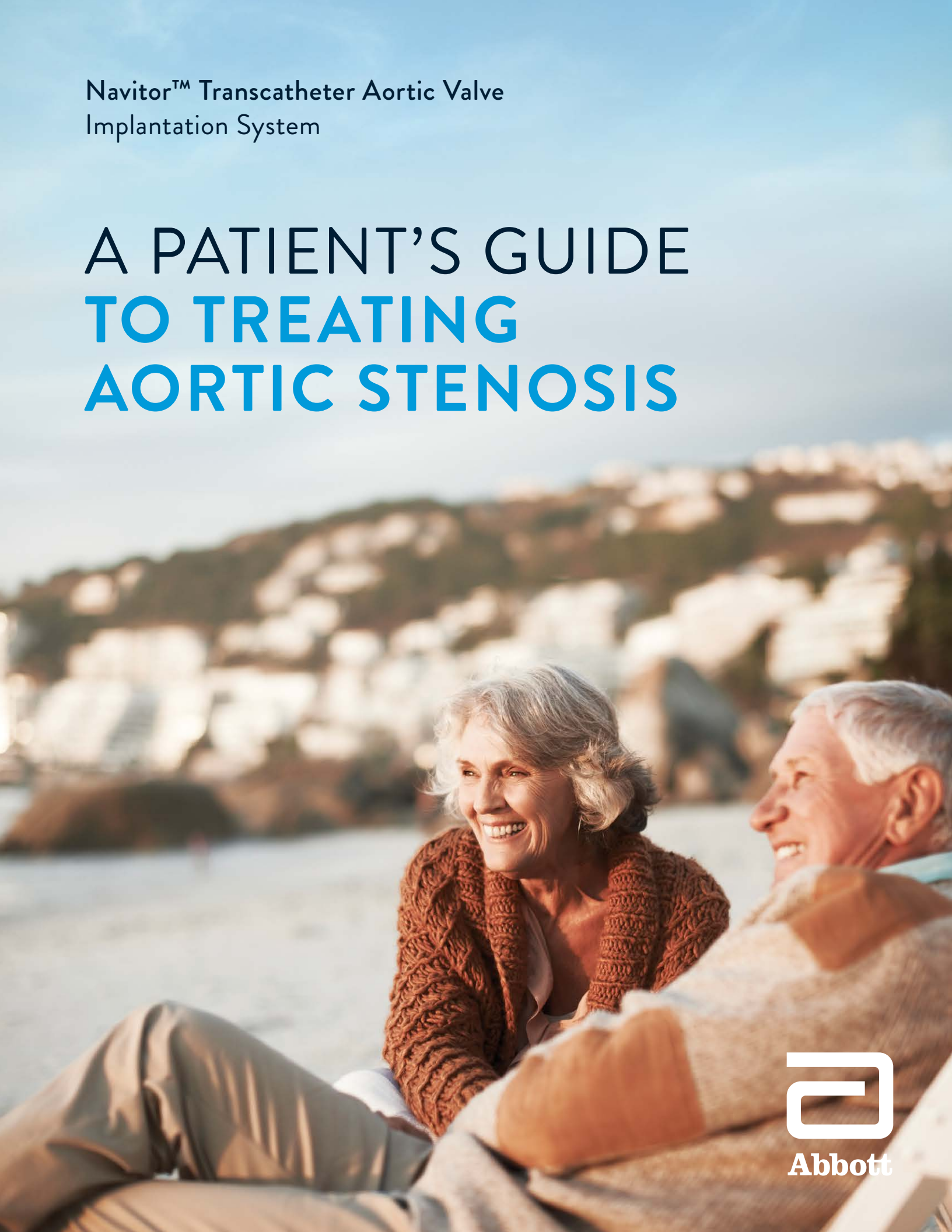
Navitor™ Transcatheter Aortic Valve
Implantation System

A PATIENT'S GUIDE TO TREATING AORTIC STENOSIS



Abbott

At Abbott, we focus every single day on restoring health and improving the quality of life for people around the world.

We are delighted that you have taken the first steps toward treating your severe aortic stenosis with transcatheter aortic valve implantation – often referred to as "TAVI" (rhymes with "savvy.")

This booklet contains great education about aortic stenosis and TAVI, a common treatment option. Of course, if you or your family have any questions, please reach out to your care team.

We wish you all the best and good health!

Dr. Lars Søndergaard
Chief Medical Officer, Abbott Structural Heart

 See Important Safety Information referenced within.

I'VE BEEN DIAGNOSED WITH AORTIC STENOSIS
WHAT IS IT?

Stenosis is defined as "abnormal narrowing of a passage in the body." So, aortic stenosis refers to a condition where the valves in the heart become narrower, causing the heart muscle to work harder to pump blood to the brain and the rest of the body.

