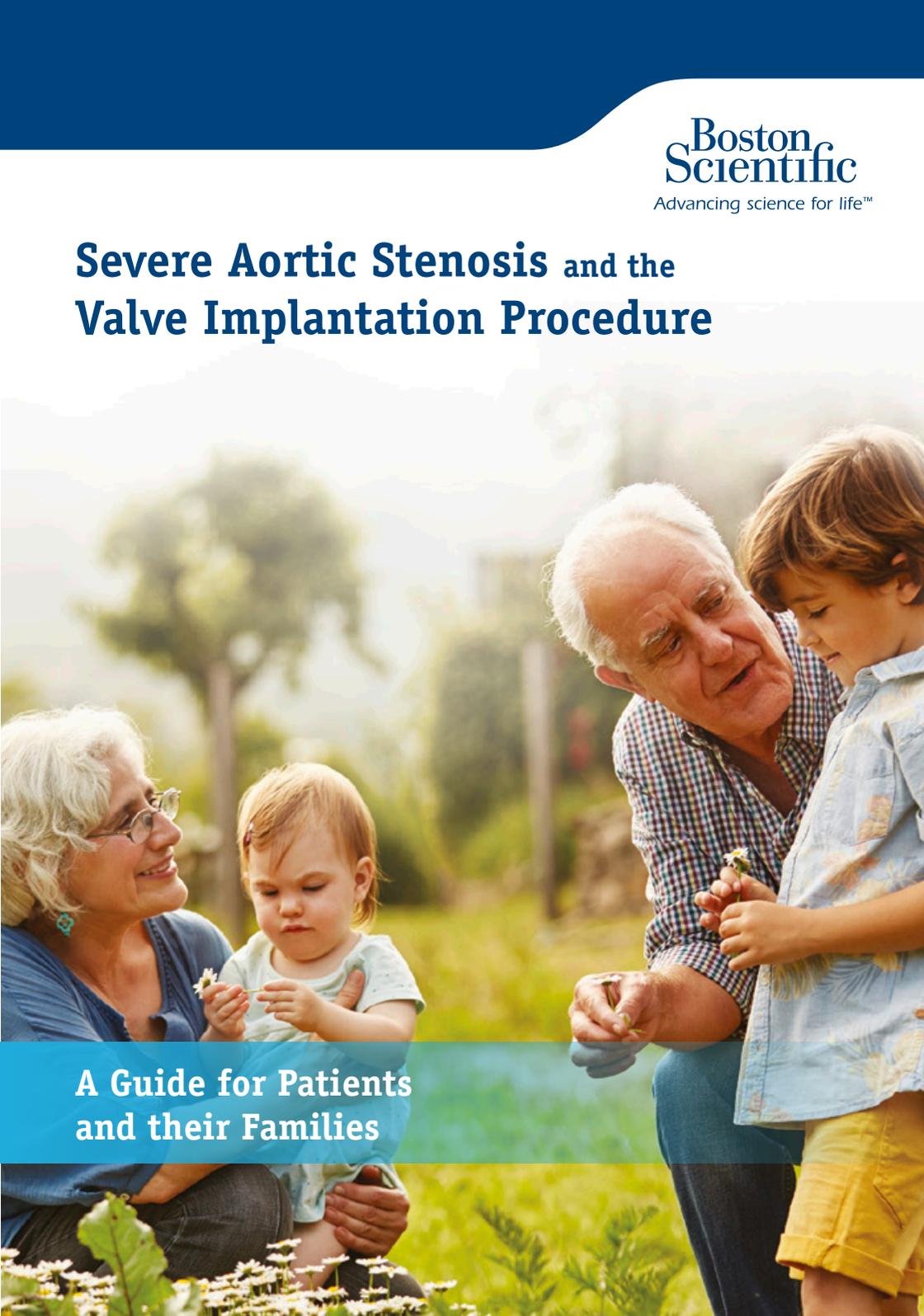


Severe Aortic Stenosis and the Valve Implantation Procedure



**A Guide for Patients
and their Families**



If you've been diagnosed with severe aortic stenosis, you probably have a lot of questions and concerns. The information in this booklet will help you learn more about your heart, severe aortic stenosis, and treatment options.

Your heart team will recommend which treatment option is best for you. Please talk with them about any questions you have.

Table of Contents

4	About Your Heart
5	What Is Severe Aortic Stenosis?
5	What Causes Severe Aortic Stenosis?
7	What Are the Symptoms of Severe Aortic Stenosis?
8	Treatment Options for Severe Aortic Stenosis
10	Before a TAVI Procedure
12	What Are the Risks of TAVI?

