

Masters Series™ Valved Graft

Patient Manual



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Contents

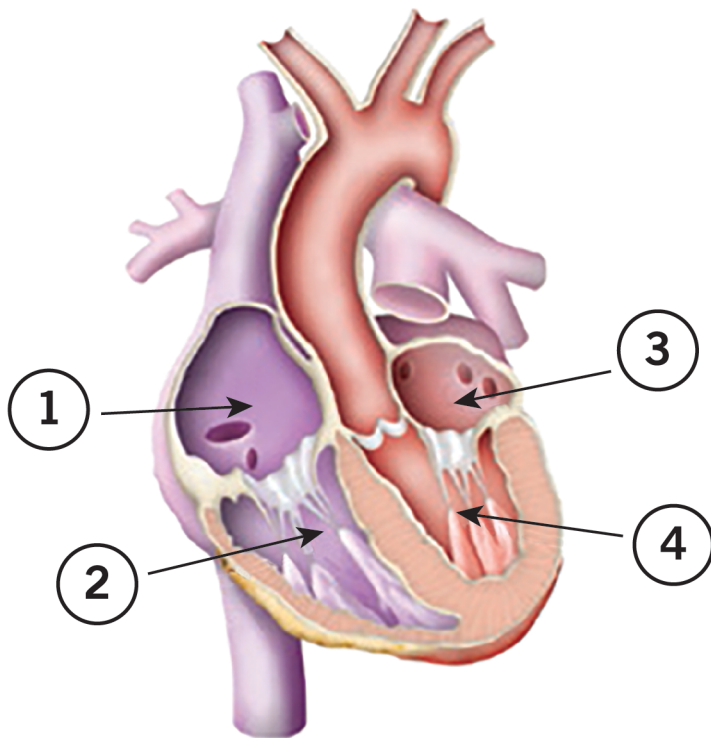
How a Healthy Heart Works.	1
What Causes Aortic Root and Valvular Heart Disease?.	2
Device Name and Model Numbers.	2
Who is Eligible for Valve Replacement and Aortic Root Repair?.	3
Who Should Not Have the Procedure?.	3
Valve Replacement Risks.	3
Valve Replacement and Aortic Root Repair Benefits.	4
What to Expect if You Have a Valve Replacement and Aortic Root Repair.	4
Before the Procedure.	4
During the Procedure.	4
After the Procedure.	4
Anticoagulation Therapy.	5
Returning Home.	5
When to Call Your Doctor.	5
Metal Detectors.	6
MRI Scan Considerations.	6
Patient Identification Card.	6
Device Lifetime.	7
Product Materials.	7
Summary of Safety and Clinical Performance.	9
Incident Reporting.	10

This patient manual provides general information about treating a diseased, damaged or malfunctioning aortic valve and a diseased ascending aorta through surgical valve replacement and aortic root repair. It is not intended to provide medical care or treatment recommendations. Be sure to ask your doctor to explain all of the treatment options and the risks and benefits of each.

How a Healthy Heart Works

The heart consists of four chambers. The two upper chambers, called atria (each one is called an atrium), receive blood; while the two lower chambers, called ventricles, pump blood. Ventricles are larger than atria because of their pumping function.

