

# Medtronic

## Contegra™ Pulmonary Valved Conduit

# For patients and families planning for pulmonary heart valve surgery

### Humanitarian device

Authorized by federal law (USA) for use in patients under 18 years of age for correction or reconstruction of the right ventricular outflow tract (RVOT) in the following congenital heart malformations: pulmonary stenosis, tetralogy of Fallot, truncus arteriosus, transposition with ventricular septal defect (VSD), pulmonary atresia. In addition, the Contegra pulmonary valved conduit is indicated for the replacement of previously implanted but dysfunctional pulmonary homografts or valved conduits. The effectiveness of this device for these uses has not been demonstrated.





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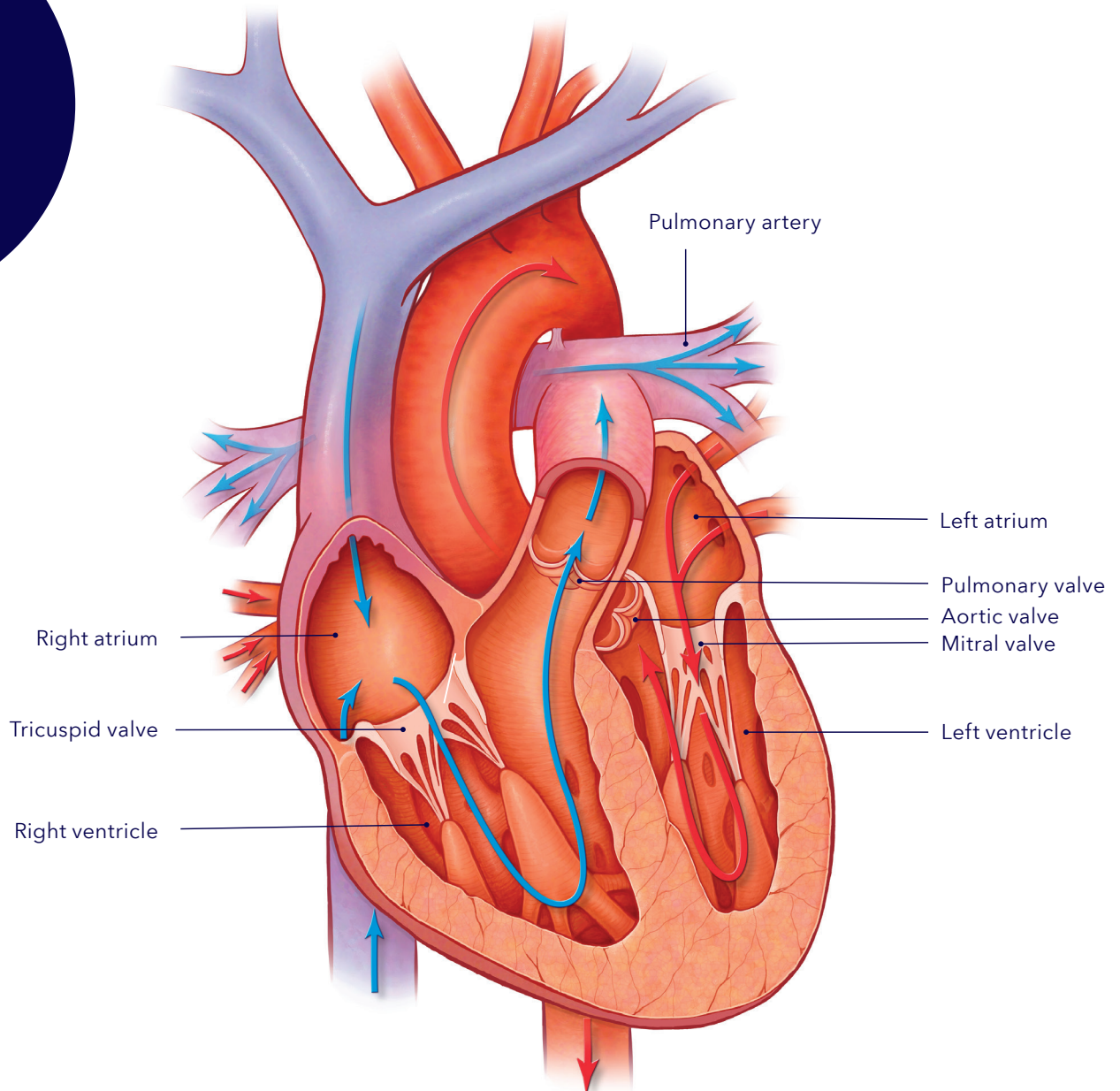
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This booklet is designed to answer questions that you and your family may have about heart valve surgery and the Contegra pulmonary valved conduit. It is not intended to replace advice or instructions from healthcare providers, who are the most qualified people to answer questions about a person’s heart valve condition.

