



CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at vascular.eifu.abbott or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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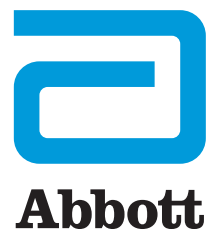
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NAVITOR™ TRANSCATHETER AORTIC
VALVE IMPLANTATION SYSTEM

A Guide to Treating Aortic Stenosis





Dear Patient,

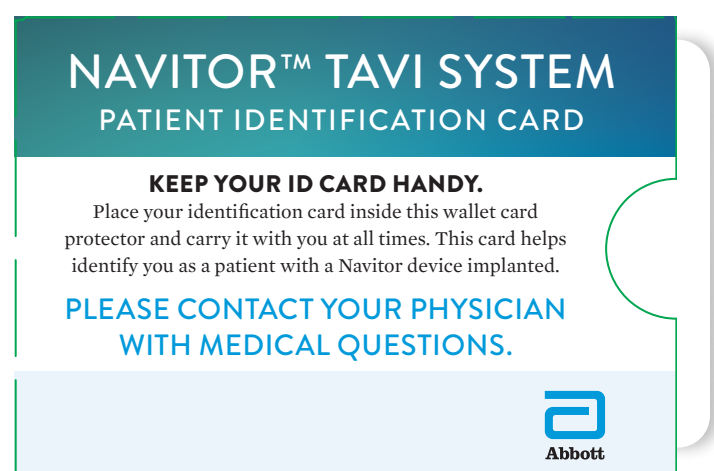
Our mission at Abbott is to restore people's health and improve their quality of life. We are delighted that you have taken the first steps toward treating your severe aortic stenosis with transcatheter aortic valve implantation (TAVI).

Please take the time to review the information found in this guide, as well as share it with your loved ones and friends. If you have any additional questions, please reach out to the healthcare professionals in your local Heart Team.

We wish you all the best and good health!



Dr. Neil Moat
Chief Medical Officer, Abbott Structural Heart



See Important Safety Information referenced within.

THIS BELONGS TO:

MY TAVI PROCEDURE IS SCHEDULED:

Date/time: _____

Location: _____

Arrival Time: _____

MY _____ FOLLOW-UP VISIT IS SCHEDULED:

Date/time: _____

Location: _____

Arrival Time: _____

MY _____ FOLLOW-UP VISIT IS SCHEDULED:

Date/time: _____

Location: _____

Arrival Time: _____

MY _____ FOLLOW-UP VISIT IS SCHEDULED:

Date/time: _____

Location: _____

Arrival Time: _____



DISCUSS ALL TREATMENT OPTIONS WITH YOUR DOCTOR.

Your doctor can describe the risks and benefits and help you decide which option is right for you.

WHAT IS AORTIC STENOSIS?

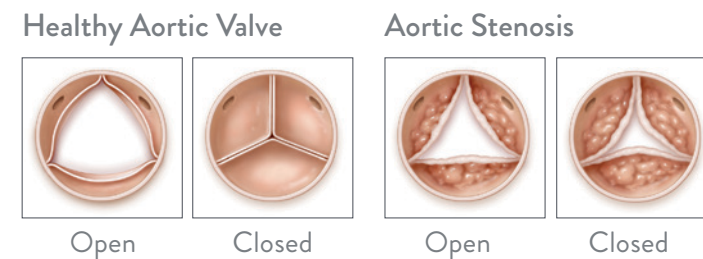
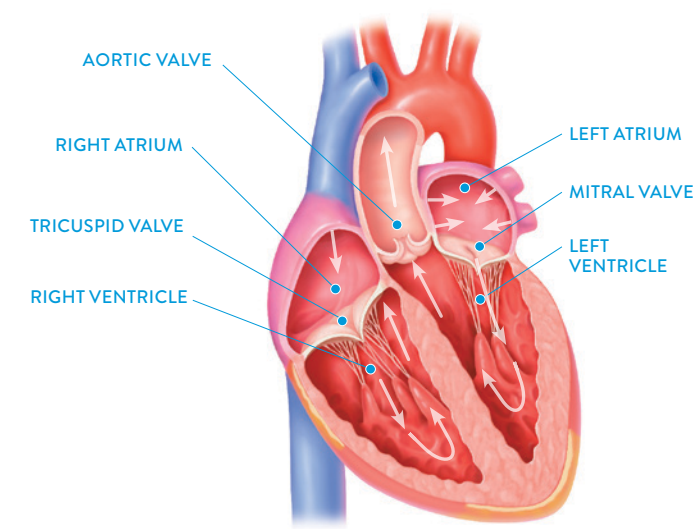
On the left side of the heart, blood flows through the left ventricle into the aorta through the aortic valve. Severe aortic stenosis is a condition in which the aortic valve leaflets become thick or stiff, reducing their ability to fully open and close. This narrowing of the valve makes your heart muscle work harder to deliver oxygen-rich blood to the brain and the rest of the body.

