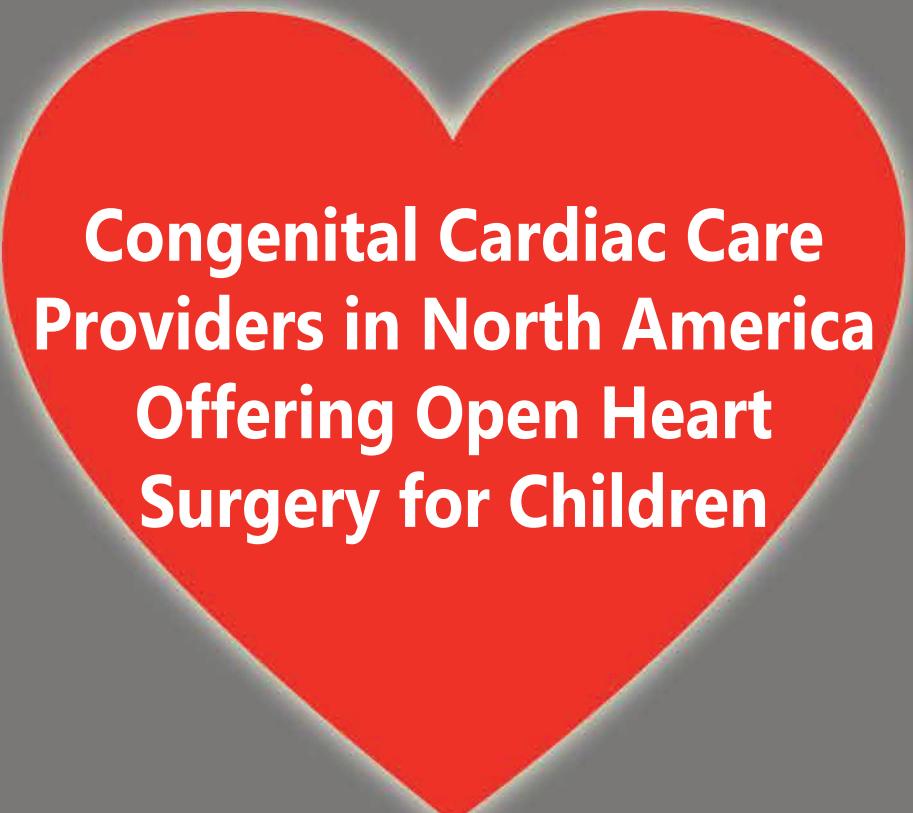


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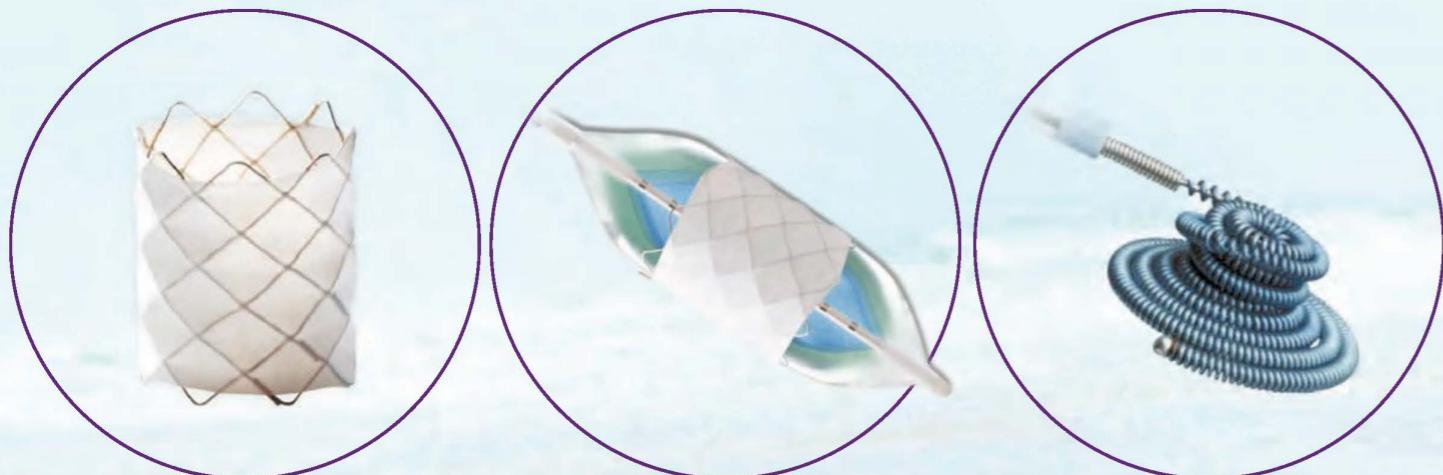
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The Nit-Occlud® PDA coil system is a permanently implanted prosthesis indicated for percutaneous, transcatheter closure of small to moderate size patent ductus arteriosus with a minimum angiographic diameter less than 4mm. Nit-Occlud Brief Statement: Do not implant the Nit-Occlud PDA into patients who have endocarditis, endarteritis, active infection, pulmonary hypertension (calculated PVR greater than 5 Wood Units), thrombus in a blood vessel through which access to the PDA must be obtained, thrombus in the vicinity of the implantation site at the time of the implantation or patients with a body weight < 11 lbs (5 kg). An angiogram must be performed prior to implantation for measuring length and diameter of the PDA. Only the pfm medical implantation delivery catheter should be used to implant the device. Administration of 50 units of heparin per kg body weight should be injected after femoral sheaths are placed. Antibiotics should be given before (1 dose) and after implantation (2 doses) in order to prevent infection during the implant procedure. Do not implant the Nit-Occlud PDA in an MR environment. Do not pull the Nit-Occlud coil through heart valves or ventricular chambers. Contrast media should not be injected through the implantation catheter. The catheter must not be connected to high pressure injectors. Patients may have an allergic response to this device due to small amounts of nickel that has been shown to be released from the device in very small amounts. If the patient experiences allergic symptoms, such as difficulty in breathing or swelling of the face or throat, he/she should be instructed to seek medical assistance immediately. Antibiotic prophylaxis should be performed to prevent infective endocarditis during first 6 months after coil implantation. Potential Adverse Events: Air embolism, Allergic reaction to drug/contrast, Apnea, Arrhythmia