Figure 1. Chambers of the Heart

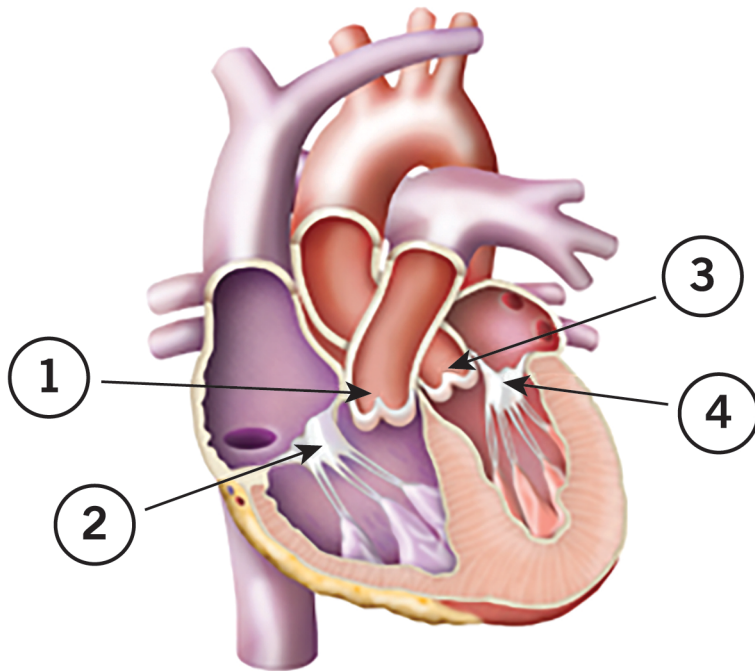


1. Right atrium
2. Right ventricle
3. Left atrium
4. Left ventricle

Heart valves move blood between the chambers of the heart, the pulmonary artery, and the aorta (the largest artery in the body). These valves act like one-way doors, allowing the blood to flow into the next chamber or artery. The valves close to prevent blood from flowing back into the chamber it came from. The following figure illustrates the heart with the different heart valves. The tricuspid valve is located between the right atrium and right ventricle. On the left side of the heart, the mitral valve is located between the left atrium and left ventricle.

Valves also separate the ventricles and the two arteries that carry blood away from the heart. On the right side of the heart, the pulmonary valve is located between the right ventricle and the pulmonary artery. On the left side of the heart, the aortic valve is located between the left ventricle and the aorta.

Figure 2. Valves of the heart



1. Pulmonary valve
2. Tricuspid valve
3. Aortic valve
4. Mitral valve

The main job of the heart is to pump oxygen-rich blood throughout the body. It does this by contracting an average of 70 times per minute, for a total of 36 million heartbeats per year.

Oxygen-poor blood enters the right atrium and flows through the tricuspid valve into the right ventricle. The right ventricle then pumps the oxygen-poor blood through the pulmonary valve into the pulmonary artery, which takes the blood to the lungs to be oxygenated.

The oxygen-rich blood from the lungs then travels back to the heart into the left atrium. From the left atrium, the oxygenated blood flows through the mitral valve into the left ventricle. The left ventricle then pumps the oxygen-rich blood through the aortic valve into the aorta, which takes it to the rest of the body.

What Causes Aortic Root and Valvular Heart Disease?

Heart valves may be impaired for a variety of reasons. Some people are born with heart valve defects while others acquire valve damage from infection, the aging process or other diseases (for example, high blood pressure). The results are the same: either a rigid valve limiting forward blood flow (called a stenotic valve) or a valve that does not close properly permitting backflow (called an incompetent, insufficient or regurgitant valve). Sometimes, along with aortic valve disease there can be also a need to address problems with the large artery coming from your heart, called the aorta. In those cases, there are products which combine a prosthetic aortic valve with a synthetic graft which can be implanted simultaneously.

The end result of valvular heart disease is the reduction in the heart's pumping ability. The heart tries to compensate for ineffective valve function by working harder to deliver oxygen-rich blood to other organs and tissues. The overworked heart may begin to fail, causing shortness of breath, dizziness, chest pains, fatigue and fluid retention. After physical examination and further tests, physicians may recommend valve replacement and aortic root repair.

Device Name and Model Numbers

The following model numbers are available for the Masters Series™ Valved Grafts:

- 19-VAVGJ-515

- 21-VAVGJ-515
- 23-VAVGJ-515
- 25-VAVGJ-515
- 27-VAVGJ-515
- 29-VAVGJ-515
- 19-CAVGJ-514 00
- 21-CAVGJ-514 00
- 23-CAVGJ-514 00
- 25-CAVGJ-514 00
- 27-CAVGJ-514 00
- 29-CAVGJ-514 00
- 31-CAVGJ-514 00
- 33-CAVGJ-514 00

Who is Eligible for Valve Replacement and Aortic Root Repair?