Aortic stenosis is one of the most common valve diseases and usually develops later in life.

Causes include:

- Buildup of calcium on the valve
- Infection of the heart
- Birth defects
- Rheumatic fever
- Radiation therapy

Chambers of the Heart and Heart Valves



TREATMENT OPTIONS FOR SEVERE AORTIC STENOSIS

Based on your level of risk, the outcomes from your diagnostic tests and lifestyle preference, your doctor will recommend the best treatment option for you. There are various treatment options for severe aortic stenosis including medication, balloon aortic valvuloplasty, surgical aortic valve replacement or transcatheter aortic valve implantation.

TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI)

Transcatheter aortic valve implantation with the Navitor™ TAVI System provides an alternative, minimally invasive treatment option for people living with severe aortic stenosis who are not candidates for open-heart surgery due to age, frailty, or other conditions that make surgery too risky.

Navitor™ Valve



WHAT ARE THE SYMPTOMS?

The symptoms of aortic stenosis are commonly misunderstood by patients as “normal” signs of aging. Symptoms of aortic stenosis include, but are not limited to:

Fatigue with normal activities	Chest pain	Trouble breathing	Dizziness, lightheadedness, or even fainting	Difficulty walking short distances	Rapid, fluttering heartbeat	Difficulty sleeping	Swollen ankles or feet

If you are experiencing any of these symptoms, talk to your doctor to receive a thorough examination and diagnosis. You should also seek treatment if you notice that your symptoms are getting worse.

SURGICAL AORTIC VALVE REPLACEMENT (SAVR)

Aortic valve replacement can be performed using several surgical approaches to open-heart surgery, including traditional sternotomy (with an incision over the chest and sternum), minimally invasive surgery that does not involve opening the chest, and less invasive robotic procedures.

WHAT IS THE NAVITOR™ TAVI PROCEDURE?

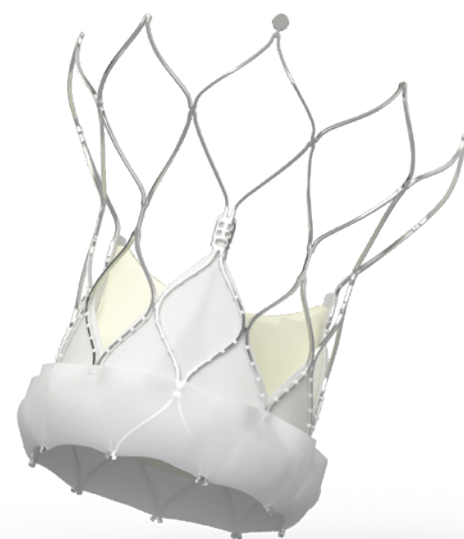
The Navitor™ Transcatheter Aortic Valve is a tissue valve attached to a stent frame with the addition of a fabric outer cuff on the exterior portion of the stent.

The Navitor™ Valve leaflets are made from bovine (cow) tissue. This tissue is treated to preserve and prevent adverse reactions once the valve is implanted. The Navitor Valve is delivered via catheter to the diseased (native) aortic valve through various access sites (transfemoral, subclavian/axillary, and transaortic) on the body. The most common approach is through a percutaneous access in the groin, also referred to as the transfemoral approach.

WHO IS ELIGIBLE FOR THE NAVITOR VALVE?

Patients with severe aortic valve stenosis who are not candidates for surgical replacement will be further screened by their doctor to see if they are eligible for a Navitor Valve.

Navitor™ Valve



DISCUSS ALL TREATMENT OPTIONS WITH YOUR DOCTOR.

Your doctor can describe the risks and benefits and help you decide which option is right for you.

