

INFORMATION FOR YOU AND YOUR FAMILY

Melody™ Transcatheter Pulmonary Valve Therapy



Medtronic

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.

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

Melody Transcatheter Pulmonary Valve (TPV) Therapy demonstrates 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 surgical valves or conduits have a proven treatment option designed to restore pulmonary valve function and delay the need for surgery.

Thousands of patients from around the world have benefited from this therapy since it became available in Europe in 2006.

TABLE OF CONTENTS

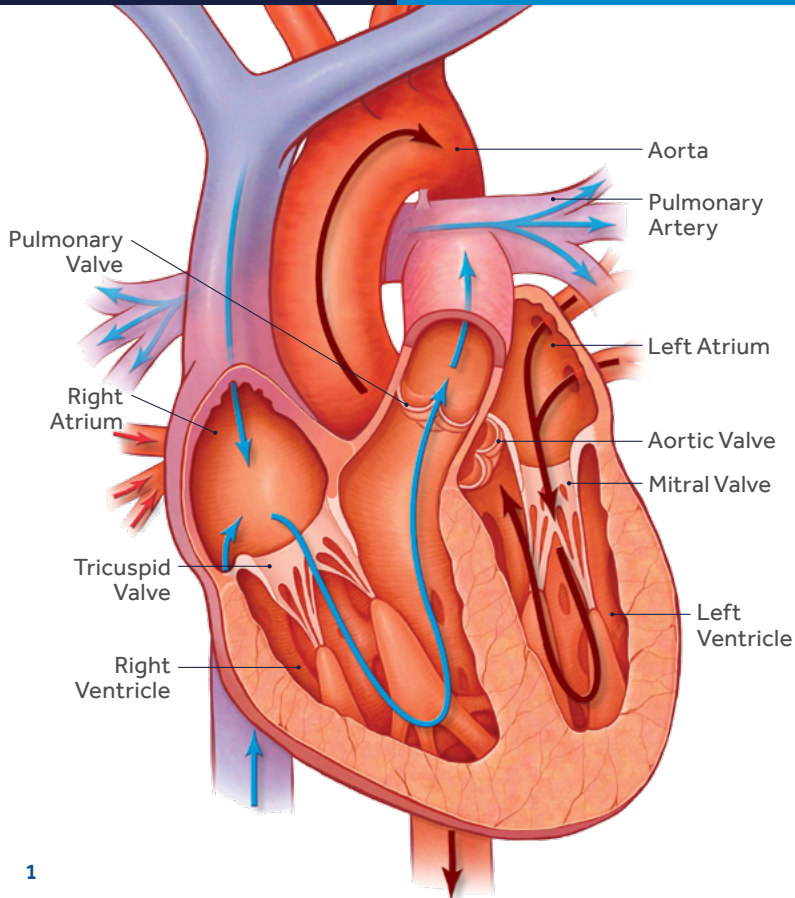
- 1 - 2 | ABOUT THE HEART
 - Congenital Heart Disease
 - How The Heart Works
 - What Heart Valves Do
- 3 - 4 | PULMONARY VALVE CONDITIONS AND VALVE FAILURE
 - Pulmonary Valve Conditions
 - Pulmonary Surgical Valve or Conduit Failure
 - Pulmonary Surgical Valve or Conduit Failure Symptoms
- 5 | PULMONARY VALVE FAILURE TREATMENT OPTIONS
 - Surgical Valve or Conduit Replacement
 - Balloon Angioplasty/Valvuloplasty
 - Transcatheter Pulmonary Valve Therapy
- 6 | MELODY TRANSCATHETER PULMONARY VALVE (TPV) THERAPY
 - About Melody™ TPV Therapy
 - Is Melody Right For You?
 - When Melody Isn't An Option
- 7 - 8 | THE MELODY TPV PROCEDURE
 - During The Procedure
 - After The Procedure
 - Follow-Up Care
- 9 - 14 | RISKS AND BENEFITS
 - Risks You Should Know
 - Other Possible Risks Associated With Melody TPV
 - Melody TPV Therapy Benefits
 - Important Information About Stent Fracture
- 15 | ADDITIONAL WARNINGS AND PRECAUTIONS
 - Warnings
 - Precautions
- 16 | FREQUENTLY ASKED QUESTIONS
- 17 | RESOURCES
 - Online Resources
 - Medtronic LifeLine Technical Support

This therapy is not for everyone. Please consult your physician. A prescription is required. For further information, please contact Medtronic at 1-877-526-7890. Please see page 9 for important risk information.

