Specifications and Ordering Information

Order Number	Description
PB1018	• 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.

Order Number	Description
01-0055	Reusable jar opener

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

- 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.

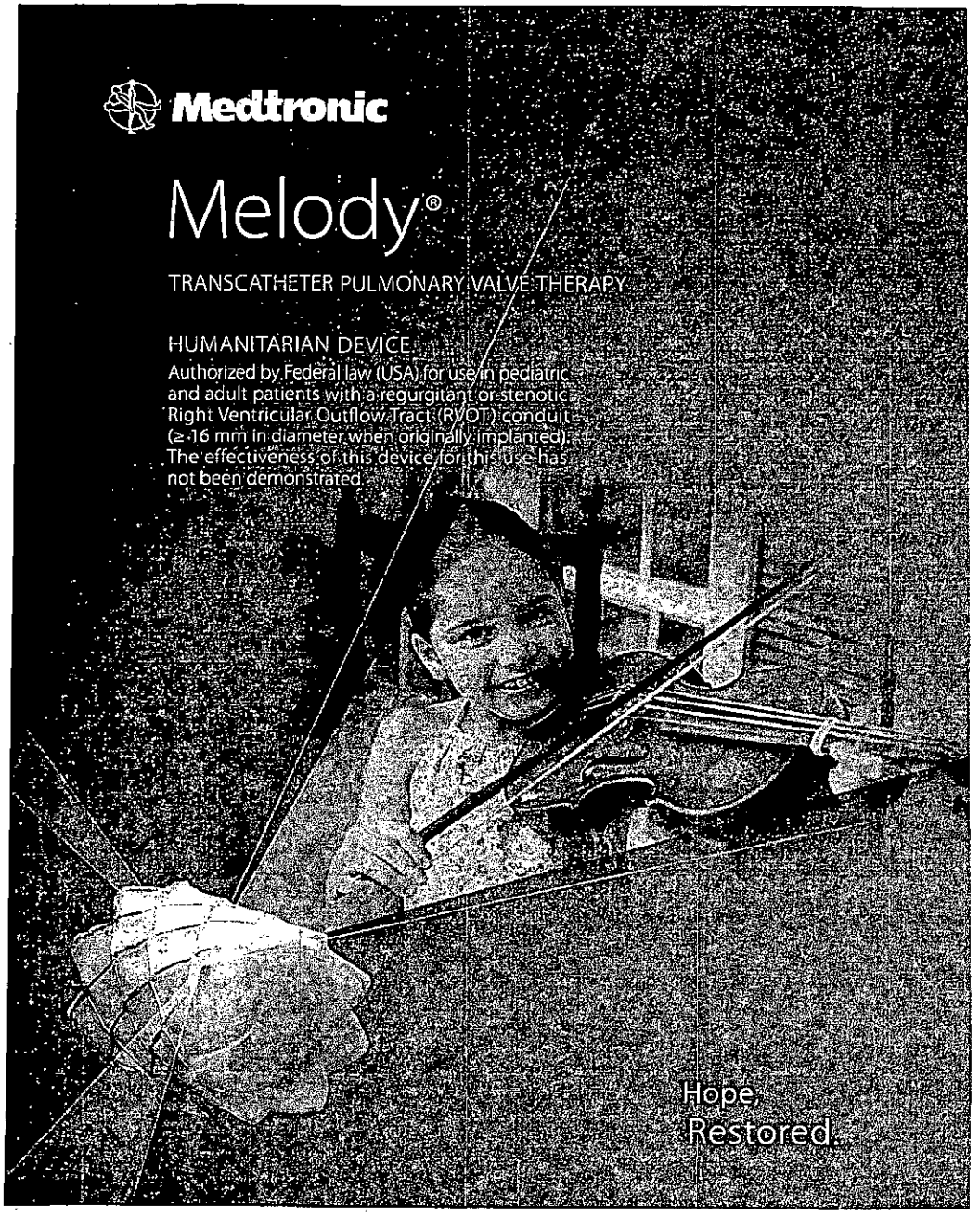
RBP = Rated Burst Pressure = Maximum Applied Pressure

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	—



www.medtronic.com

World Headquarters
Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: (763) 514-4000
Fax: (763) 514-4879

Medtronic USA, Inc.
Toll-free: 1 (800) 328-2518
(24-hour technical support for physicians and medical professionals)

