Melody™
Transcatheter Pulmonary Valve (TPV)

Know your diameter.

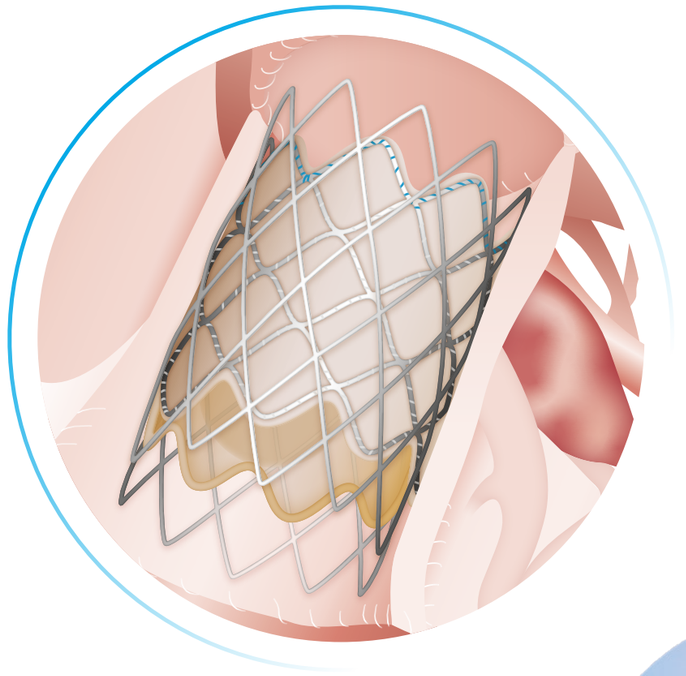
Optimize hemodynamics.
Maximize performance.

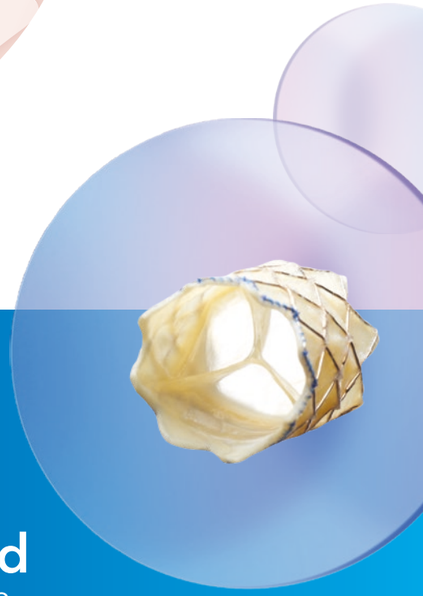


Medtronic

Know your **diameter.**

The treatable diameter of dysfunctional conduits and bioprosthetic valves is often different and smaller than the original labeled size.[1] **Choosing the right valve directly impacts long-term performance for patients.**





Melody TPV offers a solution that provides excellent **hemodynamics and unmatched** durability across its size range.[2]

What's the **TRUE ID?**

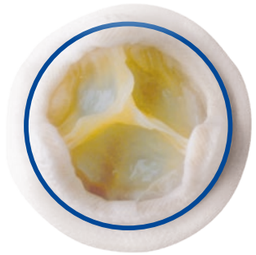
True inner diameter

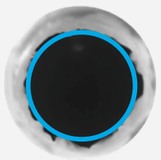
Considers the space taken up by tissue. It can be smaller than the manufacturer's labeled diameter.



Labeled valve size

Manufacturer's labeled valve size by the outside diameter of the stent.[3]





Melody TPV 22
Deployed to 24 mm†

Melody TPV is intended to have the same TRUE ID as its labeled diameter.



Competitor valve
Deployed to 26 mm

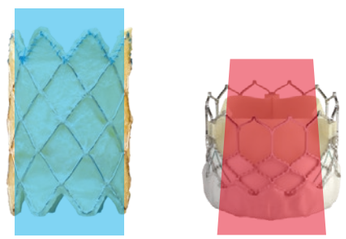
A competitor valve's design results in a smaller True ID compared to its labeled diameter with nominal inflation.