ABOUT THE HEART

Congenital Heart Disease

Congenital (from birth) heart disease (CHD) is the most common birth defect, affecting eight in one thousand infants 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. Blood is pumped through the four heart chambers with the help of four heart valves—the tricuspid, pulmonary, mitral and aortic valves. The heart's job is to supply the body with oxygen-rich blood. First it sends blood without any oxygen to the lungs to get oxygen. It then returns it to the heart where the blood containing oxygen will be pumped to other parts of the body.

What Heart Valves Do

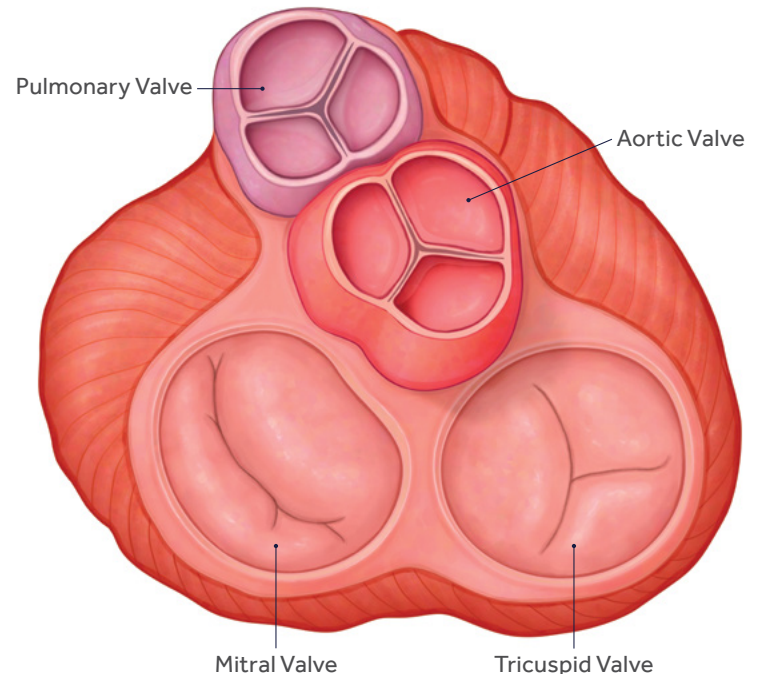
Heart valves open when the heart pumps to allow blood to flow forward, and close quickly between heartbeats to make sure blood does not flow backward. Any problem with this normal flow will make it difficult for the heart to effectively pump the blood where it needs to go.

Tricuspid Valve | sits between the right upper chamber (right atrium) and the right lower chamber (right ventricle). The tricuspid valve directs blood flow from the right upper chamber to the right lower chamber.

Pulmonary Valve | directs blood flow from the right lower chamber (right ventricle) into the pulmonary artery, which splits into two arteries so that the blood from the body can get to both lungs.

Mitral Valve | sits between the left upper chamber (left atrium) and left lower chamber. The mitral valve directs blood flow from the left upper chamber into the left lower chamber.

Aortic Valve | directs blood from the left lower chamber (left ventricle) into the aorta. The aorta is the major blood vessel that leads from the left lower chamber to the rest of the body.



PULMONARY VALVE CONDITIONS AND AND VALVE 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 | A condition where the pulmonary valve has no opening for blood to flow through. This means that blood cannot go to the lungs to pick up oxygen.

Tetralogy of Fallot | A condition which refers to four heart defects that usually occur together; a hole between the right and left pumping chambers of the heart (ventricles), a narrowed path between the heart and the lungs, an artery (aorta) that is connected to the heart closer to the right side of the heart than normal, and a thicker than normal pumping chamber (ventricle) on the right side of the heart.

Double Outlet Right Ventricle | A condition in which both main arteries, one that carries blood to the lungs (pulmonary artery) and one that carries blood to the rest of the body (aorta), are connected to the right lower chamber of the heart (ventricle). Usually, the aorta is connected to the left lower chamber of the heart.

Children and adults with these conditions have damaged, narrowed or absent pulmonary valves and need surgery for placement of:

- Right ventricular outflow tract (RVOT) conduit - a tube that connects the flow of blood from the heart to lungs
- Artificial tissue valve - made of animal tissue, often from a pig or cow

Pulmonary Surgical Valve or Conduit Failure

Over time, mineral deposits may build up on the surgical valve or conduit (calcification), and it may become narrowed and/or leaky. This may happen as you outgrow your surgical valve or conduit, or as it wears out from the pressures of pumping blood or from calcium build up.

