

Product Information for Patients

ACURATE neo2™

Heart Valve

REF

SYM-SV23-004	SYM-SV25-004	SYM-SV27-004
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Device Information

The ACURATE neo2 heart valve is a device that is placed in the body permanently. It controls blood flow through the heart valve that has been damaged by calcium build-up. It is made of pig heart tissue on a nickel-titanium (nitinol) metal frame. The valves are available in three sizes: small, medium, and large.

The valve is designed for the following patients:

- Patients with a severely narrow aortic valve opening.
- Patients with a narrow aortic valve that causes them to have signs of serious illness.

Your doctor is part of a Heart Team that will recommend which treatment option and heart valve is best for you.

Transcatheter aortic valve implantation (TAVI) is a non-surgical procedure. It replaces your damaged heart valve without open-heart surgery. Before your procedure, you may receive sleep medicine (general anesthesia). You may also remain awake and receive medicine that helps you to relax and block pain.

During the procedure, your doctor will use X-ray equipment to position and place the valve. When your doctor has placed the valve in the right spot, it will begin to function immediately. This will restore normal blood flow.

Your doctor should give you an implant card that identifies your heart valve. Always carry your implant card with you. Present it to all your health care providers (doctors, dentists, and technicians) so they know that you have an implanted heart valve. If you have not received an implant card, tell your doctor.

Information on Safe Use

Ask your dentist and doctor about taking antibiotics before dental or medical procedures to prevent valve infection.



If you need a magnetic resonance imaging (MRI) scan, tell your doctor or MRI technician that you have an implanted heart valve. You may safely have a MRI scan under standard MRI scanning conditions. Your doctor will determine the correct MR conditions for scanning. Additional detailed information can be found in the ACURATE neo2 Instructions for Use (IFU) available at www.IFU-BSCI.com or by calling +1-800-272-1001.

You can travel safely with an ACURATE neo2 heart valve. An airport full body scanner will not harm your heart valve. It may set off airport metal detectors. Always carry your implant card with you while travelling.

Warnings and/or Precautions

Here are some things you and your doctor may want to consider while deciding if you should receive an ACURATE neo2 heart valve:

- The extent of your heart disease
- Your heart function
- Your symptoms

The heart valve is implanted through a small opening in the upper part of your thigh. Your doctor will consider your preferences when deciding the medications and procedures to use to place and monitor your ACURATE neo2 heart valve.

Patient Risk Information

Here are some potential risks associated with the procedure and the inserted valve:

- An allergic reaction to the following:
 - Medications
 - The solution used to see inside your body during body imaging
 - The materials used to make the valve
- Chest pain or discomfort
- Problems with the electrical pathway of your heart that could require a medical device to control your heartbeat
- Bleeding that could require a transfusion or surgery
- Failure of your heart to pump enough blood to the body's organs
- Decreased blood flow to the brain (stroke) that could cause disability or other condition that may cause severe disability (major stroke)
- Partial or complete blockage of vessels that carry blood to and from your heart
- Death
- Incorrect placement of valve or valve movement from the insertion site
- An abnormal particle (air, blood clot, or device material) floating in the blood stream or attached to an object, including the valve
- Fever, including one caused by a bacterial infection in the blood
- Failure of the heart to pump enough blood
- Damage to the red blood cells and/or a disorder in which red blood cells are damaged faster than they are made
- High or low blood pressure
- Infection to your heart, blood, or other areas of your body
- Injury to the mitral valve can cause improper closure of the mitral valve. This can lead to blood leaking backwards from the left pumping chamber
- Heart attack
- Injury to the heart muscle or valve, including puncture or severe tearing
- Functional abnormality of a body area due to a decrease in the function of the brain, spinal cord, muscles, or nerve injury
- Pain or swelling
- Swelling of the heart, or collection of fluid or blood around your heart
- Reduced blood supply to the tissues, leading to possible tissue death
- Fluid build-up in the lungs
- X-ray used during the procedure may cause radiation injury to the skin
- Worsening or failure of kidney function
- Worsening or failure of lung function
- Problems with the valve or accessories that do not allow it to work well. These problems may include:
 - Wear, tear, or movement of the valve leaflets forward or backward from their normal position
 - Calcium build-up on the leaflets
 - A break in the metal frame
- Formation of scar tissue that may block the valve from functioning normally
- Narrowing of a heart valve which may cause blood to flow backward through the valve
- Blood vessel damage or injury due to puncture, tear, or burst

Expected Lifetime and Follow-up

After the procedure, your doctor may prescribe blood thinning medications. Take these as directed. You must follow your doctor's directions if taking blood thinning medication as it helps prevent blood clots. Blood clots can be dangerous.

Your doctor will tell you how often he or she needs to see you after your procedure. For a successful recovery, keep any scheduled doctor visits. Your doctor will check your heart valve, your healing, and your overall health.

In some patients the heart valve may eventually need to be replaced. How long your heart valve will last depends on many factors, including your health. The ACURATE neo2 heart valve has been tested in a laboratory to last 5 years without failure. Regular follow-up appointments will help your doctor know how your valve is working.

Contact your doctor if you believe that you are experiencing side effects related to the device or if you are concerned about risks. This document should not replace a consultation with your doctor if necessary.

Report any serious incident that occurs in relation to this device to Boston Scientific and to the relevant local regulatory authority for medical devices in your country.

For customers in Australia, report any serious incident that occurs in relation to this device to Boston Scientific and to the Therapeutic Goods Administration (<https://www.tga.gov.au>).











Patient Contacting Materials

The following patient contacting materials are present in the heart valve:

Material	Weight of material (grams)
Nickel-Titanium (Nitinol)	1.080
Pig heart tissue	1.826
Polyester fabric	0.039

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Symbol Definitions

 Date of Implantation	 Name and Address of the implanting healthcare institution/provider	 Patient Name or Patient ID
 Heart Valve Catalog Number	 Heart Valve Serial Number	 Heart Valve Global Trade Item Number
 Indicates the date by which the device must be used	 Name and address of the heart valve manufacturer	 Heart Valve Unique Device Identifier
 You may safely have a MRI scan under specific conditions. Consult your doctor		

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