

Boston
Scientific

PROMUS[®]

Everolimus - Eluting Coronary Stent System

Patient Information
Guide

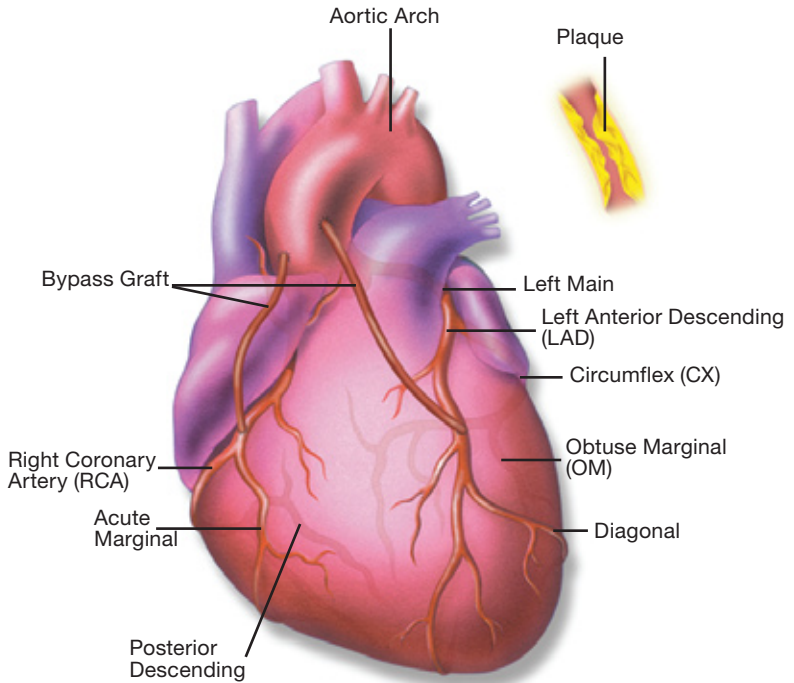
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Coronary Vasculature



Coronary Artery Disease (CAD)

Your Heart

Your heart is a muscle that pumps blood throughout your body. The blood carries oxygen and nutrients that your body needs to work correctly. For the heart to be able to function properly, it also needs a constant supply of oxygen-filled blood. The vessels that supply this blood to the heart are called coronary arteries. If these arteries become blocked or narrowed, treatment may be required to restore blood flow and the vital supply of oxygen to the heart.

What is CAD?

CAD is the most common form of heart disease. It is a condition that occurs when the arteries that supply oxygen-rich blood and nutrients to the heart muscle become narrowed or blocked by a gradual build-up of “plaque.” Plaque is made up of fatty deposits (cholesterol), white blood cells, calcium, and other substances that collect over time in the wall of a coronary artery. As the plaque narrows the opening (lumen) of a coronary artery, it makes it difficult for adequate quantities of blood to flow to the heart muscle. This process is called “atherosclerosis.” Gradual reduction of blood flow to the heart

Coronary Artery Disease (CAD)

(continued)

muscle can cause chest pain (angina). A heart attack (myocardial infarction) can occur if the artery suddenly becomes completely blocked, usually by a blood clot that forms over ruptured (broken) plaque. Heart attacks cause irreversible damage to the heart muscle. The first symptom of CAD can also be sudden death.

Improved medical treatment, combined with earlier diagnosis, and increased public awareness of the symptoms and risk factors that contribute to this disease are helping to decrease the death rate from CAD.

What are the Symptoms of CAD?

Two common symptoms of CAD are chest pain, also known as angina, and shortness of breath, which are caused by the reduction of blood flow to the heart muscle. If plaque build-up does not reduce blood flow excessively, there may be no noticeable symptoms at rest, but symptoms such as heaviness in the chest may occur with increased activity or stress.

Coronary Artery Disease (CAD)

(continued)

Other symptoms that may be experienced are:

- Pain in the jaw or neck
- Pain radiating to the arms or back
- Heartburn
- Nausea
- Vomiting
- Heavy sweating

When blood flow is significantly reduced and the heart muscle does not receive enough blood to meet its needs, severe symptoms such as chest pain (angina pectoris), heart attack (myocardial infarction), or heart rhythm disturbances (arrhythmias) may occur.

There are some patients who report no symptoms of CAD. It is possible to have a heart attack without experiencing any symptoms.

Coronary Artery Disease (CAD)

(continued)

Recent research has shown that some women experience different CAD symptoms from men and are less likely than men to report chest pain, heaviness in the chest, or chest discomfort during a heart attack. Women may notice other early symptoms, such as unusual tiredness or sleep disturbances up to one month prior to a heart attack. These differences in symptoms may cause some women to delay seeking help or treatment.

What are the Risk Factors of CAD?

Two main risk factors for CAD are:

- Increasing age (over age 65)
- Being male or a menopausal female¹

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.