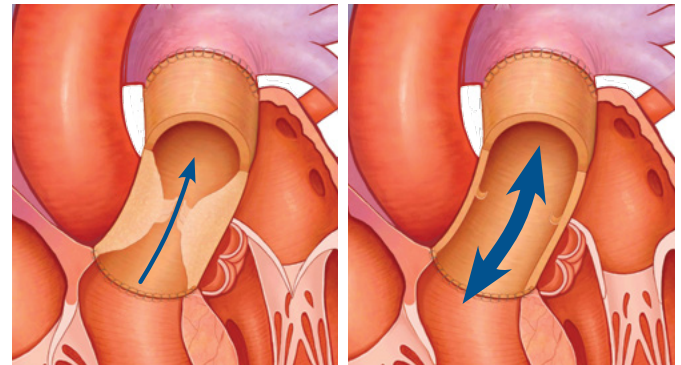
Narrowing (Stenosis) | The surgical valve or conduit opening is narrowed, which limits blood flow from the heart to the lungs and forces the heart to work harder than normal. Stenosis may be caused by a build up of minerals on the surgical valve or conduit walls (calcification). Stenosis can make the heart muscle thick and prevent it from working well. It can also limit the amount of blood pumped to the lungs.

Leaking (Regurgitation) | The surgical valve or conduit does not have a working valve which causes blood to leak backward into the right lower chamber of the heart (ventricle). This causes the heart to pump harder than it should to bring blood to the lungs and the rest of your body.

Pulmonary Surgical Valve or 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 racing or pounding in your chest
- Fainting or near 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 surgical valve or conduit is working.



Narrowing
(Stenosis)

Leaking
(Regurgitation)

PULMONARY VALVE FAILURE TREATMENT OPTIONS

Surgical Valve or Conduit Replacement

The standard treatment for narrowed or leaking pulmonary surgical valves or conduits has been another heart surgery to place a new valve. During the surgery, your doctor removes your failing surgical valve or conduit and places a new surgical valve or conduit.

Balloon Angioplasty/Valvuloplasty

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

Transcatheter Pulmonary Valve Therapy

An artificial heart valve attached to a wire, mesh-like tube (stent) is placed on a thin, flexible tube (catheter) with a balloon on the end and guided to the heart through a vein (usually at the top of the leg or a neck vein). It is put in the failed surgical valve or conduit. Once in place, the balloon is inflated to open up the valve into position. The catheter is removed from the body, and the artificial heart valve becomes the new pulmonary valve.

MELODY™ TRANSCATHETER PULMONARY VALVE (TPV) THERAPY

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



About Melody TPV Therapy

Melody TPV Therapy treats narrowed or leaking pulmonary surgical valves or conduits without open-heart surgery. With Melody TPV Therapy, a thin, hollow tube (catheter) with a specially designed heart valve inside is inserted into a vein and pushed up to your heart. The heart valve is made from a cow's vein that has been attached to a wire frame. When it is time for you to get the new valve, it is placed onto a catheter and guided through your vein to your heart where the new valve will replace the old one. Your new valve will then be able to help your heart pump blood correctly.

Melody TPV is a different option to take care of a failing pulmonary surgical valve or conduit in children and adults. Melody TPV Therapy does not replace open heart surgery but is meant to delay the need for the next surgery.

Is Melody TPV Therapy Right For You?

Melody TPV Therapy may be an option for treating your failing pulmonary valve.

When Melody TPV Therapy Is Not An Option

There are no known contraindications for the Melody TPV. See Additional Warnings and Precautions section for conditions where safety of the Melody TPV has not been proven.