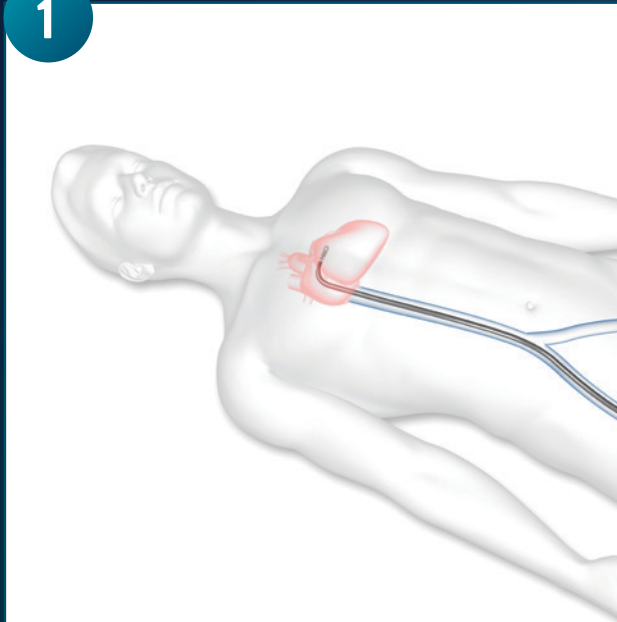


SCAN ME

TO LEARN MORE ABOUT AORTIC STENOSIS, VISIT THE CARDIOSMART WEBSITE AT:
<https://www.cardiosmart.org/topics/aortic-stenosis>

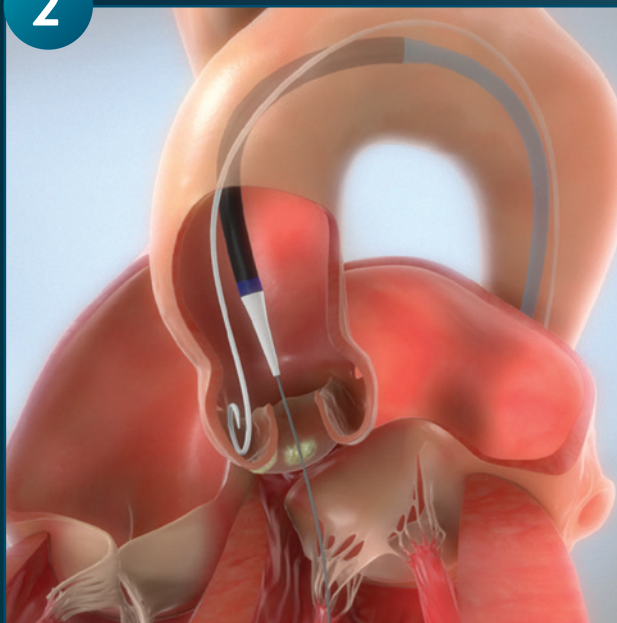
WHAT WILL HAPPEN DURING THE PROCEDURE?

1



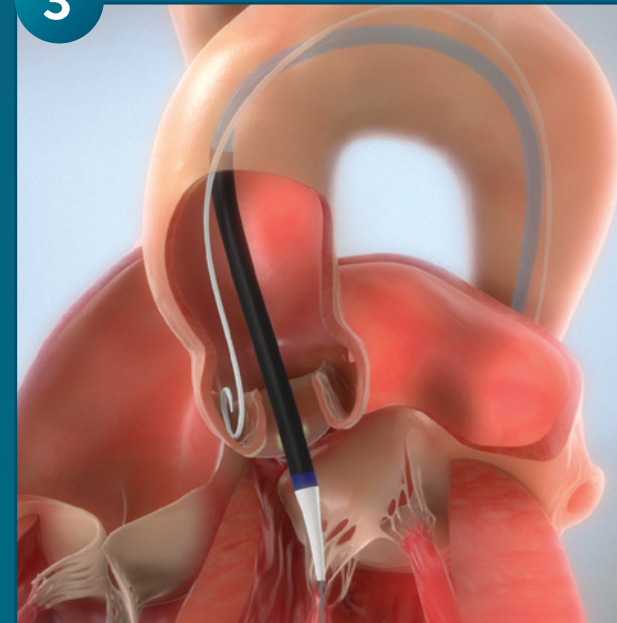
Your doctor will determine the best approach for replacing your valve, but the most common approach is the transfemoral approach, described here. A small cut is made in a large artery in your groin and a sheath (access tube) is inserted within your artery. The doctors view the movement of the sheath using special imaging equipment, which guides them to know when the sheath is in the correct position.

