A CLEAR PICTURE OF DURABILITY.

Melody™

Transcatheter Pulmonary Valve (TPV)

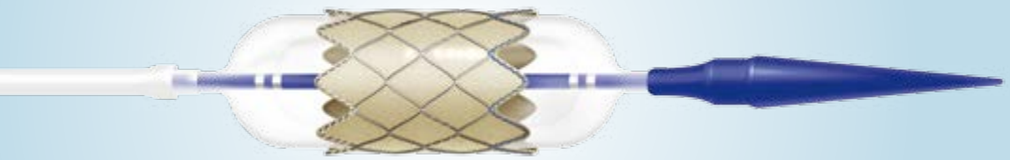
Medtronic

A Valve Designed Specifically for a Pulmonic Indication

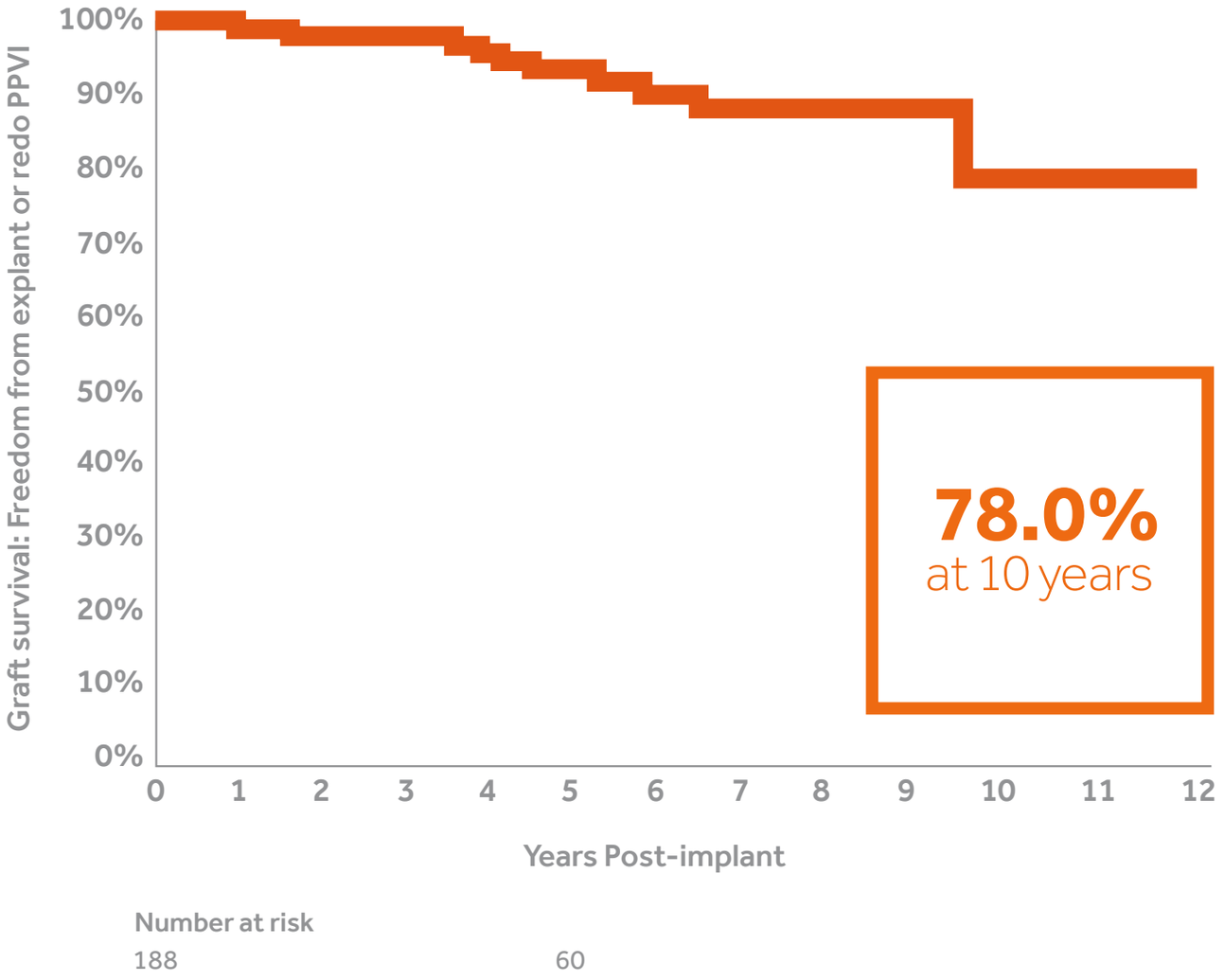
Melody™ TPV was the first transcatheter valve commercially approved. Since 2006, it has benefited over 15,000 patients globally. It has been proven to relieve conduit and surgical valve obstruction, restore valve function, and delay the patient's next surgical intervention.

