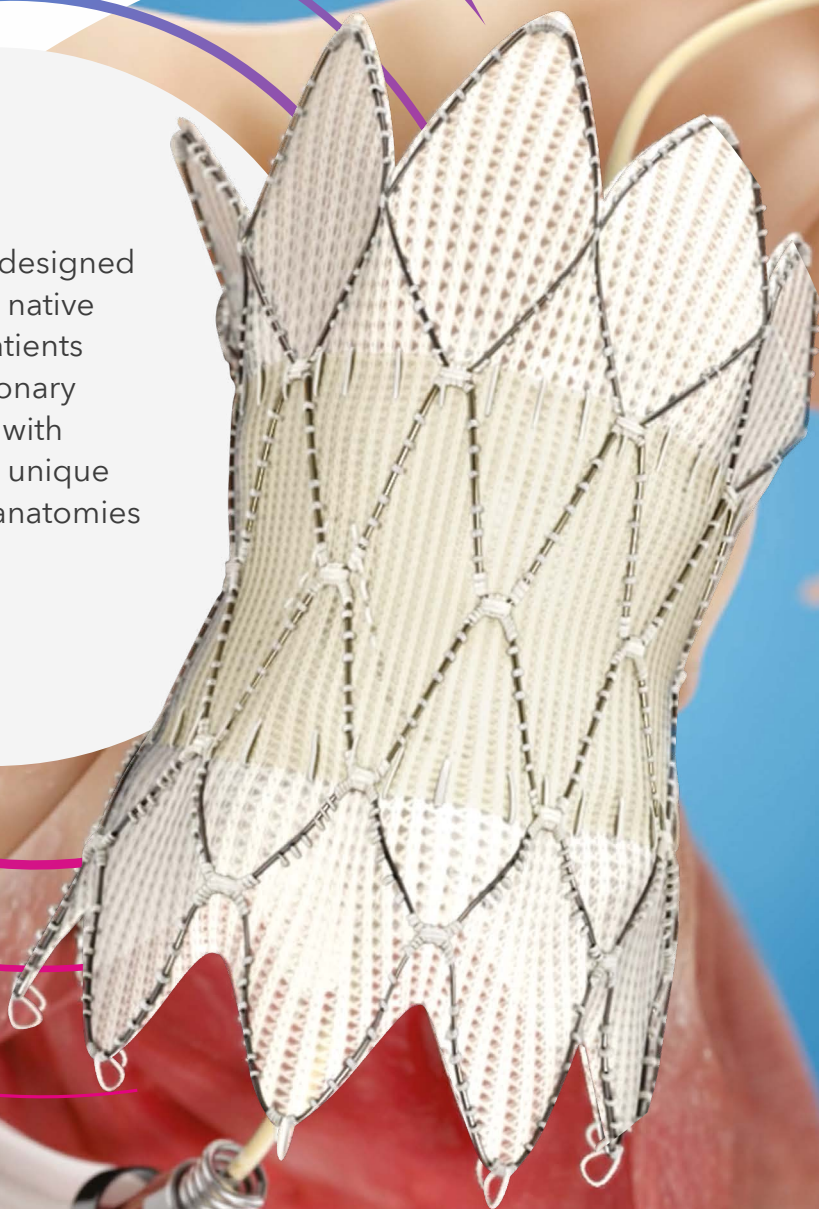


Simplify care, amplify life

**Easy loading and easy deployment of Harmony™
is excellence simplified.**

Thanks to its innovative funnel design and highly trackable
delivery system the pre-procedure steps are short.

Harmony™ TPV is designed
to conform to the native
RVOT because patients
with severe pulmonary
regurgitation live with
some of the most unique
and challenging anatomies
to treat.



Enhance care, amplify life

Seamlessly blend innovation with tradition and achieve superior patient outcomes with Harmony™ TPV.

Backed by Midterm clinical data, Harmony™ demonstrates positive sustained RV remodelling, effective valve function, and a strong safety profile, all contributing to significant improvement in patient quality of life.⁸

Adopt Harmony™, amplify your results and embrace a new era in CHD treatment.

Midterm data highlights

Harmony™ TPV sustains its excellent safety profile⁸

0%

No new late ventricular tachycardia **after 30 days through 4 years**

N = 87

0%

No device- or procedure-related mortality **through 4 years**

N = 86

4 years

Low-to-mid single digit of each major adverse events

Harmony™ TPV demonstrates positive sustained remodelling in RV⁸

Pre-
implant

155.4
ml/m²

N = 65

Post-
implant

108.6
ml/m²

N = 39

30%

reduction in right ventricular end diastolic volume index at 2 years.