2



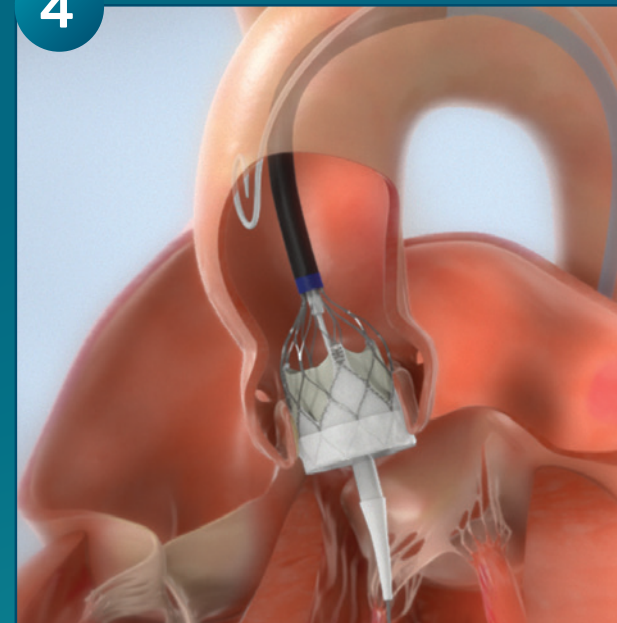
Once the sheath is in position, a guiding wire and balloon catheter (thin, flexible tube) with a balloon is delivered through the sheath and placed within your aortic valve. The balloon is inflated to open up your aortic valve as much as possible so that the Navitor™ Valve can be placed inside of it. The balloon catheter is then removed.

3



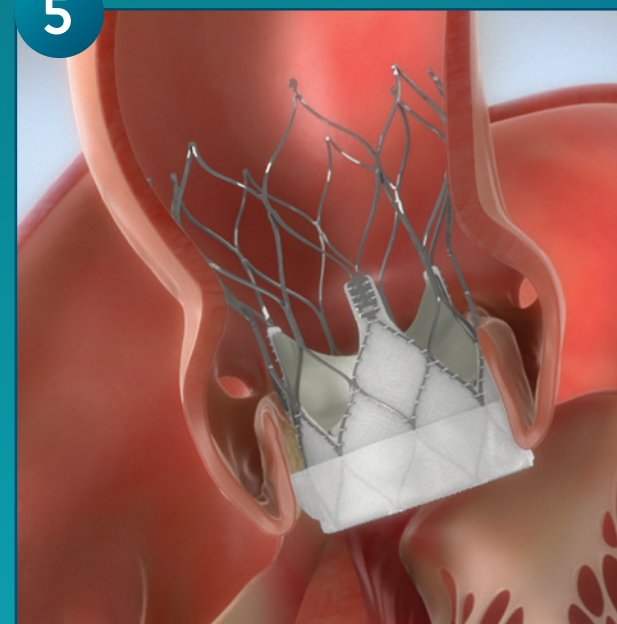
The Navitor Valve is delivered with a catheter through the sheath and placed within your opened aortic valve. Your doctor will deploy the valve into the correct positioning using special visualization equipment to ensure the valve is positioned accurately within your heart.

4



Once the valve is deployed and accurately in place, the Navitor Valve will start to function immediately.

5



The sheath and catheter are removed from your heart and groin, and the small incision in your groin is closed or sealed. The procedure is now complete.

PREPARING FOR YOUR TAVI PROCEDURE



PRE-PROCEDURE TESTS

Your doctor may order some of the tests below.

<input checked="" type="checkbox"/> Ordered	TEST	PURPOSE/EXPLANATION	<input checked="" type="checkbox"/> Completed
<input type="checkbox"/>	CT Angiography (CT Scan)	Radiology test to look at the blood vessels and valve shape and size	<input type="checkbox"/>
<input type="checkbox"/>	Transthoracic Echocardiogram (TTE)	An ultrasound of your heart which shows how your heart and valves are functioning	<input type="checkbox"/>
<input type="checkbox"/>	Electrocardiogram (EKG)	Evaluates the electrical rhythm of your heart	<input type="checkbox"/>
<input type="checkbox"/>	5-Meter Walk	Timed walk test done during the office visit to assess balance, mobility, activity tolerance, frailty and surgical risk	<input type="checkbox"/>
<input type="checkbox"/>	Kansas City Cardiomyopathy Questionnaire (KCCQ)	A questionnaire to measure your quality of life	<input type="checkbox"/>
<input type="checkbox"/>	Cardiac Function Testing	Your physician may order an invasive or non-invasive test to evaluate your heart anatomy and measure pressures within the heart	<input type="checkbox"/>
<input type="checkbox"/>	Pulmonary Function Test (PFT)	A non-invasive test that determines how well your lungs are functioning	<input type="checkbox"/>
<input type="checkbox"/>	Laboratory Tests	Baseline blood work prior to procedure	<input type="checkbox"/>
<input type="checkbox"/>	Chest X-Ray	Non-invasive imaging to review any lung abnormalities	<input type="checkbox"/>
<input type="checkbox"/>	Other		<input type="checkbox"/>
<input type="checkbox"/>	Other		<input type="checkbox"/>

CONVERSATIONS WITH YOUR CLINICIAN

The following are some suggested questions as you discuss your treatment plan. Be sure to write down any questions you have and bring them to your scheduled appointments.

