



# LOTUS Edge™ Valve System

Transcatheter Aortic Valve Prosthesis  
Premounted on Delivery System



## Patient and Caregiver Information Guide

For more information about the LOTUS Edge™ Valve System or the LOTUS Edge TAVR procedure, please visit [www.bostonscientific.com](http://www.bostonscientific.com) or call Boston Scientific customer service at 888-272-1001.

**CAUTION:** Federal (USA) Law restricts these products to sale by or on the order of a doctor.

### LOTUS Edge™ Valve

Patient Name	
Implanting Physician's Name	
Physician's Phone Number	
Catalog No:	
Lot No:	Date of Implant:



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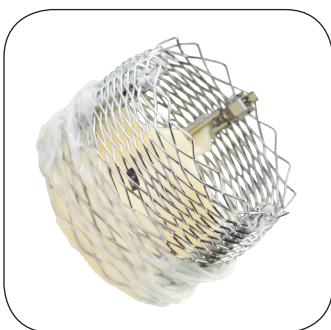
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**LOTUS Edge™ Valve System**  
Transcatheter Aortic Valve Prosthesis  
Premounted on Delivery System



# Introduction To This Guide

This information is for patients who have been diagnosed as having severe, aortic valve stenosis (a narrowing of the aortic valve that does not allow normal blood flow) and have symptoms associated with the disease. Certain patients with severe aortic stenosis have a high risk of experiencing serious complications or are too sick to undergo surgical, or open-heart aortic valve replacement.

This guide will help you learn more about your heart, your disease, and your treatment options, including a less invasive Transcatheter Aortic Valve Replacement (TAVR) procedure with the LOTUS Edge™ Aortic Valve System.



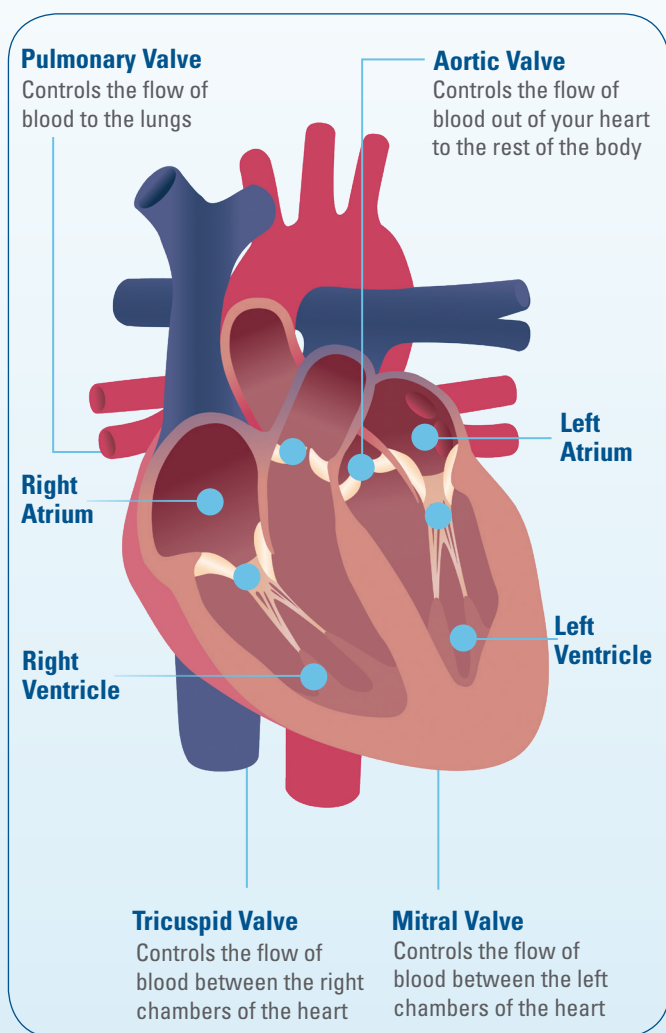
Your doctor is part of a heart team that will recommend which treatment option and heart valve is best for you. Please discuss any questions you may have about your treatment options with your doctor.

If you need additional information about the LOTUS Edge Valve System, please contact Boston Scientific Customer Service at 888-272-1001.

# About Your Heart

## How the Heart Works

The heart, as shown in the image below, is a muscle about the size of your fist. Its main function is to pump oxygen-rich blood to the rest of the body through its four chambers and four valves. Heart chambers (the right and left atrium and the right and left ventricles), contract through heartbeats to push blood through the valves and out to your body.