Patients with a malfunctioning native or prosthetic aortic heart valve and a diseased ascending aorta are eligible for screening by their doctor for valve replacement and aortic root repair.

Who Should Not Have the Procedure?

Valve replacement and aortic root repair is not recommended for patients who cannot tolerate anticoagulation therapy.

Valve Replacement Risks

There are risks with the use of replacement heart valves. These may include, but are not limited to:

- adjacent cardiac structure interference
- aneurysm/dilation
- bleeding
- death
- endocarditis (infection of the heart)
- heart block requiring pacemaker implant
- heart failure
- hemolysis (breakdown in red blood cells)
- hemorrhagic complications secondary to anticoagulation therapy
- infection
- myocardial infarction (heart attack)
- prosthetic failure
- sensitivity to device materials, including animal tissue
- stroke
- thrombus or thromboembolism (blood clots)
- unacceptable hemodynamic performance
- valve dehiscence (separation)

It is possible that these complications could lead to:

- reoperation
- explantation of the device

Valve Replacement and Aortic Root Repair Benefits

Heart valve repair surgery and aortic root repair can offer several key benefits. The procedure is designed to help your heart pump blood more effectively, which means you may begin to feel better immediately. Others may feel better gradually, regaining energy and strength over the first few weeks following the surgery. Be sure to talk to your doctor about your progress and get advice on the exercises and activities you can do to regain your strength.

What to Expect if You Have a Valve Replacement and Aortic Root Repair

The following sections provide a general overview of the valve replacement and aortic root repair procedure; however, your experience may be different. Please consult with your doctor on what to expect during a valve replacement and aortic root repair.

Before the Procedure

In the days before your procedure it is important that you:

- Follow your doctor's instructions regarding medications that you should be taking or should stop taking
- Tell your doctor if you are taking any other medications
- Make sure your doctor knows of any allergies you have
- Follow all instructions given to you by your doctor or nurse

During the Procedure

During the procedure, a general anesthetic will be administered that will put you to sleep so you do not feel any pain during the surgery.

Your surgeon will make an incision in your chest to reach your heart. Your heart will be stopped temporarily so the valve can be implanted and you will be placed on a heartlung machine. First, the surgeon will remove the diseased valve and determine the correct replacement valve size. Next, the new valve will be positioned in the original valve location and firmly sewn into place. The surgeon then closes the incision, restarts your heart and closes all the other incisions. The heart-lung machine is then removed and your natural heart rhythm is returned.

After the Procedure

After your heart valve surgery, you will be placed in the intensive care unit (ICU) where you can be monitored continuously. You will have help breathing during surgery and for a while afterward from a tube that has been placed down your throat and positioned in your lungs. You will probably wake up with this tube still in position. It will be removed as soon as you are stable and awake enough to breathe on your own. You will not be able to talk while this tube is in. Other tubes will come from your chest near the heart to drain extra blood and fluid from the surgical area.

Intravenous lines will give you fluid, blood and medications as needed, and you will have a bladder catheter to drain urine. You will be hooked up to a monitor that shows your heart rate, heart rhythm, blood pressure and other measurements that the nursing staff will use to assess your recovery status. You will receive medications to ease your pain and anxiety as needed.

The typical length of stay in the ICU is one or two days. It is important to remember that every patient recovers at a different rate. The nursing staff will monitor your recovery and remove the tubes as appropriate. From the ICU you will be moved to a cardiac medical-surgical floor where your heart will continue to be monitored, but there you may be more independent and active. The healthcare team will continue to support and instruct you in recovery care, rehabilitation, medications, nutrition and other needs.