Harmony™ TPV sustains improvement in quality of life⁸

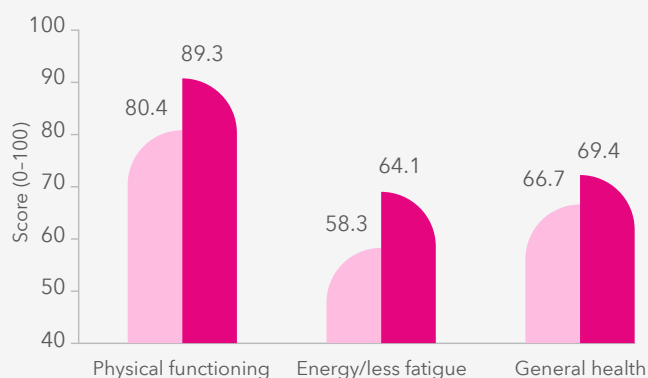
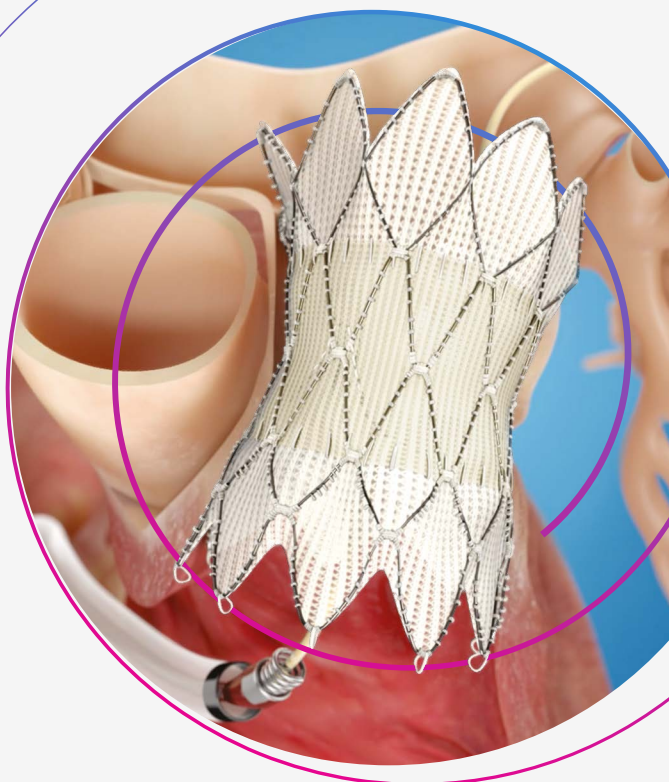
QoL scores are nearly normal at

4 years⁹

Clinically similar to normal population⁹ in patient-reported QoL outcomes in physical functioning, energy/less fatigue, and general health.

SF-36 Harmony™ TPV subject at 4 years

Sustained improvement in patient-reported quality of life at 4 years.



● Harmony TPV subjects at baseline (N = 62)
● Harmony TPV subjects at 4 years (N = 48)