The aortic valve controls the flow of blood out of your heart to the rest of the body. It consists of two or three 'leaflets' (flaps of tissue) that open at every heart contraction, allowing blood to flow forward to the next chamber, and then close tightly to prevent blood from flowing backwards. Blood flows in one direction only. This is important for a healthy heart.

# About Your Heart

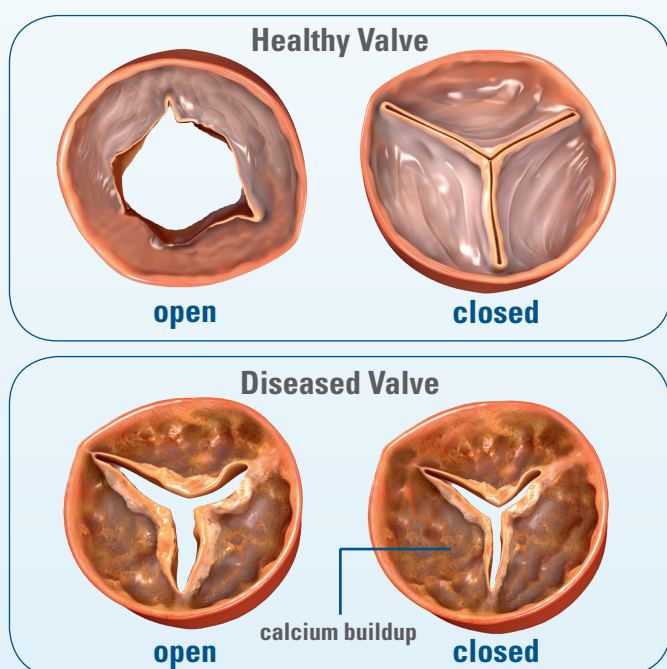
## Continued

### What is Severe Aortic Stenosis?

Severe aortic stenosis is a narrowing of the aortic valve opening not allowing normal blood flow.

- Occurs when the valve leaflets become stiff, reducing their ability to fully open and close properly
- Reduces and restricts blood flow, requiring your heart to work harder
- Less oxygen-rich blood flows from your lungs to the brain and the rest of your body

Images of healthy and diseased valves are shown below.



Severe aortic stenosis is an age-related, progressive disease. It can be caused by a heart defect at birth, bacterial infection of the heart (rheumatic fever), or radiation therapy. The most common cause is the gradual build-up of calcium (mineral deposits) on the leaflets of the aortic valve.

The most common symptoms of severe aortic stenosis include:

- Shortness of breath
- Chest pain, pressure or tightness
- Feeling lightheaded or dizzy
- Fatigue which causes difficulty when exercising or completing day-to-day activities

# Treatment Options For Severe Aortic Stenosis

Treatment options for severe aortic stenosis depend upon the progression of the disease and symptoms. If your stenosis is mild, your doctor may:

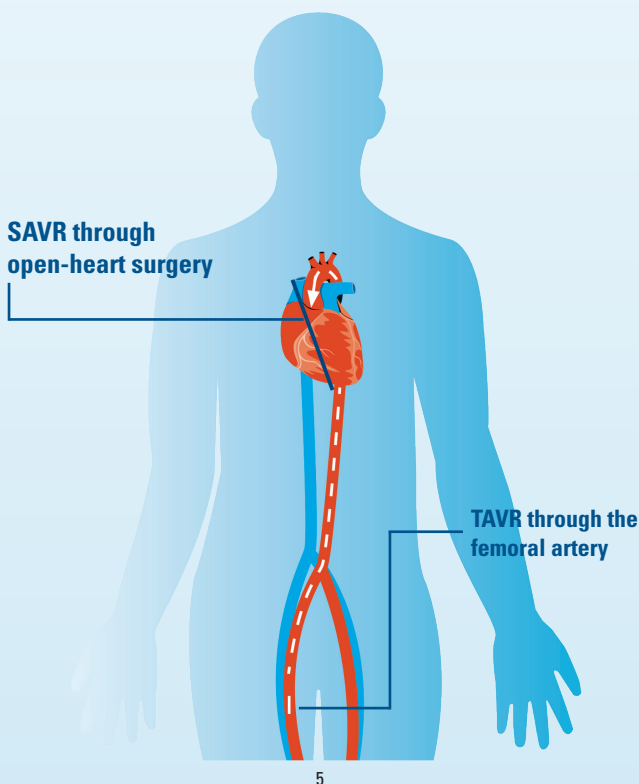
- Prescribe medications to ease the symptoms.
- Perform a procedure known as balloon aortic valvuloplasty (BAV) by placing and inflating a balloon in the valve.