Europe
Medtronic International Trading Sàrl
Route du Molliau 31
Case postale
CH-1131 Tolochenaz
Switzerland
Tel: 41.21.802.7000
Fax: 41.21.802.7900

Canada
Medtronic of Canada Ltd.
6733 Kitimat Road
Mississauga, Ontario L5N 1W3
Canada
Tel: (905) 826-6020
Fax: (905) 826-6620
Toll-free: 1 (800) 268-5346

Asia Pacific
Medtronic International, Ltd.
16/F Manulife Plaza
The Lee Gardens, 33 Hysan Avenue
Causeway Bay
Hong Kong
Tel: (852) 2891 4456
Fax: (852) 2891 6830
enquiryap@medtronic.com

Latin America
Medtronic USA, Inc.
Doral Corporate Center I
3750 NW 87th Avenue Suite 700
Miami, FL 33178
USA
Tel: (305) 500-9328
Fax: (786) 709-4244

LifeLine
CardioVascular Technical Support
Tel: (877) 526-7890
Tel: (763) 526-7890
Fax: (763) 526-7888
E-mail: rs.cstechsupport@medtronic.com

Medtronic

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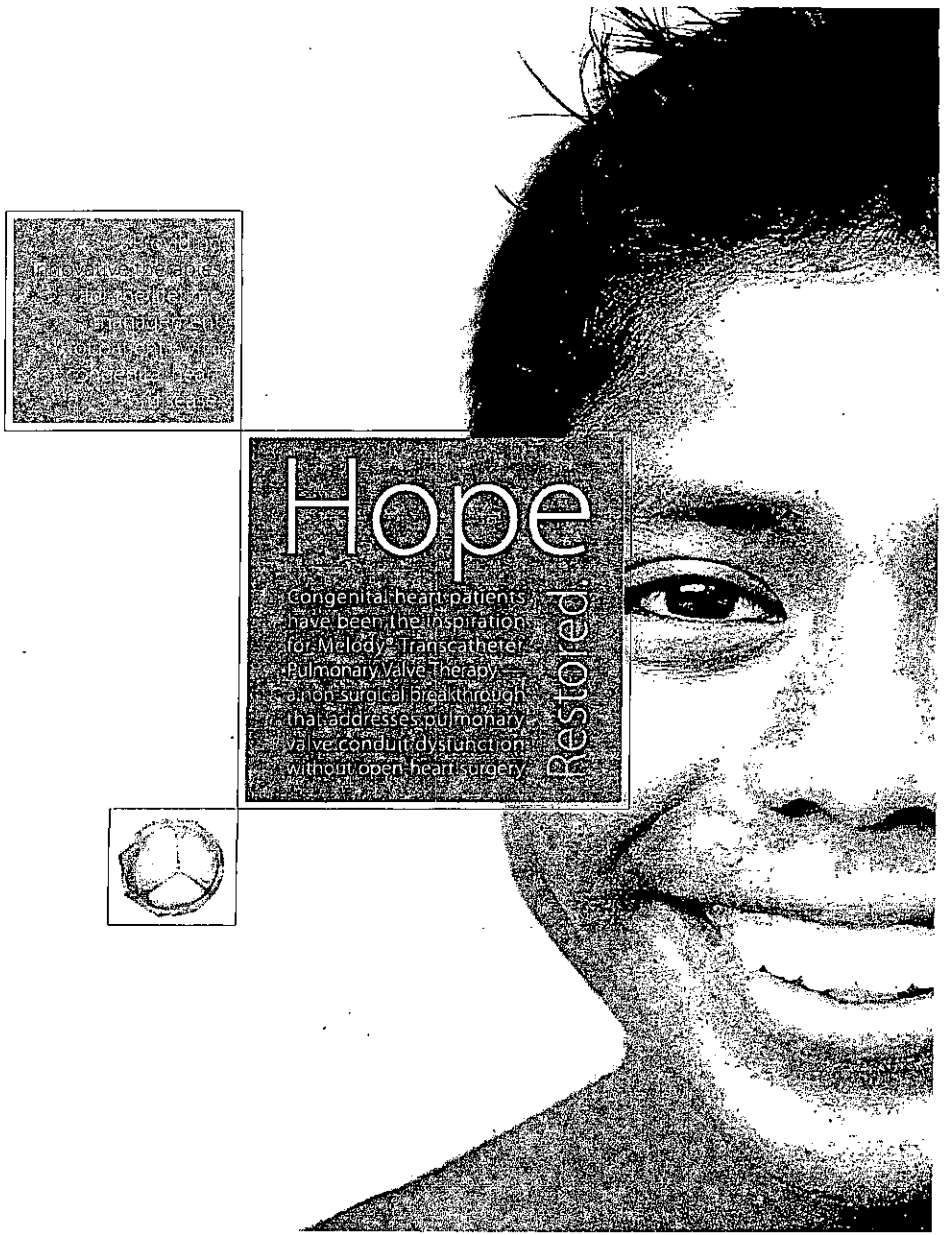
In 1957, Medtronic partnered with clinicians to pioneer the first wearable, battery-operated external pacemaker. The device was applied to a pediatric heart block patient and restored the child's heartbeat.