Coronary Artery Disease (CAD)

(continued)

Other risk factors that may increase your chances of developing CAD are:

- Family history of heart disease (close relatives with heart disease at a young age)
- Diabetes
- High blood cholesterol levels
- Smoking
- High blood pressure
- Stress
- Obesity (being overweight)
- High fat diet
- Lack of exercise

How Can My Doctor Tell if I Have CAD?

If your doctor suspects that you have CAD or if you have symptoms of the disease, he or she will ask you about your risk factors and your symptoms. A complete physical exam and blood tests to identify injury to your heart muscle will also be completed. In addition, some of the tests used to make the diagnosis are:

Coronary Artery Disease (CAD) *(continued)*

Electrocardiogram (ECG/EKG) is a commonly used test that records your heart's electrical activity and can show certain problems such as abnormal heartbeats or damage to the heart muscle. An ECG can be done at rest or while you are walking or running on a treadmill or pedaling a stationary bicycle (Stress ECG).

Stress Tests are used to evaluate your heart rate, heart rhythm, and ECG while you are exercising. The results of a stress test can help your doctor determine the areas of heart muscle that are affected by lack of blood flow due to CAD.

Echocardiography is an exam of the heart using sound waves.

Coronary Angiogram or Heart Catheterization is a procedure carried out in the cardiac catheterization laboratory (cath lab) by a cardiologist. Angiography is a procedure in which coronary arteries are visualized using X-rays.

Coronary Artery Disease (CAD)

(continued)

A catheter (long, thin, hollow tube) is inserted into an artery in the groin or arm. The tip of this tube is positioned at the beginning of the arteries supplying blood to the heart. A special fluid called contrast dye is injected through the tube to visualize the blood vessels on X-rays so that pictures called angiograms can be taken. These angiograms allow the doctor to see any blockage and/or narrowings in your coronary arteries and determine their severity.

Using the information gathered from one or more of these tests, your doctor is better able to decide the best treatment plan for you.



Cardiac Catheterization Laboratory

Your Treatment Options

Once a diagnosis has been made, your doctor will recommend the most appropriate form of treatment, depending on the condition and severity of your CAD. CAD can be managed by a combination of changes in lifestyle (eating a healthy diet low in saturated fat, regular exercise, and quitting smoking) and medical treatment. Your treatment may include medications to relieve your chest pain and/or to expand the coronary arteries, increasing blood flow to your heart.

However, because medicine alone may not clear blocked arteries, you may need more treatment, including surgery, angioplasty, and/or stenting to treat your symptoms.

Your doctor will explain the risks and benefits of your treatment options and answer any questions you or your family may have. You are encouraged to discuss your treatment options with your doctor.

Your Treatment Options *(continued)*

Surgery

Coronary artery bypass grafting is a common surgical procedure that removes a section of artery or vein from another part of your body. This vessel is then connected (grafted) to the coronary artery beyond the blockage site. This creates a new path for blood to flow around (bypass) the blocked artery and to your heart. Often, several blocked arteries are bypassed during the same operation. Most coronary bypass patients remain in the hospital for about a week, followed by a recovery period at home.

Angioplasty

Angioplasty is a procedure used to open blocked arteries. You may also hear it referred to as percutaneous transluminal coronary angioplasty (PTCA) or balloon angioplasty. This procedure is performed under local anesthetic in a cardiac catheterization laboratory. A catheter with a small balloon mounted on the end is passed into the coronary artery. The catheter is then positioned at the narrowed portion of the artery and the balloon is inflated. As the balloon inflates, it pushes out against the wall of the coronary artery and compresses the plaque. The balloon is then deflated and the catheter is removed from the artery. This opens the narrowing in the coronary artery and improves the blood flow to

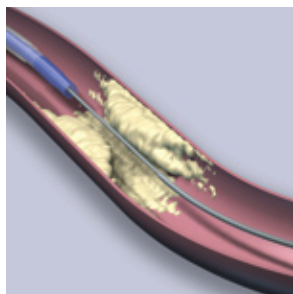
Your Treatment Options (*continued*)

the heart muscle. In balloon angioplasty, no permanent device remains in the artery after the balloon catheter is removed. Balloon angioplasty can be performed with a balloon alone or can involve placement of a permanent device called a stent, within the coronary artery.

Although balloon angioplasty enlarges the lumen of coronary arteries, many patients develop re-narrowing of the vessel in the months following the procedure. This process is called restenosis, and it is caused by the growth of scar tissue within the coronary artery.

Step 1:

The doctor guides a catheter with a small balloon through the blood vessel to the narrowed section of the artery. By watching the progress of this catheter on the fluoroscope (an X-ray device that creates real-time images of the internal structures of the body that can be viewed on a TV monitor), the doctor is able to maneuver it into the blocked coronary artery.

