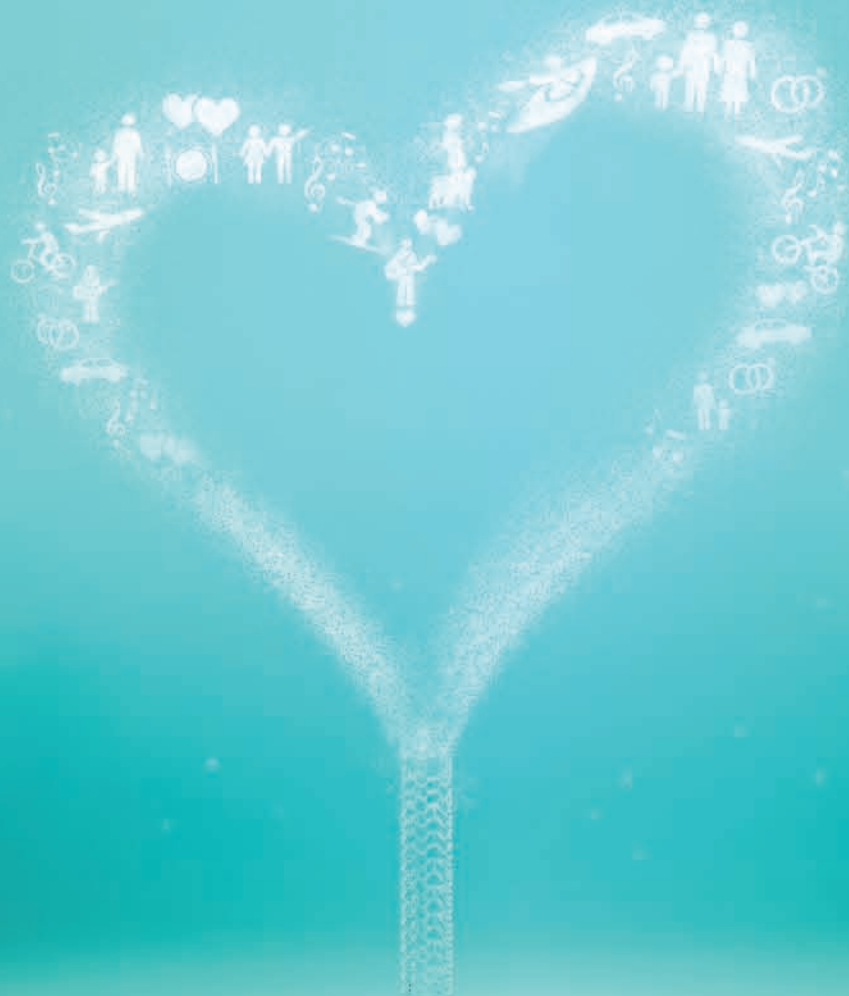


Absorb GT1™

Bioresorbable Vascular Scaffold System



Patient Information Guide





Absorb GT1 Bioresorbable Vascular Scaffold (BVS) System

Patient Information Guide

The information contained herein does not replace the medical advice of your doctor, nor does it express any preference whatsoever for one treatment option over another. If you have any questions regarding the disease or its treatment options, please contact your doctor. The information contained herein is not intended for children under the age of 14.

Not for advertising purposes.

A definition of the medical terms used in this document is available at the back of this brochure.

