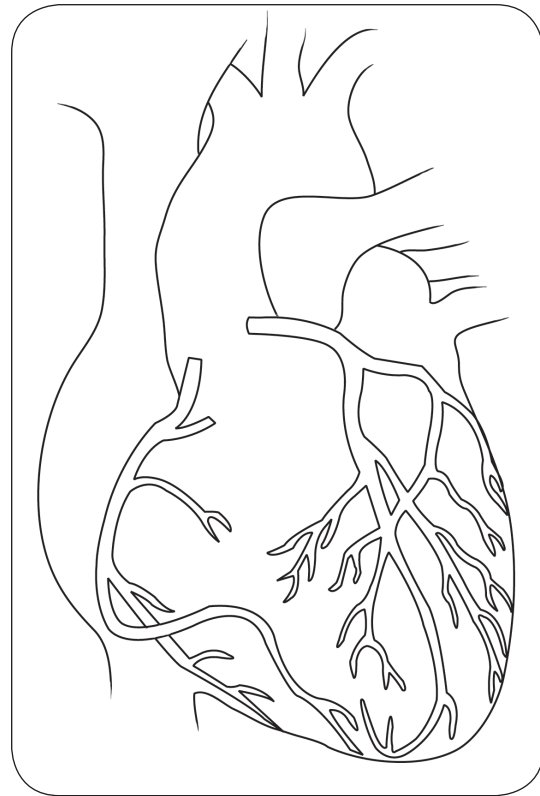


Indications, contraindications, warnings and instructions for use can be found in the labeling supplied with each product. CAUTION: Federal (U.S.A.) law and governing law outside the U.S.A. restricts these products to sale by or on the order of a physician. VeriFLEX™ Bare-Metal Coronary Stent System is a product of Boston Scientific Corporation.



VeriFLEX™
Bare-Metal Coronary Stent System

**Boston
Scientific**

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
1.888.272.1001
www.bostonscientific.com
www.stent.com

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Stent Implant Location

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VeriFLEX™

Bare-Metal Coronary Stent System

**Boston
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**Patient
Information
Guide**



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About This Booklet

Your doctor has prescribed a VeriFLEX Stent to help manage your *coronary artery disease (CAD)*. The VeriFLEX Stent will be implanted into your *coronary artery* during your procedure. This *stent* (see stent illustrations on pages 6 and 7) will act as miniature scaffolding to help your vessel maintain its shape, strength and integrity.

The information in this booklet will help to prepare you for your stent procedure and recovery. It describes the VeriFLEX Stent, how the VeriFLEX Stent is implanted and what you can do to facilitate recovery.

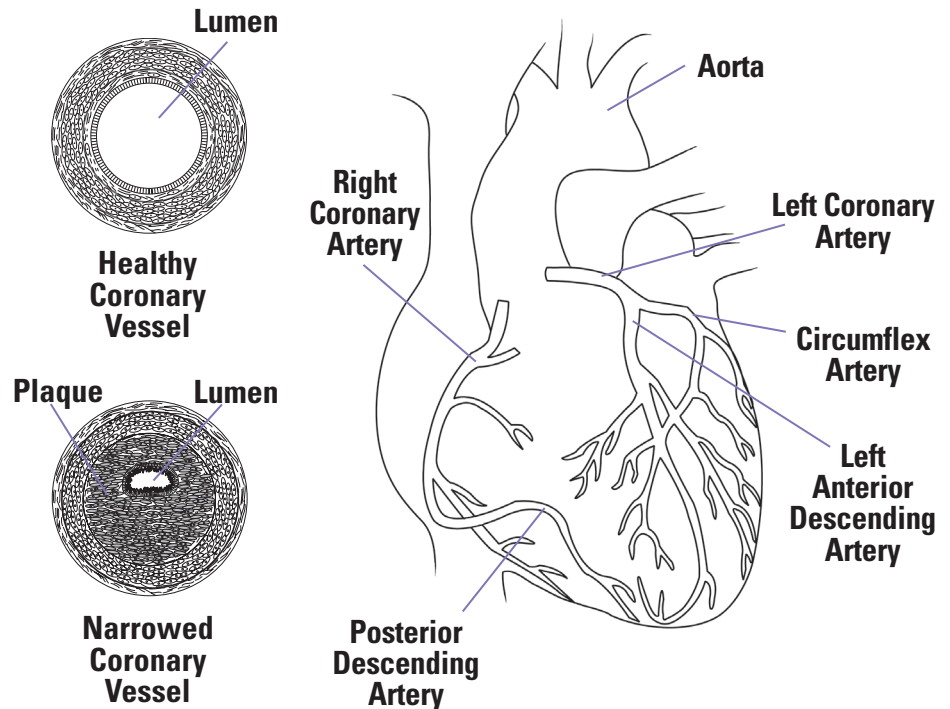
If you have any questions about your stent or the procedure after you read this booklet, be sure to ask your doctor.