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

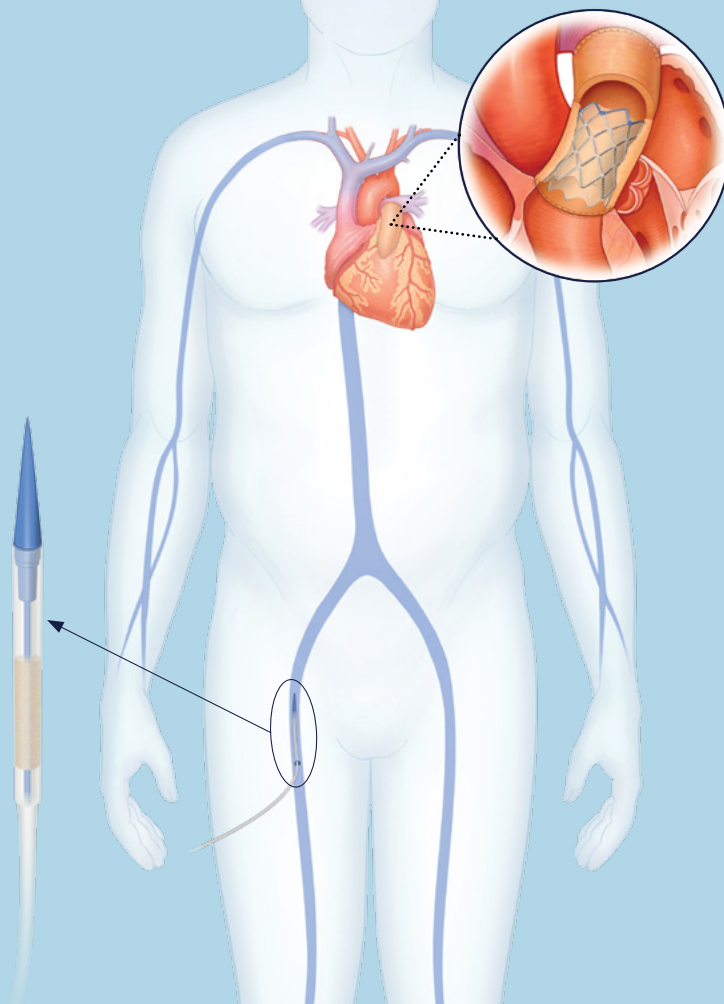
THE MELODY™ TPV PROCEDURE

During The Procedure

Typically, patients are asleep under anesthesia for the procedure and usually don't feel any pain.

- 1.** Your doctor will insert the delivery system into your vein (typically in your leg) through a small access site.
- 2.** A thin, hollow tube (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 lower chamber (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 will be closed, and the procedure will be complete.

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.



After The Procedure

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

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 may have. Usually, you can return to normal activities in one to two days. 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 heart care team'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
- Inform your other doctors about your heart valve before any medical procedure
- **If you have an unexplained, prolonged fever, contact your doctor to ensure you do not have an infection related to your heart valve**
- **Tell your dentist that you have an artificial tissue valve. During dental work, bacteria may be released into the bloodstream and cause infection in any tissue valve. This means that you may need to be on medicine (antibiotics) before any dental procedure, even routine cleaning**

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

RISKS YOU SHOULD KNOW

What are the Potential Risks One Year after Melody™ TPV Implantation in a Surgical Valve?

As with any major medical procedure there is a risk of complications after the procedure to implant a Melody TPV into a surgical valve.

The major risks one year after this procedure are as follows:

- Embolization of the TPV — movement of the valve from where it was implanted
- Major Stent Fracture — breakage of the wire frame (stent) that supports the tissue valve and may lead to blockage of the valve
- Prosthetic Valve Endocarditis — infection of the valve
- Valve Dysfunction: Regurgitation — backward flow of blood through the valve
- Valve Dysfunction: Stenosis — narrowing of the valve



The following table summarizes the potential risks one year after Melody TPV implantation in a surgical valve:

Risk	One year after Melody TPV implant
Embolization of TPV	0 out of 100 patients
Major Stent Fracture	0 out of 100 patients
Prosthetic Valve Endocarditis	0 out of 100 patients
Valve Dysfunction: Regurgitation	1 out of 100 patients
Valve Dysfunction: Stenosis	2 out of 100 patients

RISKS YOU SHOULD KNOW

What are the Potential Risks One Year after Melody™ TPV Implantation in a Conduit?

As with any major medical procedure there is a risk of complications after the procedure to implant a Melody TPV in a conduit.