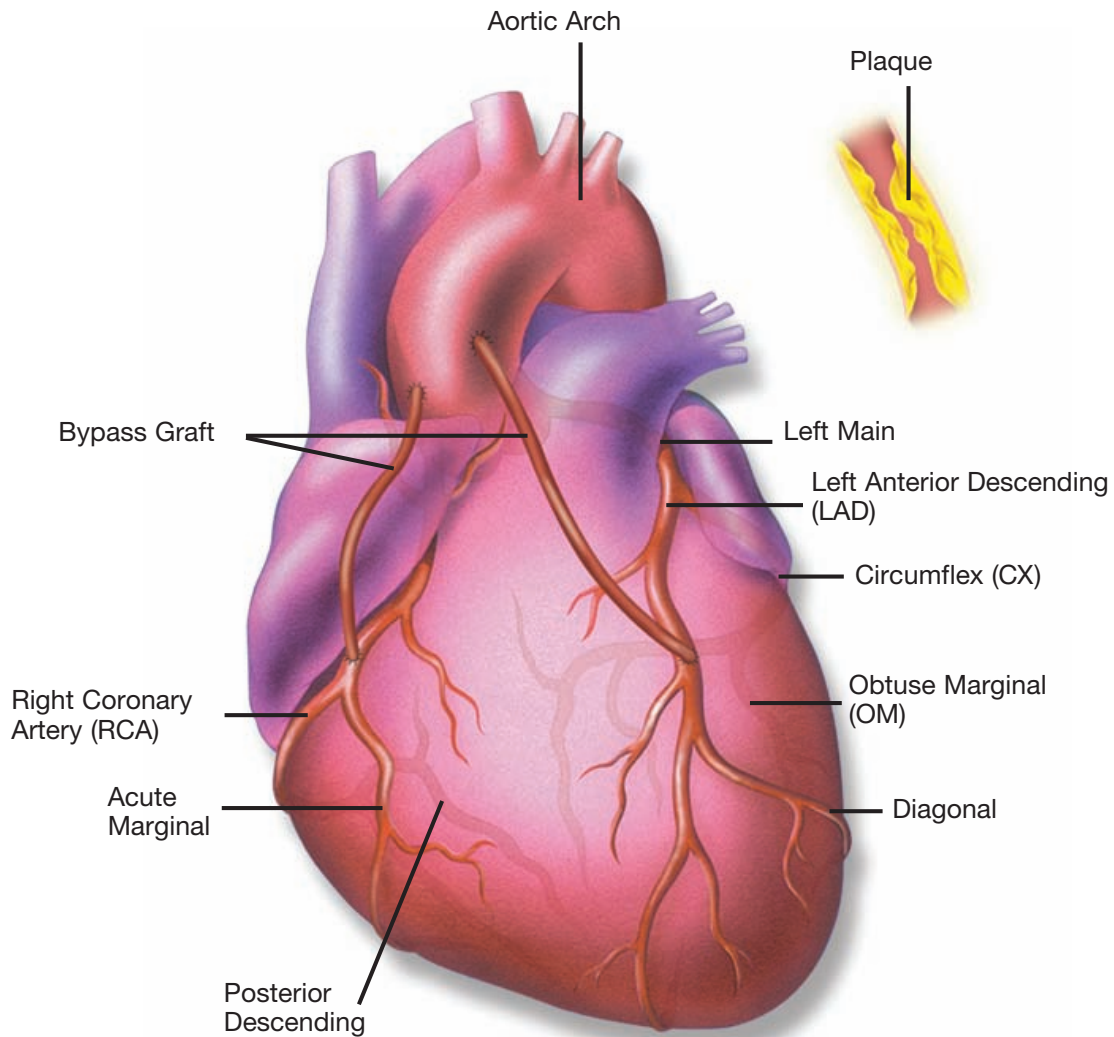


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Coronary Vasculature





Coronary Artery Disease (CAD)

Step 1: Recognize

What is Coronary Artery Disease?

The Cause

Coronary artery disease (CAD) occurs when the arteries that supply blood to your heart become narrowed or blocked by a build-up of fatty deposits called plaque. As a result, there is less blood to the heart muscle and the heart has to work harder to pump blood to the body.

The Effect

CAD symptoms can arise as a result.

These may include:

- Chest pain (Angina)
- Shortness of breath
- Heaviness in the chest
- Pain in the jaw or radiating to the arms
- Heartburn
- Nausea
- Vomiting

Who is at Risk?

There are some risk factors for CAD that are **beyond your control**, including:

- Increasing age
- Being male or menopausal female¹
- Family history of heart disease

¹Menopausal women begin to develop and die of heart disease at a rate equal to men. Menopause is the transition in a woman's life when production of the hormone estrogen in the body falls permanently to very low levels, the ovaries stop producing eggs, and menstrual periods stop.

But the majority of risk factors **can be controlled** and should be taken into consideration once you've been diagnosed with CAD. When addressed successfully, reducing these risk factors can reduce the risk of worsening heart disease:

Smoking

Each cigarette contains 2,000 to 4,000 noxious chemicals that cause direct damage to blood vessels, decrease the amount of oxygen delivered to the heart, and increase the risk of developing deadly blood clots.

Obesity

People with excess body fat, particularly around the waist, are more likely to develop heart disease even if they have no other risk factors. Excess weight increases blood pressure, raises blood fats such as cholesterol and triglycerides in the blood, and lowers HDL levels (good cholesterol).

Lack of Physical Activity

An inactive lifestyle or lack of physical exercise may contribute to CAD.

High Blood Pressure

High blood pressure, also known as hypertension, causes the heart to work harder to pump blood. The high pressure inside the arteries directly damages the walls of the blood vessel, making it easier for plaque to form.

Diabetes

In patients with diabetes, the sugar level in the blood is high because the substance needed to control it, called insulin, is either low or the patient

Coronary Artery Disease (CAD)

(continued)

is not responding to it. Diabetes can increase the severity of plaque build-up in heart arteries.

High Cholesterol

Too much cholesterol in the blood can lead to atherosclerosis, or the buildup of thick, fatty plaques that clog arteries.

How Is CAD Diagnosed?

If your physician suspects you have CAD or you have shown symptoms of the disease, you'll likely be asked to take a physical exam and blood tests to identify possible injury to your heart muscle. Some of the tests used to make the diagnosis include:

- **Blood Tests**

Some substances in the blood can be tested to determine if there is a lack of blood flow to the heart muscle.

- **Electrocardiogram (ECG / EKG)**

This is a test that records your heart's electrical activity. It can reveal certain problems such as abnormal heartbeat and lack of blood flow to the heart muscle.

- **Stress Tests**

These are tests that continuously record your heart rate and rhythm while your heart is subjected to stress such as exercise. These tests help your doctor help determine which areas of the heart muscle are affected by lack of blood flow.

- **Echocardiogram**

This test uses sound waves to get an image of your heart so that your doctor can observe many aspects of your heart including how your heart looks, how it moves, and how blood flows inside the pumping chambers of your heart.

- **Nuclear Imaging / Scan**

There are many kinds of nuclear scans. A special tracer that is injected into a vein goes to heart muscle and can be seen in the scan. Pictures of the heart are taken to show which areas lack blood supply and help determine if the lack of blood supply can be treated.

- **Coronary Angiogram or Heart Catheterization**

This procedure is performed by a cardiologist in a cardiac catheterization laboratory. A long, thin, flexible hollow tube (also known as a catheter) is inserted into an artery in the groin or arm and advanced under X-ray guidance to the heart. A special dye fluid is injected through the tube to show the heart blood vessels on a video monitor. Pictures of the heart arteries (angiograms) allow the doctor to see any blockage or narrowing in the coronary arteries, the vessels that supply blood to the heart muscle.



Step 2: Restore



Cardiac Catheterization Laboratory

What are My Treatment Options?

You should discuss with your doctor the kinds of treatment that will help you get better. This may involve a combination of any of the methods listed below:

Medications

Coronary artery disease may be treated by medications to help relieve the symptoms, improve blood flow to the heart, and treat the other conditions such as diabetes, hypertension, or high cholesterol levels.

Lifestyle Changes:

- Increase physical activity
- Stop smoking
- Improve diet
- Weight loss programs

Interventional Procedures and Surgery

Another way of treating CAD is to try to open the blocked artery that is causing the problem. Blood flow can be restored to a blocked artery by open heart surgery called coronary bypass surgery, or by inserting devices into your heart vessels without performing surgery. More information about these procedures is provided in the following pages.