Innovation through

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

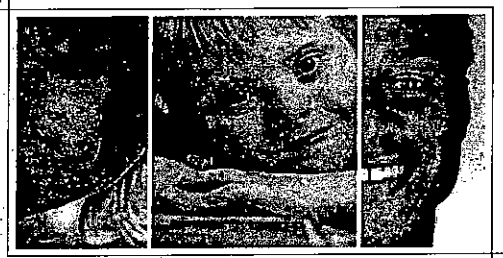


Hope

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 patients



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: ≥ moderate regurgitation, or
  - -stenosis: mean RVOT gradient ≥ 35 mm Hg.

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

Improved conduit function[1]

- Restores pulmonary valve competence
- Relieves conduit obstruction

Lengthened conduit lifespan[1]

- Delays the patient's next surgical intervention

The effectiveness of this device has not been demonstrated.

Event	U.S. Study (N=99) Freedom from Event 1 Year	European Study (N=68) Freedom from Event 1 Year	European Study (N=68) 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 stent

IMPORTANT RISK INFORMATION

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.

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

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:

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- Dysfunctional RVOT conduits with a clinical indication for intervention, and either:
  -regurgitation: ≥ moderate regurgitation, or
  -stenosis: mean RVOT gradient ≥ 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.

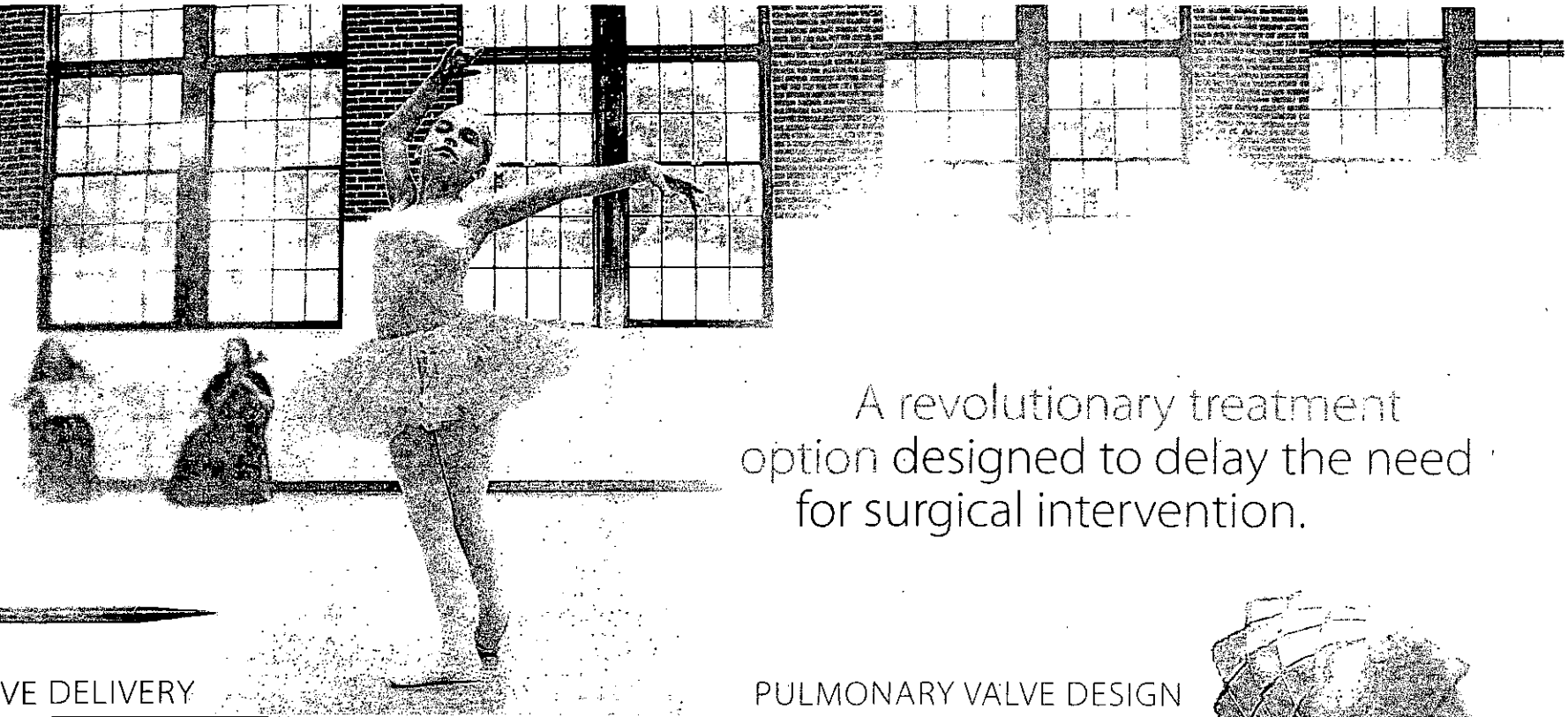
Humanitarian Device. Authorized by Federal law (USA) for use in pediatric and adult patients with a regurgitant or stenotic Right Ventricular Outflow Tract (RVOT) conduit (≥ 16 mm in diameter when originally implanted). The effectiveness of this device for this use has not been demonstrated.