If you need additional information about the VeriFLEX Stent, please call your physician.

Notes

Coronary Artery Disease

Coronary Artery Disease (CAD) is usually caused by *atherosclerosis*, and affects the coronary arteries that surround the heart. These coronary arteries supply blood with oxygen to the heart muscle to make it function properly. CAD occurs when the inner walls of the coronary arteries thicken due to a build-up of cholesterol, fatty deposits, calcium and other elements carried in the blood. This material is known as *plaque*. As plaque develops, the vessel narrows. When the vessel narrows, blood flow through the center of the vessel is restricted so less oxygen and other nutrients reach the heart muscle. Starved of proper nourishment, the heart can suffer, particularly under physical exertion. This condition, known as atherosclerosis, may cause mild to moderate chest pains. These pains, a condition known as *angina pectoris*, can also spread to the arms and jaw. But if a coronary artery becomes completely obstructed, a heart attack (*myocardial infarction*) can occur.



Over 13 million Americans suffer from CAD each year. However, treatment options for CAD have substantially improved in recent years, and many CAD patients are now able to return to a normal lifestyle shortly after treatment.

Who is at Risk?

People with a history of high cholesterol, diabetes, smoking, high blood pressure and being overweight, and those with a family history of CAD have an increased risk of developing atherosclerosis in the coronary arteries. In addition, menopausal status may play a role in women.

Diagnosis of Coronary Artery Disease

Doctors may use various tests to diagnose CAD. An *electrocardiogram (ECG/EKG)* measures your heart's electrical activity and may show whether parts of your heart muscle have been damaged by a heart attack due to CAD. A *stress test* records your heart's electrical activity while you are exercising and may tell your doctor whether part of your heart muscle is damaged. A *coronary angiogram* is a procedure performed by a cardiologist in a specially equipped area of the hospital called the cardiac catheterization laboratory. This procedure is done by injecting a contrast dye into the coronary arteries so that the vessels can be seen on an x-ray screen. The x-ray will show if any blockages and/or artery narrowing has occurred. This will help your doctor decide how to treat you.

Notes

Treatment of Coronary Artery Disease

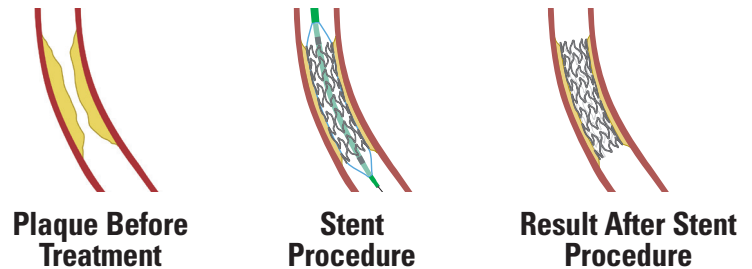
CAD may be managed through a combination of changes in lifestyle and physical activity, diet and medical treatment. The therapy your doctor recommends will depend on the condition and severity of the disease. Nitroglycerin is often given to relieve chest discomfort due to blockages, but does not treat the blockage itself. Medical treatments of the blockage may include medications, *angioplasty*, with or without stent placement, or *coronary artery bypass graft surgery (CABG)*.

