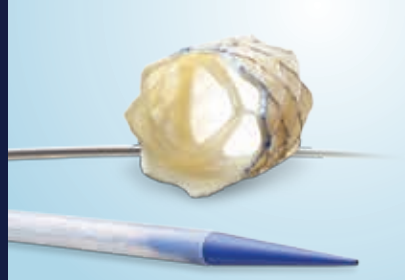
MELODY™ TPV
10 YEAR EXPERIENCE

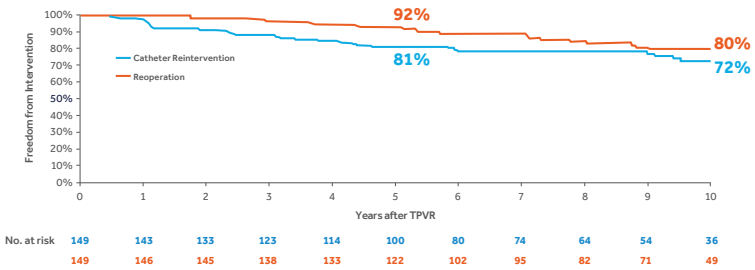
Achieve strong procedural results with an easy-to-use valve with proven durability. Ten years of clinical evidence for the Melody TPV is unmatched by any other transcatheter valve, demonstrating excellent durability and stable long-term hemodynamic performance.



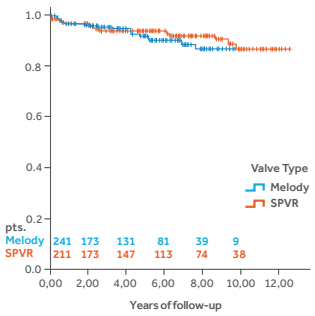
Melody™
Transcatheter Pulmonary Valve (TPV) System

Excellent Valve Durability with Low Intervention Rates Comparable to Surgery

FREEDOM FROM INTERVENTION[1]

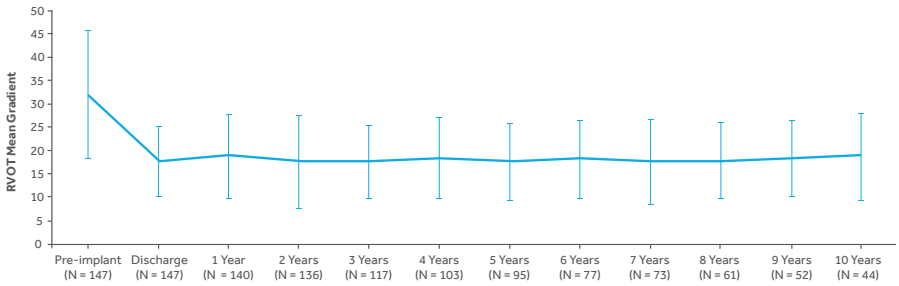


SURGERY-FREE SURVIVAL[2]



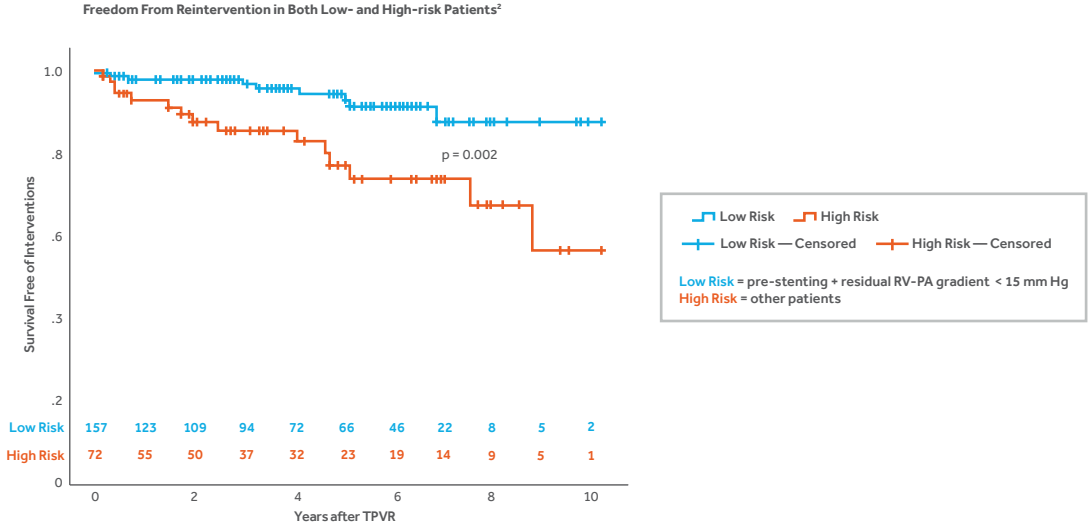
Very Stable Valve Hemodynamics Help Delay Future Intervention in Majority of Patients