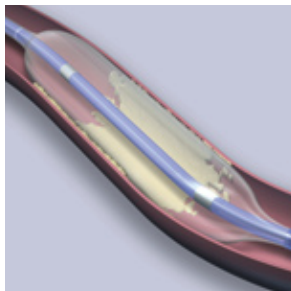


Step 1

Your Treatment Options *(continued)*

Step 2:

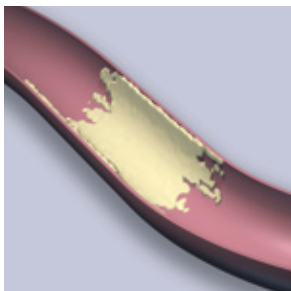
The balloon is inflated, pushing out against the wall of the artery and compressing the plaque. The balloon is deflated and the catheter is removed.



Step 2

Step 3:

The inside of the blood vessel is now larger and the blood flow is improved.



Step 3

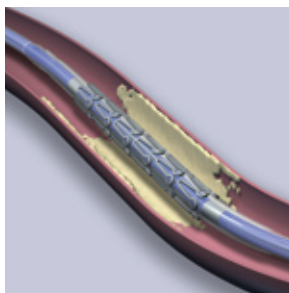
Your Treatment Options *(continued)*

Coronary Artery Stents

Coronary artery stents are devices (small metallic mesh tubes) that are placed over a balloon catheter and delivered to the narrowed portion of the coronary artery. The balloon is used to expand the stent. The stent presses against the narrowed vessel wall, holding the vessel open. This makes a wider channel to improve blood flow to the heart muscle. This may be followed by repeat balloon inflations within the stent to achieve the result desired by your doctor. Once the balloon has been deflated and withdrawn, the stent stays in place permanently, holding the coronary artery open. The inner lining of the artery grows over the surface of the stent, making the stent a permanent part of your artery.

Step 1:

The doctor maneuvers the catheter into the blocked artery and inflates the balloon.

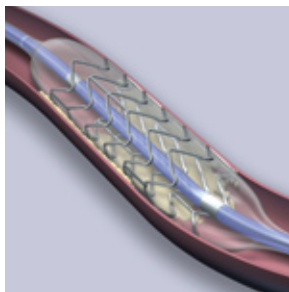


Step 1

Your Treatment Options *(continued)*

Step 2:

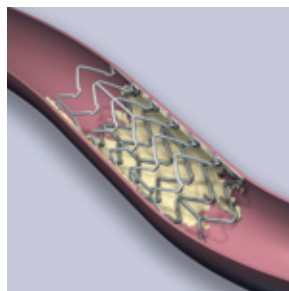
The stent expands against the vessel wall as the balloon is inflated.



Step 2

Step 3:

Once the balloon has been deflated and the catheter is withdrawn, the stent stays in place permanently, holding the blood vessel open and improving blood flow.



Step 3

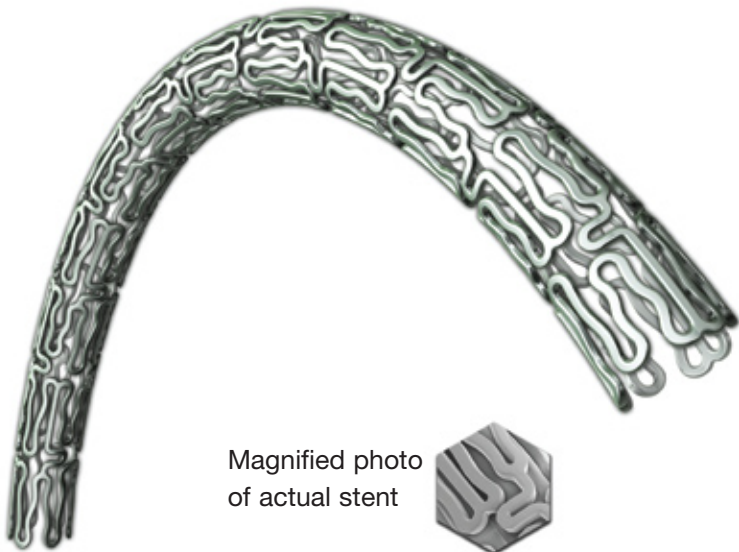
Coronary artery stents are less invasive than bypass surgery. Stenting involves a shorter hospital stay—usually one to three days—and faster recovery than surgery. However, restenosis can also occur in some patients who receive stents (in-stent restenosis), due to the build-up of scar tissue within the stent leading to narrowing of the stent lumen.

Drug-Eluting Stents (DES)

To help prevent restenosis, “drug-eluting” stents have been developed. These stents provide the same structural support as uncoated stents, but they are also coated with a drug. The drug is released over time, helping to prevent restenosis by limiting the overgrowth of normal tissue within the stent.

PROMUS Everolimus-Eluting Coronary Stent System

The illustration shown is an artist's rendition of Boston Scientific's drug-eluting stent, the PROMUS.



Magnified photo
of actual stent

PROMUS is intended for use by or under
the direction of a physician.