Coronary Bypass Surgery

In this procedure, a team of doctors will open up the patient's chest (open heart surgery) to be able to connect a healthy blood vessel to the heart artery beyond the blocked portion of the blood vessel. In effect, the blocked artery is thus "bypassed." The healthy blood vessel is usually taken from the patient's leg or chest. Patients who undergo coronary bypass surgery usually have blockages in several heart arteries. The patient stays in the hospital for several days and is carefully watched during the entire time in the operating room and after the surgery until he / she is stable for discharge home.

Your Treatment Options

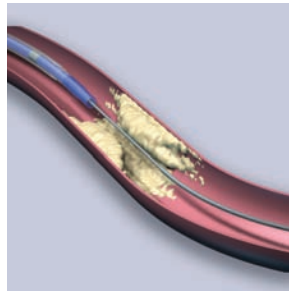
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Angioplasty

This procedure is sometimes referred to as PTCA (percutaneous transluminal coronary angioplasty) and is used to open blocked arteries without heart surgery. This procedure is performed by a team of heart specialists, nurses, and lab technicians in the hospital cardiac catheterization lab (cath lab).

Step 1:

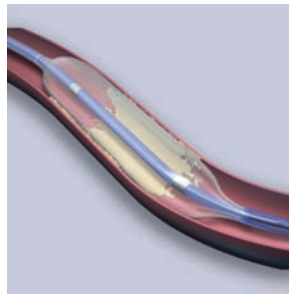
Similar to undergoing a coronary angiogram, a catheter with a small balloon on the end is inserted into an artery in the groin or arm and advanced under X-ray guidance, through the blood vessel to the part of the heart artery that is blocked by plaque.



Step 1

Step 2:

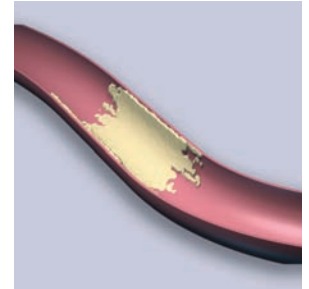
The balloon is inflated, pushing the plaque against the artery wall and widening the passage for blood flow.



Step 2

Step 3:

The narrowed artery is now open, improving blood flow to the heart muscle. The balloon is then deflated and the catheter is removed.



Step 3

Your Treatment Options

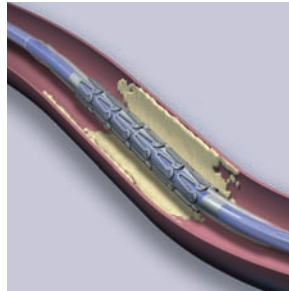
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Coronary Artery Stents

Metallic stents are small, flexible metallic mesh tubes that are placed within the narrowed artery to hold it open. Currently, most patients who are treated with stents receive drug-eluting stents. A drug-eluting stent is a coronary artery stent that has been coated with a drug. After the stent is placed in the artery, the drug is released into the wall of the blood vessel to help reduce excessive tissue growth within the stent, which can cause the artery to re-narrow. This re-narrowing is also known as “restenosis.”

Step 1:

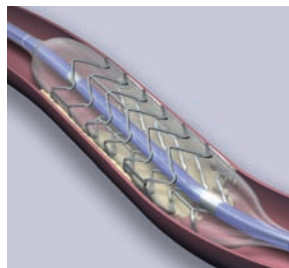
Similar to angioplasty, a catheter is guided through the blood vessel to the narrowed part of the artery. The collapsed stent is mounted on the deflated balloon at the end of the catheter.



Step 1

Step 2:

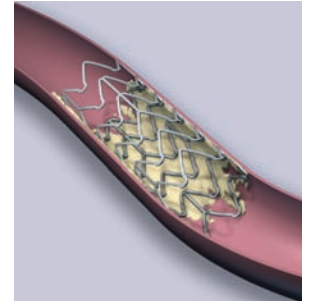
The balloon is inflated, expanding the stent and pushing the plaque against the artery wall and widening the passage for blood flow.



Step 2

Step 3:

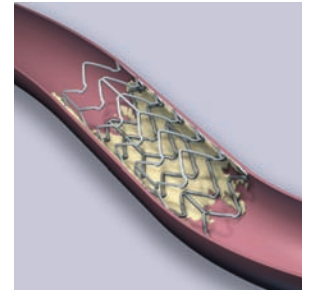
The narrowed artery is now open and there is improved blood flow to the heart muscle. The balloon is then deflated and the catheter is removed, leaving the expanded stent in place.



Step 3

Step 4:

The expanded stent is left in place and remains in the body permanently.



Step 4

Your Treatment Options

(continued)