The Melody valve is the longest studied TPV, with the largest body of clinical evidence. Accumulated data have consistently demonstrated excellent clinical results, including high rates of freedom from surgical reoperation, confirming that Melody TPV safely and effectively delays the need for surgical conduit or surgical valve exchange.

This resource provides a summary of Medtronic Melody TPV clinical studies and real-world published experiences with at least 100 patients enrolled, follow-up ≥ 5 years as of July 1, 2019, and available freedom from reoperation or valve dysfunction curves specific to Melody TPV only. While several of these studies have different endpoints, freedom from event curves demonstrate the continued safe and effective use of Melody TPV. Efforts were made to reduce double-counting the same patients by only including the most recent updates to clinical experiences.



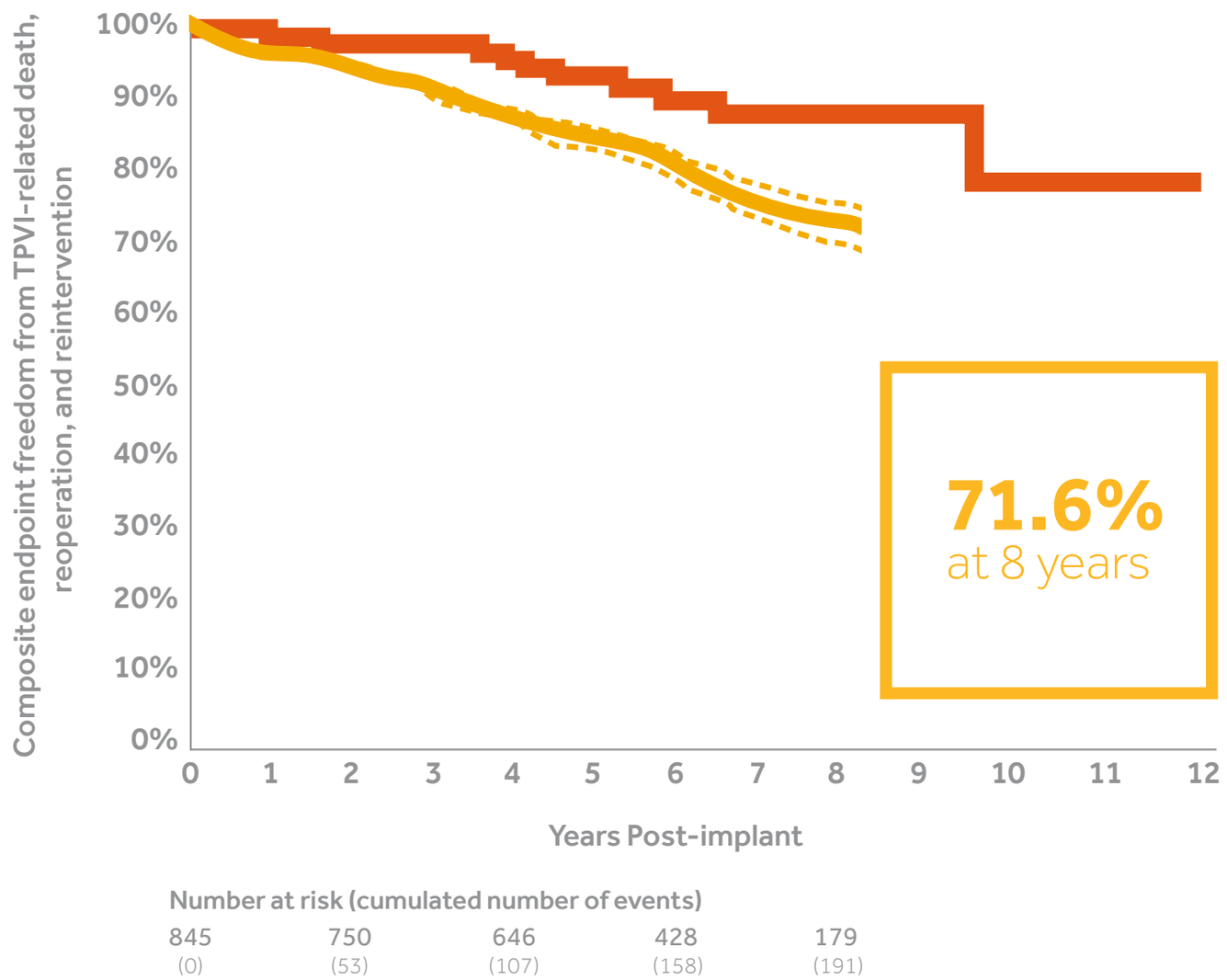
- Prospective observational study
- Single institution
- 188 Melody™ valves implanted
- 2006–2017
- Endpoint of graft survival: freedom from explant or redo PPVI



Source: Cools B, Brown S, Budts W, et al. Up to 11 years of experience with the Melody valved stent in the right ventricular outflow tract. *EuroIntervention.* October 12, 2018;14(9):e988-e994.