Harmony™ TPV sustains its excellent effectiveness profile⁸

100%

of TPV 22 patients
N = 32

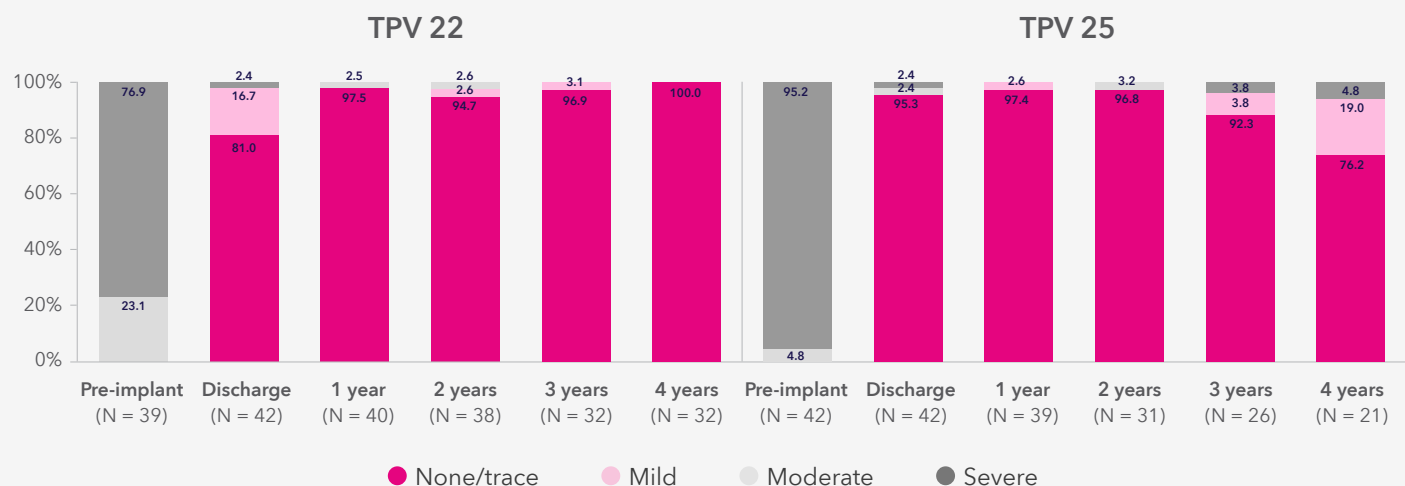
95.2%

of TPV 25 patients
N = 21

None/trace or mild pulmonary regurgitation at 4 years

Pulmonary regurgitation

Implanted Cohort - Echo Core Lab

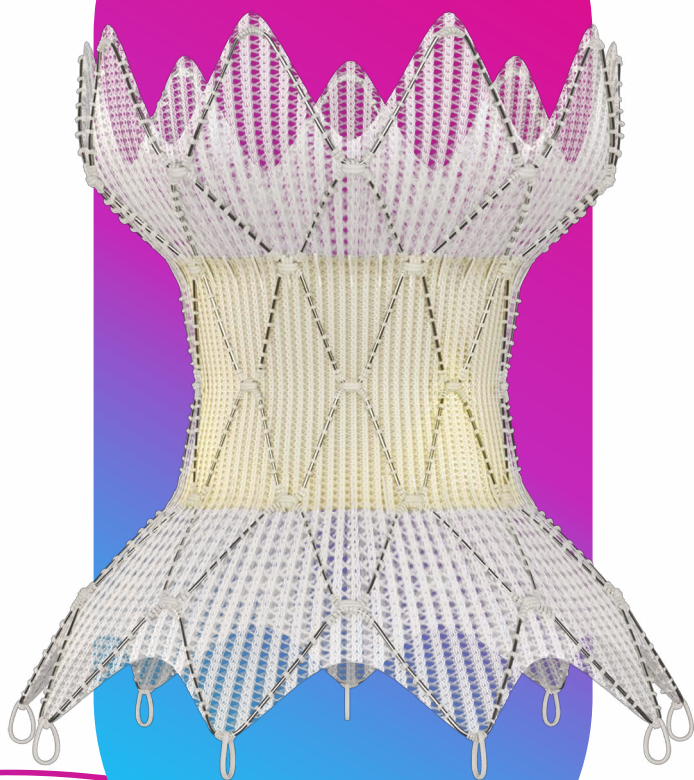


Striking the right chord

Let's stay on track – by doing more to help patients right now.

The Harmony™ TPV Post-approval Clinical Study is ongoing and vital as we strive to improve the lifelong therapy needs for CHD patients, so they can live the life they deserve.¹⁰

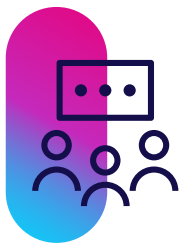
Midterm outcomes from 3–5 years provide good safety and efficacy profiles for patients and physicians alike.



Compose your success story

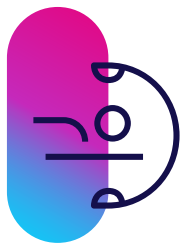
Every step of the way

Dedicated clinical CHD experts provide guidance and support in all stages of the therapy.



Physician training

The congenital medical education team provides multistep learning opportunities that build confidence and competency.



Implant

Dedicated clinical CHD experts provide pre, intra, and postoperative support.



Post-implant

Committed to data transparency, long-term data reporting, and enduring patient education.