1. What are the benefits and risks of TAVI vs. open heart surgery?

2. Is there any type of access site care that will need to be managed?

3. What type of sedation will be used for the procedure?

4. How long will I be in the hospital? Will I go home or into rehab? Will someone need to drive me home?

5. After the procedure, are there medications that I need to take or will there be a change in my medications?

6. What type of support should I arrange in advance for after I am discharged?

7. When can I return to work/normal activities?

PREPARING FOR YOUR PROCEDURE DAY

In the days before your procedure, it is important that you:

- 1 Make sure all of your lab work is complete
- 2 Gather any images you need to bring with you
- 3 Ensure you have prepared your legal documents and your caregiver knows where they are located
- 4 Make sure you have made all arrangements for after you are discharged from the hospital
- 5 Take all your prescribed medications as directed by your doctor in the days before your procedure
- 6 Tell your doctor if you are taking any other medications
- 7 Make sure your doctor knows of any allergies you have
- 8 Follow all instructions given to you by your doctor or nurse

WHAT WILL HAPPEN ON THE DAY OF YOUR PROCEDURE?

Most patients will check in for their procedure on the morning it is scheduled. Occasionally, a patient may be checked in the evening before.

Once you are checked in, you will be prepped and taken in for the procedure. Your caregiver will be directed to a waiting room.

After the procedure is complete, someone from your care team will let your caregiver know how the procedure went and how you are doing. Depending on your hospital's policy, your caregiver may be able to visit you in recovery, or they may be directed to meet you in your inpatient room.

Once your heart team is comfortable with your recovery, you will be moved into your patient room. Your caregiver will be able to bring the belongings you packed into the room for you.

PACKING FOR YOUR HOSPITAL STAY

Check with your hospital ahead of time.

Below is a handy list to help you pack for your hospital stay:

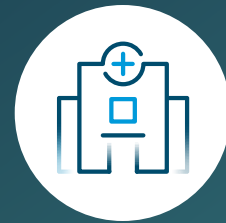
- Toiletries** (toothbrush/toothpaste, comb or brush, shampoo, etc.)
- Slippers** (with nonslip soles)
- Glasses**
- Denture case**
- Hearing aids**
- List of your current medications**
- Contact information** for key family members and friends
- Entertainment items** (books, phone/charger, tablet/charger)
- Pajamas**
- Comfortable clothes** to go home in

It is recommended that you do not bring cash or valuables to the hospital.

LIFE AFTER THE PROCEDURE:

A TIMELINE FOR RECOVERY

YOUR HOSPITAL STAY



As you recover in the hospital, your team will work with you on discharge planning. They will evaluate your medications and make any recommended changes. They may also perform follow-up tests to evaluate your recovery.

THE FIRST FEW WEEKS



Don't stress yourself. That means no strenuous exercise and no lifting heavy objects (nothing heavier than a gallon of milk). Have someone drive you to appointments. Walk only short distances on level ground.

30-DAY CHECK-UP



You will need to see your doctor 30 days after your procedure. There you will have repeat imaging to see how the new heart valve is working. You may also need additional lab work or testing at the time of your visit.

LONG-TERM CARE



As you recover from your procedure, it is important you focus on creating a healthy lifestyle that will support the activities you wish to pursue. That includes focusing on diet, exercise, and maintaining a healthy mindset.

YOUR ONE-YEAR EXAM



Similar to your 30-day exam, you will be asked to return at one year to have your heart valve checked. Repeat imaging will be conducted to see how your heart valve is working.

IT'S GOOD TO BE BACK HOME,
BUT REMEMBER TO TAKE TIME
TO RECOVER.



RECOVERING AFTER YOUR PROCEDURE

You should be back to your baseline activity at 1-2 weeks. Your doctor will provide more detailed instructions about when you can return to normal activities. For now, be sure that you are familiar with these important recovery tips.

TEND TO YOUR ACCESS SITE

Keep your access site dry for the first 24 hours

- Avoid soaking the area, you are likely able to take a shower
- Avoid perfumes, lotions, etc.