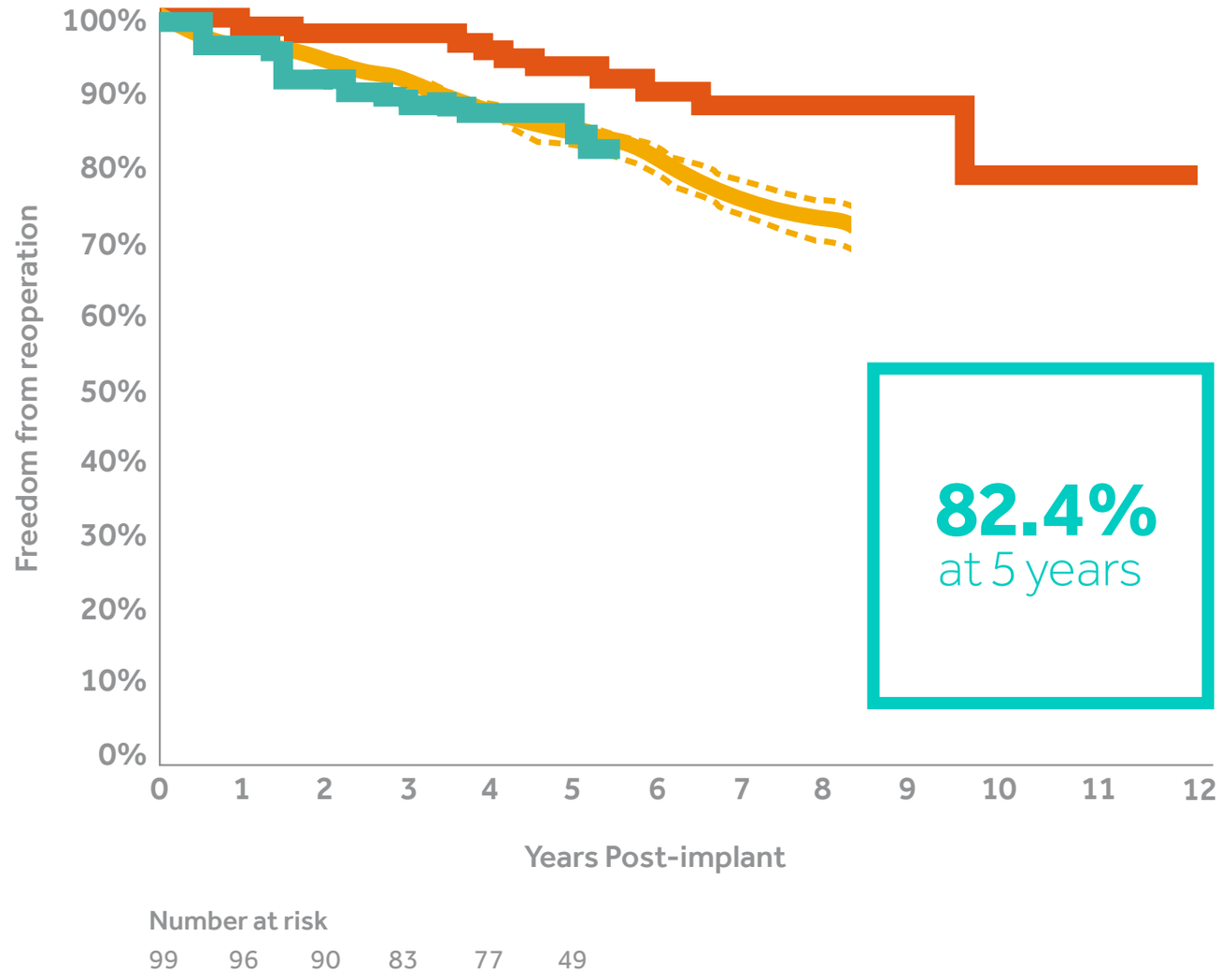
- Retrospective analysis
- 42 centers
- 845 Melody™ TPV patients implanted
- December 2006–September 2013
- Composite endpoint of transcatheter pulmonary implantation-related death, reoperation, and reintervention

Source: Nordmeyer J, Ewert P, Gewillig M, et al. Acute and midterm outcomes of the post-approval MELODY Registry: a multicentre registry of transcatheter pulmonary valve implantation. *Eur Heart J.* July 14, 2019;40(27):2255-2264.