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.

catheter



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

VALVE DELIVERY

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

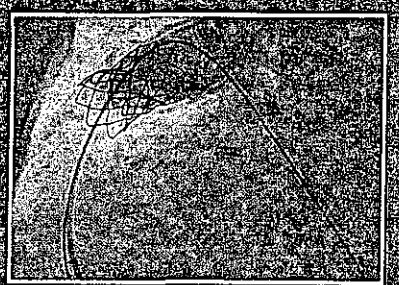
22 Fr delivery catheter offers the lowest crossing profile on the market.

Balloon-in-balloon deployment enables minor adjustments to facilitate accurate placement.

Unique coverage sheath protects valve during delivery to the point of deployment.

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.

PATIENT LABELING

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:

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Melody and Ensemble are registered trademarks of Medtronic, Inc.

Reference

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

www.medtronic.com

World Headquarters
Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: (763) 514-4000
Fax: (763) 514-4879

Medtronic USA, Inc.
Toll-free: 1 (800) 328-2518
(24-hour technical support for physicians and medical professionals)

LifeLine CardioVascular Technical Support
Tel: (877) 526-7890
Tel: (763) 526-7890
Fax: (763) 526-7888
E-mail: rs.cstechsupport@medtronic.com

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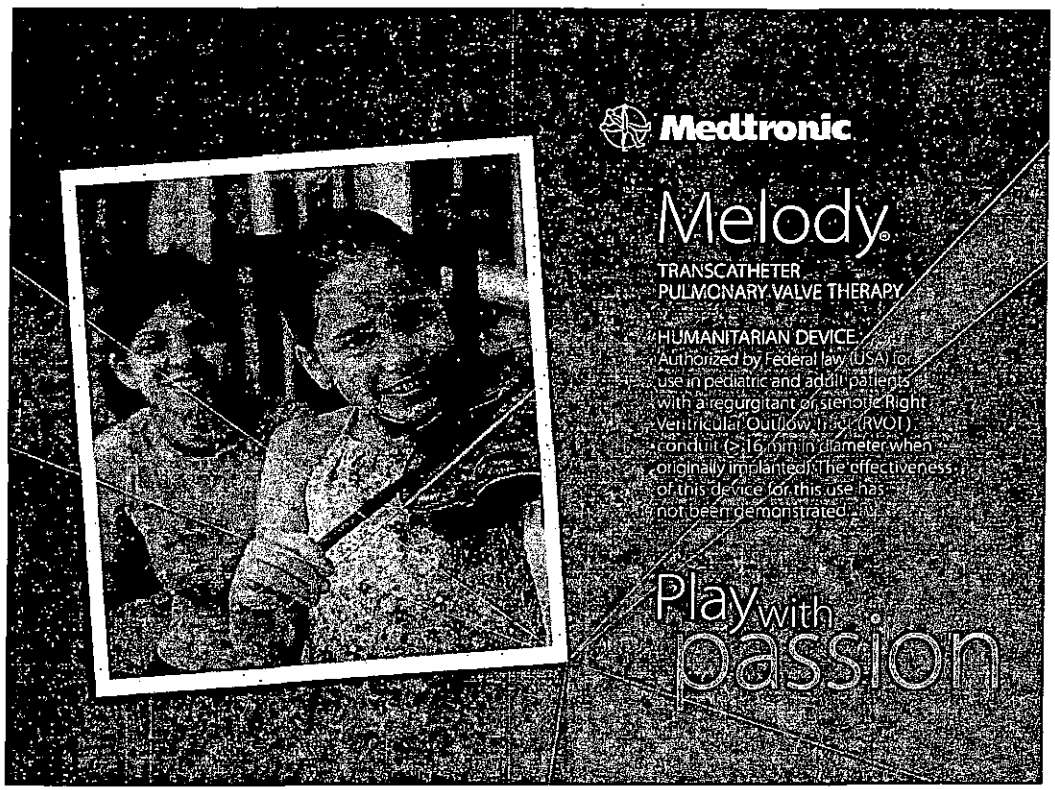