# The human heart



The heart is a strong muscular organ, serving as the main pump in the blood system. Blood pumped by the heart carries oxygen and energy to the brain, muscles, and organs.

Each human heart is made up of four unique chambers, separated by four individual heart valves. The valves are tissue flaps designed to allow one-way movement of blood through the heart's four chambers. Healthy heart valves open fully to let blood flow forward into the next chamber and then close to prevent blood from flowing backward. Healthy heart valves keep blood flowing correctly through the heart. When heart valves are defective, the heart has to work harder to move blood through the body.

People with valve disease may have one or more of the following symptoms:

- Problems breathing with mild exertion or while resting
- Wheezing or coughing during exercise
- A sensation of fluttering or fast pounding in the chest
- Fatigue
- Dizzy spells or fainting
- Swelling in the hands or ankles
- Pressure or pain in the chest
- Physician-diagnosed heart "murmur"

Symptoms that might indicate a heart problem in a child include:

- Getting out of breath sooner than other children
- Not being able to keep up physically with other children
- Getting sweaty with activity sooner than other children
- Turning blue around the gums/tongue
- Passing out

Infants may get out of breath and sweaty while feeding. Older children and teens may experience chest pain and/or dizziness with exercise and palpitations.

# The human heart, cont'd.

A doctor may prescribe a series of tests to diagnose the type of heart valve disease a person has. These tests may include a chest X-ray, an echocardiogram, an electrocardiogram, and/or an MRI.

## **Electrocardiogram (ECG or EKG)**

An electrocardiogram is one of the most common tests used to evaluate the function of a person's heart and to assist in the diagnosis of a potential problem. It is performed by placing electrode patches on a person's chest and legs or arms. These patches and wires are attached to a machine that reads the electrical impulses from the heart.

## **Echocardiogram**

An echocardiogram emits sound waves that bounce off the heart structures and creates images. An echocardiogram allows the doctor to view the heart while it is pumping.

## **Transesophageal echocardiogram (TEE)**

This is an echocardiogram in which the probe is inserted through a person's mouth, down the throat, and into the esophagus. This type of test allows the images to be taken much closer to the heart. It allows the doctor to obtain a much more detailed view of the heart and major blood vessels.

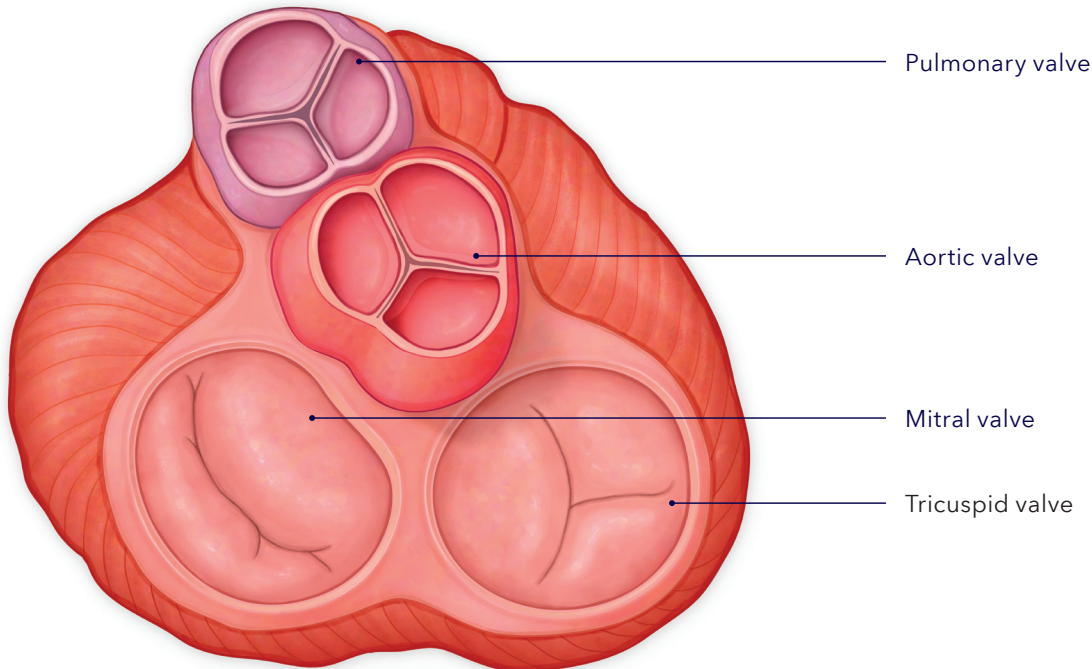
## **Magnetic resonance imaging (MRI)**

MRI uses a combination of magnetic and radio waves. This technology makes very detailed pictures of almost all of the five tissues in the body. With an MRI scan, it is possible to take pictures from almost every angle. Therefore, it can provide the doctor with information on changes in the thickness of the heart muscle as well as all other structures of the heart and its surrounding vessels.