requiring medical treatment or pacing, Arteriovenous fistula, Bacterial endocarditis, Blood loss requiring transfusion, Chest pain, Damage to the tricuspid or pulmonary valves, Death, Embolization of the occluder, requiring percutaneous or surgical intervention, Endarteritis, False aneurysm of the femoral artery, Fever, Headache/migraine, Heart failure, Hemolysis after implantation of the occluder, Hypertension, Hypotension or shock, Infection, Myocardial infarction, Occluder fracture or damage, Perforation of the heart or blood vessels, Stenosis of the left pulmonary artery or descending thoracic aorta, Stroke/TIA, Thromboembolism (cerebral or pulmonary), Valvular Regurgitation, Vessel damage at the site of groin puncture (loss of pulse, hematoma, etc.).

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The CHiP Network, the Congenital Heart Professionals Network, is designed to provide a single global list of all CHD-interested professionals in order to

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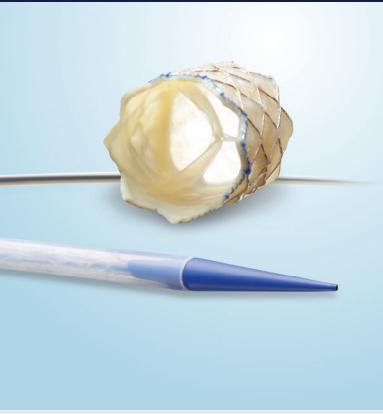
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RIGHT CHOICE.



Melody™
Transcatheter Pulmonary
Valve (TPV) System

Not intended to constitute medical advice or in any way replace the independent medical judgment of a trained and licensed physician with respect to any patient needs or circumstances. Melody TPV is not suitable for all patients and ease of use, outcomes, and performance may vary. See the Instructions for Use for indications, contraindications, precautions, warnings, and adverse events.

Restoring lives for
11
years and counting.



The only transcatheter pulmonary valve specifically designed for RVOT conduits and bioprosthetic valves. The longest studied, with the largest body of clinical evidence at 7 years post-implant.* Over 11 years of implants, more than 12,000 patients' lives have been changed.

**Melody TPV — The Right Choice
for Your Patients**

*Melody Transcatheter Pulmonary Valve Study:
Post Approval Study of the Original IDE Cohort.