PROMUS Everolimus-Eluting Coronary Stent System *(continued)*

The PROMUS Everolimus-Eluting Coronary Stent System (PROMUS EECSS or PROMUS Stent System) is a private-labeled XIENCE V[®] Everolimus Eluting Coronary Stent System manufactured by Abbott and distributed by Boston Scientific Corporation.

The PROMUS stent is designed to prevent re-narrowing within the stent (in-stent restenosis). It consists of a medical grade cobalt chromium stent with a thin coating of a drug called everolimus on its surface. This stent is based on the design of the clinically proven MULTI-LINK VISION[®] stent and provides mechanical support to the artery while everolimus is slowly released into the artery wall around the stent from a thin polymer (a type of plastic) coating. The polymer coating helps control the release of everolimus into the arterial wall. The polymer used on the PROMUS stent has a long history of being used in medical products in contact with blood. The release of everolimus is intended to limit the overgrowth of tissue within the coronary stent. The PROMUS stent is available in various diameters (2.25, 2.5, 2.75, 3.0, 3.5 and 4.0 mm).

PROMUS Everolimus-Eluting Coronary Stent System *(continued)*

Contraindications

- If you have a known hypersensitivity (allergy) or contraindication to everolimus or the structurally-related compounds, cobalt, chromium, nickel, 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 will not allow complete inflation of the angioplasty balloon or proper placement of the stent

Potential Adverse Events Associated with the PROMUS Stent

The risk of using the PROMUS stent is similar to those that are associated with standard stent procedures. If the stent clots, you may need another angioplasty procedure. It may also lead to a heart attack, the need for urgent bypass surgery, or death. Even with successful stent implants, there is a chance of re-narrowing of your coronary artery. This may require further treatments, such as repeat angioplasty and/or bypass surgery, to reopen the artery and to increase blood flow to the heart. The risks from using balloon catheters after stent implants are similar to the risks that may occur during the initial stent implant. These may be serious enough to require surgery or cause death.

Other risks from these devices are the same as treatment procedures for a narrowed coronary artery. Some problems associated with standard balloon angioplasty and stenting include, but are not limited to:

Potential Adverse Events Associated with the PROMUS Stent *(continued)*

Common Risks

- Bruise or bleeding at the catheter insertion site in the groin or arm
- Pain at the catheter insertion site
- Irregular heartbeats
- Chest pains during and after the procedure
- Spasm of the coronary artery
- Decreased or increased blood pressure

Rare Risks

- Tearing, puncture, or rupture of the coronary artery
- Air, pieces of devices, or fragments of clots blocking the coronary or peripheral arteries
- Complete blockage of the coronary artery, which may require a repeat procedure to reopen the coronary artery
- Compression of the heart due to accumulation of blood around the heart
- Re-narrowing of the coronary artery
- Heart attack

Potential Adverse Events Associated with the PROMUS Stent (*continued*)

- Damage to the stent or injury to the coronary artery, requiring emergency heart surgery
- Bleeding, requiring transfusion or surgery
- Allergic reaction (may include X-ray dye, cobalt, chromium, nickel, tungsten, everolimus, acrylic-polymers or fluoropolymers)
- Infection
- Nerve injury
- Kidneys fail to function normally
- Aneurysm (weakening of a portion of the wall of a blood vessel)
- Shock
- Stroke
- 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 20 mg/day when taken by mouth. The amount

Potential Adverse Events Associated with the PROMUS Stent *(continued)*

of drug in your blood from the PROMUS stent is several-fold lower than that obtained with oral doses (1.5 mg to 20 mg/day). Potential adverse events related to taking everolimus daily by mouth (based on long-term everolimus drug studies in organ transplant patients and in patients with advanced renal cell carcinoma) may include:

- Abdominal pain
- Abnormal laboratory tests which may include:
 - Increased levels of creatinine in the blood (which reflect reduced kidney function)
 - Increased or decreased levels of potassium in the blood
 - Decreased levels of magnesium or phosphorous in the blood
 - Increased sugar (glucose) levels in the blood (possible new-onset diabetes)
 - Increased cholesterol levels in the blood
 - Increased levels of fats and triglycerides in the blood
- Reactive swelling, usually in the face
- Back pain
- Blood in the urine
- Constipation
- Cough

Potential Adverse Events Associated with the PROMUS Stent *(continued)*

- Shortness of breath, and lung or breathing problems
- Decrease or changes in sense of taste
- Decreased red blood cell, white blood cell, or platelet cell counts (platelet cells help the blood clot)
- Decrease or loss of sperm count in men
- Delayed wound healing/fluid accumulation (may include surgical wounds)
- Diarrhea
- Dry or itchy skin
- Fatigue
- Fever
- Headache
- Increased blood pressure
- Indigestion
- Infections: increased risks of bacterial, viral, fungal, or protozoal infections (may include herpes virus infections, BK virus infection, polyoma virus infection, opportunistic infections, or a combination of the above)
- Inflammation of the lining of the digestive system and mucous membranes
- Inflammation of the lung (not due to infections)