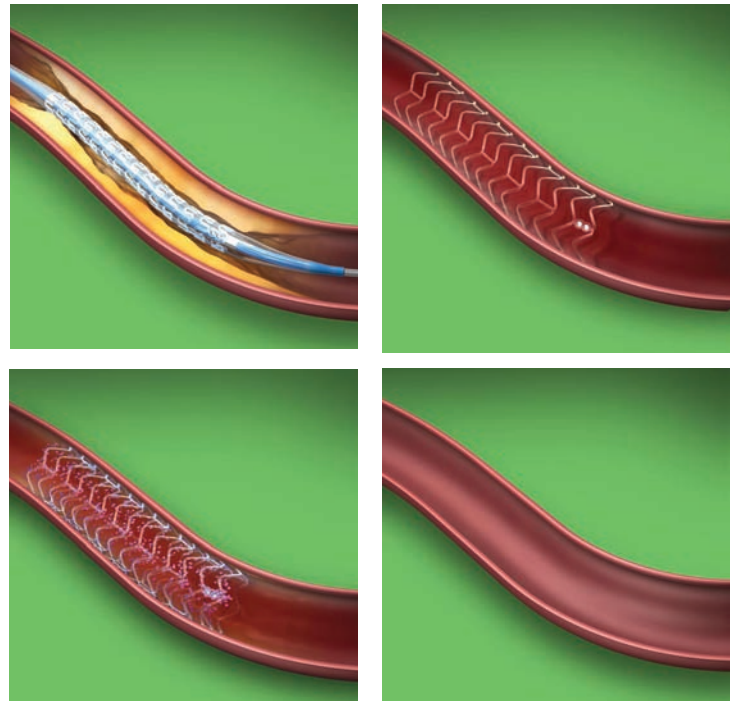
Absorbable Coronary Drug-Eluting Stent

An absorbable coronary drug-eluting stent is similar in design to a drug-eluting stent, but is not metallic and is instead made from a material that gradually dissolves and is absorbed by your body. An absorbable coronary drug-eluting stent functions like a drug-eluting stent in the first year, holding the artery open while the drug is released into the vessel wall to help reduce excessive tissue growth within the absorbable stent. However, unlike a drug-eluting stent that is a permanent metallic implant, an absorbable coronary drug-eluting stent will gradually dissolve and be absorbed over time, leaving the vessel free of a permanent device.

Absorb GT1 Bioresorbable Vascular Scaffold (BVS)

The Absorb GT1 BVS, or Absorb, is the first commercially-available FDA-approved absorbable coronary drug-eluting stent, also known as a bioresorbable vascular scaffold. It consists of a bioresorbable polymer scaffold containing a drug (everolimus) and bioresorbable polymer coating. The scaffold design is based on the same design as the clinically proven XIENCE drug-eluting metallic stent and provides support to the artery while everolimus (same drug as on the XIENCE stent) is slowly released. The release of everolimus is intended to prevent the overgrowth of tissue within the BVS. Over time, the scaffold will dissolve and resorb into the body, leaving nothing behind but four very small platinum markers embedded

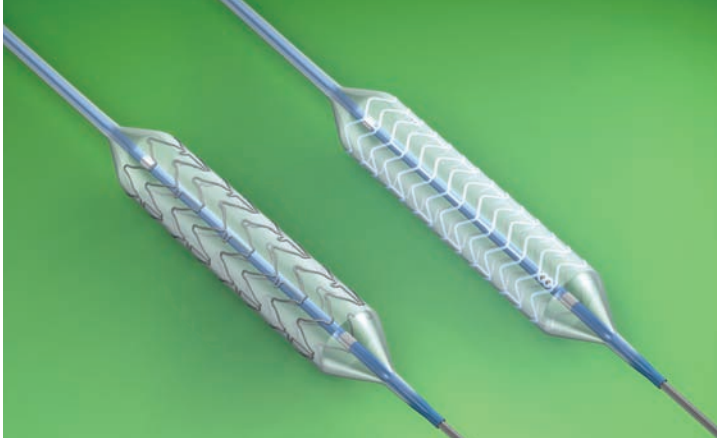
in the walls of the artery. These markers help your doctor identify where the scaffold was placed in your artery. As the scaffold dissolves and resorbs, it gradually disappears and is replaced with new cells. Eventually, Absorb completely resorbs and the vessel can remain open without needing support from the scaffold. Since a permanent implant is not left behind, the motion of the vessel treated with Absorb may eventually be similar to a normal vessel.



The illustration shown is an artist's rendition of the Absorb GT1 BVS.



What is the Difference Between a Metallic Coronary Drug-Eluting Stent and an Absorbable Coronary Drug-Eluting Stent?



The illustration shown is an artist's rendition of a metallic coronary drug-eluting stent (left) and an absorbable coronary drug-eluting stent (right).

- A metallic coronary drug-eluting stent is made of metal that stays in your artery permanently after treatment.
- An absorbable coronary drug-eluting stent is made from material that gradually dissolves over time, leaving behind only 4 very small platinum markers embedded in the walls of the artery to help your doctor identify where the absorbable coronary drug-eluting stent was placed.

What Happens to the Absorbable Coronary Drug-Eluting Stent?

An absorbable coronary drug-eluting stent is made from the same type of material that has been used in other medical procedures for many years such as absorbable sutures. When the absorbable coronary drug-eluting stent begins to dissolve, it turns into natural elements in your body — water and carbon dioxide.

Contraindications to Stenting and Use of an Absorbable Stent:

- If you have a known hypersensitivity (allergy) to everolimus or the structurally related compounds in a metallic stent or absorbable stent such as poly(L-lactide), poly(D,L-lactide), cobalt chromium, nickel, platinum, tungsten, acrylic-polymers, or fluoropolymers
- If you cannot take aspirin or blood-thinning medications (also called antiplatelet or anticoagulant therapy)
- If your physician decides that the coronary artery blockage cannot be treated by angioplasty balloon or proper placement of the stent



Potential Adverse Events Associated with the Absorb GT1 Bioresorbable Vascular Scaffold

What are the Potential Risks and Complications?

Angioplasty and stent placement for CAD have become increasingly common but, as with any invasive procedure, there are potential risks and known complications. Serious complications do not occur often, and research is ongoing to make these procedures even safer and more effective.