As the disease progresses, symptoms will probably worsen to heart failure and possibly even death.<sup>1-3</sup>

As your stenosis worsens, your doctor may recommend either surgical aortic valve replacement or minimally-invasive (transcatheter) valve replacement.

## Surgical Aortic Valve Replacement (SAVR)

Surgical aortic valve replacement is done through open-heart surgery where a surgeon replaces the diseased aortic valve with a new artificial valve. Open-heart surgery is a major undertaking that requires a patient's medical condition to be sufficient to withstand the operation. Quite often people afflicted with severe aortic stenosis are older and have other medical conditions which prohibit them from undergoing open-heart surgery.



# Treatment Options For Severe Aortic Stenosis

## *Continued*

### **Transcatheter Aortic Valve Replacement (TAVR)**

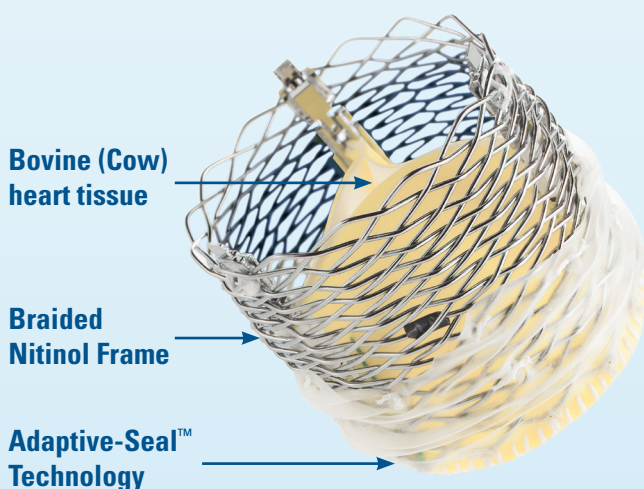
Transcatheter aortic valve replacement is a less invasive procedure to replace the aortic valve without opening the chest to reach the heart.

- The doctor makes a small incision in an artery in the groin.
- The artificial valve is compressed into a catheter that travels up through an artery to the heart.
- The doctor expands the replacement valve, pushing the diseased parts of the aortic valve out of the way. The replacement valve functions in the same manner as a healthy, non-diseased, aortic valve.

Your heart team will determine which replacement procedure is best for you. Be sure to talk with your doctor about your treatment options and the possible risks and benefits.

### **Transcatheter Aortic Valve Replacement with LOTUS Edge™**

The LOTUS Edge Aortic Valve as shown in the image below is made up of a wire valve frame and bovine (cow) tissue leaflets. During the TAVR procedure, the doctor will use special X-ray equipment to guide positioning and placement of the new valve.



**Image of LOTUS Edge Valve is not to scale**

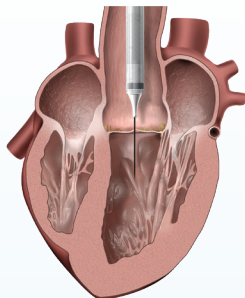
# Treatment Options For Severe Aortic Stenosis

## *Continued*

### Step 1

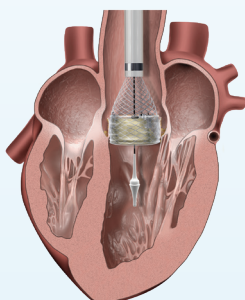


**Compressed**



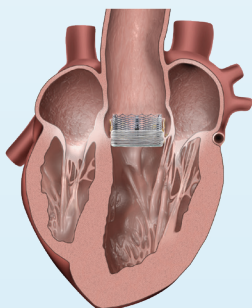
The artificial valve is compressed into a catheter that travels up through an artery all the way to the heart.

### Step 2



Your doctor will expand the artificial valve, pushing the diseased aortic leaflets out of the way.

### Step 3



Your new valve will begin to function immediately and restore healthy blood flow. Once the valve is in place, your doctor will remove the catheter, close the incision, and transfer you to the recovery area.

# After The TAVR Procedure

How quickly you recover depends upon your overall state of health. Most people begin feeling better and can resume normal everyday activities soon after the TAVR procedure. Follow your doctor's recommendations for resuming your daily activities.