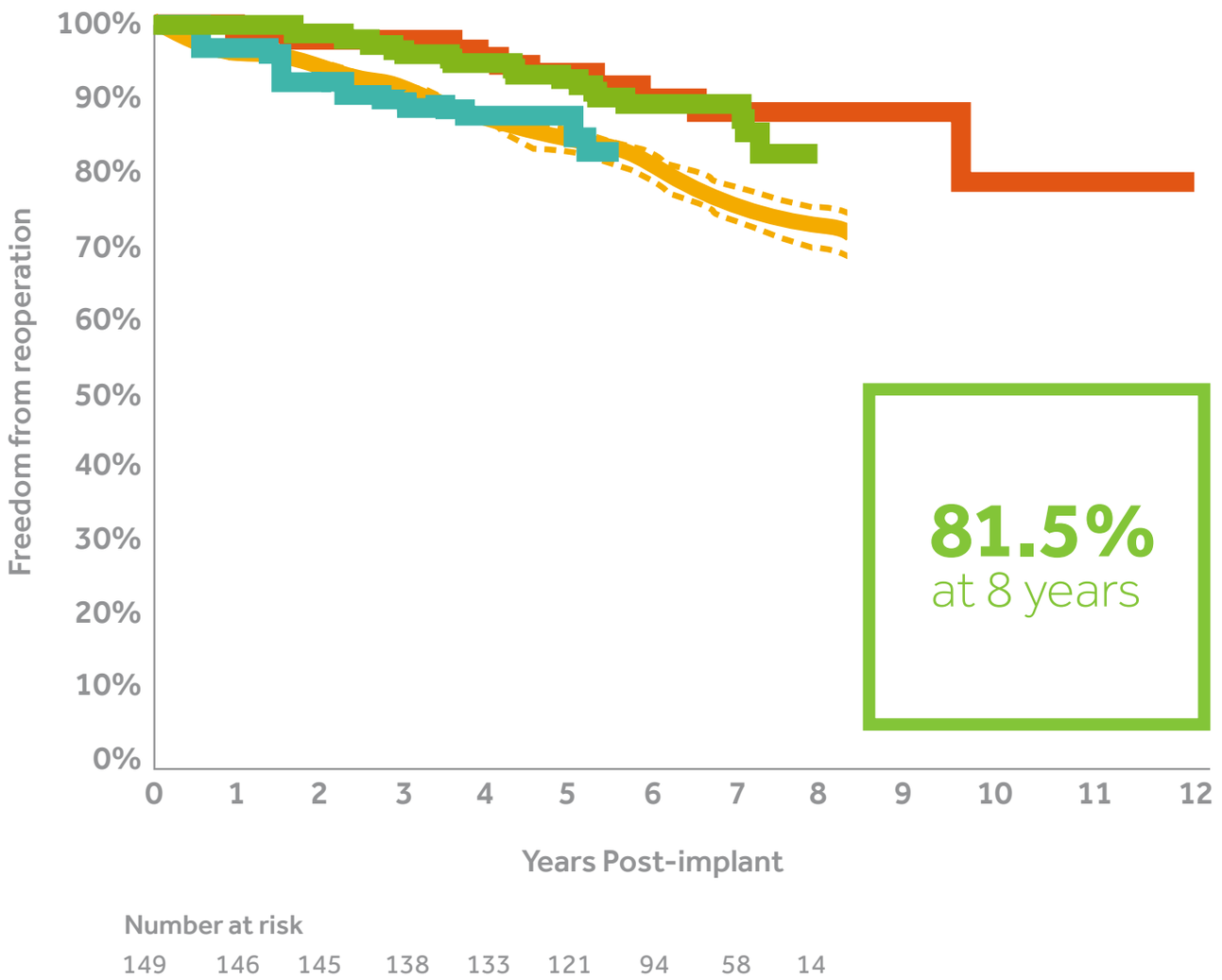


- Prospective clinical study (U.S. PAS)
- 10 centers
- 100 Melody™ TPV patients implanted
- 2010–2012
- Endpoint: freedom from surgical RVOT conduit reoperation

Source: Medtronic data on file.



- Prospective clinical study (U.S. IDE)
- 5 centers
- 150 Melody™ TPV patients implanted
- 2007–2010
- Endpoint: freedom from surgical RVOT conduit reoperation



Source: Medtronic data on file.

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.

For additional information, please refer to the Instructions for Use provided with the product or available on http://manuals.medtronic.com.

The Melody Transcatheter Pulmonary Valve and Ensemble II Transcatheter Delivery System has received CE Mark approval and is available for distribution in Europe.

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