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Medtronic
Further, Together

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

Important Labeling Information for the United States

Indications: The Melody TPV is indicated for use in the management of pediatric and adult patients who have a clinical indication for intervention on a dysfunctional right ventricular outflow tract (RVOT) conduit or surgical bioprosthetic pulmonary valve that has ≥ moderate regurgitation, and/or a mean RVOT gradient ≥35 mm Hg.

Contraindications: None known.

Warnings/Precautions/Side Effects:

- **DO NOT implant in the aortic or mitral position. Pre-clinical 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. Standard medical and surgical care should be strongly considered in these circumstances.
- 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% of 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, blistering, or peeling of skin, 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>.

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

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.

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^{*}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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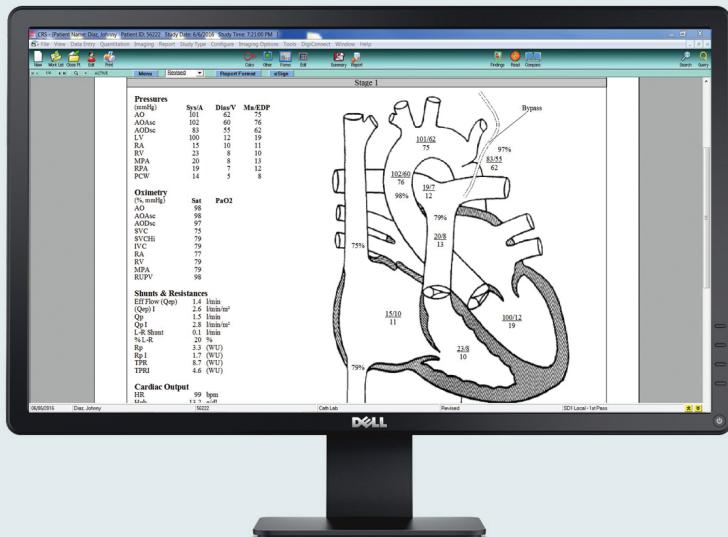
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Pediatric Echocardiography Report

Patient Name:	Braun, Mark	Gender:	M
Study Date:	3/18/2017	MRI#:	84187
Height:	34 in	Ordering MD:	Kimberly Correa, MD
Weight:	12.9 kg	Interpreting MD:	Heidi Hayes, RDMS
Indications:	Abdominal Physical Exam	Technologist:	RDCS
Hospital/Clinic:	Cystic Fibrosis	DOB/Age:	11/18/2009, 7yr

Doppler

LVDDa	39 mm (zuc -1.8)	LA Vol	16.3 ml
LVDDc	29.5 mm (zuc 0.5)	Index	13 ml/m ²
LVEDV	24.4 mm (zuc -0.3)*	Septal Thickness	8.4 mm (zuc -0.2)
LVEDVd	IVSd	9.4 mm (zuc -0.9)	
LVEF	85%	Mitral Valve Area	1.8 cm ² (zuc 0.2)
LVEF%	64.7% (zuc 0.3)	LVPWd	13.2 mm (zuc -0.2)
LVMass	124.4 g (zuc 3.6)*	LVPWs	68.8% (zuc 0.2)
LVMDA	123.2 g (zuc 3.8)*	PW PW	1.2 cm (zuc 0.2)
RVDDa	44 mm	PW Vol	29 ml (zuc 2.6)*
IVSd	29 mm (zuc 2.5)*	PW Vol	32 ml (zuc 2.6)*

Mode

LVDDa	38 mm (zuc -1.8)	IVSd	7.5 mm (zuc -0.6)
LVDDc	28 mm (zuc 0.1)	IVSd	11.1 mm (zuc 0.2)
LVEDV	26.7% (zuc -0.2)*	IVSPw	52%

Doppler

AIV pkVol	13.6 cm ³ (zuc -1.80)	MPeE	1 cm/s (zuc -5.2)*
AIV pkVel	7.7 cm/s (zuc -1.8)	PAeE	0.7 cm/s (zuc -5.2)
AIV minPG	3.3 mmHg	MV E/A	1.2 (zuc -0.6)
AIV VTi	2.8 cm		

Findings

Sites and Cardiac Position: Levocardia with atrial situs solitus, discordant atrioventricular and ventriculoatrial connections and normally related great arteries.

Ventricular Connections: Normal systemic venous connections. Normal pulmonary veins connections.