## Important things to keep in mind

**Medications:** You may be prescribed blood thinning medications. Take these as directed by your doctor, even after you leave the hospital.

**Post-procedure Doctor Visits:** Successful recovery requires keeping scheduled visits with your doctor. Your doctor will check how well your heart is working, your healing, and your overall health. You can expect to visit the heart team 30 days and one year after your procedure.



**Identification Card:** You will receive an identification card with information about your LOTUS Edge™ Aortic Heart Valve. Always carry this with you. Be sure to share this information with all your healthcare providers. If you have not received an identification card, inform your doctor.

People with artificial heart valves are at risk of the valve getting infected if bacteria enter the bloodstream. This commonly occurs with dental or endoscopic procedures. Speak with your doctor regarding the need for antibiotics if you have any invasive procedures after receiving your new heart valve. For patients who are at increased risk of infection, your doctor or dentist may prescribe antibiotics before a procedure.



# Clinical Studies

## TAVR CLINICAL DATA FOR HIGH RISK AND EXTREME RISK PATIENTS

The risks associated with surgical valve replacement depend on how sick a patient is. Based on their health, some patients may be considered high risk or extreme risk (too sick) for open-heart surgery. If you are high risk or are too sick for surgery, these clinical data reflect what you may expect.

The REPRISE III Clinical Trial studied the Lotus™ Valve System in patients who were at high risk or who were too sick for open-heart surgery. Patients in this trial received either the Lotus Valve or the CoreValve® Aortic Valve (another transcatheter valve which is approved for use in the United States). A total of 912 patients (607 Lotus, 305 CoreValve) were included in the study at 55 hospitals in the United States, Australia, Canada and Europe.

Patients were examined by their doctor before discharge from the hospital and at 30 days, 6 months and 1 year after the procedure. Yearly check-ups will continue for 5 years.

The REPRISE III Clinical Trial assessed patients when they reached 30 days and 1 year after their valve replacement procedure. The results showed the Lotus Valve is safe and effective for the treatment of aortic stenosis in patients like those studied.

The number of deaths was similar between patients who received the Lotus Valve or CoreValve device. Patients who received the Lotus Valve were less likely to have a serious stroke but were more likely to need a pacemaker implant.

The following tables summarize the potential risks 30 days and 1 year after a Lotus Valve implant procedure for patients at high risk or too sick for surgery. These tables are results from the REPRISE III Clinical Trial. Talk to your doctor about these risks and how they may apply to you.

*Continued on next page* →

# Clinical Studies

## Continued

### Potential Risks Within 30 Days after TAVR in High and Extreme Risk Patients

Risk	30 Days	
	Lotus™ (607 patients)	CoreValve® (305 patients)
Death from any cause	2 out of 100 patients	2 out of 100 patients
Death from a heart related cause	2 out of 100 patients	2 out of 100 patients
All stroke	5 out of 100 patients	4 out of 100 patients
Disabling stroke	2 out of 100 patients	3 out of 100 patients
Serious blood vessel damage	7 out of 100 patients	5 out of 100 patients
New permanent pacemaker (device) to help regulate the heartbeat	35 out of 100 patients	20 out of 100 patients
Bleeding	13 out of 100 patients	11 out of 100 patients
Life-threatening or disabling bleed	8 out of 100 patients	5 out of 100 patients
Serious bleeding	5 out of 100 patients	6 out of 100 patients
Heart attack (myocardial infarction)	1 out of 100 patients	1 out of 100 patients
Acute kidney injury	2 out of 100 patients	4 out of 100 patients
Need for additional procedure on your aortic valve	0 out of 100 patients	1 out of 100 patients
Hospitalization due to complication with your aortic valve	2 out of 100 patients	3 out of 100 patients
Need for another valve to be implanted inside your TAVR valve	0 out of 100 patients	3 out of 100 patients
Formation of blood clot on valve (valve thrombosis)	0 out of 100 patients	0 out of 100 patients