The **risk of complications from percutaneous treatment methods** may be higher for individuals:

- 75 years of age and older
- Who are women
- Who have kidney disease or diabetes
- Who have serious heart disease
- Who have had prior cardiac procedures

Potential Risks

Listed below are known potential risks that may occur to you during or after placement of the Absorb GT1 BVS. These risks are not specific to the Absorb GT1 BVS device and may occur with any coronary artery stent:

- Allergic reaction or hypersensitivity to rubber, contrast agent, anesthesia, device materials (platinum, polymer), and everolimus, anticoagulation, or antiplatelet drugs
- Vascular complications in arteries used to access the coronary artery which may require blood transfusion or surgical artery repair, including:
 - Complications at the groin or arm access site

- Bleeding
- Formation of an abnormal connection between an artery and a vein next to it
- Leaking of blood from an artery to the surrounding tissue (usually as a result of a puncture to the artery)
- Weakness in wall of artery (causing possible serious bleeding complications)
- Partial or complete tear of the wall of the artery
- Vessel puncture or rupture
- Movement of air, tissue, plaque, blood clot, or device material downstream in the arteries resulting in blockage in blood flow
- Nerve damage caused by compression of the nerves, injury to the nerve, or interruption of blood supply to the nerves
- Decreased blood supply to the arms and / or legs which may cause cramping or pain
- Complications at the heart arteries which may require additional treatment or surgery, including:
 - Complete blockage of the coronary artery, which may require a repeat procedure or emergency surgery to reopen the coronary artery
 - Formation of an abnormal connection between a heart artery and the vein next to it

Potential Adverse Events Associated with the Absorb GT1 Bioresorbable Vascular Scaffold *(continued)*

- Leaking of blood from a heart artery to the surrounding tissue (usually as a result of a puncture to the artery)
- Weakness in wall of the heart artery (causing possible serious bleeding complications)
- Partial or complete tear of the wall of the artery supplying the heart muscle
- Puncture or rupture of the wall of the artery supplying the heart muscle
- Movement of air, tissue, plaque, blood clot, or device material that partially or completely blocks the heart artery and/or implanted scaffold
- Development of blood clots partially or completely blocking blood flow within the artery and / or the implanted scaffold
- Narrowing or re-narrowing of the treated heart artery
- Complications in the sac around the heart which may require additional treatment, including:
 - Rapid accumulation of blood in the sac around the heart resulting in compression of the heart so it cannot pump out blood to the rest of the body, which may require additional treatment or emergency surgery
 - An abnormal accumulation of blood around the heart
 - Inflammation of the tissue around the heart (causing possible chest pain)
- Irregular heartbeats (caused by abnormal electrical activity in the heart from the upper or lower heart chambers)
- Decreased blood and / or oxygen supply to a part of the heart muscle may which cause:
 - Heart attack (permanent damage of an area of the heart tissue, due to interruption in the blood flow to the heart muscle)
 - Chest pain (which may radiate to jaw or arm) or discomfort caused by inadequate supply of blood to the heart)
 - Temporary spasm of the heart arteries
- Stroke or temporary stroke symptoms as a result of decreased oxygen to the brain causing blurred vision, dizziness, faintness, and numbness
- Altered organ function in acutely ill patients including:
 - Stoppage of the heart
 - Heart function failure potentially leading to the development of fluid in the lungs and severe breathing difficulty
 - Lung function failure potentially leading to the development of severe breathing difficulty
 - Kidney failure
 - Shock (a life-threatening condition in which blood pressure is too low to maintain adequate blood flow to organs)
- Blood count abnormalities
- Low or high blood pressure
- Infection

Potential Adverse Events Associated with the Absorb GT1 Bioresorbable Vascular Scaffold *(continued)*

- Nausea and vomiting
- Feeling of the heart beating rapidly (palpitations), dizziness, or fainting
- Chest pain
- Fever
- Pain
- Death

Zortress[®], the oral formulation of everolimus developed by Novartis Pharmaceuticals Corporation, has been evaluated in clinical trials and is approved in the United States for the prevention of organ rejection in adult kidney transplant recipients at the dose of 1.5 mg/day. Outside the U.S., Zortress is sold under the brand name Certican[®] in more than 70 countries. Everolimus is also approved in the United States under the name of Afinitor[®] for patients with advanced renal cell carcinoma (cancer), at doses of 5 to 10 mg/day when taken by mouth.

Potential adverse events related to taking everolimus daily by mouth are listed below. The amount of everolimus drug in your blood from the Absorb GT1 scaffold is several times lower than with taking oral doses of 1.5 mg to 10 mg/day.

- Abdominal pain
- Low number of red blood cells that can cause tiredness and shortness of breath. May require a blood transfusion.
- Swelling that happens just below the surface of the skin, most often around the lips and eyes

- Development of blood clots that may block arteries
- Bleeding and clotting disorders (including abnormal premature destruction of red blood cells and platelets which may eventually cause kidney failure and blood clots to form in small blood vessels)
- Difficulty passing stool
- Coughing
- Diabetes (high blood sugar)
- Diarrhea (frequent, loose watery stools), which can cause dehydration and may require hospitalization and treatment with intravenous fluids
- Shortness of breath
- Fetal injury or death
- Redness of the skin
- Inflammatory skin disease with redness of the skin
- Headache
- Blood clot formation that causes obstruction of the arteries in the liver
- Liver disorders (including inflammation of the liver, yellowing of the skin and eyes, and darkened urine)
- Allergic reaction to everolimus
- High blood pressure
- Infection, symptoms of infection may include fever, pain, redness, and / or difficulty breathing
- Blood clot formation that causes obstruction of the arteries and / or veins in the kidneys

Potential Adverse Events Associated with the Absorb GT1 Bioresorbable Vascular Scaffold *(continued)*

- Abnormal blood and urine laboratory test results (increases in waste molecules generated from muscle metabolism; abnormal amount of protein in urine; low blood potassium concentrations; changes in blood cholesterol and fat parameters; liver function test abnormalities; decreases in red and / or white blood cells and platelets)
- Cancer of the lymph nodes and skin cancer
- Inability to father children (for men)
- Feeling sick to the stomach (nausea)
- Drug interactions resulting in decreased kidney function (and possible kidney failure)
- Inflammation of the lungs caused by autoimmune diseases, chemical burns, or drug reactions, which can cause shortness of breath
- Mouth blisters or sores
- Pain
- Inflammation of the pancreas causing pain in the upper abdomen. This could become severe and cause nausea, vomiting, fever, and rapid heart rate
- An abnormal accumulation of blood around the heart
- Swelling of arms or legs
- Collection of fluid around the lungs in the chest cavity, which can cause shortness of breath and may require treatment
- Lung Infection
- Fever
- Skin rash
- Kidney dysfunction
- Infection of sinuses, nose and throat
- Infection of the urinary system
- Formation of a blood clot that blocks or partially blocks a vein
- Vomiting
- Wound healing complications (including wound infection and an abnormal collection of lymph fluid)



