

HARMONY™ TRANSCATHETER PULMONARY VALVE (TPV)

Information for You and Your Family



Medtronic

This booklet is provided to help you learn more about severe pulmonary regurgitation and Harmony™ Transcatheter Pulmonary Valve TPV therapy. Please discuss any questions with your heart doctor or heart team. Only your doctor can help you decide if Harmony TPV is right for you.

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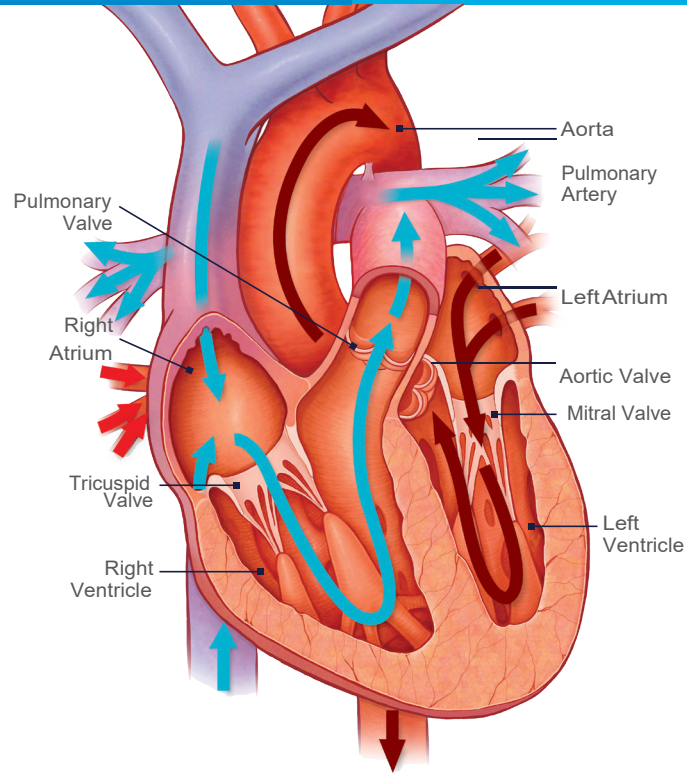
This therapy is not for everyone. Please consult your physician. A prescription is required. For further information, please contact Medtronic at 1-877-526-7890. Please go to pages 13–14 for important risk information.

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 (pulmonary artery and/or aorta) connected to the heart.

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 hard for the heart to pump the blood where it needs to go.



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.

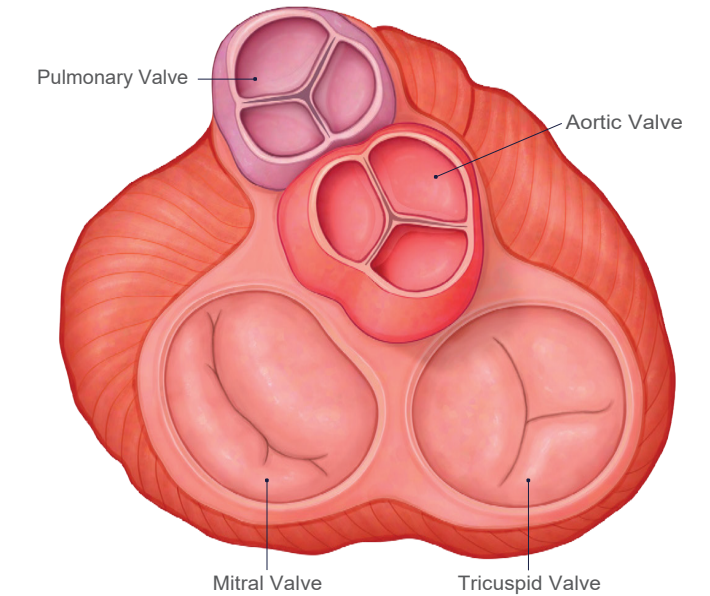
A normal heart has four chambers. The upper two chambers are the right and left atria. The lower two chambers are the right and left ventricles. Blood is pumped through the four heart chambers with the help of four heart valves — the tricuspid, pulmonary, mitral, and aortic valves. The heart's job is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

Tricuspid Valve | Directs blood flow from the right upper heart chamber to the right lower pumping chamber.

Pulmonary Valve | Directs blood flow from the right lower pumping chamber into the main pulmonary artery, which branches into the left and right pulmonary arteries, taking blood to the right and left lung.

Mitral Valve | Directs blood flow from the left upper heart chamber into the left lower pumping chamber.

Aortic Valve | Directs blood from the left lower pumping chamber into the aorta. The aorta is the major blood vessel that carries oxygenated blood from the left pumping chamber out to the rest of the body.