Side View of Coronary Artery



Angioplasty

Angioplasty, also known as *percutaneous transluminal coronary angioplasty (PTCA)*, is a minimally invasive treatment of the coronary arteries performed in the hospital to open blocked arterial vessels. A thin tube known as a *catheter* is inserted through the groin or wrist and is then threaded through a major blood vessel to the site of the blockage. A small balloon, located on the tip of the catheter, is then expanded to reduce the blockage. PTCA can be performed with a balloon alone, or can involve the placement of a coronary stent.

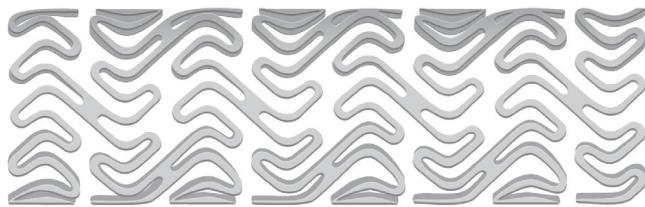


Coronary Artery Stents

Coronary artery stents are devices that can help to reduce the risk of renarrowing of the treated artery following an angioplasty procedure. Stents are small steel tubes that are implanted into a vessel and expanded to fit the size, shape and bend of the vessel wall, propping it open to help prevent further blockages. Once in place, the stent will remain in your artery. Over time, the artery wall will heal around the stent as it continues to support the vessel.

Your VeriFLEX™ Bare-Metal Coronary Stent System

The VeriFLEX Stent is a small, stainless steel, mesh tube. The VeriFLEX Stent is secured to a balloon at the end of a delivery catheter. The catheter delivers the stent to the location where it will be implanted. When the balloon is inflated, the stent expands until it has made full contact with the vessel wall, adapting to fit the shape, size and bend of the vessel. Once in place, the stent will remain in your artery. Over time, the lining of the artery wall will grow around the stent as the stent continues to support the vessel.



Undeployed VeriFLEX Coronary Stent

Notes

What Are the Potential Risks of Treatment with the VeriFLEX™ Stent?

The following complications may be associated with the use of a coronary stent in native coronary arteries. These complications may occur during or after placement of a coronary stent in your body.

- Air bubble in artery
- Artery blockage or closure caused by stent
- Artery spasm
- Bleeding that would require a blood transfusion
- Blood clot in artery
- Damage to heart due to reduced oxygen
- Death
- Emergency bypass surgery
- Heart attack
- High or low blood pressure
- Improper stent placement
- Infection or pain at insertion site in groin or arm
- Irregular heartbeat
- Localized swelling consisting of clotted blood
- Reaction to contrast dye, stent material or medication
- Renarrowing of treated artery
- Ruptured or torn artery
- Stroke
- Weakened artery wall

Alternative Practices and Procedures

Treatment of patients with coronary artery disease, including in-stent *restenosis*, may include exercise, diet, drug therapy, percutaneous coronary interventions (such as angioplasty and other stents) and coronary artery bypass surgery.

The Angioplasty Procedure

Preparation for the Procedure

Your doctor will instruct you on how to prepare for the angioplasty and stent implantation procedure prior to being admitted to the hospital. Your doctor may ask you to take aspirin and other prescribed medications for several days before the procedure. This is done to “thin” the blood to prevent blood clots from forming during the procedure. It is important to tell your doctor if you cannot take aspirin or have a history of bleeding problems. Your doctor also needs to know if you are taking any other medications or have drug allergies.

Angioplasty and Stent Placement Procedure

Your angioplasty procedure will be performed in a specially equipped area of the hospital called the cardiac catheterization laboratory.