The ABSORB Family of Clinical Trials

The safety and effectiveness of Absorb in patients with coronary artery disease has been demonstrated in the ABSORB III RCT. A short description of this study as well as additional supporting studies is detailed below:

► **ABSORB III RCT**

ABSORB III RCT is a large randomized study conducted in the United States that compared Absorb with the XIENCE metallic stent. The trial enrolled 1322 patients treated with Absorb and 686 patients treated with XIENCE. All patients will be followed for 5 years. At 1 year, the combined rate of cardiac death, heart attack associated with the vessel treated by the scaffold or stent, or retreatment of the lesion due to vessel re-narrowing was 7.8% in the Absorb group and 6.1% in the XIENCE group. The rate of blood clot formation within the scaffold or stent was 1.5% in ABSORB and 0.7% in XIENCE. An additional analysis showed that the use of ABSORB to treat blockages in small heart arteries was associated with an increased risk of cardiac events (primarily heart attack and blood clot formation within the scaffold) compared to treatment with the XIENCE stent. Based on these results, avoiding use of Absorb in small vessels will be important to reduce the risk for cardiac problems. Your physician has been advised to perform additional imaging of your heart arteries if needed to ensure that they meet the minimum size requirement (2.5 mm) before treating your heart vessel blockage with Absorb.

► **ABSORB Cohort B**

The ABSORB Cohort B trial was one of the first trials to evaluate the safety and performance of Absorb in patients. The trial enrolled 101 patients in Europe, Australia, and New Zealand and they were followed for 5 years. The purpose of this study was to assess the safety and performance of Absorb. Through 5 years, the observed combined rate of cardiac death, heart attack associated with the vessel treated by the scaffold or stent, or retreatment of the lesion due to vessel re-narrowing was 11.0% and there were no coronary artery blood clots associated with Absorb.

► **ABSORB EXTEND**

This trial enrolled 812 patients in Europe, Australia, Canada, Africa, South America, and Asia treated with Absorb, and they will be followed for 3 years. The purpose of this study is to continue to assess the safety and performance of Absorb in more complex heart artery blockages. Data showed an observed combined rate of cardiac death, heart attack associated with the vessel treated by the scaffold or stent, or retreatment of the lesion due to vessel re-narrowing was of 5.1% at 1 year, 6.9% at 2 years, and 9.0% at 3 years. The coronary artery blood clot rate was 1% at 1 year, 1.5% at 2 years, and 2.0% at 3 years.

The ABSORB Family of Clinical Trials

(continued)

► **ABSORB II RCT**

This trial is the first randomized study that compared Absorb with a metallic stent (the XIENCE stent). The trial enrolled 335 patients in Europe and New Zealand treated with Absorb and 166 patients treated with XIENCE. All patients will be followed for 5 years. The combined rates of cardiac death, heart attack associated with the vessel treated by the scaffold or stent, or retreatment of the lesion due to vessel re-narrowing were 4.8% and 3.0% for Absorb and XIENCE at 1 year, respectively. At 2 years, these rates were 7.0% for Absorb and 3.0% for XIENCE. The coronary artery blood clot rate at 1 year was 0.9% for Absorb and 0.0% for XIENCE. At 2 years, the coronary artery blood clot rate was 1.5% for Absorb and 0.0% for XIENCE.

► **ABSORB Japan RCT**

This randomized trial conducted in Japan compared Absorb with a metallic stent, XIENCE, and enrolled 266 patients treated with Absorb and 134 patients treated with XIENCE. All patients will be followed for 5 years. At 1 year, the combined rate of cardiac death, heart attack associated with the vessel treated by the scaffold or stent, or retreatment of the lesion due to vessel re-narrowing was 4.2% in the Absorb group and 3.8% in the XIENCE group.



Your Absorb GT1 BVS Procedure

How Do I Prepare for My Procedure?

In the days prior to your treatment, make sure you:

- Take all of your prescribed medicines
- Tell your doctor if you are taking any other medication
- Tell your doctor if, for any reason, you cannot take aspirin and / or antiplatelet inhibitor medications such as Plavix (clopidogrel), Effient (prasugrel), or Brilinta (ticagrelor)
- Make sure your doctor knows about any allergies you have
- Refrain from eating and drinking after midnight on the night before your procedure
- Follow all instructions given to you by your doctor or nurse

You may be given a mild sedative to help you relax, but you will be awake during the procedure.

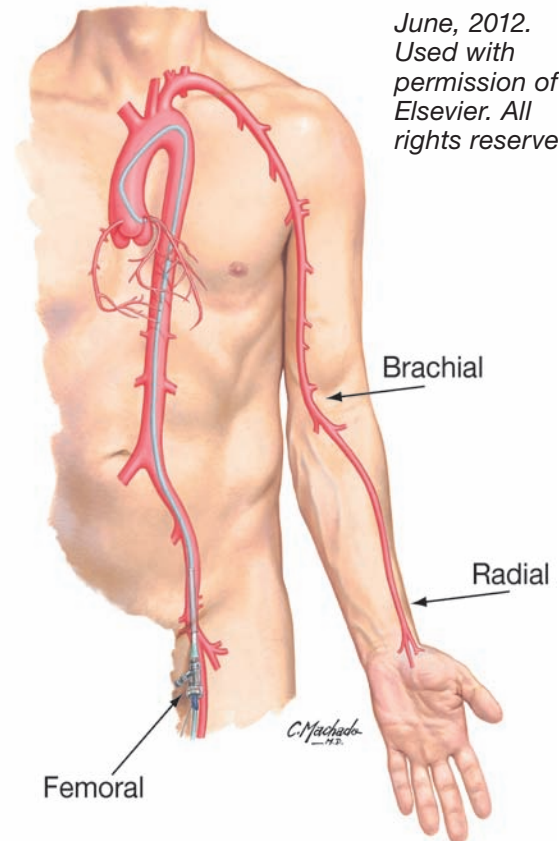
There are two reasons for this:

1. Most people find they experience little to no discomfort from the procedure.
2. Your doctor may need to ask you questions and / or ask you to take a deep breath while X-rays are being taken to improve the quality of the pictures.

