PATIENT BOOKLET

MEDTRONIC MITRAL AND TRICUSPID HEART VALVE REPAIR
ARE MEDTRONIC HEART VALVE REPAIR THERAPIES RIGHT FOR YOU?

Prosthetic (artificial) heart valve repair products are used by physicians to repair the heart's natural valves (the most often repaired valves are the mitral and tricuspid) when they have been damaged, diseased, or weakened by age and no longer adequately control the flow of blood within the heart. This booklet will help you learn more about the Medtronic heart valve repair products.
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ABOUT THE HEART

How the Heart Works
A healthy heart beats around 100,000 times a day. The heart’s job is to supply the body with oxygen-rich blood.
The heart has four chambers. Blood is pumped through the four chambers with the help of four heart valves.
What Heart Valves Do

Heart valves open when the heart pumps to allow blood to flow. They close quickly between heartbeats to make sure blood does not flow backward. Any trouble in this normal flow will make it hard for the heart to pump the blood where it needs to go.

**Pulmonic Valve** | controls the flow of blood to the lungs to get oxygen.

**Aortic Valve** | controls the flow of blood as it exits the heart and is pumped to the rest of the body.

**Mitral and Tricuspid Valves** | control blood flow as it moves between the chambers of the heart.
Overview

Heart valve disease can disturb the normal flow of blood through the heart. This can affect your overall health and keep you from enjoying the activities you love.

Heart valves can develop one or both of these problems:

- The valve opening becomes narrow (stenotic) — which limits the amount of blood pumped to the rest of the body
- The valve does not close completely (valve insufficiency or regurgitation) — which means that blood can flow backward instead of only forward. Backward blood flow reduces your heart’s ability to pump blood to the rest of your body. This also causes a buildup of back pressure in your heart and lungs.
Symptoms

There are a number of symptoms that may indicate heart valve disease, including:

- Shortness of breath or difficulty catching your breath, especially after you have been active or when you lie down flat in bed
- Often feeling dizzy or too weak to perform your normal activities
- Pressure or weight in your chest, especially when you are active or when you go out into cold air
- Heart palpitations or a feeling that your heart is beating irregularly, skipping beats, or flip-flopping in your chest
- Swelling in your ankles, feet, or belly. Sudden weight gain with possibly as much as two to three pounds in one day

Symptoms can range from mild to none at all and do not always indicate the seriousness of heart valve disease.
Diagnosis

Your doctor can detect a mitral or tricuspid valve problem and find out the nature of your valve damage by talking with you about your symptoms and performing a number of tests. These tests may include:

- Listening to your heart to hear the valves opening and closing and the rush of blood through them
- Conducting an echocardiogram, which uses sound waves to produce detailed images of your heart valves moving as your heart beats
- Ordering a magnetic resonance imaging (MRI) scan, which uses a magnetic field and radio waves to get detailed images of the inside of your heart
- Taking an x-ray image of your chest to check your heart, its major vessels, and your lungs for abnormalities
- Using an ECG to measure the electrical impulses given off by your heart. An ECG gives your doctor important information about your heart’s rhythm and its size
Valve Repair

If valve repair is an option for you, the surgeon may perform an annuloplasty procedure. During annuloplasty, the surgeon may also need to repair the leaflet tissue, remove calcium deposits or repair the tough chords that control movement of the mitral valve leaflets. These cords are called chordae tendineae. During the procedure, surgeons can choose a number of techniques to successfully repair many mitral and tricuspid diseased valves.

For heart valve repair, one of the following procedures is done:

- Reshaping of the valve by removing excess valve tissue
- Attaching the valve to its chords
- Adding support to the valve annulus by adding tissue or by sewing a band or ring around the outside of the valve
Valve Repair with an Annuloplasty Ring or Band

An annuloplasty ring or band is made up of durable plastic, metal, and fabric. It may be rigid, semi-rigid or flexible. Rings and bands are designed to maintain the natural shape, motion and flexibility of your annulus. The rings or bands may also contain a radiopaque marker that makes it possible for the healthcare professional to see them on x-ray.
Mitral Solutions

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Tricuspid Solutions

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Open-heart Surgical Valve Repair for Mitral and Tricuspid Valves

Valve repair surgery is an effective, life-saving treatment option for people with mitral or tricuspid valve disease. Depending on your risk factors, such as health, diagnosis, and age, your health care providers will be able to recommend the appropriate valve repair for you.