Did you know?
Aortic Stenosis is one of the most common and serious heart valve diseases. It affects millions of older adults, and that number is increasing.[1]

COMMON SYMPTOMS OF AORTIC STENOSIS

Many symptoms of aortic stenosis are often misunderstood by patients as being "normal" signs of aging. The list below shows symptoms of aortic stenosis, but there may be others. Tell your doctor of any new or worsening symptoms you're experiencing.

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

HOW CAN AORTIC STENOSIS **BE TREATED?**

Based on your level of risk, the outcomes from your diagnostic tests, and your lifestyle preferences, it is important that you discuss all available treatment options with your doctor, to determine which treatment is right for you. There are several treatment options for severe aortic stenosis including medication, procedures that stretch the valve wider, surgical aortic valve replacement, or transcatheter aortic valve implantation (commonly called "TAVI").

TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI)

As shown below, the Navitor™ valve is a wire-frame device with leaflets made of bovine (cow) tissue designed to function like a native aortic valve.

The valve is implanted in a minimally-invasive procedure called TAVI, which is often recommended by doctors for patients with severe aortic stenosis who are not candidates for invasive open-heart surgery due to age, frailty or other conditions that make surgery too risky.

25 millimeter Navitor™ valve
Available valve sizes: 23, 25, 27, 29, 35 mm

24 millimeter US quarter

TO LEARN MORE ABOUT AORTIC STENOSIS, VISIT THE CARDIOSMART WEBSITE AT:

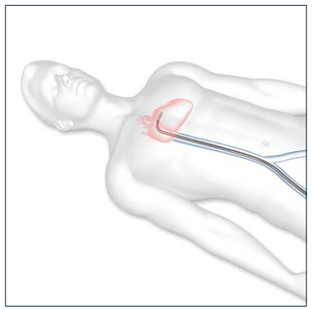
www.cardiosmart.org/topics/aortic-stenosis

SCAN ME

WHAT HAPPENS DURING **A TAVI PROCEDURE?**

The procedure to implant the device inside the heart will take place in a special cardiac suite with your heart team to perform the procedure and care for you. Below is a simplified overview of the steps.

A catheter is used to guide the device into position.



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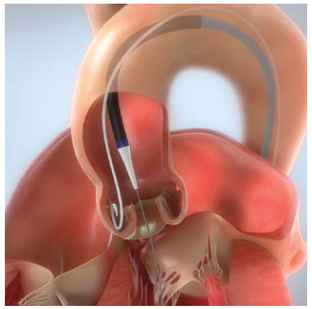
Your physician will determine the best approach for placing your valve, but using the femoral artery in your leg is the most common. A small incision is made, and the physician uses special imaging equipment to carefully guide the catheter to the precise location.



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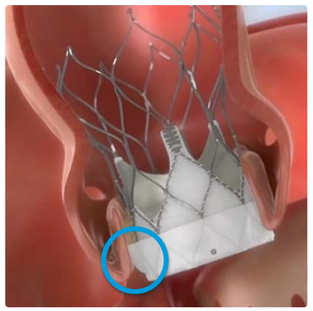
The Navitor Valve is delivered with a catheter through the sheath and placed within your opened aortic valve. Your doctor will deploy the valve using special visualization equipment to ensure the valve is positioned accurately within your heart.



3

Once the device has been positioned correctly, it starts to function immediately. The physician then removes the delivery system catheter and the small incision is closed. The procedure is complete.

WHAT RISKS ARE ASSOCIATED WITH THE TAVI PROCEDURE?

There are risks with any heart valve implantation procedure. Serious risks include, but are not limited to:

- Death
- Stroke
- Serious damage to the arteries
- Serious bleeding
- Access site complications (e.g., pain, bleeding, infection, blood vessel damage)
- Heart attack - blockage of blood flow to the heart muscle
- Allergic reaction to medication or products/devices used during the procedure (medication to prevent blood clotting, x-ray die, components of the valve delivery process)
- Tear or burst of the aorta
- Disruption or injury of electrical system in your heart leading to the need for a permanent pacemaker implant
- Tear or separation of the layers of the wall of an artery
- Emergency surgery

CONTACT YOUR DOCTOR OR EMERGENCY SERVICES **IF YOU EXPERIENCE ANY OF THE FOLLOWING:**

- Redness or drainage from incision
- Shortness of breath
- Swelling of feet or ankles
- Bruising
- Excessive bleeding
- Blood in your urine
- Bloody or tarry bowel movements
- 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

HOW DO I PREPARE FOR MY TAVI PROCEDURE?

If your doctor has recommended the TAVI procedure for you, below are some ways they may ask you to prepare.