# Heart valve disease

When people listen to their own heartbeats, they hear the familiar two-part sound often described as “lub-dub.” This sound is caused by the opening and closing of the heart valves. A human heart beats more than 100,000 times each day, requiring the heart valves to open and close nearly one million times per week!

Heart valve disease is diagnosed when valves fail to open and close properly. There are several causes of heart valve disease. Some people are born with a defective valve – this is known as a congenital heart valve defect. A minor defect can progress over time to be a condition that requires treatment. Diseases such as rheumatic fever and bacterial endocarditis can damage heart valves, causing scarring.

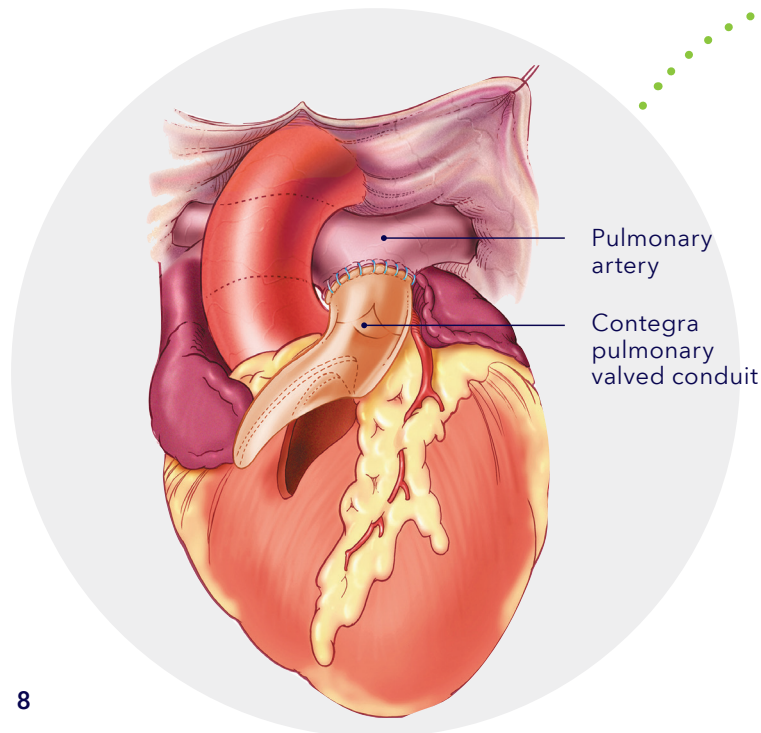


# The pulmonary valve

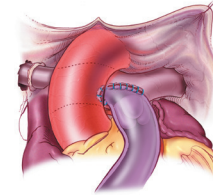
The most common congenital heart defects affecting the pulmonary valve include:

- Pulmonary atresia
- Transposition of the great arteries
- Tetralogy of Fallot
- Double outlet right ventricle

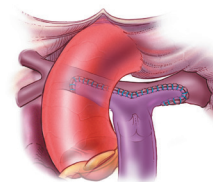
Children or adults with these conditions have narrowed or missing pulmonary valves and need surgery for placement of a right ventricular outflow tract (RVOT) or pulmonary conduit. A pulmonary conduit is a tube that opens up the RVOT and contains an artificial valve to control blood flow between the right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



Implant inside the heart



Implant outside the heart



Contegra pulmonary valved conduit



# The Contegra pulmonary valved conduit



Prosthetic (artificial) heart valves are used to correct, reconstruct, or replace the heart's natural valves when they are malformed at birth, damaged, diseased, or weakened and do not adequately control the flow of blood within the heart.

The Contegra conduit is a bovine (cow) jugular vein containing a valve with three leaflets and a natural sinus. The sinus is a dilated portion of the wall of the vein. The anatomy of the bovine valve is similar to the human heart valve.

The Contegra conduit is used to allow surgical correction or reconstruction of the natural RVOT and to provide and/or restore pulmonary valve function – enabling blood to flow effectively from the lower right chamber of the heart through the pulmonary artery and into the lungs. There, the blood is enriched with oxygen and then sent through the heart and body again.

A Contegra conduit is also used for the replacement of previously implanted but dysfunctional pulmonary homografts or valved conduits.

# The implant procedure/ potential risks

This is a brief overview of the implant procedure. Be sure to ask your doctor for more information and instructions on how to prepare for the surgery. Ask lots of questions if there is something you don't understand.

Standard procedures will be used to prepare you for surgery. This includes not eating or drinking for at least 12 hours before the implant.