The major risks one year after this procedure are as follows:

- Embolization of the TPV — movement of the valve from where it was implanted
- Major Stent Fracture — breakage of the wire frame (stent) that supports the tissue valve and may lead to blockage of the valve
- Prosthetic Valve Endocarditis — infection of the valve
- Valve Dysfunction: Regurgitation — backward flow of blood through the valve
- Valve Dysfunction: Stenosis — narrowing of the valve



The following table summarizes the potential risks one year after Melody TPV implantation in a conduit:

Risk	One year after Melody TPV implant
Embolization of TPV	0 out of 100 patients
Major Stent Fracture	9 out of 100 patients
Prosthetic Valve Endocarditis	3 out of 100 patients
Valve Dysfunction: Regurgitation	1 out of 100 patients
Valve Dysfunction: Stenosis	4 out of 100 patients

Other Possible Risks Associated with Melody™ TPV

As with any medical procedure, there is a risk of side effects or complications during or after the Melody TPV procedure, which may be serious, including death. Complications that may occur during or after this procedure include:

- Pain, swelling, and bruising at the site where the thin, hollow tube (catheter) entered your body
- Bleeding or pain at the site where the thin, hollow tube (catheter) entered your body
- Fever
- Reddening, peeling, or blistering of the skin due to x-rays
- Infection
- Irregular heart beat
- Tearing of the blood vessel where the thin, hollow tube (catheter) is inserted
- Tearing of a heart chamber or the pulmonary conduit
- Allergic reaction to the x-ray dye
- Stroke (a condition in which decreased blood flow to the brain causes brain cells to die)
- Tearing of the conduit during the procedure
- Squeezing of the arteries near the failed conduit when the stent or valve is expanded
- Development of a blood clot within the valve which affects its function or travels to the lung
- Movement of the valve from where it was implanted
- Breakdown of red blood cells
- Leakage of blood around the valve or valve frame
- Poking a hole in a large blood vessel (perforation)

RISKS AND BENEFITS

Melody™ TPV Therapy Benefits

Restored pulmonary valve function¹

- Relief of narrowing (stenosis)
- Relief of leaking (regurgitation)

Increased pulmonary valve lifespan¹

- Delay of a patient's next open-heart surgery

Important Information About Stent Fracture

In some patients, the wire frame (stent) of the Melody TPV may fracture because of the forces it is exposed to in your body. In some cases, the fractured stent may not require additional treatment.

However, you should realize a fractured stent has the potential to become serious and could result in the need for another procedure to replace your conduit. Your doctor will decide your best treatment option. There is up to a 3% chance that your Melody TPV stent will break within one year of placement, requiring you to have another procedure.

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



ADDITIONAL WARNINGS AND PRECAUTIONS



Warnings

The safety and effectiveness of the Melody™ Transcatheter Pulmonary Valve (TPV) has only been established in patients who have a narrowed or leaky pulmonary surgical valve or conduit.

Precautions

The safety and effectiveness of the Melody Transcatheter Pulmonary Valve has not been proven in the following:

- Patients who have a disease of their aortic valve (valve that controls blood from the heart to the body) or mitral valve (valve that controls blood from the top left chamber of the heart to the bottom left chamber of the heart). The Melody TPV may not work properly when used in these locations.
- Patients whose blood vessels are not big enough for the device
- Patients who have an infection in the heart (endocarditis) or somewhere else in the body

CAUTION: This device is restricted to sale by or on the order of a physician.

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 a magnetic heart scan (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 or show your doctor your Melody implant card.

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?

The length of time that your Melody valve will last depends on several factors including your unique anatomy and health condition. Some patients may require another procedure to restore function of the valve. Procedures to restore function of the Melody valve may include non-surgical procedures such as balloon angioplasty (inflating a balloon to push the valve open so that blood may flow better) or open-heart surgery. The table below provides information from Medtronic's clinical study, showing the number of patients who needed another procedure within seven years after their Melody valve was implanted.

IDE Study (# of subjects)			
	Three Years Post-Implant	Five Years Post-Implant	Seven Years Post-Implant
Non-Surgical Procedures	12 out of 100	19 out of 100	21 out of 100
Surgery	3 out of 100	8 out of 100	11 out of 100

IDE - Investigational Device Exemption

RESOURCES

Medtronic

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

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
www.medtronic.com

www.Melody-TPV.com
www.medtronic.com

Online Resources

- Adult Congenital Heart Association: www.achaheart.org
- American Heart Association: www.americanheart.org
- Children's Heart Foundation: www.childrensheartfoundation.org
- Congenital Heart Information Network: www.tchin.org
- European Congenital Heart Disease Organization: www.echdo.org
- The International Society for Adult Congenital Heart Disease: www.isachd.org
- Melody™ TPV Therapy: www.Melody-TPV.com

We're Here 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

©2017 Medtronic. All rights reserved. Medtronic, Medtronic logo and Further, Together are trademarks of Medtronic. All other brands are trademarks of a Medtronic company.
UC201501803b EN 02/2017