If bruising around the access site suddenly gets bigger or harder:

- Call your doctor immediately
- If any bleeding occurs or depending on the severity of your symptoms, you may need to seek emergency medical treatment.



Call for help if you experience any of the below symptoms.
Contact your doctor or emergency services.

- Redness or drainage from your incision
- Shortness of breath
- Swelling of your feet or ankles
- Chest, jaw, shoulder or arm pain
- Bruising
- Excessive bleeding
- Blood in your urine
- Bloody or tarry bowel movements (blood will typically look like tar after it has been exposed to the body's digestive juices)
- Unusual nosebleeds
- Fever
- Numbness or tingling in your arms or legs
- General weakness or loss of energy
- Blurred or loss of vision
- Unusual chest sensation

DEVELOPING A HEART HEALTHY DIET

After your procedure, it is a good idea to develop a heart-healthy diet. Below are some tips on healthy eating from the American Heart Association (AHA):



DEVELOP A BALANCED APPROACH TO YOUR DIET:

Tailor healthy eating to meet your personal and cultural food preferences



PLAN YOUR GROCERY TRIPS WITH HEALTH IN MIND:

Developing and sticking to a list makes it easier to avoid mindlessly grabbing tempting foods from the shelves



INCORPORATE MORE OF THE FOLLOWING INTO YOUR DIET:

Fresh fruits and vegetables, whole grains, healthy protein sources, and lower sodium food options



WORK TO MINIMIZE YOUR CONSUMPTION OF:

Processed foods, added sugars and salt, and alcohol



FOR MORE RESOURCES, VISIT THE AHA'S HEALTHY EATING WEBSITE:

<https://www.heart.org/en/healthy-living/healthy-eating>

SCAN ME



EXERCISE, DIET, AND PHYSICAL ACTIVITY

DURING YOUR RECOVERY

Getting and staying active can help you take care of your heart health. Your doctor will let you know when you can return to normal activities. Be sure to check with your doctor to see when you can start exercising as well. Until then, use this time to make a plan for after your recovery period.

BEGIN THESE AFTER YOU HAVE BEEN CLEARED TO START PHYSICAL ACTIVITIES



SIT-TO-STAND

Rising from a chair uses some of the largest and most important muscles in your body. Using a firm chair, try doing 12 sit-to-stands without using your hands.

Work up to doing 12 sit-to-stands 2 to 3 times a day.



WALKING

Try to walk for 5 minutes every day. Then, slowly increase how far and how fast you walk over time.

Take someone with you the first few times you walk, and wear comfortable clothes and shoes.



LONG-TERM ACTIVITY GOALS

Developing a long-term strategy to stay physically active is a great way to help keep your heart healthy. Below are things that can help you build that plan:

FIND THINGS YOU ENJOY DOING

Being physically active doesn't have to mean driving to and from a gym. Gardening, walking, golfing or bowling with friends—these are all physical activities, too!

MAKE A PLAN

We stand a better chance of doing most things in life when we make a plan and stick to it. Put your activities on your calendar. It's important to make time to take care of yourself.

PARTNER UP

If you are exercising, look for an accountability partner. Join a walking club or other league. Including friends and family in your plan helps you stick to it, and is also more enjoyable.

DEVELOPING A HEALTHY MINDSET

Developing a healthy mindset can do wonders for your physical health. It is also very normal for patients to experience stress and anxiety following a health event. Below are actions you can take to focus on your mental health.



DEVELOP POSITIVE GOALS AS YOU RECOVER

What do you want to do? Be sure to celebrate the positive steps you are taking in your recovery.



CONNECT WITH FELLOW PATIENTS WHO ARE NAVIGATING HEART CONDITIONS

Your hospital may have local recommendations, or you could join national organizations like Mended Hearts[†] that are building a community of support for patients like you.



INFORM YOUR CARE TEAM IF YOU ARE EXPERIENCING ANY UPSET OR ANXIETY FOLLOWING YOUR PROCEDURE

They may recommend talking to a mental health professional or joining a support group at your hospital.



CONSIDER DEVELOPING A MINDFULNESS PRACTICE

Meditation, tai chi, yoga, and even breathing exercises have been shown to decrease stress and promote a positive mindset.



FOR MORE RESOURCES AND SUPPORT, VISIT THE MENDED HEARTS[†] PROGRAM WEBSITE:

<https://mendedhearts.org/about-us/>

SCAN ME



RESOURCES FOR CAREGIVERS

As a caregiver, you have an important role to play in supporting the recovery of the patient. Below are things you should be considering both before and after the procedure.