The procedure usually lasts about 90 minutes, during which time your doctor will ask you to remain very still. For the most part, you will be comfortable, but you may feel some pressure or chest pain when the balloon is inflated in your heart blood vessel. This is normal and will quickly fade when the balloon is deflated.

During the Procedure

Your procedure will be performed in a cardiac catheterization laboratory (cath lab). You will lie on the X-ray table, and an X-ray camera will move over your chest during the procedure. The staff will monitor your heart by attaching several small temporary patches to your chest and using a specialized ECG recorder and monitor.



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Blood vessel access for heart catheterization through the femoral, radial or brachial artery

Your Absorb GT1 BVS Procedure

(continued)

The groin is the most common site for catheter introduction and requires a very small skin cut to be made on the inside of your upper thigh. The area will be shaved and cleaned with an antiseptic, and you will be given a local anesthetic to numb the area. This small cut will allow an introducer sheath (short tube) to be inserted into your femoral artery (the main artery of the thigh, supplying blood to the leg). Your doctor will then insert a guiding catheter (long, flexible tube) into the introducer sheath and advance it to where the coronary arteries branch off to the heart. A guide wire is then advanced through the guiding catheter to the narrowing in the coronary artery. This helps carry all the necessary devices required during the procedure.

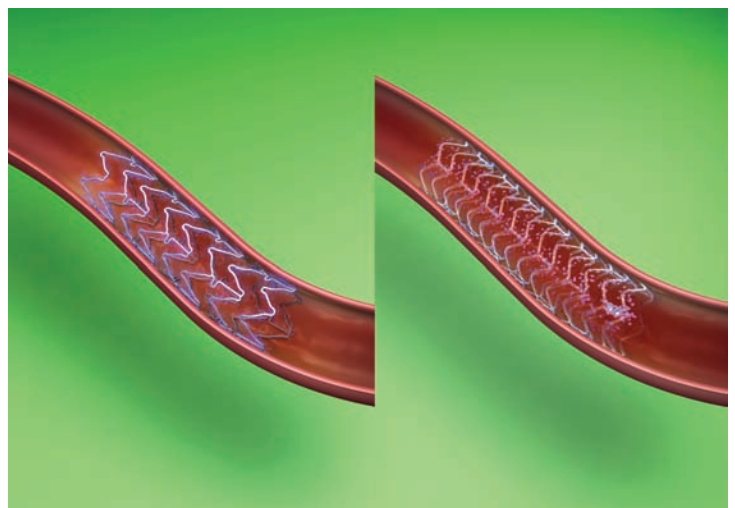
Additional options for catheter introduction are the arm / brachial approach (incision is made on the inside of your elbow) and the wrist / radial approach (incision is made on the inside of your wrist). After the catheters are inserted, your doctor will inject a contrast dye through the guiding catheter into your artery to view the heart vessel narrowing.

Your doctor will watch the injection on a video monitor, much like a TV screen. While X-rays are being taken, your doctor may ask you to take a deep breath and hold it for a few seconds.

You may also be asked to cough after the X-ray picture is completed to help speed the removal of the contrast dye from the arteries.

The medications that are commonly used during the procedure are blood thinners (anticoagulants) such as Heparin to prevent clotting of the blood, and drugs like nitrates to keep the artery open and relieve chest pain.

A catheter with a balloon will be inserted into the guiding catheter and advanced through your vessels until it is positioned in the narrowing of the coronary artery. The balloon is then inflated, which compresses the plaque against the artery wall and widens the coronary artery. This part of the procedure is called pre-dilatation. The balloon catheter is removed and a catheter with the Absorb GT1 BVS is inserted until it reaches the site of the blockage in the artery. The balloon is inflated, and this causes the scaffold to expand against the artery wall, further compressing the plaque. The balloon will be deflated and then removed. The scaffold is left inside the artery permanently. Your doctor may insert another balloon to further expand the scaffold. This is called post-dilatation. After your doctor has checked that the blood flow in the treated artery has improved, all the remaining catheters will be removed.



Your Absorb GT1 BVS Procedure

(continued)

Immediately after Procedure

A vascular closure device may be used to seal the access site in your groin (femoral). Pressure may also be placed on the access site to prevent bleeding. If a vascular closure device is not used, you will be asked to lie flat for four to six hours without bending your leg. An access site in the wrist (radial) and above elbow (brachial) allows you to sit after the procedure. A wrist band is required for radial access and brachial access requires suturing and pressure of the incision site. Your doctor will make the decision on which access site is best for you. Your hospital stay may be less than one day or up to three days.

Post-Treatment Medications

Antiplatelet medications, aspirin, Plavix (clopidogrel), Effient (prasugrel), or Brilinta (ticagrelor) are the most commonly prescribed. They help prevent a blood clot (thrombus) from forming and blocking the vessel opened by the scaffold. Your doctor or nurse will give you instructions about your medications before you leave the hospital. Upon leaving the hospital, your doctor may prescribe medications as a key part of your treatment to help prevent complications. These medications may include:

- **Aspirin** and other **antiplatelet medications** to thin the blood and help prevent blood clots.
- **Beta-blockers** to slow your heart rate and lower your blood pressure.
- **Statins** to lower your cholesterol, which may reduce your risk of heart attack.
- **Nitrates** to relieve chest pain and other symptoms of angina.