What's **EOA?**

Effective orifice area (EOA) is the functional cross-sectional area available for blood flow through a valve under physiologic conditions, reflecting the combined effects of valve design, expansion, and leaflet motion.[4]

Flow design comparison

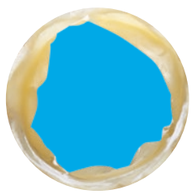
Melody TPV 22 | Competitor valve[5]



Melody TPV is a natural bovine jugular vein valve designed by nature to maximize its EOA in lower pressure environments.[6]

Geometric orifice area (GOA) comparison

Melody TPV 22



Thinner bovine jugular vein leaflets

Bovine jugular vein allows for complete opening of the leaflets.

Competitor valve



Thicker bovine pericardial tissue

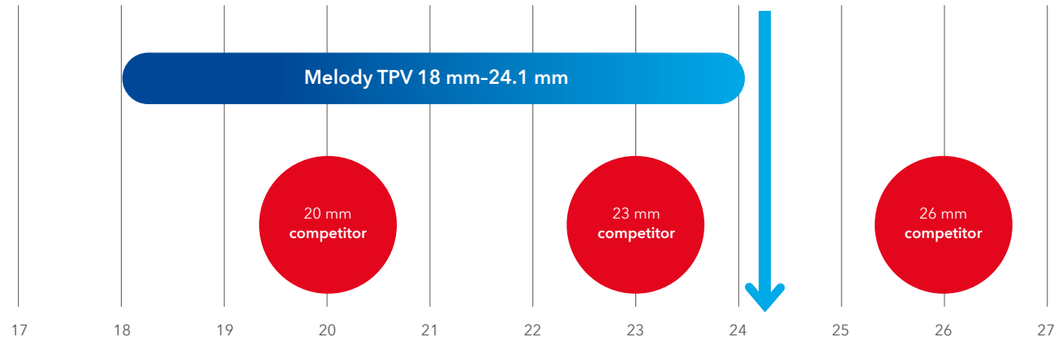
Incomplete opening of leaflets to avoid tissue on stent interaction.

Bench testing is not indicative of clinical performance.
† Deployed diameter refers to outer diameter.

Know your **diameter.**

Knowing the true diameter of the landing zone may offer better valve selection to ensure sustained hemodynamic performance over time.

Chart shows outer diameters of each valve's treatable range.[6,7]

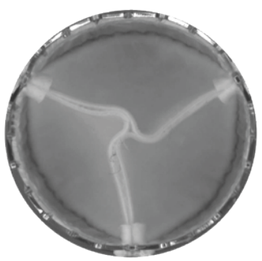


The **Competition.**

Dysfunctional pulmonary valves, either BPV or conduits, are rarely straight tubes at the desired diameter.[10] Underexpansion and smaller valve area of competitors' valves are strongly associated with the need for reintervention.[11]



Competitor valve
Nominal deployment

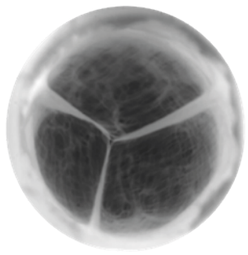


Competitor valve[5]
2 mm underdeployed

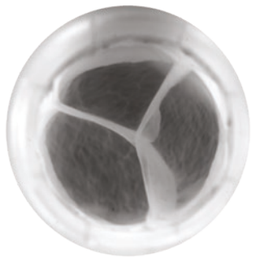
Pinwheeling refers to abnormal torsional deformation of valve leaflets. It commonly occurs when a transcatheter valve is underexpanded or constrained by noncylindrical landing zones.[12]

Each degree of underexpansion significantly increases the stress and strain on the valve leaflets, which may lead to early leaflet degeneration.[11]

Nature made **design.**

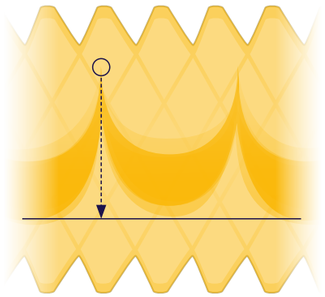


Melody TPV 22
Deployed to 24 mm†



Melody TPV 22
Deployed to 22 mm

Melody TPV can be deployed across a spectrum of sizes with little to no deformation of the leaflets during coaptation.[2]



