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FRONT COVER



Xience
Everolimus Eluting
Coronary Stent System

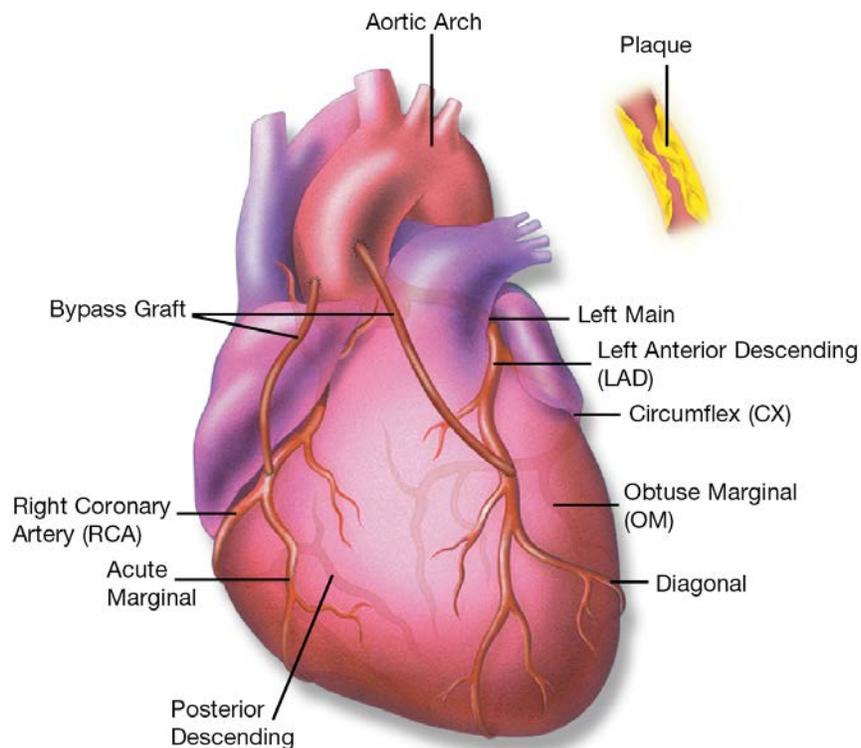
Patient Information Guide



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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, an inadequate supply of nutrients and oxygen are not available to be delivered. Therefore, treatment may be required to restore blood flow and the vital supply of oxygen to the heart.

What is CAD?

Coronary artery disease, or CAD is the most common form of heart disease. It is a condition that occurs when the coronary 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 of plaque formation and narrowing of the vessel diameter is called “atherosclerosis.” Reduction of blood flow to the heart muscle can cause chest pain (angina), shortness of breath, sweating, and pain down the arms (most commonly the left arm). Narrowing of a heart blood vessel that results in a complete blockage can progress gradually or can occur suddenly resulting in a heart attack, known as a myocardial infarction. Heart attacks cause irreversible damage to the heart muscle. Unfortunately the first symptom of CAD may be sudden death without any other “warning” signs.

Advancements in medical understanding and treatment, earlier recognition of disease, and improved testing, combined with earlier diagnosis, and increased public awareness of the heart disease symptoms and risk factors have helped to reduce the death rates associated with 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 both associated with the reduction of blood flow to the heart muscle due to narrowing of heart blood vessels. 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 and difficulty with breathing may occur with increased activity or stress.

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
- Dizziness

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. These symptoms occur intermittently or, as the narrowing worsens, at a more frequent interval.

There are some patients who report no symptoms of CAD. It is possible to have a heart

attack without experiencing any symptoms.

Recent research has shown that women may experience different CAD symptoms from men and therefore are may be 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. Given a lack of awareness that these different in symptoms could be due to the CAD, women may be less likely than men to realize they are suffering a heart attack and seek 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

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:

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

¹ Menopausal 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.

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). An ECG is noninvasive and requires pads to be placed on your chest to measure the heart's electrical activity.

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. The test is performed by having the patient exercise on a treadmill or, if he/she is unable to walk, receive medication to mimic exercise to “stress” the heart.