- **Calcium channel blockers** to slow your heart rate and lower your blood pressure. They also help widen your coronary arteries and reduce angina.
- **Angiotensin-converting enzyme (ACE) inhibitors** to lower your blood pressure and reduce the strain on your heart.
- **Angiotensin II receptor blockers (ARBs)** work much the same way as ACE inhibitors and may be prescribed if you cannot tolerate certain side effects of an ACE inhibitor.

FOLLOWING YOUR DOCTOR'S ORDERS IS AN IMPORTANT STEP TO A HEALTHY HEART.

Keep Your Implant Card Handy

Show your implant card if you report to an emergency room. This card identifies you as a patient who has had a scaffold implanted.

If you require a magnetic resonance imaging (MRI) scan, tell your doctor or MRI technician that you have an Absorb scaffold in your heart blood vessels. Test results indicate the Absorb scaffolds are MR Conditional. A patient with this device can be safely scanned in all MRI environments of 3T or less. The scaffold(s) should not migrate in this MRI environment, and MRI may be performed immediately following the implantation of the Absorb scaffold(s).

Your Absorb GT1 BVS Procedure

(continued)

Step 3: Revive

Taking Control of Your CAD

Once a CAD care plan has been established by your doctor, its success mostly depends on your commitment to seeing it through. In addition to getting regular checkups with your doctor, there are a number of steps you can take when you commit to making your heart healthier:

- If you smoke, create a plan to stop. There are supportive resources you can contact to help you quit, as well as medications to make stopping easier.
- If losing weight sounds like a difficult challenge, remember that even a 5 to 10 lb. weight loss could significantly reduce your risk of heart disease.
- Regular physical exercise is a great way to help lose weight and improve your heart health. Make sure you talk with your doctor before starting an exercise program.
- Steps you can take to reduce high blood pressure include limiting salt intake, monitoring your blood pressure regularly, and engaging in physical activity. You should always contact your physician for advice.
- Successful control of blood sugar through diet, exercise, and for some, medications, are important in managing diabetes.
- To reduce elevated cholesterol levels, eat foods that are low in saturated fats and cholesterol, exercise regularly, and maintain a healthy weight.

Set a Goal and Celebrate Your Success

By setting achievable goals for yourself, you may be surprised at the level of success you're able to reach. Don't try to become a new person overnight. Instead, select an area or two to work on and go from there.

Consider the following:

- Focus on incremental change. If you want to lose weight, establish a realistic goal and work toward it. Every pound you lose is a step in the right direction.
- Cutting out sugar completely may work for a few days or a week, but it may prove difficult to stop altogether. Consider restricting desserts to weekends only. Small changes over time increase the chance of making a permanent change.
- Get support from friends or family members. If your goal is to take more walks or join a fitness club, ask a supporter to accompany you.
- Be sure to celebrate your success. When you have achieved a goal, reward yourself.



Definition of Medical Terms

Angina – Chest pain caused by not enough supply of blood to the heart.

Angioplasty (also referred to as PTCA) – A minimally invasive procedure involving a balloon dilation catheter being passed through to the blocked area of an artery. Once inflated, the catheter compresses the plaque against the blood vessel wall. An angioplasty can also be performed with a stent.

Anticoagulant – A blood thinning medication to prevent or slow the clotting of blood.

Atherosclerosis – A disease that causes narrowing or blockage of arteries caused by a build-up of fat (cholesterol) within the artery wall. This build-up is sometimes referred to as “plaque.”

Beta-blockers – A medication that slows the heart rate and lowers blood pressure.

Bioresorbable vascular scaffold (BVS) – A new treatment option for CAD that works like a drug-eluting stent (DES) but does not become a permanent part of the body because the scaffold dissolves over time.

Calcium channel blockers – A medication that slows heart rate, lowers blood pressure, helps widen coronary arteries, and reduces angina.

Cardiac catheterization laboratory (cath lab) – A sterile X-ray theater in which heart catheterization is performed.

Catheter – A thin, hollow, flexible tube used to access the coronary arteries during an angiogram or during an angioplasty procedure. The catheter can be used to inject medication, fluids, or X-ray

dye during the procedure. The word catheter is also used to describe the device used to deliver the balloon or stent during an angioplasty procedure.

Coronary arteries – The blood vessels that carry oxygenated blood from the aorta to the heart muscle. There are 4 major coronary arteries: the left main, the right coronary artery, the left anterior descending, and the circumflex.

Coronary artery disease (CAD) – The formation of blockages or atherosclerotic plaques within the coronary arteries that result in reduced blood flow to the heart muscle.

Coronary artery stent – A metallic mesh tube that is implanted into an artery during an angioplasty, providing support to hold an artery open and increase blood flow to the heart muscle.

Drug-eluting stent (DES) – A metallic tube that has been coated with a drug and a special polymer to help reduce tissue growth within the stent that could lead to vessel re-narrowing.

Electrocardiogram (ECG / EKG) – A test that records changes in the electrical activity of the heart. An ECG / EKG may show whether parts of the heart are damaged due to decreased blood flow to the heart muscle.

In-stent restenosis – Reblockage or re-narrowing of a previously stented vessel.

Local anesthetic – A substance used to numb the area to which it is applied.

Nitrates – A medication that relieves chest pain and other symptoms of angina.

Definition of Medical Terms

(continued)

Plaque – Deposits within blood vessels composed of cholesterol, white blood cells, calcium, and scar tissue.

Restenosis – A reblockage caused by excessive cell growth inside the artery or stent following a procedure such as angioplasty.

Statin – A medication that lowers cholesterol, which may reduce the risk of heart attack.

Thrombus – A blood clot within the vascular system.

TOWARD A HEALTHIER HEART

The more you know about CAD, the more you'll be able to take control of your therapy and your lifestyle. Don't hesitate to ask your doctor any questions you may have. Every positive step you take can bring you closer to successful management of your CAD.

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