



Melody[®]

TRANSCATHETER PULMONARY VALVE THERAPY

HUMANITARIAN DEVICE.

Authorized by Federal law (USA) for use in pediatric and adult patients with a regurgitant or stenotic Right Ventricular Outflow Tract (RVOT) conduit (≥ 16 mm in diameter when originally implanted). The effectiveness of this device for this use has not been demonstrated.



Hope,
Restored.

Melody® Transcatheter Pulmonary Valve Ensemble® Transcatheter Valve Delivery System

The Melody TPV is indicated for use as an adjunct to surgery in the management of pediatric and adult patients with the following clinical conditions:

- Existence of a full (circumferential) RVOT conduit that was equal to or greater than 16 mm in diameter when originally implanted and
- Dysfunctional RVOT conduits with a clinical indication for intervention, and either:
 - regurgitation: \geq moderate regurgitation, or
 - stenosis: mean RVOT gradient \geq 35 mm Hg

Contraindications: None known.

Warnings/Precautions/Side Effects:

- **DO NOT implant in the aortic or mitral position. Preclinical bench testing of the Melody valve suggests that valve function and durability will be extremely limited when used in these locations.**
- DO NOT use if patient's anatomy precludes introduction of the valve, if the venous anatomy cannot accommodate a 22-Fr size introducer, or if there is significant obstruction of the central veins.
- DO NOT use if there are clinical or biological signs of infection including active endocarditis.
- Assessment of the coronary artery anatomy for the risk of coronary artery compression should be performed in all patients prior to deployment of the TPV.
- To minimize the risk of conduit rupture, do not use a balloon with a diameter greater than 110% than the nominal diameter (original implant size) of the conduit for pre-dilation of the intended site of deployment, or for deployment of the TPV.
- The potential for stent fracture should be considered in all patients who undergo TPV placement. Radiographic assessment of the stent with chest radiography or fluoroscopy should be included in the routine postoperative evaluation of patients who receive a TPV.
- If a stent fracture is detected, continued monitoring of the stent should be performed in conjunction with clinically appropriate hemodynamic assessment. In patients with stent fracture and significant associated RVOT obstruction or regurgitation, reintervention should be considered in accordance with usual clinical practice.

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 at the catheterization site.

Potential device-related adverse events that may occur following device implantation include the following: 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.

For additional information, please refer to the Instructions For Use provided with the product.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Humanitarian Device. Authorized by Federal law (USA) for use in pediatric and adult patients with a regurgitant or stenotic Right Ventricular Outflow Tract (RVOT) conduit (≥ 16 mm in diameter when originally implanted). The effectiveness of this device for this use has not been demonstrated.

For more information about Melody Transcatheter Pulmonary Valve Therapy, contact your Medtronic Sales Representative, your local Medtronic office or visit www.Melody-TPV.com.

Reference

1. Melody Transcatheter Pulmonary Valve Clinical Evidence Report. Data on file. Medtronic, Inc. 2009.

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In 1957, Medtronic
partnered with clinicians
to pioneer the first wearable,
battery-operated external
pacemaker. The device was
applied to a pediatric heart
block patient and restored
the child's heartbeat.



Innovation through

And today our culture continually inspires us to push the boundaries
of medical technology to help patients live better, longer.

Providing innovative therapies for the lifetime management of patients with congenital heart disease.

Hope

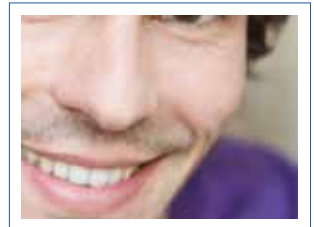
Congenital heart patients have been the inspiration for Melody® Transcatheter Pulmonary Valve Therapy — a non-surgical breakthrough that addresses pulmonary valve conduit dysfunction without open-heart surgery.

Restored.





Committed to patient



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In clinical study, the Melody TPV has shown the following probable benefits:

Improved conduit function¹

- Restores pulmonary valve competence
- Relieves conduit obstruction

Lengthened conduit lifespan¹

- Delays the patient's next surgical intervention

The effectiveness of this device has not been demonstrated.