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In the 1950s, Medtronic partnered with cardiologists to create the first external pacemaker.

The pacemaker restored the heart beat of a young boy with heart block, saving his life.

At Medtronic, our culture continually inspires us to push the boundaries of medical technology to help **patients live better, longer.**

Melody® Transcatheter Pulmonary Valve (TPV) Therapy exemplifies our commitment to providing **innovative therapies** for the lifetime management of patients with congenital heart disease.

With Melody TPV Therapy, children and adults with failed pulmonary valve conduits have a **revolutionary treatment option** designed to restore pulmonary valve function and delay the need for surgical intervention.

Table of Contents

Please go to pages 11-12 for important risk information.

This booklet is provided to help you and your loved ones learn more about Melody® Transcatheter Pulmonary Valve (TPV) Therapy. Please discuss any questions with your heart doctor. Only your doctor can help you decide if Melody TPV is the right therapy for you.

About The Heart

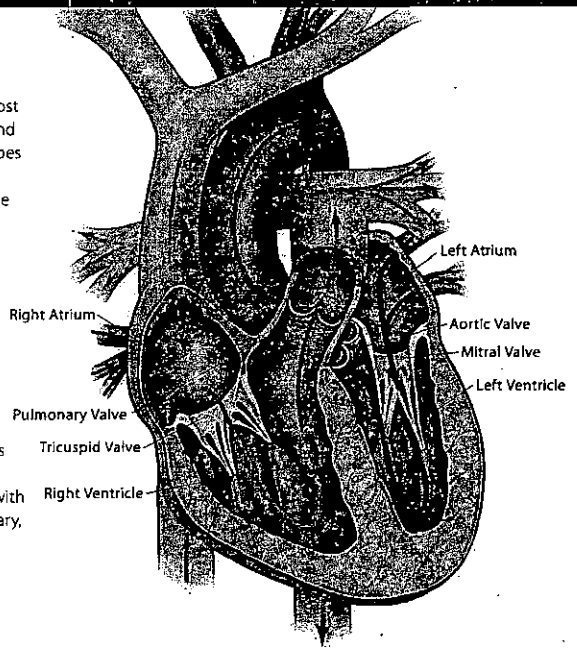
Congenital Heart Disease

Congenital (from birth) heart disease (CHD) is the most common birth defect, affecting eight in one thousand children born each year. There are many different types of CHD. Most have to do with a heart that doesn't develop like it should or with problems with the large blood vessels (the pulmonary artery, and/or aorta) connected to the heart.

How The Heart Works

A healthy heart beats about 100,000 times a day and pumps about five quarts of blood each minute or 75 gallons (284 liters) of blood every hour.

A normal heart has four chambers. The upper two chambers are the right and left atria. The lower two chambers are the right and left ventricles. The heart's job is to supply the body with oxygen-rich blood. Blood is pumped through the four heart chambers with the help of four heart valves—the tricuspid, pulmonary, mitral and aortic valves.