- ☐ Complete all the lab work requested by your doctor.
- ☐ Request oral health clearance from your dentist.
- ☐ Prepare your legal documents and ensure your caregiver knows where they are located.
- ☐ Make arrangements for a ride home from the hospital upon discharge, and for some help at home. Your care team can advise on what you may need help with and for how long.
- ☐ Take your prescribed medications as directed by your doctors in the days before your procedure.
- ☐ Tell your doctor of all medications you are taking.
- ☐ Tell your doctor of any allergies you have.
- ☐ Follow all directions from your doctor or nurse.

WHAT WILL HAPPEN THE DAY OF MY PROCEDURE?

Here's what your day is likely to look like:

CHECK-IN

Most people check-in for their procedure the morning it is scheduled. Your care team may ask that you check-in the evening before.

PRE-OP PREP

You'll set aside your belongings for safe-keeping in a room or locker. The care team will get you ready for your procedure, including getting you in a gown and socks for your comfort. Your caregiver will be directed to a waiting room.

AFTER THE PROCEDURE

While you're resting in a recovery room, the care team will let your caregiver(s) know how the procedure went and how you're doing. Depending on the hospital policy, they can visit you either in recovery or in your inpatient room.
Your belongings will be returned to you. The length of stay varies and is determined by your doctor.

WHAT WILL HAPPEN DURING MY RECOVERY PERIOD?

AT THE HOSPITAL

Your care team will work with you on discharge planning. They will evaluate your medications and make any recommended changes.
They may perform follow-up checks to evaluate your recovery.

THE FIRST DAY AT HOME

The first 24 hours after surgery it is important to tend to your incision site and keep it dry. You can carefully take a shower but avoid soaking the area. Avoid lotions and perfumes.

THE FIRST FEW WEEKS

Take it easy. Don't do strenuous exercise, and don't do any heavy lifting (nothing heavier than a gallon of milk). Limit driving. Walk only short distances on level ground. You should be back to regular activity at 1-2 weeks.

YOUR 30-DAY CHECK-UP

Your doctor will want to see how you're doing 30 days after the procedure. The care team will get new images to see how your new heart valve is working, and they may do additional lab work and testing.

FOCUS ON YOUR HEALTH

As you continue to recover from your procedure, it is important that you lead a healthy lifestyle with diet, exercise, and maintaining a healthy mindset.

YOUR ONE-YEAR EXAM

Similar to your 30-day check-up, you will be asked to return for more images to assess how your heart valve is working.

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

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

DEVELOPING A **HEART HEALTHY LIFESTYLE**

A balanced approach to your diet, activity level, and mental health can have a large positive impact on your overall physical health.

PLAN YOUR GROCERY TRIPS WITH HEALTH IN MIND A FEW TIPS ON HEALTHY EATING FROM THE AMERICAN HEART ASSOCIATION (AHA).

SCAN THE CODE ON PAGE 11 FOR MORE.

- Plan your meals and make a list to take to the grocery store to help you stay on track.
- Maximize fresh fruits and vegetables, whole grains and healthy proteins.
- Minimize processed food, added sugars and salts, and alcohol.

GET MOVING

Your doctor will tell you when you can return to normal activity and are cleared to begin exercise.

- Start slowly with something like sit-to-stand exercises a few times perday.
- Then start walking five minutes each day. Over time, slowly increase your distance and speed. Take someone with you the first few times.

DEVELOP A HEALTHY MINDSET

It's normal to experience stress and anxiety following a health event, yet let your care team know if you are as they may have helpful recommendations. Additionally, below are a few actions you can take to support your mental health.

- Develop some health-related goals as you recover. Be sure to celebrate your achievements along the way.
- Connect with others 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.

GUIDE FOR **CAREGIVERS**

Caregivers play an important role in supporting the recovery of the patient. Here are some useful tips.

1. Accompany the patient to their doctor visits. Write down questions you have for the care team and take notes about the answers.
2. Ensure the patient has prepared their legal documents, and that you know where they are.
3. Help the patient pack for their hospital stay.
4. Have a discharge plan. The patient may need additional support after they get home (e.g., taking medications, getting to doctor visits, etc.)
5. Watch over the patient's incision site and physical activity to ensure they're following the care team's instructions.
6. Help the patient develop and maintain healthy eating habits.

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

www.heart.org/en/healthy-living/healthy-eating

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:

NOTES

 See Important Safety Information referenced within.

NOTES

AVAILABLE BY PRESCRIPTION ONLY

IMPORTANT SAFETY INFORMATION

Rx ONLY NAVITOR™ TRANSCATHETER AORTIC VALVE IMPLANTATION SYSTEM

WHAT IS THE NAVITOR™ TAVI SYSTEM APPROVED FOR?

Transcatheter Aortic Valve Implantation (TAVI) with the Navitor™ TAVI System provides an alternative, minimally invasive treatment option for people living with severe aortic stenosis, a condition where the aortic valve does not fully open or close, who are not candidates for open-heart surgery due to age, frailty, or other conditions that make surgery too risky.