Potential Adverse Events Associated with the PROMUS Stent *(continued)*

- Infection of the lungs and upper airways
- Insomnia
- Interactions with medications that are influenced by the CYP3A4 metabolic pathway (consult your doctor for more information)
- Loss of appetite
- Lymphoma and other malignancies (may include skin cancers)
- Mouth ulcers or sores
- Nosebleeds
- Nausea
- Pain in the arms, legs, incision site or related to the procedure
- Pain or difficulty with urination
- Presence of protein in the urine
- Rash
- Swelling in the body (usually in the legs) caused by water retention
- Tremor
- Urinary tract infection
- Vomiting
- Weakness

Potential Adverse Events Associated with the PROMUS Stent *(continued)*

Live vaccines and close contact with people that have received them should also be avoided. There is also potential harm to a fetus for pregnant women.

When used with cyclosporine medication, there may be an increased risk of the following:

- Blood clots in the small blood vessels
- Bleeding that appears as purple patches or spots on the skin
- Blood clotting in the smallest blood vessels of the body that may affect the kidneys

Exposure to drug and polymer on the PROMUS stent is directly related to the number and lengths of the stents implanted. The use of multiple PROMUS stents will result in your receiving larger amounts of drug and polymer. It should be noted that a kidney transplant patient usually receives a daily dose of the drug everolimus by mouth that is about seven times more than the maximum dose of the drug contained on one PROMUS stent.

Everolimus, when given by mouth daily to organ transplant patients, may interact with other drugs or substances. Please tell your physician about any medications you are taking.

The SPIRIT Family of Clinical Trials

The PROMUS Everolimus-Eluting Coronary Stent System (PROMUS EECSS or PROMUS Stent System) is a private-labeled XIENCE V[®] Everolimus Eluting Coronary Stent System manufactured by Abbott and distributed by Boston Scientific Corporation. There have been five clinical trials thus far that together have shown the safety and effectiveness of the XIENCE V[®] drug-eluting stent in patients with coronary artery disease. A short description of these trials, known as the XIENCE V[®] SPIRIT Family of Trials, is detailed below:

SPIRIT FIRST

SPIRIT FIRST was the first clinical trial. This study had 60 patients and was performed outside the United States. The purpose of the study was to compare the XIENCE V[®] stent that is coated with a drug to that of an approved metallic stent that is not coated with a drug. There were 28 patients who received the XIENCE V[®] stent and 32 patients who received the metallic stent (patients who received the metallic stent are also known as the “control” group).

After six months, the XIENCE V[®] stent was significantly better than the metallic stent at reducing the re-narrowing of the artery where the stent was placed. After five years, patients who had received

The SPIRIT Family of Clinical Trials

(continued)

the XIENCE V stent had fewer major adverse cardiac events (16.7%) compared to patients who received the metallic stent (28.0%). (Patients were considered to have major adverse cardiac events if they died due to cardiac causes, or had heart attacks, or underwent bypass surgery or repeat angioplasty at the site of the lesion.)

SPIRIT II

The SPIRIT II clinical trial was the second study of the XIENCE V[®] stent. The purpose of the study was to compare the XIENCE V[®] stent to an approved drug-eluting stent, called TAXUS[®] Express[®] stent or TAXUS[®] Liberté[®] stent (TAXUS stent). The SPIRIT II study was conducted outside of the United States.

After six months, the XIENCE V[®] stent was significantly better than the TAXUS stent at reducing the re-narrowing of the artery where the stent was placed. At four years, patients who had received the XIENCE V[®] stent had a rate of major adverse cardiac events of 7.7% compared to a rate of 16.4% for those patients receiving the TAXUS stent.

SPIRIT III

SPIRIT III was the third clinical study of the XIENCE V[®] stent. This was a much bigger study than either the

The SPIRIT Family of Clinical Trials *(continued)*

SPIRIT FIRST or SPIRIT II studies, and was conducted in the United States. In one part of this study, 1002 patients were given either the XIENCE V[®] stent or the TAXUS stent. There were 669 patients who received the XIENCE V[®] stent and 333 patients who received the TAXUS Express stent (TAXUS stent).

After eight months, the XIENCE V[®] stent was significantly better than the TAXUS stent at reducing the re-narrowing of the artery where the stent was placed. At three years, patients who had received the XIENCE V[®] stent had a rate of major adverse cardiac events of 9.7% compared to a rate of 16.4% for those patients receiving the TAXUS stent.

SPIRIT IV

SPIRIT IV was the fourth clinical study of the XIENCE V[®] stent. This is the largest study of the four randomized SPIRIT clinical trials and was conducted in the United States. A total of 3,687 patients were given either the XIENCE V[®] stent or the TAXUS Express stent (TAXUS stent). There were 2,458 patients who received the XIENCE V[®] stent and 1,229 patients who received the TAXUS stent.