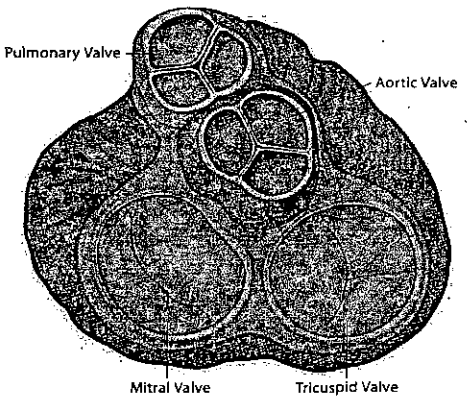


1

What Heart Valves Do

Normal heart valves repeatedly open and close as the heart beats to ensure that blood flows forward through the heart's chambers but not backwards. Any problem with this normal flow will make it hard for the heart to pump the blood where it needs to go.

- The tricuspid valve sits between the right atrium (upper chamber) and right ventricle (lower chamber). The tricuspid valve directs blood flow from the right atrium to the right ventricle.
- The pulmonary valve directs blood flow from the right ventricle into the pulmonary artery, which splits into two arteries so that the blood from the body can get to both lungs.
- The mitral valve sits between the left atrium (upper chamber) and left ventricle (lower pumping chamber). The mitral valve directs blood flow from the left atrium into the left ventricle.
- The aortic valve directs blood flow from the left ventricle into the aorta. The aorta is the major blood vessel that carries blood from the heart out to the rest of the body.



2

Pulmonary Valve Conditions And Conduit Failure

Pulmonary Valve Conditions

If your doctor has recommended that you read this booklet, you may have one of the following congenital heart conditions that most commonly affect the pulmonary valve:

- Pulmonary Atresia
- Transposition of the Great Arteries
- Tetralogy of Fallot
- Double Outlet Right Ventricle

Children and adults with these conditions have narrowed or missing pulmonary valves and need surgery for placement of a right ventricular outflow tract (RVOT) or pulmonary conduit. A pulmonary conduit is a tube that opens up the RVOT and contains an artificial valve to control blood flow between the right ventricle and the pulmonary artery.

Pulmonary Valve Conduit Failure

Over time, the conduit may become narrowed or begin to leak. This may happen as you outgrow the conduit or as the conduit wears out from the pressures of pumping blood or from calcium build up.

A Narrowed Conduit (Stenosis) The conduit opening is narrowed, which limits blood flow from the heart to the lungs and forces the heart to work harder than normal. Stenosis may be caused by calcification of the conduit walls. Stenosis can make the heart muscle thick and prevent it from working well. It can also limit the amount of blood pumped to the lungs.

A Leaky Conduit (Regurgitation) The valve does not fully close, which allows blood to leak backward into the right ventricle of the heart. This causes the heart to pump harder than it should to bring blood to the lungs and the rest of your body.

A Narrowed Conduit (Stenosis) A Leaky Conduit (Regurgitation)

Pulmonary Valve Conduit Failure Symptoms

- Becoming tired or short of breath with activity
- Feeling tired, dizzy or too weak to do your normal activities
- Irregular heart beats or the feeling that your heart is flip-flopping in your chest
- Pain in your chest
- Fainting

Symptoms can range from mild to severe. If you are experiencing any of these symptoms, talk with your doctor. Regular check ups and testing can help determine how your pulmonary valve conduit is working.

Pulmonary Valve Conduit Failure Treatments

Surgical Conduit Replacement

Standard treatment for failed pulmonary valve conduits has been conduit replacement with open-heart surgery. During the surgery, your doctor removes your failing conduit and puts a new pulmonary conduit containing an artificial pulmonary valve in its place.

Balloon Angioplasty

During this procedure, a catheter (a thin, hollow tube) is inserted into a vein in your leg and guided up to your heart. An uninflated balloon is placed through the opening of the narrowed pulmonary conduit. Your doctor then inflates the balloon, which pushes the narrowed conduit open so that blood may flow better.

Bare Metal Stenting

With this procedure, a catheter is inserted into a vein in your leg and guided up to your heart. An uninflated balloon placed inside a stent (wire frame) is placed through the opening of the narrowed pulmonary conduit. Your doctor then inflates the balloon, which forces the stent to expand and push the narrowed conduit open for better blood flow.

Transcatheter Pulmonary Valve Therapy

During transcatheter pulmonary valve therapy, a catheter holding an artificial heart valve is inserted into a vein in your leg and guided up to your heart. The heart valve is attached to a stent (wire frame) that expands with the help of balloons to deliver the valve. The new valve begins to work immediately.