Keep in mind that every patient recovers at a different rate. Once you leave the hospital, it will typically be six to eight weeks before you are able to return to your normal routine.

Anticoagulation Therapy

Anticoagulation therapy is recommended for patients with mechanical heart valves. Guidelines have been established for the management of patients with prosthetic heart valves. Abbott recommends that you consult with your physician about these guidelines and what anticoagulation regimen is right for you.

Returning Home

When you return home, you must take special care of yourself until you are fully recovered. Depending on your past physical abilities, you may need help with rehabilitation to reach full physical capabilities. You may feel better each day, but it is normal to experience some ups and downs. You will need time to rest regularly; as that will help to speed your recovery.

After returning home, remember to:

- take medication as prescribed
- follow-up with blood tests as directed by your doctor
- enjoy a heart-healthy diet

Valve replacement does not mean a sedentary lifestyle. Many people who receive valves are able to lead a more active and fulfilling life than before surgery. Ask your doctor what kinds of activities and sports you should avoid. Report any falls, blows to the body or head, or other injuries to your doctor right away. Your involvement in caring for the health of your heart begins now. By understanding the recovery process and lifelong management necessary for your valve, you can make better heart-healthy decisions. Longterm management of your health requires your active participation. With your physician, you can work toward a healthy recovery.

When you return home, you must take special care of yourself until you are fully recovered. It may be about six to eight weeks before you are able to return to your normal routine. You will feel better each day; however, it is normal to experience some ups and downs. You will need to allow time to rest regularly; this will help speed your recovery.

At your follow-up visit to your doctor around three weeks, you may need to undergo tests such as an electrocardiogram, echocardiogram or chest X-ray to evaluate how your new valve is working. Your doctor may also perform blood work to assess your medication levels.

When to Call Your Doctor

Contact your doctor if you experience any of these symptoms:

- redness or drainage of your incision
- shortness of breath
- swelling of your feet or ankles
- chest, jaw, shoulder or arm pain
- bruising
- excessive bleeding
- blood in your urine
- bloody or tarry (blood will typically look like tar after it has been exposed to the body's digestive juices) 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

Metal Detectors

The amount of metal used in the valve is very small. It is usually not enough to set off the metal detectors; however, if it does, simply show security personnel your patient identification card. Passing through a metal detector will not harm your heart valve.

MRI Scan Considerations

If you are told you need to have an MRI (magnetic resonance imaging), tell the doctor that you have an artificial heart valve and show your ID card, which contains important information about how to perform an MRI safely with your valve.

Your doctor or MRI technician may request the following information:

Non-clinical testing has demonstrated that Masters Series™ Valved Grafts are MR conditional.

They can be scanned safely under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0-Tesla (3.0T) only
- Maximum spatial gradient field of 2000 gauss/cm (20 T/m) or less
- Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of <2.0 W/kg (normal operating mode)

If you have questions or concerns about this and other diagnostic tests and your heart valve, please talk to your doctor. It is wise to provide your doctor with the information outlined above about MRI testing and your heart valve.











Patient Identification Card

Following your procedure, you will receive a Patient Identification Card that was filled out by your doctor. You must carry it at all times.


If you have questions about your implant card or need a replacement, contact your primary care physician.

IMPORTANT: Show your Implant Identification Card if you go to a hospital emergency room. This card shows that you have a Masters Series™ Valved Graft.

The following symbols are used on the Patient Identification Card:

Symbol	Description
	Catalog Number
	Date
	Healthcare center or physician
	Patient identification
	Physician telephone
	Medical Device
	Lot Number
	Serial number
	Unique device identification number
	Patient Information Website

medical.abott/manuals

Symbol	Description
	Manufacturer

Device Lifetime

The product is designed and tested to support a minimum lifetime of 10 years. In addition, long-term clinical data published in the literature indicates that the Masters Series™ Mechanical Heart Valves perform as intended for at least 20 years.