After one year, the XIENCE V stent was significantly better than the TAXUS stent at reducing the need for

The SPIRIT Family of Clinical Trials *(continued)*

bypass surgery or repeat angioplasty where the stent was placed. The total rate of cardiac death, heart attacks, and bypass surgery or repeat angioplasty where the stent was placed, was significantly lower for the XIENCE V stent (4.0%) compared to the TAXUS stent (6.8%) at one year.

SPIRIT Small Vessel

The SPIRIT Small Vessel clinical study was conducted in the United States to evaluate the performance of the XIENCE nano™ stent (smallest diameter XIENCE V® stent) in small coronary arteries. There were 144 patients who received the XIENCE nano™ stent.

After one year, the rate of occurrence of events related to target lesion failure, which includes cardiac death, heart attacks, bypass surgery or repeat angioplasty at the site of the lesion, was 8.1% with the XIENCE nano™ stent.

For patients treated with the XIENCE V® stent in ways not studied in these clinical trials, clinical results may vary.

Your Drug-Eluting Stent 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 thienopyridine medications such as Plavix® or Effient®
- Make sure your doctor knows about any allergies you have
- Refrain from eating and drinking after midnight on the night before your treatment
- 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 not be put to sleep. There are two reasons for this. First, most people find they experience little to no discomfort from the procedure. Secondly, your doctor may need to 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

Your Drug-Eluting Stent Procedure *(continued)*

balloon is inflated. This is normal and will quickly fade when the balloon is deflated.

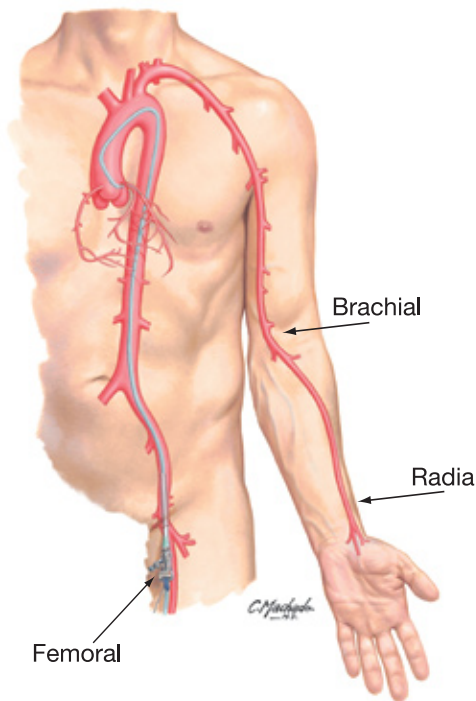
Your Drug-Eluting Stent Placement Procedure

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 sticky patches to your chest and using a specialized ECG recorder and monitor.

The groin is the most common site for catheter introduction and requires a very small skin incision 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 incision 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 stenting procedure.

Your Drug-Eluting Stent Procedure (continued)

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).



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

Your Drug-Eluting Stent Procedure

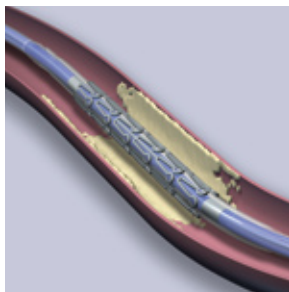
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After the catheters are inserted, your doctor will inject a contrast dye through the guiding catheter into your artery to view the narrowing. Your doctor will watch the injection on an X-ray monitor, much like a TV screen. While these X-rays are being 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.

Using the guiding catheter, a balloon catheter is positioned in the narrowing in the coronary artery and the balloon is then inflated. This compresses the plaque and widens the coronary artery. This procedure is called pre-dilatation.

Step 1:

The stent mounted on a balloon catheter is delivered to the narrowing in the coronary artery by a delivery catheter.

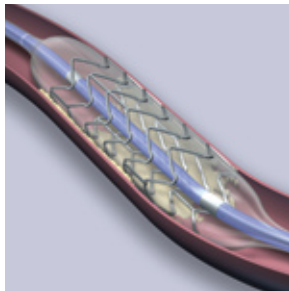


Step 1

Your Drug-Eluting Stent Procedure (continued)

Step 2:

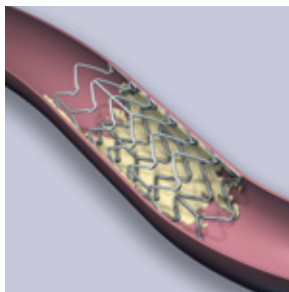
The balloon is then inflated and this expands the stent, pressing it against the coronary artery wall. Your doctor may choose to expand the stent further by using another balloon so that the stent can make better contact with the artery wall. This is known as post-dilatation.



Step 2

Step 3:

Once in place, the PROMUS stent will remain as a permanent implant in your coronary artery.