Long, naturally integrated commissural attachment allows stress to be shared over a larger area. Short commissural attachments influence stress on leaflets.[8,9]

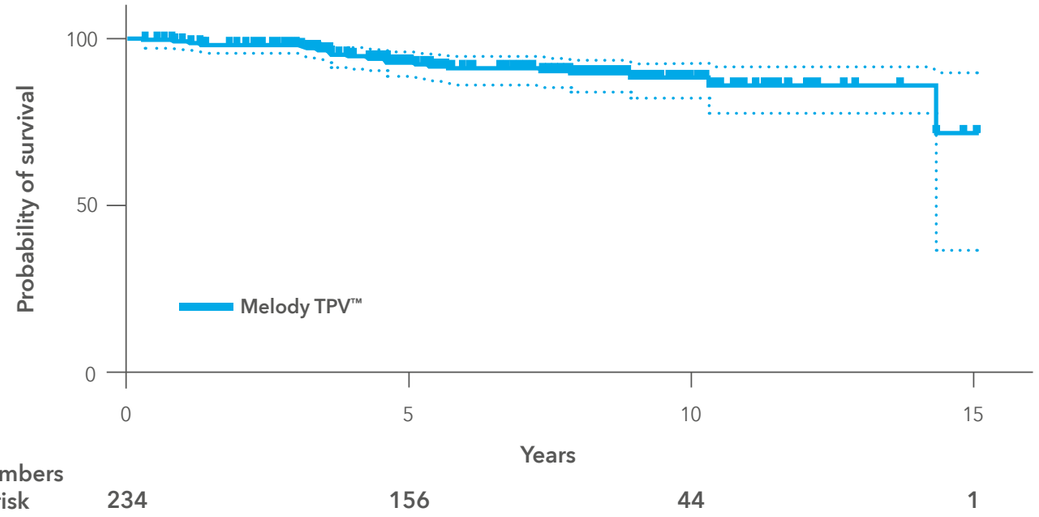
† Deployed diameter refers to outer diameter.



Designed by nature. **Proven** by time.

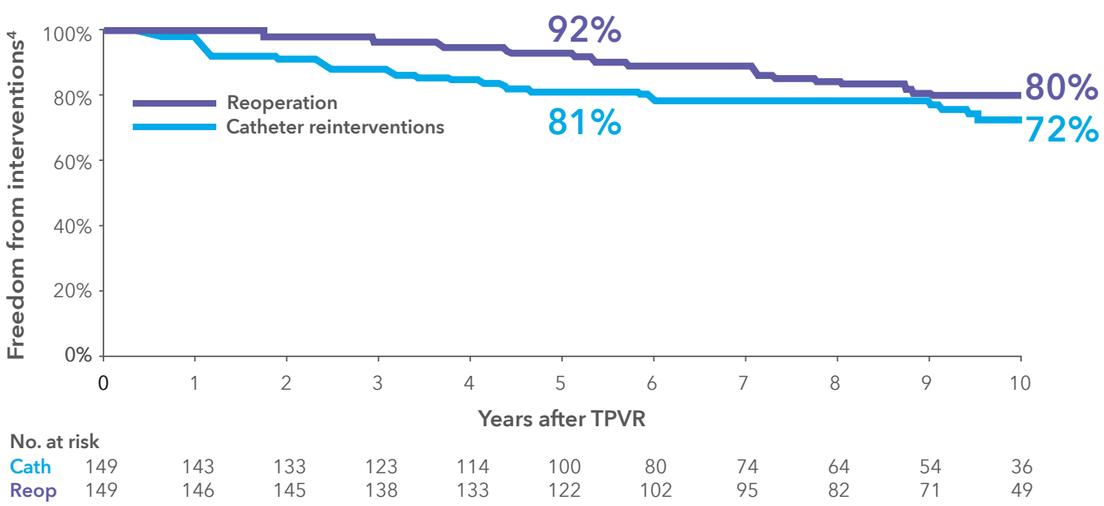
Melody TPV is the only transcatheter valve with 15 years of follow-up and low rates of reintervention, outperforming surgery beyond 10 years.[13,14]