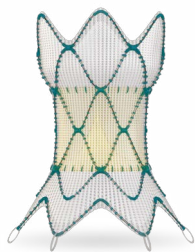
References

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. Medtronic data on file. Design Verification Test Report for Harmony TPV 22 Hydrodynamic Performance – D00266155. Design Verification Test Report for Hydrodynamic Performance of Harmony Modified TPV 25 – D00064319. Bench testing may not be representative of clinical performance (n = 6). Bench testing performed in a nonanatomical test fixture.
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9. Burholt V, Nash P. Short Form 36 (SF-36) Health Survey Questionnaire: normative data for Wales. J Public Health (Oxf). 2011;33(4):587-603.
10. Harmony TPV Post-Approval Study. Medtronic Cardiovascular; 2024. Accessed September 13, 2024. <https://research.ebsco.com/linkprocessor/plink?id=543059cc-7178-3f84-9a83-35ebbf2227f8>

Product specifications and ordering information

Transcatheter pulmonary valve

Harmony™ TPV



Harmony™ TPV 22 22 mm valve

Model number:
Harmony-22



(240)Harmony-22

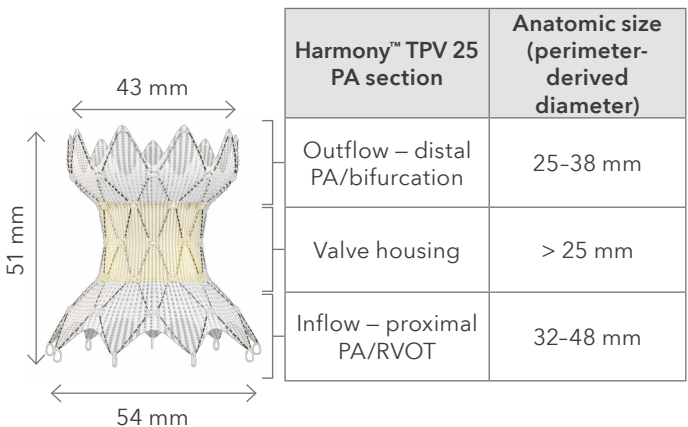
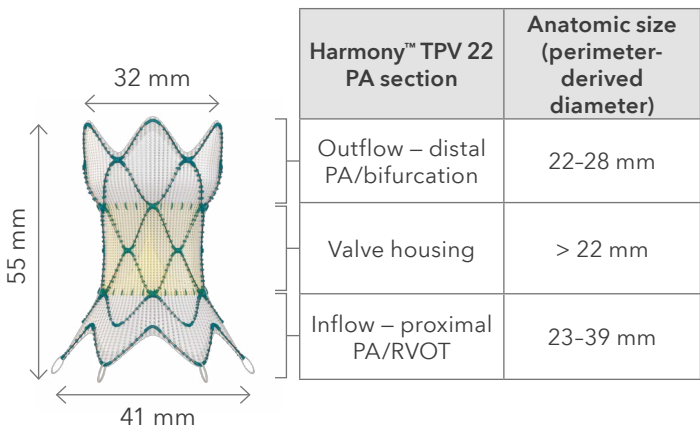


Harmony TPV™ 25 25 mm valve

Model number:
Harmony-25



(240)Harmony-25



Delivery catheter system

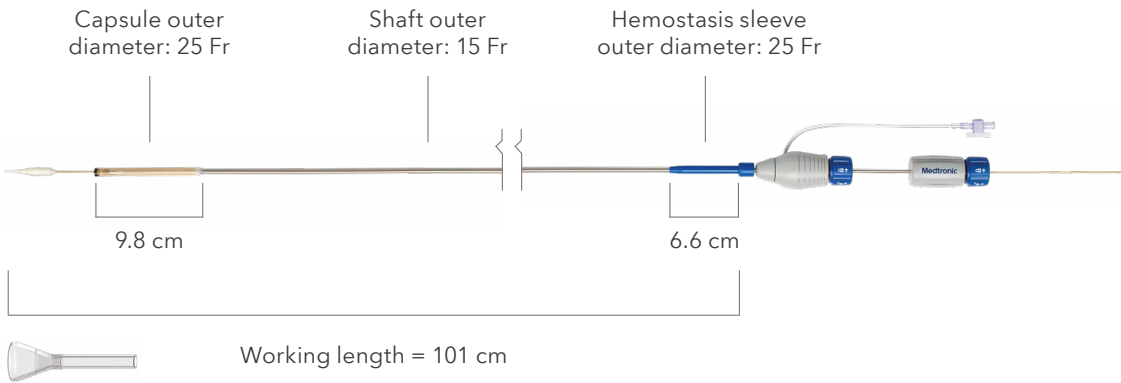
Harmony™ DCS

Model Number:
HARMONY-DCS



(240)HARMONY-DCS

All items above are single-use.
Refer to Instructions for Use
for a complete list of warnings,
precautions, and contraindications.



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