Traditional heart valve repair surgery for mitral or tricuspid valve repair often requires an incision over the chest and sternum (some surgeries may be performed using a minimally invasive technique without opening the chest). The chest is then opened and spread apart using a surgical instrument. This provides the surgeon access to the heart and chest cavity, in order to repair your heart valve.

Since each patient has a unique medical history, this information cannot replace discussions with your doctor.

During the Procedure

The operation varies from patient to patient, lasting a minimum of two hours and often longer. During this time, you are asleep under general anesthesia.

During the operation, the surgeon will remove any tissue and calcium deposits that are interfering with the normal function of the valve. Your damaged valve will be repaired. After the surgeon makes sure your valve is working properly, blood flow will be restored to your heart and the incisions will be closed. Your surgery is performed while the function of your heart is taken over by a heart-lung machine (called cardiopulmonary bypass or CPB).
Procedural Overview of a Typical Open-heart Surgery

1. You will be administered general anesthesia to remain asleep and pain free during the procedure.
2. After preparation, an incision to access your heart is made.
3. You will be connected to a heart-lung machine to isolate the heart.
4. Your valve will be repaired.
5. You are then weaned from cardiopulmonary bypass.
6. Your newly repaired heart valve will begin working. The doctor will conduct a test to confirm the valve is working properly.
7. All incisions are closed.
8. You are then transferred to ICU and kept on ventilator until deemed ready to be transferred to a recovery room.
Valve repair can include the following risks:

- Death
- Blood clot formation on or around the valve. These blood clots may break loose and travel in the bloodstream (thromboembolism/thrombosis)
- Damage to red blood cells (hemolysis)
- Any problem with the ring or band that causes narrowing of the valve opening (stenosis)
- Small amounts of blood leaking through the valve opening even after it closes
- Abnormal heart rhythms
- Inflammation of the lining of the heart (endocarditis)
- Anticoagulant-related bleeding or hemorrhage

The potential risks are shown in the order of severity, from most severe to least severe. This list is not inclusive of all risks. Talk to your physician regarding more information about valve repair surgery.
Appropriate repair and annular remodeling may correct combined valvular insufficiency and stenosis. The Chordal Guide feature of the Duran AnCore™ Annuloplasty Ring and Band should be used by physicians who have received proper training in valve repair. Adverse events can include: thromboembolic events, dehiscence, hemolysis, stenosis, residual incompetence, heart block, endocarditis, systolic anterior motion, left ventricular outflow tract obstruction, anticoagulant-related bleeding or hemorrhage.

**Duran AnCore Annuloplasty Ring and Band**

**Indications:** This device is indicated for the reconstruction and/or remodeling of pathological mitral and tricuspid valves. Appropriate repair and annular remodeling may correct combined valvular insufficiency and stenosis. **Note:** The Chordal Guide feature of the Duran AnCore™ Ring/Band is indicated only for chordal replacement surgery of pathological mitral valves.

**Contraindications:** Heavily calcified valves, valvular retraction with severely reduced mobility, active bacterial endocarditis. **Warnings/Precautions/Adverse Events:** Only physicians who have received proper training in valve repair should use this device. Adverse events can include: thromboembolic events, dehiscence, hemolysis, stenosis, residual incompetence, heart block, endocarditis, systolic anterior motion, left ventricular outflow tract obstruction, anticoagulant-related bleeding or hemorrhage.