U.S. Study (N=99)

European Study (N=68)

Event	Freedom from Event 1 Year	Freedom from Event 1 Year	Freedom from Event 4 Years
Death	99%	100%	94%
Reoperation (conduit exchange)	99%	95%	85%
Catheter Reintervention	94%	94%	76%
Major Stent Fracture	91%	92%	75%
All Stent Fracture	77%	84%	60%

Notes:

Catheter reinterventions included balloon angioplasty and repeat implantation of a second TPV. Stent fractures that required intervention were defined as major.

ts



IMPORTANT RISK INFORMATION

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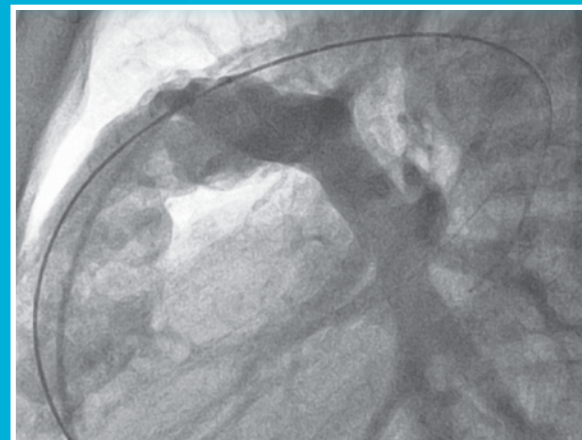
For more information about Melody TPV Therapy, visit www.Melody-TPV.com.

Transcatheter

VALVE DELIVERY

The Melody valve is delivered by catheter, with fluoroscopic guidance, through the body's cardiovascular system:

- 22 Fr delivery catheter offers the lowest crossing profile on the market
- Balloon-in-balloon deployment enables minor adjustments to facilitate accurate placement
- Unique coverage sheath protects valve during delivery to the point of deployment

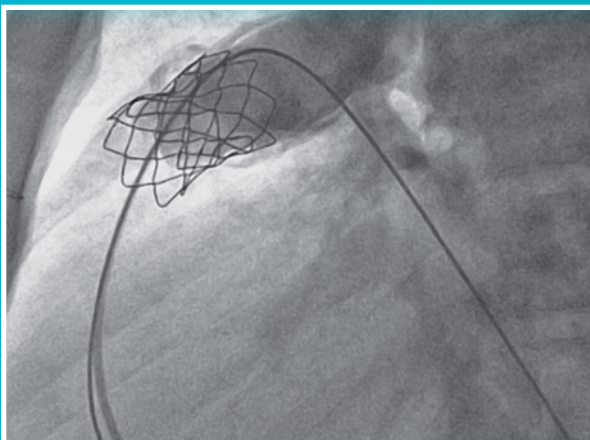


A revolutionary treatment option designed to delay the need for surgical intervention.

PULMONARY VALVE DESIGN



The Melody valve was specifically designed to treat RVOT conduit dysfunction:



- Deep coaptation of the leaflets provides valve competency across a range of diameters and geometries
- Natural venous valve leaflets open and close under minimal pressure for optimal hemodynamics
- Sutures at every node are designed to enhance valve integrity

Specifications and Ordering Information

Melody® Transcatheter Pulmonary Valve	
Order Number	Description
PB1018	<ul style="list-style-type: none"> A bovine jugular vein valve sutured within a platinum iridium stent. One size valve (18 mm) that is crimped to 6 mm and re-expanded from 18 mm to 22 mm. Thin, compliant leaflets open fully and close readily with a minimum of pressure. Preservation in a proprietary sterilant of glutaraldehyde and alcohol.

Torque Wrench	
Order Number	Description
01-0055	Reusable jar opener

Ensemble® Transcatheter Delivery System			
Order Number	Balloon Size	French Size	Overall Length
NU1018	18 mm	22	100 cm
NU1020	20 mm	22	100 cm
NU1022	22 mm	22	100 cm

Description
<ul style="list-style-type: none"> 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® System Sizing Information

Melody® System Sizing Chart					
Delivery System Size – Inner Balloon / Outer Balloon	Inner Balloon Maximum Applied Pressure ^[RBP]		Outer Balloon Applied Pressures		Corresponding Valve Outside Diameter (mm)
	atm	kPa	atm	kPa	
Size 18 mm 9 mm x 3.5 cm / 18 mm x 4 cm	5	506	1	101	17.93
			2	203	18.57
			3	304	19.42
			4 ^[RBP]	405	20.06
Size 20 mm 10 mm x 3.5 cm / 20 mm x 4 cm	5	506	1	101	19.65
			2	203	20.70
			3	304	21.73
			4 ^[RBP]	405	22.42
Size 22 mm 11 mm x 3.5 cm / 22 mm x 4 cm	4.5	456	1	101	21.80
			2	203	22.79
			3 ^[RBP]	304	24.06

Note: Do not exceed **bolded** pressure values for either the inner or outer balloon of the delivery system size.
RBP = Rated Burst Pressure = Maximum Applied Pressure
atm = atmosphere kPa = kilopascal

Approximate Inner Diameter Post Deployment After Balloon Removal				
Average Stent Inner Diameter (mm) per Size				
Size	1.0 atm	2.0 atm	3.0 atm	4.0 atm
18	14.87	15.50	16.32	16.94
20	16.70	17.72	18.73	19.41
22	18.80	19.77	21.01	—

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