# Clinical Studies

## Continued

### Potential Risks Within 1 Year after TAVR in High and Extreme Risk Patients

Risk	1 Year	
	Lotus™ (607 patients)	CoreValve® (305 patients)
Death from any cause	12 out of 100 patients	13 out of 100 patients
Death from a heart related cause	8 out of 100 patients	10 out of 100 patients
All stroke	7 out of 100 patients	9 out of 100 patients
Disabling stroke	4 out of 100 patients	7 out of 100 patients
Serious blood vessel damage	8 out of 100 patients	6 out of 100 patients
New permanent pacemaker (device) to help regulate the heartbeat	41 out of 100 patients	23 out of 100 patients
Bleeding	18 out of 100 patients	18 out of 100 patients
Life-threatening or disabling bleed	10 out of 100 patients	10 out of 100 patients
Serious bleeding	8 out of 100 patients	8 out of 100 patients
Heart attack (myocardial infarction)	3 out of 100 patients	4 out of 100 patients
Acute kidney injury	3 out of 100 patients	4 out of 100 patients
Need for additional procedure on your aortic valve	0 out of 100 patients	2 out of 100 patients
Hospitalization due to complication with your aortic valve	11 out of 100 patients	14 out of 100 patients
Need for another valve to be implanted inside your TAVR valve	0 out of 100 patients	4 out of 100 patients
Formation of blood clot on valve (valve thrombosis)	2 out of 100 patients	0 out of 100 patients

## Possible Benefits Of TAVR

Some of the benefits of the procedure are:

- An improved heart valve function
- Less or no more shortness of breath and chest pain
- Lower risk of death from the disease
- Less anxiety related to aortic valve disease
- Better quality of life
- Faster recovery compared to open heart surgery



## Possible Risks Of TAVR

As with any major medical procedures, there is a risk of complications with the LOTUS Edge™ Valve System. The most serious risks of the TAVR procedure with a LOTUS Edge Valve include:

- **Death from any cause** - death due to any cause, whether related to the heart or not
- **Major stroke** - a condition when blood flow to the brain is decreased, which may cause severe disability
- **Major vascular complication** - a tear or hole in a blood vessel or a hematoma (a large blood clot under the skin), which could require another surgery
- **Major bleeding** - a bleeding event causing abnormal lab values or requiring blood to be put back into the body

# Possible Risks Of TAVR

## *Continued*

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### **Additional potential risks associated with the procedure include:**

- Patient lab test results that are not normal
- Pain or changes at the incision site including abnormal connection between an artery and a vein, or collection of blood or fluid outside of a blood vessel
- Allergic reaction to medications prescribed to prevent blood clots, the contrast dye used during the valve placement procedure, or the materials used to make the valve
- Chest pain or discomfort
- Insufficient healthy red blood cells to carry enough oxygen to the body's tissues
- Problem with the electrical pathway of your heart that could require a pacemaker
- Bleeding that could require blood to be put back into your body or another procedure
- Sudden loss of blood flow resulting from the failure of the heart to pump effectively
- Decreased blood flow to the brain or stroke that could cause disability
- Blockage of blood flow in a heart vessel
- Incorrect placement of device or device movement from the site of implantation
- An abnormal particle (air, blood clots, or device material) floating in the blood stream
- Infection to your heart, blood or other areas
- Elevation of body temperature above the normal range
- Heart failure: Failure of the heart to pump enough blood
- Instability in blood pressure which can lead to inadequate blood flow to organs
- Breaking of red blood cells and release of their contents into the blood stream
- High or low blood pressure
- Improper closure of the mitral valve when the heart pumps out blood, which allows abnormal leaking of blood from the left pumping chamber of the heart

# Possible Risks Of TAVR

## *Continued*

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- 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 nerves
- Pain
- Constriction or inability of the heart to pump due to build-up of blood or fluid around the lining of the heart
- Decreased blood supply to the limbs causing a shortage of oxygen needed to keep tissue alive, which could result in amputation
- Permanent impairment of a body structure or function
- Excess fluid around the lungs which may impair breathing
- Lack of oxygen available for the body due to fluid in the lungs
- Worsening or failure of kidney function
- Worsening or failure of lung function
- Formation of scar tissue that may cover or block the valve from functioning normally
- Failure of heart valve to perform as required
- Blood clot inside the valve and/or blockage or blood flow through the valve
- Narrowing of a heart valve which may cause backward flow of blood through the valve
- Vessel injury due to contraction, trauma, split, puncture or break, collection of blood resulting from injury to the vessel or an abnormal connection between an artery and a vein

As a result of these potential complications, you may require additional medical or surgical care. Close follow-up with your doctor will ensure your valve is functioning properly and your medications are modified appropriately.

# Precautions

In some patients the LOTUS Edge™ Heart Valve may eventually need to be replaced. Long-term durability of the LOTUS Edge Heart Valve has not been established.

