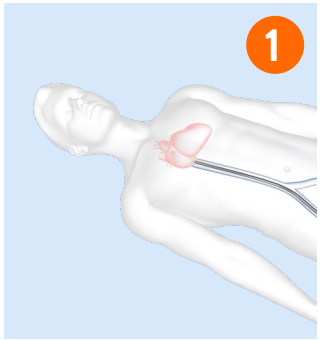
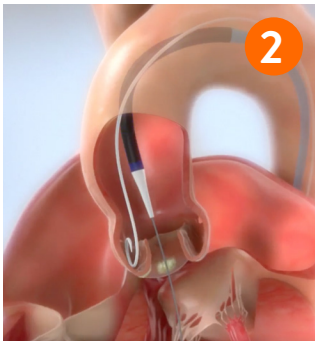
LEARN ABOUT POSSIBLE NEXT STEPS

If your doctor has suggested treating your aortic stenosis with Transcatheter Aortic Valve Implantation (TAVI) therapy, you may have some questions. TAVI therapy is a minimally invasive procedure usually performed under sedation or light anesthesia. Keep reading for more details about the procedure, and on the Navitor™ TAVI Valve your physician recommends for you.

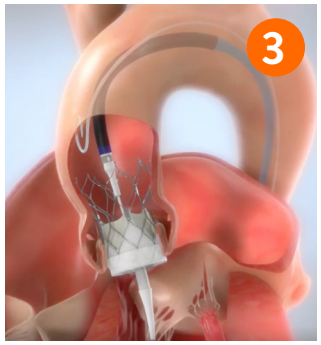
REPLACING YOUR AORTIC VALVE WITH TAVI THERAPY



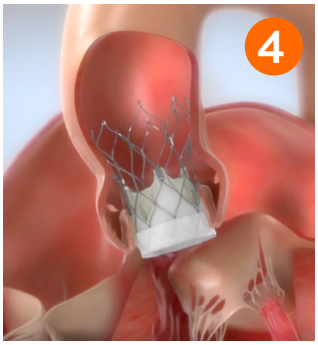
Your surgeon will make a small incision and insert a thin, flexible catheter tube into an artery in your leg. Other access sites may be considered. Next, the catheter will be carefully threaded to your heart and into your aortic valve.



A tiny balloon on the tip of the catheter is inflated to prepare your native valve for the replacement TAVI valve. The Navitor Valve is then guided through the catheter and positioned inside the aortic valve.



The replacement valve begins to regulate blood flow immediately. Once your surgeon has determined the new valve is working smoothly, the catheter is removed and the incision is closed.



The TAVI procedure typically takes one to two hours, and most patients recover more quickly than with open-heart surgery, often leaving the hospital within a few days.

See Important Safety Information referenced within.

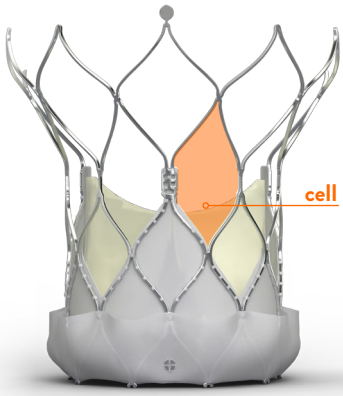
GET TO KNOW THE NAVITOR™ VALVE

Your heart team considered all valve options for your TAVI procedure, and selected the Navitor Valve. Explore why the Navitor Valve is one of the top choices for TAVI therapy:

1. The Navitor delivery system is flexible, which helps your doctor gently guide the valve through your arteries and into your heart. This approach helps reduce the risk of complications in your blood vessels.

2. The Navitor Valve comes in a range of sizes—your physician will select the right match for your specific anatomy.

3. The Navitor Valve was designed with your future in mind—the large size of the cells in the frame gives your physician access to your coronary arteries if an intervention (like stents) were ever required.



SCAN TO LEARN MORE ABOUT HEART HEALTH

AVAILABLE BY PRESCRIPTION ONLY

IMPORTANT SAFETY INFORMATION

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 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.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs.
Photo(s) on file at Abbott.

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