About Your Heart

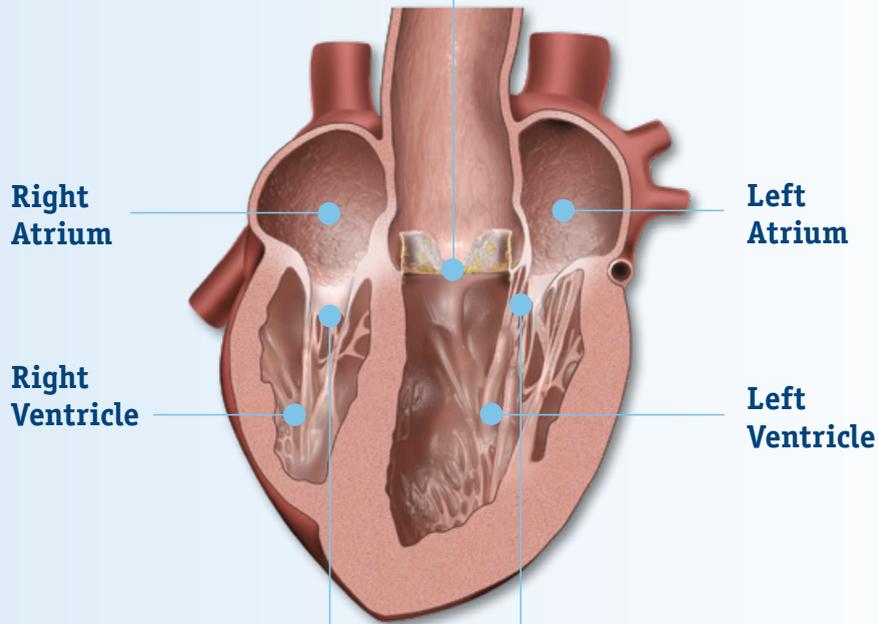
The heart is a muscle about the size of your fist. It is a pump that works nonstop to send oxygen-rich blood throughout your entire body. The heart is made up of four chambers and four valves. The contractions (heartbeats) of the four chambers push the blood through the valves and out to your body.

Pulmonic Valve

controls the flow of blood to the lungs (not shown below)

Aortic Valve

controls the flow of blood out of your heart to the rest of the body



Tricuspid and Mitral Valves

control the flow of blood between the chambers of the heart

What Is Severe Aortic Stenosis?

The aortic valve is made up of three tissue flaps, called leaflets. Healthy valves open at every heart contraction, allowing blood to flow forward to the next chamber, and then close tightly to prevent blood from backing up. Blood flows in one direction only. This is important for a healthy heart.

Severe aortic stenosis occurs when the valve leaflets become stiff, reducing their flexibility and ability to fully open and close properly. This results in a narrowing (stenosis) of the valve opening.

This narrowing reduces and restricts blood flow, requiring your heart to work harder. As a result, less oxygen-rich blood flows from your lungs to the brain and the rest of your body.

What Causes Severe Aortic Stenosis?

Severe aortic stenosis is an age-related, progressive disease. The most common cause is the gradual buildup of calcium (mineral deposits) on the leaflets of the aortic valve. More rarely it can be caused by a congenital heart defect, rheumatic fever, or radiation therapy.

See the difference between healthy and diseased valves

Healthy Valve



open



closed

Diseased Valve



open



closed

calcium buildup

Affecting about 7% of all people over the age of 65, aortic stenosis is the most common valvular heart disease in the world.¹



**AN ESTIMATED
626,000 people over 65 years
SUFFER FROM AORTIC STENOSIS IN EUROPE.²**

**427,000 of those people
HAVE SYMPTOMATIC SEVERE CONDITION (2019)²**

Severe aortic stenosis is a life-threatening condition. Your doctor may prescribe medications to ease the symptoms of your severe aortic stenosis. However, if the diseased valve is not replaced, your symptoms will probably worsen to heart failure and possibly even death.³⁻⁵

What Are the Symptoms of Severe Aortic Stenosis?

In the earlier stages of aortic stenosis, many people don't experience symptoms. As the severity increases, the most frequent symptoms include:

Shortness of breath



Chest pain, pressure, or tightness



Feeling lightheaded or dizzy



Other symptoms can include fatigue causing difficulty when exercising or completing day-to-day activities.