Step 3

Your Drug-Eluting Stent Procedure

(continued)

Immediately after Procedure

You will be asked to lie flat for four to six hours following the procedure and to not bend your leg or arm, depending on which area your doctor used to insert the catheters. Pressure will also be placed on the area.

A vascular closure device may be used to seal the incision site in your groin or arm. You will be allowed to get up and walk around sooner if this type of device is used. Your hospital stay may range from one to three days.

Medications will be prescribed for you before and after stent placement. Antiplatelet medications such as aspirin and thienopyridine medications (such as Plavix[®] or Effient[®]) are the most commonly prescribed. They help prevent a blood clot (thrombus) from forming and blocking the stent lumen. Your doctor or nurse will give you instructions about your medications before you leave the hospital.

CAUTION: If you have any chest pain, or discomfort or bleeding from your incision site, call your doctor immediately. If your doctor is

Your Drug-Eluting Stent Procedure

(continued)

unavailable, call for an ambulance to take you to the nearest hospital emergency room.

Take All Medications as Instructed

After you leave the hospital, your cardiologist will instruct you to take a daily dose of aspirin and another antiplatelet drug such as Plavix® or Effient®. Your doctor will tell you how long you should continue taking the antiplatelet drugs. It is very important that you take these medications exactly as your doctor instructs you:

- Follow your medication schedule exactly to avoid possible complications after you receive your stent. Do not miss any doses.
- Call your doctor if you cannot keep taking your medications because of side effects such as rash, bleeding, or upset stomach.
- **CAUTION: Do not stop taking your prescribed medications unless you are instructed to do so by the doctor who performed your stent procedure.**
- **CAUTION: Notify your cardiologist or family doctor if you are scheduled to see the dentist while on antiplatelet medication. Your doctor may prescribe antibiotics to avoid the potential of an infection. You should review with your**

Your Drug-Eluting Stent Procedure (continued)

doctor any recommendations from your dentist to stop your prescribed medications.

- **CAUTION:** Before undergoing implantation of a drug-eluting stent, if you plan to have any type of surgery that may require you to stop taking antiplatelet medications, you and your cardiologist should discuss whether or not placement of a drug-eluting stent is the right treatment choice for you.

If surgery or dental work that would require you to stop taking antiplatelet medications is recommended after you have received the stent, you and your doctors should carefully consider the risks and benefits of this surgery or dental work versus the possible risks from early discontinuation of these medications.

If you do require discontinuation of antiplatelet medications because of significant bleeding, your cardiologist will carefully monitor you for possible complications. Once your condition has stabilized, your cardiologist may put you back on these medications.

Your Drug-Eluting Stent Procedure

(continued)

Follow-up Care

You will be discharged to the care of your cardiologist or family doctor. You should be able to return to your normal activities soon.

CAUTION: Notify your doctor immediately if you experience chest pain (angina), or notice any changes such as more severe or frequent chest discomfort, especially in the first month after a procedure. These symptoms may indicate a re-narrowing in your coronary arteries.

Your doctor will ask you to return for follow-up visits. The first visit is usually two to four weeks after your stent is implanted, with follow-up visits every six months for the first year. Be sure to keep all appointments for follow-up care, including blood tests.

Keep Your ID Card Handy

CAUTION: Show your identification card if you report to an emergency room. This card identifies you as a patient who has had a stent implanted.

Your Drug-Eluting Stent Procedure *(continued)*

If you require a magnetic resonance imaging (MRI) scan, tell your doctor or MRI technician that you have a stent implant. Test results indicate that patients with single or overlapped PROMUS stents can undergo MRI scans safely under the following conditions:

- Static magnetic field of 1.5 or 3 Tesla
- Spatial gradient field of 2500 Gauss/cm or less
- Maximum whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode) for each duration of a sequence

The stent(s) should not migrate in this MRI environment, and MRI may be performed immediately following the implantation of the PROMUS stent(s). Prior to undergoing an MRI scan, inform your doctor that you have a PROMUS Everolimus-Eluting Coronary Stent.

Preventing CAD

Coronary artery disease can be treated effectively, but it has no cure. You can help to prevent your coronary artery disease from progressing by carefully following your doctor's advice. Your doctor may prescribe medications to help control your blood pressure, diabetes, and/or high cholesterol. Your doctor may also recommend some lifestyle changes. Among the healthy choices you can make:

Stop smoking. If you smoke, quitting is the single most important thing you can do to lower your risk of coronary artery disease. Chemicals in cigarette smoke may make it easier for plaque to build up on your artery walls. And smoking increases your heart rate and blood pressure, raising your risk of heart attack and stroke. If you are ready to quit, ask your doctor for advice—he or she can recommend smoking cessation aids to help you quit.