Follow your doctor's instructions on your medications, especially prescribed medication that thins the blood, to help prevent complications that could shorten the device lifetime.

Product Materials

A patient implanted with a Masters Series™ Valved Graft will be exposed to the following materials.

Table 1. CAVGJ Models

Component	Material Description	Substance	Substance Concentration within each component (% w/w) (maximum)	Maximum Component Weight (g)
Leaflets and Orifice	Graphite Substrate with Pyrolytic Carbon Coating	Graphite Substrate with Pyrolytic Carbon Coating	100	3.1
Graft	Prism Conduit, Collagen	Polyester Blend		6.4
		Type 1 Collagen	100	
		Glycerol		
Cuff	Polyester Fabric	Polyester Blend		
Sutures	PTFE-impregnated braided polyester	PTFE/PET Blend	100	1.2
Ring Retainers	Cobalt Chromium Alloy	Nickel	35	0.4
		Cobalt	35	
		Chromium	20	
		Molybdenum	10	
Spring	Cobalt Chromium Alloy	Cobalt	40	0.6
		Chromium	20	
		Nickel	15	
		Molybdenum	7	
		Manganese	2	
		Silicon	1.2 MAX	
		Carbon	0.15 MAX	
		Beryllium	0.10 MAX	
Phosphorous	0.015 MAX			
		Iron	Balance	

CAUTION: One or more components of the Masters Series™ Aortic Valved Graft contains the following substance defined as CMR 1B in a concentration above 0.1% weight by weight:

Cobalt; Chemical Abstracts Service CAS No. 7440-48-4; EC No. 231-158-0
Current scientific evidence supports that medical devices manufactured from metal alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.

VAVGJ Models

Component	Material Description	Substance	Substance Concentration within each component (% w/w) (maximum)	Maximum Component Weight (g)
Leaflets and Orifice	Graphite Substrate with Pyrolytic Carbon Coating	Graphite Substrate with Pyrolytic Carbon Coating	100	3.1
Graft	Valsalva Conduit, Gelatin	Polyester Blend	51	5.7
		Bovine Gelatin	7.9	
		Formaldehyde	0.1	
		Glycerol	41	
Cuff	Polyester Fabric	Polyester Blend		
Sutures	PTFE-impregnated braided polyester	PTFE/PET Blend	100	1.0
Ring Retainers	Cobalt Chromium Alloy	Nickel	35	0.4
		Cobalt	35	
		Chromium	20	
		Molybdenum	10	
Spring	Cobalt Chromium Alloy	Cobalt	40	0.6
		Chromium	20	
		Nickel	15	
		Molybdenum	7	
		Manganese	2	
		Silicon	1.2 MAX	
		Carbon	0.15 MAX	
		Beryllium	0.10 MAX	
		Phosphorous	0.015 MAX	
Iron	Balance			

CAUTION: One or more components of the Masters Series™ HP Valved Graft contains the following substance defined as CMR 1B in a concentration above 0.1% weight by weight: Cobalt; Chemical Abstracts Service CAS No. 7440-48-4; EC No. 231-158-0
Current scientific evidence supports that medical devices manufactured from metal alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.

Summary of Safety and Clinical Performance

A summary of the safety and clinical performance (SSCP) for this device is available at <https://ec.europa.eu/tools/eudamed>. Search for the device using the basic UDI-DI listed in the following table. This is the SSCP location after the launch of the European Database on Medical Devices/Eudamed.

Table 2. Masters Series™ Valved Graft Basic UDI-DI

Basic UDI-DI	Basic UDI-DI Description
5415067SHV2100PP	Surgical Heart Valve Products, Valved Grafts

Incident Reporting

If, in the course of use of this device, you have reason to believe that a serious incident occurred, please report it to the manufacturer. For customers in the European Union, report the serious incident to your national authority as well as to the manufacturer.



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