Melody Transcatheter Pulmonary Valve (TPV) Therapy

About Melody TPV Therapy

Melody Transcatheter Pulmonary Valve (TPV) Therapy treats narrowed or leaking pulmonary valve conduits without open-heart surgery. With Melody TPV Therapy a thin, hollow tube (catheter) holding a specially designed heart valve is inserted into a vein in your leg and guided to your heart. The heart valve is attached to a wire frame that expands with the help of a balloon to push your blocked pulmonary conduit open.

Melody TPV Therapy is an alternative to surgery for children and adults with Right Ventricular Outflow Tract (RVOT) conduit failure. Melody TPV Therapy does not replace open-heart surgery as a treatment for conduit failure, however it is intended to delay the need for surgical intervention.

Is Melody TPV Therapy Right For You?

Melody TPV Therapy may be an option for treating your pulmonary valve conduit failure if you have a narrowed or leaking conduit that connects the right ventricle to the pulmonary artery.

When Melody Is Not An Option

There are certain circumstances where Melody TPV Therapy should not be used. Melody TPV Therapy should not be used in a patient:

- Whose conduit is too large or too small;
- Whose veins are too small for the delivery system; and/or
- Who has signs of infection.

Your heart doctor can help you decide if Melody TPV Therapy may be right for you.

The goal of Melody TPV Therapy is to restore pulmonary valve conduit function while delaying your next open-heart surgery as long as possible.

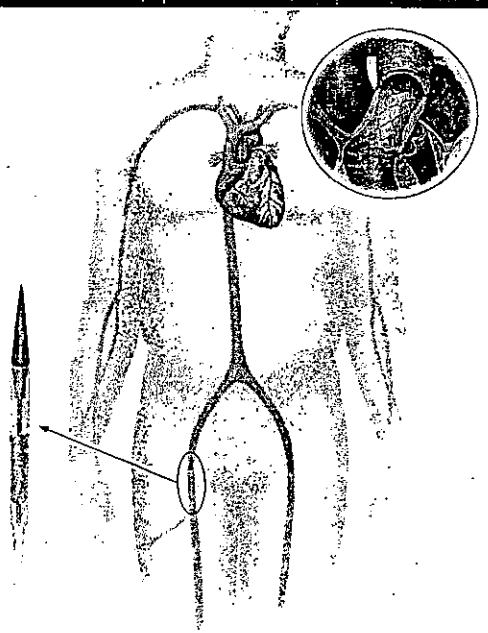
The Melody TPV Procedure

The following section describes what happens during the Melody TPV procedure. It is intended as a general overview. Your experience may be different. Please talk to your doctor for more information about what to expect.

During The Procedure

Typically, the Melody TPV procedure takes 1-2 hours. Patients are asleep for the procedure and usually don't feel any pain.

1. Your doctor will insert the delivery system into your leg through a small access site.
2. The catheter holding the Melody valve will be placed into the vein and guided into your heart.
3. Once the Melody valve is in the right position, the balloons will be inflated to deliver the valve.
4. The Melody valve will expand into place and begin to direct blood flow between the right ventricle and your lungs.
5. The catheter will then be removed and the doctor will conduct a test to make sure the valve is working properly.
6. The access site in your leg will be closed, and the procedure will be complete.



After The Procedure

After the Melody TPV procedure, you will go to a recovery room. Once you are fully awake and able to drink and eat, you will be moved to a regular hospital room.

You likely will need to stay in the hospital overnight as most people go home the next day. Your doctor will provide you with more specific care instructions as well as any limitations you will have. **You will need about one week to recover from the procedure before returning to your everyday activities.** If you have any questions, please ask your heart doctor or nurse.

Follow-up Care

After your Melody TPV procedure, it is important to follow your doctor's instructions to ensure the best possible results.

- Continue to take medications as prescribed
- Follow your daily care plan
- Keep appointments to have your heart and Melody TPV checked
- Talk with your doctor if you have pain or other symptoms
- Tell your dentist that you have a tissue valve. (During dental work, bacteria may be released into the bloodstream and cause infection in any biological valve. This means that you will need to be on antibiotics before any dental procedure, even routine cleaning.)
- Inform your other doctors about your heart valve before any medical procedure

Talk with your heart doctor or nurse if you have more questions about living with your Melody valve.