- 1 Accompany the patient to their doctor's visits.**
If possible, join the patient on their visit to help ensure they bring their list of questions for the heart team, and that those questions are answered and written down. Bring your own list of questions, as well. A list of suggested questions is provided in the back of this guide.
- 2 Check that the patient has prepared their legal documents.**
If needed, work with the patient to make sure their legal documents are organized and ready before the procedure.
- 3 Help the patient pack for their hospital stay.**
It can be easy to forget a needed item—earlier in this patient guide you will find a packing list to help ensure everything is there for the patient to have a more comfortable stay.
- 4 Go over the discharge plan ahead of time.**
Once the patient is home, they may need additional support in many ways. They may need assistance taking their medicines and getting to follow-up doctor visits. They may also need help with their routine care and chores or errands around the home.
- 5 Watch over the patient's physical activity after their procedure.**
Make sure they are following the heart team's instructions.
- 6 Help the patient develop and maintain healthy eating habits.**
It's important to understand dietary changes recommended for the patient, and to help them create and stick to a well-balanced diet.

NOTES

NOTES

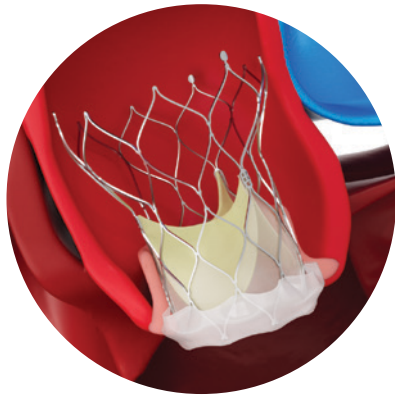
NOTES

AN OVERVIEW OF TREATING STRUCTURAL HEART CONDITIONS

VALVE THERAPIES

Aortic Stenosis

Aortic stenosis is a condition in which the aortic valve leaflets become thick or stiff, reducing their ability to fully open and close, resulting in reduced blood flow from the left ventricle to the aorta. Transcatheter aortic valve implantation (TAVI) is a minimally invasive option to treat severe aortic stenosis by placing an artificial valve within the diseased aortic valve.



Mitral Regurgitation

Mitral regurgitation is a condition in which the mitral valve does not completely close during the contraction of the left ventricle, causing blood to leak backward into the left atrium.

Transcatheter edge-to-edge repair (TEER) is a treatment option for select patients with mitral regurgitation who would otherwise go untreated.



LEARN MORE

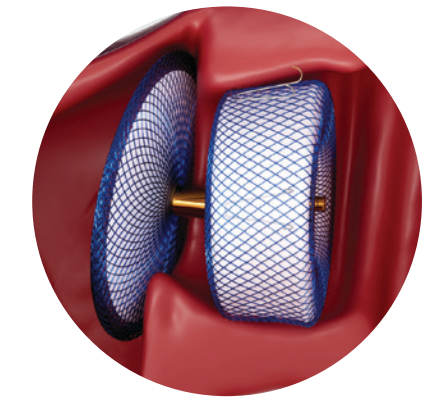
<https://www.structuralheart.abbott/patients/patient-guides>

The information provided is not intended for medical diagnosis or treatment or as a substitute for professional medical advice. Consult with a physician or qualified healthcare provider for appropriate medical advice.

STROKE RISK REDUCTION

Left Atrial Appendage (LAA) and Atrial Fibrillation

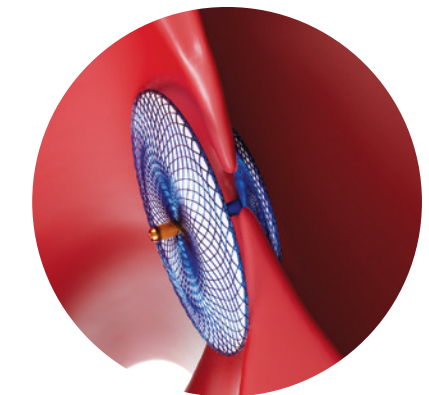
When the upper chambers of the heart (atria) are unable to contract properly in patients with atrial fibrillation, clots are able to form in the LAA. LAA closure can reduce the risk of stroke in nonvalvular atrial fibrillation patients.



Patent Foramen Ovale (PFO)

In rare cases, the small PFO opening can allow a blood clot to pass from the right side of the heart to the left side, and then travel to the brain, where the clot can block a blood vessel, resulting in a stroke.

Percutaneous closure of the PFO may be considered as an option to prevent thrombus formation and the risk of recurrent ischemic stroke.