RVOT MEAN GRADIENT (MMHG)[1]



Evolution of Therapy Could Further Improve Outcomes

Freedom From Reintervention in Both Low- and High-risk Patients[2]



10 years
after implantation:
90%
freedom from all-cause mortality[1]: survival without re-operation compares favorably with SPVR[2]

10 years
after implantation:
97%
patients showed none/trace/mild pulmonary regurgitation[1]

Consistent gradient
< 20 mm Hg[1]

- Minimizing the post-implant RVOT gradient is associated with lower rates of valve intervention over time and with lower rates of endocarditis requiring TPV intervention.[3]
- Evolutions in implantation practices like minimization of post-implant gradient, along with new patient resources and education materials, offer new avenues to further reduce risk of IE.

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REFERENCES
[1] Melody Transcatheter Pulmonary Valve Study: Post Approval Study of the Original IDE Cohort.
[2] Georgiev S, Ewert P, Eicken A, et al. Munich Comparative Study: Prospective Long-Term Outcome of the Transcatheter Melody Valve Versus Surgical Pulmonary Bioprosthesis With Up to 12 Years of Follow-Up. *Circ Cardiovasc Interv*. July 2020;13(7):e008963.
[3] Georgiev S, Ewert P, Tanase D, et al. A low residual pressure gradient yields excellent long-term outcome after percutanous pulmonary valve implantation. *JACC Cardiovasc Interv*. August 26, 2019;12(16):1594-1603.

Melody™ Transcatheter Pulmonary Valve, Ensemble™ II Transcatheter Valve Delivery System

Important Labeling Information for Geographies Outside of the United States

Indications: The Melody™ TPV is indicated for use in patients with the following clinical conditions:
- Patients with regurgitant prosthetic right ventricular outflow tract (RVOT) conduits or bioprostheses with a clinical indication for invasive or surgical intervention, OR
- Patients with stenotic prosthetic RVOT conduits or bioprostheses where the risk of worsening regurgitation is a relative contraindication to balloon dilatation or stenting

Contraindications: Venous anatomy unable to accommodate a 22 Fr size introducer sheath
- Implantation of the TPV in the left heart
- RVOT unfavorable for good stent anchorage
- Severe RVOT obstruction, which cannot be dilated by balloon
- Obstruction of the central veins
- Clinical or biological signs of infection
- Active endocarditis
- Known allergy to aspirin or heparin
- Pregnancy

Potential Complications/Adverse Events: Potential procedural complications that may result from implantation of the Melody device include the following: rupture of the RVOT conduit, compression of a coronary artery, perforation of a major blood vessel, embolization or migration of the device, perforation of a heart chamber, arrhythmias, allergic reaction to contrast media, cerebrovascular events (TIA, CVA), infection/sepsis, fever, hematoma, radiation-induced erythema, pain, swelling or bruising at the catheterization site.

Potential device-related adverse events that may occur following device implantation include the following: stent fracture,* stent fracture resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, hemolysis.

*The term "stent fracture" refers to the fracturing of the Melody TPV.
However, in subjects with multiple stents in the RVOT it is difficult to definitively attribute stent fractures to the Melody frame versus another stent.

See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.eu.

For applicable products, consult instructions for use on manuals.medtronic.com. Manuals can be viewed using a current version of any major internet browser.
For best results, use Adobe Acrobat® Reader with the browser.

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