Atria: The left atrium (LA) is normal in size. The right atrium (RA) is normal in size.

Atrial Septum: Intact atrial septum with no evidence of atrial level shunting.

Atrioventricular Junctions: Structurally and functionally normal mitral and tricuspid valves with normal spectral and color flow Doppler.

Ventricles: The left and right ventriles are both normal in size with normal wall thickness and normal systolic function.

Ventricular Septum: intact ventricular septum. No evidence of ventricular level shunting.

Outflow Tracts: The left ventricular and right ventricular outflow tracts are normal in size with unobstructed flow.

Semilunar Valves: The aortic and pulmonary valves are structurally and functionally normal. Normal antegrade flow, physiologic regurgitation.

Aortic & Pulmonary Root: The aortic root, sinuses of Valvulus, sinistroauricular junction, proximal ascending aorta and pulmonary root are normal.

Images

Memorial Outpatient Clinic

Fetal Echocardiography Report

Gender:	F	Patient ID:	26550
BP:	126/74	Referring MD:	Natalia Franklin
		Interpreting MD:	Stacey Martinez, MD
		Technologist:	Denise Don, RDCS
		DOB/Age:	8/26/1977, 36 yr

Assess CHD
ability suspected

2-D MEASUREMENTS

(Normals)	Right Ventricle	(Normals)
3.5 cm	Dias Dimen	3.6 cm
3.1 cm	Mitral Valve	1.6 cm
1.6 cm	Ann Diam	

DOPPLER MEASUREMENTS

(Normals)	Heart Rate	(Normals)
0.3		142 bpm

SUMMARY

ID: 7/31/14 by ultrasound.
Study Summary: Small VSD observed.
PFO with R-L flow.
PDA with R-L flow.
Follow-up fetal Echo advised.

Methodist Hospital
Cardiac Catheterization Report

Gender:	M	Patient ID:	RHB0255620
BP:	138/67	Priority:	ROUTINE
HR:	85	DOB/Age:	1/08/1973, 2 yr

Heart Catheterization w/o LV Angiography, Angioplasty and Stenting of Aortic Coarctation

Stage 1

EDP		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		

PAC

141.82 ml O2d

PVC

175.93 ml O2d

PtB CO

1.45 l/min

PtB CI

2.74 l/min/m²

Arterial Blood Gases

pH: 7.3

PaCO₂: 32 mmHg

PaO₂: 42 mmHg

HC03: 23.1 mEq/l

Memorial Medical Center
100 Medical Center Drive, Houston, TX 77080

Cardiac MR Report

Gender:	M	Patient ID:	D154113
		Interpreting MD:	Joseph Franklin, MD
		DOB/Age:	7/31/2010, 7 yr

cavernous sinus S/P balloon aortoplasty January 2011

MR MEASUREMENTS

(Normals)	(Normals)
Transverse Aorta Diam-1	1.1 cm
Transverse Aorta Diam-2	1.2 cm
Isthmus Diam-1	1.1 cm
Isthmus Diam-2	1.5 cm
Posterior Aorta Diam-1	1.5 cm
Posterior Aorta Diam-2	1.5 cm

LVEF
Ejection Fraction: 60.8 ml/m²

RVEF
Ejection Fraction: 58.3 % /66 ml/m²

Hemia is normal in size. Appearances are normal. Ascending aorta is mildly enlarged. Aneurysm is visualized. Aneurysm is visualized. Aneurysm is visualized.

Structural Evaluation: Aneurysm was performed utilizing a Siemens 1.5T scanner assisted by respiratory compensation (breath-holding). Cardiac gated, contrast-enhanced, myocardial perfusion, Gadolinium-based contrast (Gadovist to 0.1 mmol/kg), and delayed enhancement imaging were utilized. Indirect complications. Image acquisition and/or volunteer-referenced reconstruction.

Normal: atrial size: atrial size: atrial size. Ventricular looping: D: Great vessel position: S: normal position. coronary sinus: Innominate bridging vein absent. Normal pulmonary veins: drainage. atrial septal defect visualized. Correct rate of the presence of a small atrial shunt and atrial septal defect. valve not evaluated. Mitral / left atrioventricular valve not evaluated. ventricle size is qualitatively normal. ed. Left atrio-auricular valve with normal branching pattern. Atrial size is upper limit of normal size. Ascending aorta is normal in size. No dissection or aneurysm could be visualized.

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