Risks And Probable Benefits

Possible Adverse Events

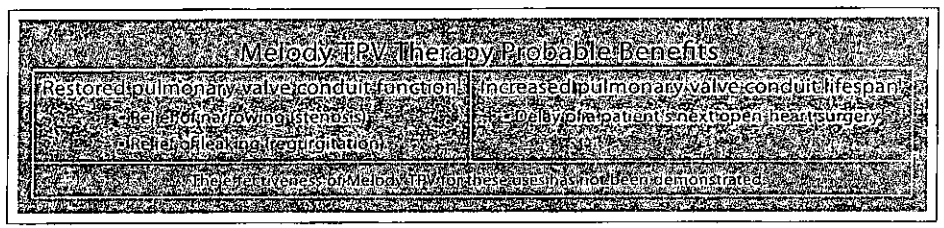
As with any cardiac catheterization procedure, certain complications may occur. The potential risks associated with Melody TPV are similar to those if you had a cardiac catheterization procedure to have the narrowing in your homograft or conduit stretched with a balloon and/or a wire frame placed to hold the conduit open.

Cardiac catheterization has been associated with serious complications, including death. Complications that may occur from any catheterization procedure include the following:

- Tearing of the blood vessel where the catheter is inserted
- Bleeding from the site where the catheter is inserted
- Irregular heart beat
- Perforation of a heart chamber.
- Allergic reaction to the x-ray dye
- Infection
- Pain, swelling, and bruising at the site where the catheter was inserted
- Fever
- Reddening of the skin due to x-ray
- Stroke

Other complications that may result from implantation of the Melody TPV include the following:

- Breakage of the wire frame that supports the tissue valve
- Ineffective function of the valve (leakage of the valve)
- Dislodgment of the valve from where it was implanted
- Clot formation within the valve that affects its function or travels to the lung
- Infection of the valve (endocarditis)
- Tearing of the conduit during the procedure
- Blockage of arteries that supply the heart



Important Information About Stent Fracture

In some patients, the wire frame (stent) of the Melody TPV may break because of the forces it is exposed to in your body. The chance of the stent breaking may increase the longer the device is in your body. There is up to a 35 percent chance that the Melody TPV stent will break within one year of placement. In some cases, the broken stent does not require additional treatment.

However, you should realize a broken stent has the potential to become serious and could result in the need for another catheter intervention, an operation to replace your conduit, or could lead to death. Your doctor will decide your best treatment option.

For the complete data set, additional information and Instructions for Use documentation, contact **Medtronic LifeLine CardioVascular Technical Support at 877-526-7890.**

FAQs and Resources

Frequently Asked Questions

- *Are physical activities safe?*

  Physical activities are safe for most patients but you should talk with your heart doctor to decide what is best for you.

- *Is it safe to have an x-ray with a Melody valve?*

  It is completely safe to have an x-ray with a Melody valve.

- *Is it safe to have an MRI with a Melody valve?*

  You may safely undergo MRI scanning under specific conditions. If you need a magnetic resonance imaging (MRI) scan, tell your doctor or MRI technician that you have a Melody valve.

- *Is it safe to go through airport security with a Melody valve?*

  Yes. Airport security systems do not affect Melody valves, and the valve will not set off airport alarms.

- *How long will my Melody valve last?*

  Because relatively few patients have had a Melody valve implanted for more than three years, it is hard to predict how long your Melody valve will last beyond that duration. However, from the information we have, you should understand there is up to a 15% chance that you may require another catheterization procedure to restore the function of the Melody valve within one year of placement. Catheterization procedures to restore function of the Melody valve may include balloon angioplasty or placement of another Melody valve within the first year. In addition, you should understand there is up to a 25% chance your conduit may require surgical replacement within three years after placement of your Melody valve.

Online Resources

- Adult Congenital Heart Association: **www.achaheart.org**
- American Heart Association: **www.americanheart.org**
- Children's Heart Foundation: **www.childrensheartfoundation.org**
- Children's Hospital Boston: **www.childrenshospital.org**
- Congenital Heart Information Network: **www.tchin.org**
- European Congenital Heart Disease Organization: **www.echdo.org**
- Johns Hopkins: **www.pted.org**
- The International Society for Congenital Heart Disease: **www.isachd.org**
- Mayo Clinic: **www.mayoclinic.com/health/congenital-heart-defects/DS01117**
- Melody® TPV Therapy: **www.Melody-TPV.com**

We're There When You Need Us. Medtronic LifeLine Technical Support

With more than 60 years of experience, Medtronic has a very knowledgeable staff who can speak directly with you about non-medical questions you may have about your Melody valve.

Please contact us with any questions or concerns about living with your Melody valve.

Medtronic LifeLine
CardioVascular Technical Support
877-526-7890

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