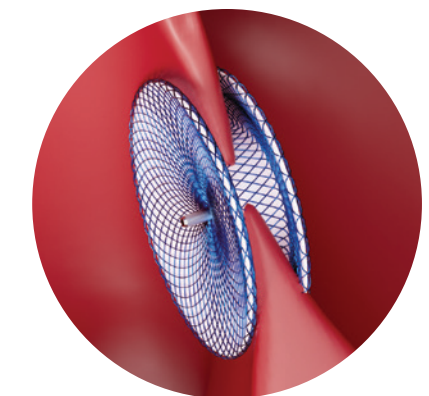


CONGENITAL DEFECTS

Several types of congenital heart disease involve openings or holes that allow blood to flow in the wrong direction.

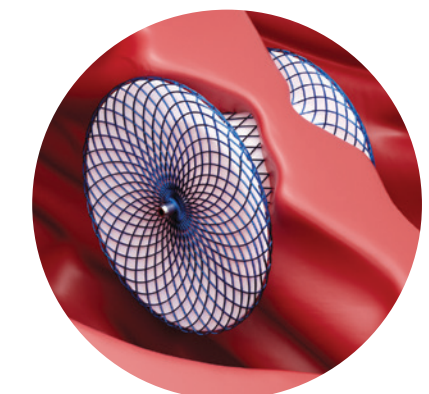
Atrial Septal Defect (ASD)

An ASD may allow abnormal flow of blood between the atria chambers and usually results in too much blood flow to the lungs. This may damage the blood vessels in the lungs. A percutaneous transcatheter device is a treatment option for closure of an ASD.



Ventricular Septal Defect (VSD)

A VSD is a hole in the wall that separates the right ventricle and the left ventricle. A VSD allows oxygen-rich blood to mix with oxygen-poor blood, creating extra work for the heart. A percutaneous transcatheter device is a therapeutic option for closure of a VSD.



IMPORTANT SAFETY INFORMATION

R_x ONLY NAVITOR™ TRANSCATHETER
AORTIC VALVE IMPLANTATION SYSTEM

INDICATIONS

The Navitor™ Transcatheter Aortic Valve Implantation System is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality $\geq 8\%$ at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical comorbidities unmeasured by the STS risk calculator).

CONTRAINDICATIONS

The valve is contraindicated for patients with inability to tolerate antiplatelet/anticoagulant therapy or nitinol alloy (nickel and titanium), or who have active infections, including endocarditis.

POTENTIAL ADVERSE EVENTS

Adverse events potentially associated with the use of transcatheter bioprosthetic heart valves include but are not limited to: access site complications (e.g., pain, bleeding, infection, hematoma, pseudoaneurysm, etc.); acute coronary obstruction; acute myocardial infarction; allergic reaction to antiplatelet agents, contrast medium, or valve components; aortic rupture; ascending aorta trauma; atrio-ventricular node block; cardiac arrhythmias; conduction system injury; conversion to open surgical procedure; death; dissection; embolism; emergent balloon valvuloplasty; emergent percutaneous coronary intervention (PCI); emergent surgery (i.e., coronary artery bypass, heart valve replacement); endocarditis; explantation; heart failure; hemodynamic compromise; hemolysis; hemolytic anemia; hemorrhage; hypotension or hypertension; infection; myocardial ischemia; mitral valve insufficiency; multi-organ failure; non-structural dysfunction (i.e., entrapment by pannus, paravalvular leak, inappropriate sizing or positioning); pannus; pericardial effusion; perforation of the myocardium, ventricle, or a blood vessel; permanent disability; permanent pacemaker; regurgitation; renal insufficiency or renal failure; reoperation; respiratory failure; sepsis; stroke; structural deterioration (i.e., calcification, leaflet tear); thrombosis; tamponade; transfusion; valve embolization or migration; vessel dissection or spasm.



Navitor™
Transcatheter Aortic
Valve Implantation System

CAREGIVER QUESTIONS FOR THE HEART TEAM

Below are questions you may want to discuss with the heart team prior to the patient's Transcatheter Aortic Valve Implantation (TAVI) procedure.

1. How long will the patient be in the hospital?

2. Will I need to stay with them overnight in the hospital (or am I able to if I would like)?

3. What legal documents should the patient have prepared?

4. What symptoms will they have after the procedure, and for how long?

5. What kind of support will need to be provided?

6. Will physical therapy or rehab be required?

7. Will there be any medication changes?

8. How long does it typically take for a patient to fully recover?

9. What else can I do to support recovery?

Other Notes:

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