WHO SHOULD NOT RECEIVE TRANSCATHETER AORTIC VALVE IMPLANTATION WITH THE NAVITOR™/NAVITOR TITAN™ VALVE?

You should not receive the Navitor/Navitor Titan valve if you have any of the following conditions: any kind of infection, including an active infection in the heart; cannot tolerate medication that thins the blood or prevents blood clots from forming; have a reaction or allergy to nitinol, an alloy of nickel and titanium. The Navitor™ TAVI System has not been studied in the following patient populations and therefore should not be used in patients who: have any evidence of a blood clot (thrombus), intracardiac mass or vegetation in, on or around the heart; have narrow veins or arteries with calcification that make insertion of the delivery sheath and access to the aortic valve impossible; have stenotic (narrowed) aortic valve without calcium deposits; have a heart valve defect from birth with either one or two leaflets vs. the normal three leaflets; are pregnant or breastfeeding; are age 21 or younger at the time of diagnosis or treatment; have an ejection fraction, or volume of blood fluid, less than 20%; have unstable heart function requiring mechanical assistance or drug therapy to support the normal function of the heart; are low or intermediate surgical risk; have had a previous heart valve or ring in any position in the heart; have mixed aortic valve disease (stenosis and regurgitation); have severe mitral valve disease (calcification, stenosis or inefficiency); have a medical condition that affects the cellular or plasma components of the blood; have significant coronary artery disease that requires treatment; have abnormally thick heart muscle (hypertrophic cardiomyopathy); are on dialysis, have kidney failure or inefficiency; have known allergy or sensitivity to aspirin, heparin, ticlopidine (Ticlid), or clopidogrel (Plavix), or sensitivity to contrast media/dye; have bulky calcium build up on the valve leaflets close to the coronary ostia which are the main arteries delivering blood from the heart to the rest of the body; have significant aortic disease, including abdominal aorta, thoracic aneurysm or any other folding, bending or narrowing which would make access to the aortic valve impossible.

WHAT ARE THE POSSIBLE COMPLICATIONS ASSOCIATED WITH TRANSCATHETER AORTIC VALVE IMPLANTATION WITH THE NAVITOR/ NAVITOR TITAN VALVE?

There are risks with any heart valve implantation procedure. The most serious risks are: death, stroke, serious damage to the arteries and serious bleeding. Additional risks include, but are not limited to: access site complications (e.g., pain, bleeding, infection, blood vessel damage); buildup of deposits (plaque) in and on the walls of coronary arteries; heart attack - blockage of blood flow to the heart muscle; allergic reaction to medication or products/devices used during the procedure (medication to prevent blood clotting, x-ray die, components of the valve delivery process); tear or burst of the aorta; irregular heart rate; disruption or injury of electrical system in your heart leading to the need for a permanent pacemaker implant; tear or separation of the layers of the wall of an artery; obstruction of an artery, typically by a clot of blood or an air bubble; inflammation of the lining of your heart; failure of your heart to pump enough blood to the body's organs; unstable blood flow; rupture or destruction of blood cells; blood cell damage; low red blood cell count; bleeding, infection, clotting in or on the valve or tissue of the valve; loose clots in the bloodstream that may block an artery in your arms, legs, or brain; escape of blood from a ruptured blood vessel; blood pressure changes above or below the normal levels; infection; reduced blood flow to your heart, preventing the heart muscle from receiving enough oxygen; changes to the Mitral valve where it doesn't close tightly; multi-organ failure - inflammation from a severe infection or injury causes dysfunction in two or more organ systems; wrong sizing or positioning of the implanted valve; collection of fluid or blood around your heart; perforation or tear of the heart muscle, ventricle or blood vessel; formation of scar tissue that may cover or block the valve from functioning normally; leakage of blood around the edge of the valve; valves in your heart don't close tightly, allowing blood to flow backward in your heart; kidneys lose the ability to remove waste and balance fluids; blood doesn't have enough oxygen or has too much carbon dioxide; sepsis; structural deterioration of the implanted valve (i.e., calcification, leaflet tear); having an abnormal particle (air or blood clots) floating in the bloodstream or attached to an object, including the valve; when extra fluid builds up in the space around the heart; when the transcatheter valve moves or is dislodged from the deployment position/location; permanent disability; the need for additional medical procedures to include blood transfusions, operation to remove the valve, use of a balloon to adjust the valve (valvuloplasty), and catheter insertion into coronary arteries to treat blockages.

References
1. What is Aortic Stenosis? Aortic Stenosis Resources, American Heart Association. Accessed 04-15-2024. https://www.heart.org/en/health-topics/heart-valve-problems-and-disease/heart-valve-disease-resources/aortic-stenosis-resources.

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Patient Information Guide is also available at https://www.eifu.abbott/

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