Fifteen years of experience with the Melody™ TPV for percutaneous pulmonary valve replacement[14]

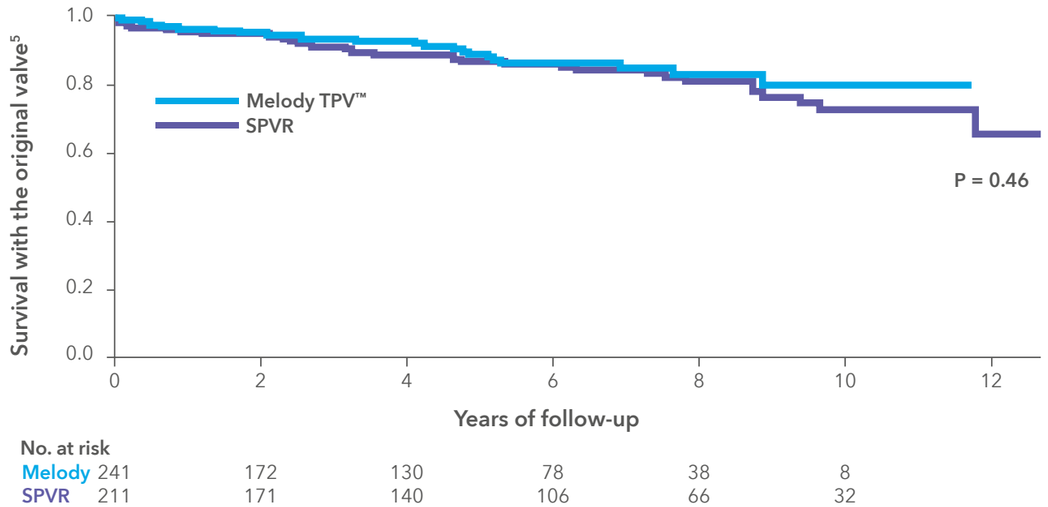


Freedom from valve failure. Kaplan-Meier curvers depict the freedom from valve explant (yellow line).

Long-term outcomes after melody transcatheter pulmonary valve replacement in the US investigational device exemption trial 10-year-follow-up[13]



Munich comparative study: prospective long-term outcome of the transcatheter melody valve versus surgical pulmonary bioprosthesis with up to 12 years of follow-up[15]



Product ordering information

Melody Transcatheter Pulmonary Valve

Product order number	Description A bovine jugular vein (BJV) valve sutured within a platinum-iridium frame
PB1016	• Melody TPV 20 • 16 mm BJV valve • Acceptable deployment: up to 20 mm
PB1018	• Melody TPV 22 • 18 mm BJV valve • Acceptable deployment: up to 22 mm

Note: To facilitate manufacturing (sewing of the tissue onto the TPV frame), the initial out-of-the-jar lengths of the two valves will differ slightly (30 mm length for PB1016 and 28 mm length for PB1018). Once crimped on the delivery system, the length of both TPV sizes will be the same and will remain as such during deployment to any size.

Ensemble and Ensemble II Transcatheter Delivery System

Ensemble II product order number	Balloon size	French size	Overall length
ENS1018	18 mm	22	100 cm
ENS1020	20 mm	22	100 cm
ENS1022	22 mm	22	100 cm

- Balloon-in-balloon catheter delivery system with a retractable polytetrafluoroethylene (PTFE) sheath covering.
- Nylon inner and outer balloons available in three sizes: 18 mm, 20 mm, and 22 mm. At inflation, the inner balloon is half the diameter of the outer balloon.
- Sheath with side port for flushing the system and a hemostatic sleeve to minimize bleeding at the insertion site.

Melody TPV 20 (PB1016) is not designed to be dilated greater than 20 mm. Choose delivery system and valve size based on prepared conduit or surgical valve inside diameter and intended final implant size. Valve performance for both sizes is comparable, per bench testing data.[1]

[1] Medtronic bench testing data on file.

Notes

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12. Mostafa A, Azadani AN. Leaflet stress and strain distributions following incomplete transcatheter aortic valve expansion. *J Biomech*. October 15, 2015;48(13):3663–3671.

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