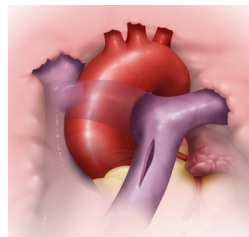
SEVERE PULMONARY REGURGITATION



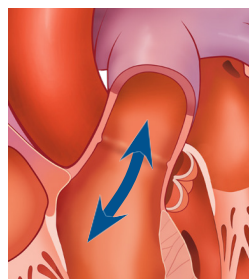
Severe Pulmonary Regurgitation and the Need for a Pulmonary Valve Replacement

If your heart doctor or heart team has recommended that you read this booklet, you may have a congenital heart condition that affected your pulmonary valve. This may have required a procedure early in life to help blood flow to the lungs, leaving you with a native or surgically-repaired right ventricular outflow tract.

After having one of these procedures, you may or may not have a working pulmonary valve, which could cause regurgitation or blood leaking backward into the right lower chamber of the heart (ventricle). This causes the heart to pump harder than it should to bring blood back to the lungs. If the leakiness of the valve is severe, replacement of the pulmonary valve may be recommended.



Native or Surgically-Repaired Right Ventricular Outflow Tract



Leaking (Regurgitation)

Symptoms That May Mean You Need a New Valve:

- Becoming tired or short of breath with activity
- Feeling tired, dizzy, or too weak to do your normal activities
- Problem with the rate or rhythm of the heartbeat, 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 having any of these symptoms, talk with your doctor. Regular checkups and testing can help determine how well your heart is working.



OPTIONS FOR PULMONARY VALVE REPLACEMENT

Surgical Valve Replacement

The traditional treatment for pulmonary valve replacement has been open-heart surgery. Open-heart surgery is done to place a new artificial valve. Patients usually need to stay in the hospital for a week or more before beginning a long period of recovery.

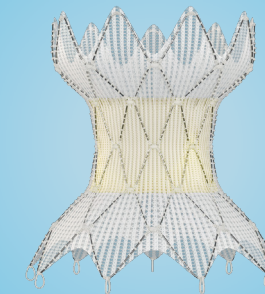
Transcatheter Pulmonary Valve Therapy

TPV therapy does not require open-heart surgery and is meant to delay the need for the next open-heart surgery. This generally means a shorter stay in the hospital, a quicker return to normal activities, and a much smaller incision.



HARMONY™ TRANSCATHETER PULMONARY VALVE (TPV) THERAPY

The goal of Harmony TPV therapy is to restore pulmonary valve function while delaying your next open-heart surgery.



About Harmony TPV Therapy

With Harmony TPV therapy, a thin, hollow tube (catheter) with a heart valve inside is inserted into a vein and pushed up to your heart. The heart valve is made from tissue from a pig's heart 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 Harmony valve will be put in place. Your new valve will begin to function immediately.

Harmony TPV is an option to help patients who may or may not have a working pulmonary valve. Harmony TPV therapy does not replace open-heart surgery, but is meant to delay the need for the next surgery.

Is Harmony TPV Therapy Right for You?

Your heart doctor can help you decide whether Harmony TPV therapy is right for you. For some patients, the Harmony procedure risks may outweigh the benefits. See pages 14–15 for the risks.

When Harmony TPV Is Not an Option

The Harmony TPV should not be used in certain situations:

- Have an infection
- Cannot take blood-thinning medicines
- Have a reaction to some metals