You will have to lie flat on your back during the procedure and you will remain awake, allowing you to follow your cardiologist’s instructions (e.g., “breathe deeply”). Your groin or arm will be shaved and cleaned with antiseptic and you will be given a local anesthetic to numb the area.

Your cardiologist will place an introducer sheath either in your groin or in your arm to gain access to the artery. The sheath enables the cardiologist to slide a small guiding catheter up to the entrance of the coronary artery. Through the guiding catheter, a contrast dye will be injected that helps the doctor see the coronary arteries on the x-ray machine. A fine wire is then advanced through the guiding catheter to the stenosis, or blockage, in the diseased artery. This provides the “railway track” which carries all the equipment necessary for the procedure.

Using the guiding catheter, a balloon catheter is then positioned precisely in the clogged area of the coronary artery. Once in place, the balloon is inflated, compressing the plaque build-up and widening the artery. At this time you may experience some chest pain. Although this is normal, let your doctor know if you are experiencing any pain.

After the artery has been widened, your doctor will then pass the stent, mounted on a balloon catheter, into the coronary artery where the balloon was inflated. Your doctor will inflate the balloon to expand the stent and deliver it to the inner wall of the artery. The stent will expand to shape itself to the size and contours of your vessel.

Your doctor may choose to expand the stent further by using another balloon. If required, the balloon catheter is inserted inside the stent and then inflated to help the stent make better contact with the artery wall. This part of the procedure is called *post-dilatation*. Once in place, the VeriFLEX™ Stent will remain in your artery permanently.

Post-Treatment

After the Procedure

Following an angioplasty procedure, you may be instructed to lay flat for several hours. Most patients spend a night in the hospital to be monitored. After leaving the hospital you should be able to return to normal activities according to your physician's instructions.

- Follow your doctor's guidelines
- Return to normal activities gradually, pacing your return to activity as you feel better
- Check with your doctor about strenuous activities
- Let your doctor know about any changes in lifestyle you make during your recovery period
- Keep all follow-up appointments, including laboratory blood testing

PRECAUTIONS

- Do not stop taking your medications unless you are asked to stop by the doctor who implanted your stent
- Report side effects from medications immediately, including headaches, nausea, vomiting or rash
- Carry your Patient Information Card (provided in the back of this booklet) at all times
- If you receive dental or medical care or report to an emergency room/center, show your Patient Identification Card

Medications

Your doctor may prescribe a number of medications to thin the blood and prevent blood clots from forming and adhering to the surface of the stent. Patients who take these medications also are required to take blood tests frequently so their blood clotting time can be monitored. Your doctor will let you know when you can stop taking these medications. Until then, it is extremely important to follow your medication regimen. Check with your doctor before taking antacids as they may decrease absorption of some medications.

Follow-Up Examinations

You will need to see the doctor who implanted your stent for routine follow-up examinations. During these visits, your doctor will monitor your progress and evaluate your medications and check the clinical status of your CAD and how the stent is working for you.

Magnetic Resonance Imaging (MRI)

If you require a *magnetic resonance imaging* (MRI) scan, tell your doctor or MRI technologist that you have a VeriFLEX™ Stent. Test results indicate that the VeriFLEX Stent is MR Conditional. Patients with single or overlapped VeriFLEX Stents can undergo MRI scans safely under the following conditions:

- Static magnetic field of 1.5 or 3 Tesla
- Spatial gradient field of 700 Gauss/cm or less
- Normal operating mode (maximum whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg) for 15 minutes or less of scanning

The stent(s) should not migrate in this MRI environment, and MRI may be performed immediately following the implantation of a VeriFLEX Stent(s).

FREQUENTLY ASKED QUESTIONS

Can I undergo MRI or scanner testing with a stent?

MRI safety testing has shown that the VeriFLEX™ Stent is MR Conditional and that a patient with an VeriFLEX Stent may safely undergo an MRI scan under certain conditions listed on the patient implant card. Prior to undergoing an MRI scan, inform your doctor or MR technologist that you have a VeriFLEX Stent.