The cardiac surgeon will need to make your heart visible for the procedure. You will be asleep during the operation and will feel no pain.

The surgeon will place the Contegra conduit either inside the heart in the natural position of the pulmonary valve or outside the heart to provide an alternative path for blood flow. How the valve is implanted depends on each patient's condition.

During the majority of procedures, the heart will temporarily be stopped and you'll be put on a heart/lung machine that takes over your breathing and blood circulation. Alternatively, there are some procedures that may be performed on a beating heart. Your surgeon will decide which type of procedure is best for your particular needs.

When the Contegra conduit is in place, your heart will be allowed to start beating again. All incisions will be sewn or stapled closed.

Following the surgery, you'll spend some time in the intensive care unit (ICU), where you will be closely monitored to make sure there are no complications. After that, you'll be moved to a regular hospital room where your family and friends will be able to visit you.

Your doctor will provide you with more specific care instructions after you go home from the hospital.

As with any surgery, complications may occur that are associated with valved conduits and tissue valves implanted which may be serious, including death. Complications that may occur during or after a procedure include:

- Infection
- Infection of the valve (endocarditis)
- Blood clot formation
- Bleeding

Your doctor can tell you more about potential risks of surgery and implanting a pulmonary valved conduit.

# Living with a Contegra conduit



## How long will a Contegra conduit last?

The length of time that the Contegra conduit will remain implanted depends on:

- The nature and severity of the abnormality and function of the heart
- Patient conditions such as age and growth

The doctor will monitor the function of the valve and blood flow through the heart.

## Is anticoagulation or other medication necessary?

Anticoagulation medication is used to prevent blood clots, which can be a serious health risk. The need for anticoagulation medication is usually minimal with tissue valves. The doctor will determine if anticoagulation is necessary.

Anticoagulation medication helps prevent blood clots by delaying the blood clotting (coagulation) process. This means that cuts and scrapes will bleed a little longer than normal. If anticoagulation medication is prescribed, it should be taken exactly as instructed.

Before dental work or surgical procedures, antibiotics may be necessary. Before any dental or medical procedure, be sure to let the dentist and doctor know about the Contegra conduit.

## Is it safe to have an X-ray with a Contegra conduit?

All prosthetic heart valves, including the Contegra conduit, are completely safe with X-ray examinations.

## Is it safe to have an MRI with a Contegra conduit?

The Contegra conduit contains no metals and therefore poses no known hazards in MRI environments.

## Is it safe to go through airport security with a Contegra conduit?

Airport security systems have no adverse effects on the Contegra conduit, and normally will not activate any alarms.

# Online resources for patients, families, and caregivers

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

- American Heart Association: [heart.org](http://heart.org)
- Children's Heart Foundation:  
[childrensheartfoundation.org](http://childrensheartfoundation.org)
- Congenital Heart Information Network: [tchin.org](http://tchin.org)
- Health Central Heart Disease:  
[healthcentral.com/heart-disease](http://healthcentral.com/heart-disease)
- Mayo Clinic Health Information: [mayoclinic.org](http://mayoclinic.org)
- Med Help International: [medhelp.org](http://medhelp.org)
- Medscape Cardiology: [theheart.org](http://theheart.org)
- WebMD Heart Health Center: [webmd.com/heart](http://webmd.com/heart)

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## **CONTEGRA® Pulmonary Valved Conduit**

**Indications:** See Humanitarian Use Device section below.

**Contraindications:** None known.

**Warnings/Precautions/Side Effects:** Acceptable clinical performance has been established for the Contegra conduit in pediatric patients under the age of 10. Because of the possibility that complications of the device could become apparent only after extended use, a benefit-risk consideration of the long-term use of the Contegra conduit in pediatric patients over 10 years of age is particularly important. General complications reported with valved conduits and biological tissue valves implanted in the heart include: hemorrhage, bleeding diathesis due to use of anticoagulants, residual or increasing transvalvular gradients, progressive neointimal thickening and peeling, progressive stenosis and obstruction, progressive pulmonary hypertension, graft infection, endocarditis, regurgitation, hemolysis, valve malfunction, physical or chemical deterioration, thromboembolism, thrombus, conduit dilatation. 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 USE DEVICE:** Authorized by Federal law (USA) for use in patients under 18 years of age for correction or reconstruction of the Right Ventricular Outflow Tract (RVOT) in the following congenital heart malformations: Pulmonary Stenosis, Tetralogy of Fallot, Truncus Arteriosus, Transposition with Ventricular Septal Defect (VSD), Pulmonary Atresia. In addition, the Contegra® Pulmonary Valved Conduit is indicated for the replacement of previously implanted but dysfunctional pulmonary homografts or valved conduits. The effectiveness of this device for these uses has not been demonstrated.

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