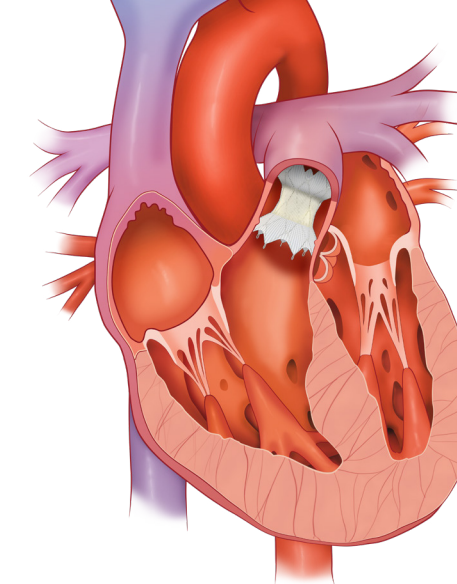
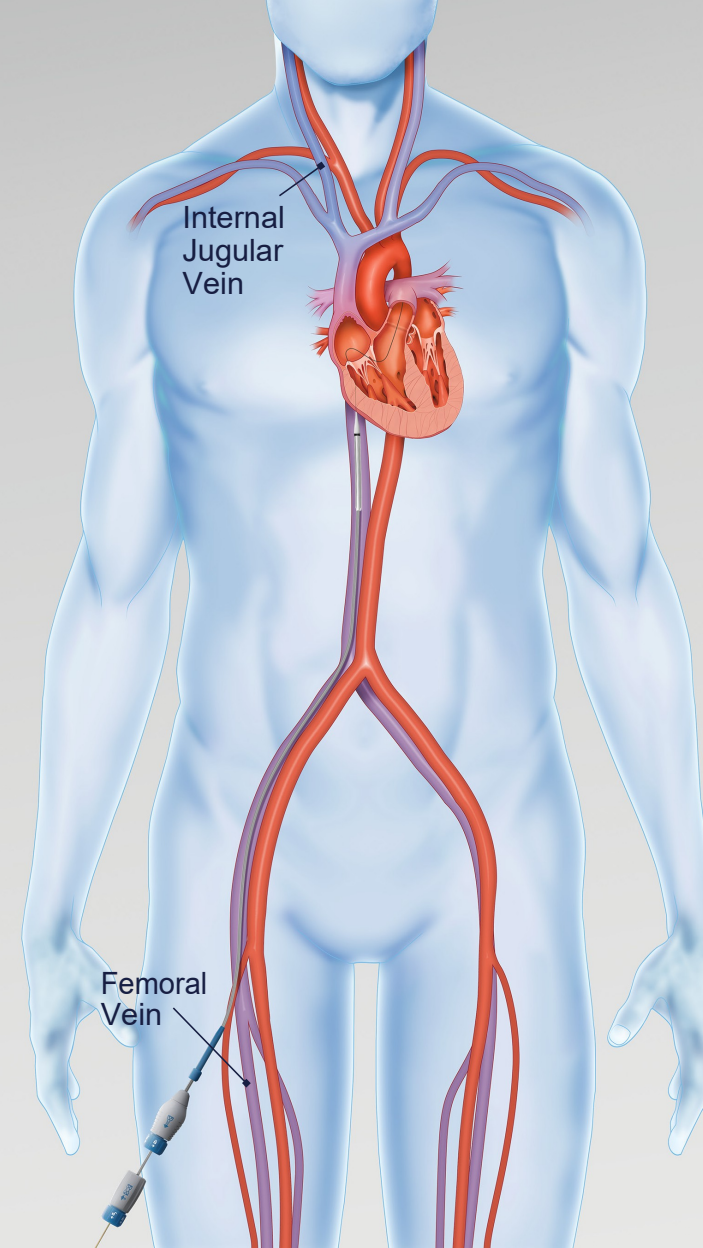
THE HARMONY™ TPV PROCEDURE



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

During the Procedure

1. You will be asleep under anesthesia.
2. The large vein at the top of your leg (femoral vein) and/or the vein in your neck (internal jugular vein) will be used.
3. The delivery catheter system (a thin, hollow tube) holding the Harmony valve will be placed into the vein and guided into your heart by special X-ray equipment.
4. Once the Harmony valve is in the pulmonary position, the valve will be uncovered, which allows it to expand to fit in place. The new valve will then be released from the delivery catheter.
5. The Harmony valve will immediately begin to work, allowing blood to flow from the right pumping chamber, across the new valve, and out to the lungs.
6. The delivery catheter will then be removed. The pressure across the valve will be measured and imaging pictures will be taken to make sure the valve is working properly.
7. All catheters will be removed, the access site will be closed, and the procedure will be completed.



After the Procedure

After the Harmony 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 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. You should be able to return to normal activities within an average of one to two days. If you have any questions, please ask your heart doctor or a member of your heart team.

FOLLOW-UP AFTER THE PROCEDURE

After your Harmony TPV procedure, it is important to follow your heart doctor and 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 Harmony TPV checked.
- Talk with your heart doctor or heart team if you have pain or other symptoms.
- If you have an unexplained, prolonged fever, contact your heart doctor or heart team.
- An implant card will be given to you. Please be sure to keep it with you at all times.

Talk with your heart doctor or heart team if you have more questions about living with your Harmony valve.



RISKS



Risks Associated with Replacing Your Pulmonary Valve

Both surgical and transcatheter valve replacement procedures have risks that sometimes lead to surgery to fix the problem or, very rarely, death. Surgical valves have been used for many years, and while much is known about their risks, there is more to learn. The Harmony TPV is a new device that has been studied in animals and humans, but long-term results remain unknown. Your heart doctor and heart surgeon can discuss which procedure is right for you.

Talk to your heart doctor or heart team regarding more information about transcatheter pulmonary valve therapy.