**Profile 3D Annuloplasty Ring**

**Indications:** This device is indicated for the reconstruction and/or remodeling of pathological mitral valves. Valvular insufficiency and/or stenosis may be corrected by appropriate repair and annular remodeling. **Contraindications:** Heavily calcified valves, valvular retraction with severely reduced mobility, active bacterial endocarditis. **Warnings/Precautions/Adverse Events:** Only physicians who have received proper training in valve repair should use this device. Adverse events can include: thromboembolic events, dehiscence, hemolysis, stenosis, residual incompetence, heart block, endocarditis, systolic anterior motion, left ventricular outflow tract obstruction, anticoagulant-related bleeding or hemorrhage.

**Simulus Flexible Annuloplasty System**

**Indications:** The Simulus flexible annuloplasty ring and band are for use in those patients undergoing surgery for diseased or damaged mitral or tricuspid valves in whom the surgeon determines that the valve can be preserved by employing the appropriate surgical repair. The annuloplasty ring and band provide support for the mitral or tricuspid annulus and restrict expansion of the annulus. **Contraindications:** Severe, generalized or localized bacterial endocarditis, heavily calcified valves, greatly dilated annulus (not reducible by standard techniques), severe valvular dysfunction (not correctable by standard techniques), valvular retraction with severely reduced mobility, congenital malformations with lack of valvular tissue. **Warnings/Precautions/Adverse Events:** Only physicians who have received proper training in valve repair should use this device. Adverse events can include: thromboembolic events, dehiscence, hemolysis, stenosis, residual incompetence, heart block, endocarditis, systolic anterior motion, left ventricular outflow tract obstruction, anticoagulant-related bleeding or hemorrhage.

**Simulus Semi-Rigid Annuloplasty Ring and Band**

**Indications:** The Simulus semi-rigid annuloplasty ring and band are for use in patients undergoing surgery for diseased or damaged mitral valves. The Simulus semi-rigid annuloplasty ring and band provide support for and restrict expansion of the annulus. **Contraindications:** Severe, generalized or localized bacterial endocarditis, heavily calcified valves, greatly dilated annulus (not reducible by standard techniques), severe valvular dysfunction (not correctable by standard techniques), valvular retraction with severely reduced mobility, congenital malformations with lack of valvular tissue. **Warnings/Precautions/Adverse Events:** Only physicians who have received proper training in valve repair should use this device. Adverse events can include: thromboembolic events, dehiscence, hemolysis, stenosis, residual incompetence, heart block, endocarditis, systolic anterior motion, left ventricular outflow tract obstruction, anticoagulant-related bleeding or hemorrhage.

**Tri-Ad Adams Tricuspid Ring**

**Indications:** Tri-Ad Adams tricuspid annuloplasty rings are for use in patients undergoing surgery for diseased or damaged tricuspid valves. The Tri-Ad Adams tricuspid annuloplasty ring provides support for and restricts expansion of the annulus. **Contraindications:** Severe, generalized or localized bacterial endocarditis, heavily calcified valves, greatly dilated annulus (not reducible by standard techniques), severe valvular dysfunction (not correctable by standard techniques), valvular retraction with severely reduced mobility, congenital malformations with lack of valvular tissue. **Warnings/Precautions/Adverse Events:** Only physicians who have received proper training in valve repair should use this device. Adverse events can include: thromboembolic events, dehiscence, hemolysis, stenosis, residual incompetence, heart block, endocarditis, right ventricular outflow tract obstruction, anticoagulant-related bleeding or hemorrhage.

**Simplici-T Annuloplasty System**

**Indications:** This device is indicated for the reconstruction and/or remodeling of pathological mitral and tricuspid valves. Appropriate repair and annular remodeling may correct combined valvular insufficiency and stenosis. **Contraindications:** Heavily calcified valves, valvular retraction with severely reduced mobility, active bacterial endocarditis. **Warnings/Precautions/Adverse Events:** Only physicians who have received proper training in valve repair should use this device. Adverse events can include: thromboembolic events, band dehiscence, hemolysis, stenosis, heart block, endocarditis, systolic anterior motion, left ventricular outflow tract obstruction, anticoagulant-related bleeding or hemorrhage, uncorrected or recurrent regurgitation, low cardiac output, thrombosis, damage to coronary arteries.

**Caution:** Federal law (USA) restricts these devices to sale by or on the order of a physician.