Increase your activity and eat a healthy diet. A sedentary lifestyle increases your risk. Your doctor can recommend an activity program tailored for your situation. Regular exercise can help you lower your blood pressure and blood cholesterol and reach a healthy weight. It can also help you manage the daily stresses of modern life more easily. Choose a healthy diet. A diet low in saturated fats and

Preventing Coronary Artery Disease *(continued)*

cholesterol and rich in lean protein, fresh fruits, vegetables and whole grains, can help you achieve a healthy weight, as well as help you control your blood pressure and cholesterol levels.

Manage your stress. Stress is an inescapable aspect of modern day living, but you can help lessen its negative health effects by practicing the “relaxation response.” Research has shown that relaxation techniques can improve your ability to cope with stressful events while decreasing your heart rate, blood pressure, and stress hormone levels.

Frequently Asked Questions

How long will the stent stay in my body?

Stents are designed to stay in your body permanently.

What are the restrictions or cautions after I've received a stent?

If you require magnetic resonance imaging (MRI), tell your doctor or MRI technician that you have an implanted stent.

When can I resume my regular activities?

Your doctor will advise you. Many patients can return to work and follow their normal routine about a week after their stent procedure.

Will my stent set off the metal detector at airport security checkpoints?

No, your stent implant will not trigger alarms at security checkpoints.

Will I be able to feel the stent inside me?

No, you will not be able to feel the stent once it has been implanted in your artery.

Frequently Asked Questions

(continued)

Could I have recurring symptoms?

Yes, it is possible that you will experience symptoms again, either due to a new blockage in the region treated with the stent or due to a blockage at another place in your coronary arteries. Your doctor will monitor your progress.

How can I help prevent a recurrence of symptoms?

While there is no sure way to prevent a recurrence of symptoms, you can reduce the risk through exercise, not smoking, and eating a healthy diet. Your doctor can advise you about lifestyle changes.

Definition of Medical Terms

Angina: Chest pain caused by inadequate supply of blood to the heart.

Angioplasty (also referred to as PTCA or balloon angioplasty): A minimally invasive procedure in which a balloon dilatation catheter is passed through to the blocked area of an artery. Once inflated the catheter compresses the plaque against the blood vessel wall and enlarges the vessel opening. An angioplasty can also be performed with placement of a stent.

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

Antiplatelet: A substance to reduce clumping of platelets in the blood. An antiplatelet medicine helps thin the blood to prevent clot formation.

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

Cardiac Catheterization Laboratory (Cath Lab): A sterile X-ray theater in which heart catheterization is performed.

Definition of Medical Terms

(continued)

Catheter: A thin, hollow, flexible tube used to access the coronary arteries during an angiogram or during an angioplasty procedure. This catheter can be used to inject medication, fluids, or contrast dye during your procedure. Catheter is also used to describe the device used to deliver the balloon or stent during an angioplasty procedure.

Coronary Angiography (or Heart Catheterization or Cardiac Cath): A test in which contrast dye is injected to create images of the coronary arteries and the chamber of the heart. This allows the doctor to see the extent of the disease in the coronary arteries and make a decision on how to best treat the blockages.

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

Coronary Artery Bypass Graft Surgery (CABG): Open-heart surgery to treat CAD.

Definition of Medical Terms

(continued)

Coronary Artery Disease (CAD): The formation of blockages or atherosclerotic plaques within coronary arteries that result in restricted blood flow to the heart muscle.

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 muscle are damaged due to decreased blood flow to the heart muscle.

Femoral Artery: The main artery of the thigh, supplying blood to the leg.

Fluoroscope: An X-ray device that creates an image of the body that can be viewed on a TV monitor. This permits the doctor to obtain real-time images of the internal structures of a patient.

In-stent Restenosis: Recurrent blockage or narrowing of a previously stented vessel.

Local Anesthetic: A substance used to numb the area to which it is applied.

Definition of Medical Terms

(continued)

Lumen: The inner channel or cavity of a vessel or tube. In a blood vessel, it is the opening through which blood flows.

Myocardial Infarction (MI): Also called a heart attack. Permanent damage of an area of the heart tissue, due to interruption in the blood flow to the heart muscle (myocardium).

Magnetic Resonance Imaging (MRI): A non-invasive diagnostic procedure used to obtain images of internal body structures through the use of magnets and radio waves.

Percutaneous: Performed through the skin.

Plaque: An accumulation or build-up of fatty deposits, calcium, white blood cells, and other substances in the wall of an artery that results in narrowing of the vessel lumen.

Restenosis: A recurring blockage caused by the excessive growth of scar tissue inside the artery or stent, following an interventional procedure such as angioplasty.

Definition of Medical Terms

(continued)

Stent: A metallic mesh tube that is implanted into an artery during an angioplasty, providing a scaffold to help hold the artery open, ensuring blood flow to the heart muscle.

Transluminal: Through the inside opening of a vessel or artery.

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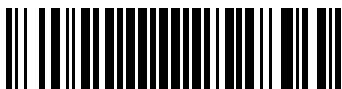
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