Risks You Should Know

Possible risks of the Harmony TPV therapy include the following:

- Death
- Irregular valve function, including narrowing of the valve
- Parts of the valve or valve tissue breaking down
- Bruising
- Heart failure
- Stroke (a condition in which decreased blood flow to the brain causes brain cells to die)
- Poking a hole in a large blood vessel (perforation)
- Rupture of the area between the pumping chamber and lung artery
- Pressing of the valve against the parts of the heart that could affect blood flow
- Infection in the bloodstream
- Bulging of the blood vessel causing blood to leak into the surrounding areas of the heart
- Wearing away of heart tissue where the valve is implanted
- Break (fracture) in the valve frame
- Irregular rate or rhythm of the heartbeat
- Movement of the valve from where it was placed
- A piece of blood clot, air, or heart tissue traveling to and causing problems with lung function
- Blocking of the main artery to the lungs
- Placement of the valve in an unplanned location or upside down (misorientation)
- Backward flow of blood through the valve
- Leakage around the valve frame
- Not enough (inadequate) blood flow through the valve
- Thickening of the valve preventing proper blood flow to lungs
- Unexpected bleeding that may require a blood transfusion
- Infection of the heart valve
- A blood clot can form, and may travel to another part of the body
- Weakening of the valve or buildup of calcium on the valve, leaflets, or tissue
- Bleeding problems, which could be major or life-threatening
- Bleeding caused by blood-thinning medication used during the procedure
- Fever
- Pain or swelling at the site where the catheter was inserted
- Allergic reaction to X-ray dye
- Infection
- High blood pressure in the lungs
- Thickening or peeling of the heart wall
- Damage to red blood cells

HARMONY™ TPV CLINICAL DATA



Harmony TPV Clinical Study

The Medtronic Harmony TPV was studied in patients at hospitals in the United States, Canada, and Japan. Patients were examined before the procedure, after the procedure, at one month, and at six months. Checkups will also be performed at one year and annually for up to 10 years.

The study results showed that the Harmony TPV was reasonably safe and effective in treating patients with severe pulmonary regurgitation who have a native or surgically-repaired right ventricular outflow tract, and are in need of a pulmonary valve replacement.

Potential risks with Harmony TPV at six months are listed in the table below:

Risks	Six Months after Harmony Implant
Death from any cause	0 out of 100 patients
Irregular rate or rhythm of the heartbeat Irregular heart rate in lower chamber of the heart (right ventricle)	24 out of 100 patients 14 of 100 patients
Leakage around the valve frame Major leakage	9 out of 100 patients 2 of 100 patients
Narrowing of the valve	4 out of 100 patients
Movement of the valve	4 out of 100 patients
Break in the valve frame	1 out of 100 patients

Potential Benefits of Harmony TPV Therapy

- Restored pulmonary valve function
- Restored quality of life over time
- Delay of patient's next open-heart surgery

FREQUENTLY ASKED QUESTIONS

When can I return to normal activities, work, and sports?

On average, most patients are able to return to their normal activities and work within a couple of days. Talk to your heart doctor or heart team about when it's safe to return to competitive sports.

Is it safe to have an X-ray with a Harmony valve?

It is completely safe to have an X-ray with a Harmony valve.

Is it safe to have heart imaging done, for example, magnetic resonance imaging (MRI), with a Harmony valve?

Under specific conditions, you may undergo MRI scanning. If you need a magnetic resonance imaging (MRI) scan, tell your heart doctor or MRI technician that you have a Harmony valve or show your heart doctor your implant card.

Is it safe to go through airport security with a Harmony valve?

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

How long will my Harmony valve last?

The length of time your valve will last depends on many things, including your health and the condition of your heart. It is important to realize that no artificial tissue valve will last a lifetime. Some patients may require another procedure to fix their valve.

What if I need another medical procedure?

Please notify your heart doctor and dentist prior to any medical or dental procedure. They will determine whether you receive medicine prior to any medical or dental procedure, including a routine dental cleaning.

Can I have body piercings or tattoos?

It is very important to discuss body piercings and/or tattoos with your heart doctor. They may recommend that you avoid these; however, if you choose to have either, medicine may be necessary before the procedure.

Talk with your heart doctor or heart team if you have more questions about living with your Harmony valve.

RESOURCES

Online Resources

For more information on congenital heart disease, visit the following websites:

- Adult Congenital Heart Association: www.achaheart.org
- American Heart Association: www.americanheart.org
- Children's Heart Foundation: www.childrensheartfoundation.org
- International Society for Adult Congenital Heart Disease: www.isachd.org

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

Harmony has been approved by the FDA for specific patient populations only. Refer to the Instructions for Use for a full list of warnings, precautions, indications, and adverse events.