Patients should take blood-thinning medications after the procedure, as directed by their doctor. Patients who do not take blood-thinning medication may be at increased risk of developing a dangerous blood clot. This may result in a stroke. Blood-thinning medicine may increase the risk of bleeding in the brain (stroke).

The safety and performance of the LOTUS Edge valve has not been established in patients who have:

- An existing artificial aortic heart valve
- An aortic heart valve that only has one or two leaflets
- A heart that does not pump efficiently
- A condition in which the heart muscle becomes thick and makes it difficult for the heart to pump blood
- A blood clot or an abnormal growth in the heart
- Low white blood cell count, low red blood cell count or other abnormality in the blood
- A previously implanted medical device in any heart valve
- Blockage of the major blood vessels (coronary arteries) that supply the heart with blood and oxygen
- Severe kidney disease
- Vessels that cannot accommodate the device
- Severe disease of the aortic, mitral or tricuspid valve that includes valve leakage



# Patients who SHOULD NOT Receive the LOTUS Edge™ Valve

Are those who:

- Have an aortic valve that is not calcified
- Have an active infection in the heart or elsewhere
- Cannot tolerate blood-thinning medications, contrast dye that is injected during the procedure, or who are allergic to the valve materials including nickel, titanium, tantalum, bovine (cow) derived materials
- Have arterial vessels that are heavily diseased or too small for the delivery device





# Frequently Asked Questions

## ○ Will I feel the LOTUS Edge™ Aortic Heart Valve?

Once the heart valve is in place and the access site is healed, you will not feel the device. If you feel anything abnormal, please contact your doctor.

## ○ Will the replacement valve cause any problems with metal detectors or interfere with future X-ray procedures?

No. The device will not set off a metal detector. The device is visible on X-ray but will not hamper the ability to perform future medical imaging procedures. However, you should notify your doctors that you have an artificial valve, especially before you have X-rays, CT or MRI scans.

## ○ Can I have an MRI (Magnetic Resonance Imaging) Procedure?

Remember to have your LOTUS Edge Implant Card with you to show doctors and technicians.

If you require an MRI, it is very important that you let your doctor and MRI technician know that you have an artificial aortic valve. Failure to do so could result in damage to your implanted heart valve that could lead to death.

## ○ How often should I see my doctor?

Your doctor will tell you how often you need to be seen and explain any special symptoms you should look for.

## ○ Is the LOTUS Edge Valve System sterile?

Yes. The artificial valve is not a live tissue implant. The valve has been processed and sterilized prior to being placed into the body.

## ○ Will the LOTUS Edge Aortic Heart Valve rust?

No. The device is made from a special medical-grade metal alloy that will not rust.

1. Bach D, Radeva J, Birnbaum H, et al. Prevalence, Referral Patterns, Testing, and Surgery in Aortic Valve Disease: Leaving Women and Elderly Patients Behind. *J Heart Valve Disease*. 2007:362-9.

2. Iivanainen A, Lindroos M, Tilvis R, et al. Natural History of Aortic Valve Stenosis of Varying Severity in the Elderly. *Am J Cardiol*. 1996:97-101.

3. Aronow W, Ahn C, Kronzon I. Comparison of Echocardiographic Abnormalities in African-American, Hispanic, and White Men and Women Aged >60 Years. *Am J Cardiol*. 2001:1131-3.

**PLEASE CARRY YOUR CARD AT ALL TIMES.**

Please ask your physician for a copy of the Patient and Caregiver Information Guide. Additionally, the Patient and Caregiver Information Guide for this product is available on the Boston Scientific website. To view, download or print the Patient and Caregiver Information Guide, go to [www.bostonscientific.com](http://www.bostonscientific.com). You may also request a hard copy of the Patient and Caregiver Information Guide by calling **888-272-1001**.

**MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION**

Non-clinical testing has demonstrated that the LOTUS Edge™ Valve is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 and/or 3.0 tesla
- Maximum spatial field gradient of 9,900 gauss/cm (99 T/m) or less (static field)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the LOTUS Edge™ Valve is expected to produce a maximum temperature rise of 1.5°C after 15 minutes of continuous scanning.

In non-clinical testing, the largest image artifact caused by the device extends as far as 10.4 mm from the LOTUS Edge Valve frame when imaged with a gradient echo pulse sequence and a 3 Tesla MR System.