Can the stent move or rust?

Once positioned by your physician, the stent does not move on its own. It will not rust because it is made of non-corroding metal.

Can I walk through metal detectors with a stent?

Yes, without any fear of setting them off. The stent is made of non-magnetic metals.

How soon can I go back to work?

The majority of people return to work within a few days following the procedure.

What if I still get pains?

If you experience pain, inform your cardiologist or the center where the procedure was performed immediately.

Can I play sports?

Yes, but be cautious! Your doctor will tell you what sports you can play and when you can start them.

What should I change in my diet?

Your doctor may prescribe a low-fat, low-cholesterol diet to help reduce the levels of fat in your blood and reduce your risk.

GLOSSARY

Angina Pectoris — Symptoms experienced when the heart muscle is not receiving adequate oxygen (may include chest, arm or back pain, shortness of breath).

Angioplasty — A minimally invasive treatment of the coronary arteries to open blocked arterial vessels. Also known as percutaneous transluminal coronary angioplasty (PTCA).

Atherosclerosis — A disease in which the flow of blood to the heart is restricted by plaque deposits and, therefore, less oxygen and other nutrients reach the heart muscle. This may lead to chest pain (angina pectoris) or to a heart attack (myocardial infarction).

CABG — See **Coronary Artery Bypass Graft Surgery**.

CAD — See **Coronary Artery Disease**.

Catheter — A small, thin plastic tube used to provide access to parts of the body, such as the coronary arteries.

Coronary Angiogram — A test to determine if CAD is present. Contrast dye is injected into the coronary arteries and a fluoroscope allows the doctor to see the vessels on an x-ray machine.

Coronary Arteries — The arteries that surround the heart and supply blood containing oxygen and nutrients to the heart muscle.

Coronary Artery Bypass Graft Surgery (CABG) — Open heart or bypass surgery.

Coronary Artery Disease (CAD) — Disease affecting the coronary arteries that surround the heart and supply blood to the heart muscle. CAD occurs when the lumen (inner channel) of the coronary arteries becomes narrowed with plaque deposits (a build-up of cholesterol and other fats, calcium and elements carried in the blood).

ECG/EKG — See **Electrocardiogram**.

Electrocardiogram (ECG/EKG) — A test that records changes in the electrical activity of the heart. May show whether parts of the heart muscle have been damaged due to insufficient oxygen flow to the heart.

Magnetic Resonance Imaging (MRI) — A non-invasive way to take pictures of the body. MRI uses powerful magnets and radio waves, unlike x-rays and computed tomographic (CT) scans which use radiation.

Myocardial Infarction — Permanent damage to the heart tissue and muscle due to the interruption of the blood supply to the area. Commonly referred to as a heart attack.

Percutaneous Transluminal Coronary Angioplasty (PTCA) — See **Angioplasty**.

Plaque — Accumulation or build-up of cholesterol, fatty deposits, calcium and collagen in a coronary vessel that leads to blockages in the blood vessel.

Post-Dilatation — After the stent has been expanded, another balloon catheter may be inserted inside the stent and inflated to size the stent more precisely to the vessel.

Restenosis — Recurrent blockage or narrowing of a previously treated vessel.

Stent — An expandable metal tube that supports the vessel wall and maintains blood flow through the opened vessel.

Stress Test — A test that records the heart's electrical activity while the patient exercises. May show whether parts of the heart muscle have been damaged due to insufficient oxygen flow to the heart.

VeriFLEX™ Bare-Metal Coronary Stent System

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The stent(s) should not migrate in this MRI environment, and MRI may be performed immediately following the implantation of a VeriFLEX Stent(s).

Please carry your card at all times.

MR image quality will be compromised if the area of interest is in the same area or relatively close to the position of the stent. Please contact 1.888.272.1001 for more information about MR image artifact.

Stent Identification Information

Patient Name	Patient Phone Number
Product Lot Number	Product Lot Number
Stent Location	Stent Location
Product Name	Product Name