Treatment Options for Severe Aortic Stenosis

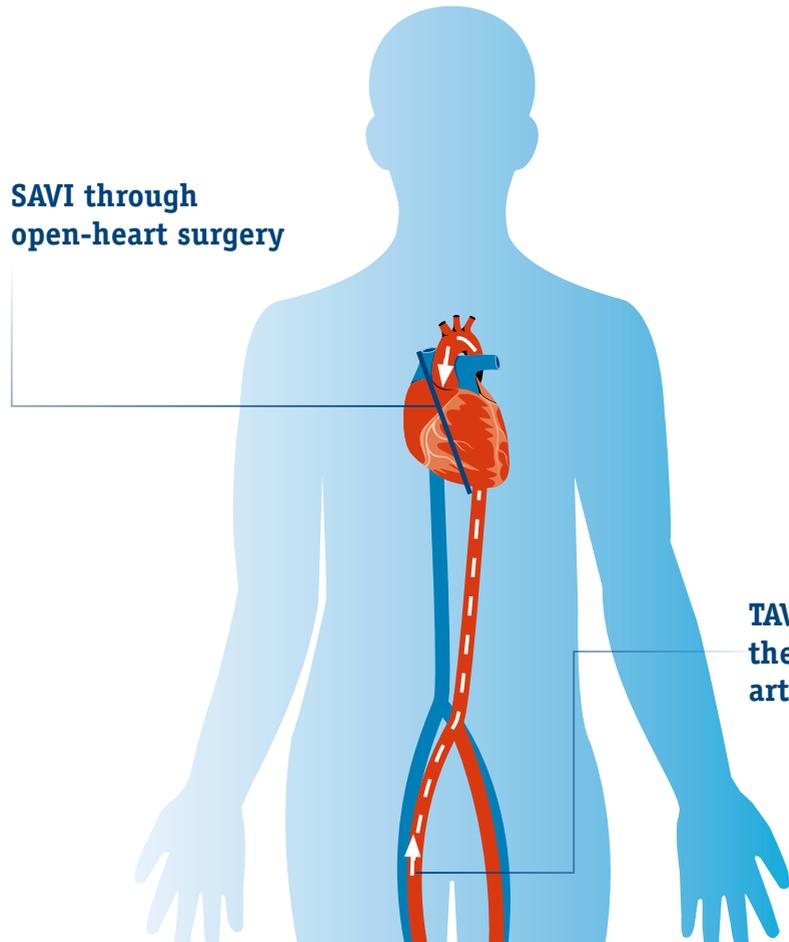
The only effective treatment for severe aortic stenosis is implantation of the aortic valve. There are two possible treatment options.

Surgical Aortic Valve Implantation (SAVI)

Surgical aortic valve implantation is done through open-heart surgery. During the operation, your heart is stopped and a heart-lung machine temporarily takes over the function of pumping blood through your body. A surgeon will replace the diseased aortic valve with an artificial valve. Recovery from open heart surgery frequently takes weeks to months.

SAVI through open-heart surgery

TAVI through the femoral artery



Transcatheter Aortic Valve Implantation (TAVI)

Transcatheter aortic valve implantation is a less-invasive procedure that replaces the aortic valve *without* opening your chest to reach your heart. To access your heart, your doctor makes a small incision in your artery or blood vessel, most often in the groin.

The artificial valve is compressed onto a catheter that travels through a hollow tube up through a blood vessel, all the way to your heart. Your doctor will expand the implantation valve, pushing the diseased parts of the aortic valve out of the way. Special X-ray equipment is used to guide positioning and placement of the new valve.

Patients who undergo a TAVI procedure typically have an easier time recovering and experience less discomfort. How quickly you recover and return to your daily routine will depend on your overall state of health.

Stroke Risk Reduction

During the aortic valve implantation procedure, pieces of the calcified heart valve or tissue can break loose and travel in the bloodstream toward the brain. If this material reaches a vital organ serious consequences, such as a stroke, may occur.

This material may cause a stroke by blocking blood flow to the brain causing long-term damage. Talk with your heart team about a cerebral embolic protection system that may reduce your risk of stroke during the TAVI procedure.



What Are the Risks of TAVI?

A valve implantation is a major heart procedure. There are risks with all medical procedures. Speak with your heart team to understand the risks and benefits for you.

Risks of TAVI include but are not limited to:

- Access site complications, typically in the groin, including arteriovenous fistula, hematoma or lymphatic problems
- Allergic reaction to device or procedural materials
- Arrhythmia, abnormal heart beats, or new conduction system injury including need for permanent pacemaker
- Heart attack or heart failure
- Stroke, transient ischemic attack (TIA), cerebral infarction or neurologic deficits
- Death
- Clotting in the blood stream or thrombosis (including air, tissue, thrombus or device fragments)
- Heart tissue or valve injury
- Permanent disability
- Fluid in the space that surrounds the lungs or heart
- Kidney failure or damage
- Difficulty breathing
- Problems with the artificial valve such as leakage (regurgitation) or restriction (stenosis).

These complications may require additional medical, percutaneous or surgical intervention, including re-operation and implantation of the valve. These complications can be very serious and possibly fatal.

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