Echocardiography is a heart exam using sound waves. It can be performed with a probe placed on the chest, or the probe is placed in the food pipe (esophagus) while the patient is under anesthesia.

Troponin, CK-MB, CK are enzymes that are released into the bloodstream when cardiac muscle cells are injured due to reduced blood flow. Blood tests for these enzymes are performed to help determine if a patient is suffering a heart attack.

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. 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 and the affected areas of the heart muscle.

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.

If the CAD is mild, it can often 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 lower cholesterol, reduce blood pressure, and relieve your chest pain by increasing blood flow to your heart.

However, because dietary changes and medicine may not clear the severity of the 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.

Surgery

Coronary artery bypass graft surgery (CABG surgery) 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 at 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 minimally invasive, or nonsurgical, procedure used to open blocked arteries. You may also hear it referred to as Percutaneous Transluminal Coronary Angioplasty (PTCA). This procedure is performed under local, and at times, monitored sedation in a cardiac catheterization laboratory. A catheter with a small balloon mounted on the end is passed into the coronary artery after it is inserted through the femoral (leg) or radial (wrist) artery. The catheter is then positioned at the narrowed portion of the artery and the balloon is inflated. As the balloon inflates, it stretches the wall of the coronary artery and compresses the plaque. The balloon is then deflated, and the catheter is removed from the artery. 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.

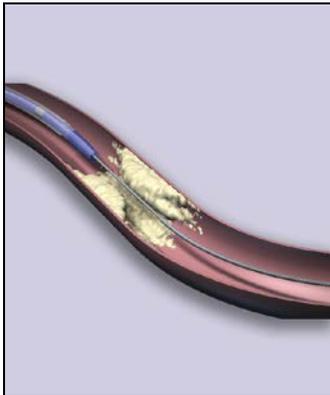
Although balloon angioplasty enlarges the lumen of coronary arteries, some patients may develop re-narrowing of the vessel in the months following the procedure. This process is called restenosis, and it is caused by the growth of scar tissue within the coronary artery.

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.

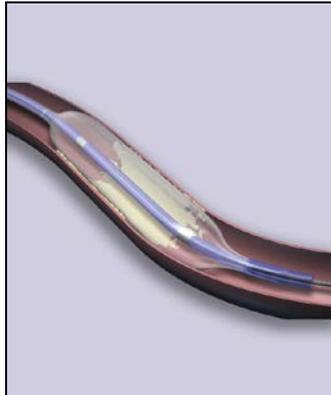
Step 2: The balloon is inflated, pushing out against the wall of the artery and compressing the plaque. The balloon is deflated and the catheter is removed.

Step 3: The inside of the blood vessel is now larger and the blood flow is improved.

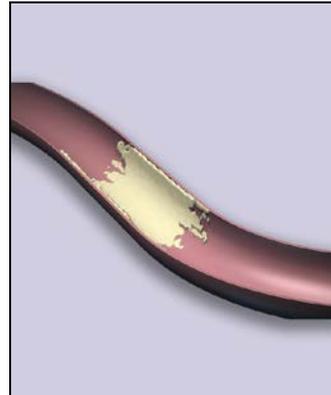
Step 1



Step 2



Step 3



Coronary Artery Stents

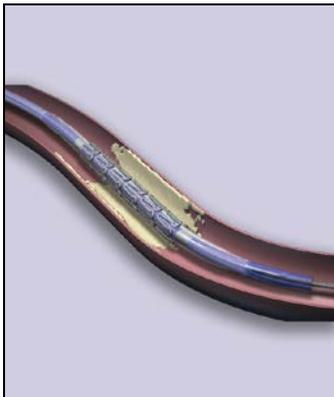
Coronary artery stents are devices (small metallic mesh tubes) that are placed over a balloon catheter and delivered to the narrowed portion of the coronary artery. The balloon is used to expand the stent. The stent presses against the narrowed vessel wall, holding the vessel open. This results in a wider artery 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 2: The stent expands against the vessel wall as the balloon is inflated.

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.

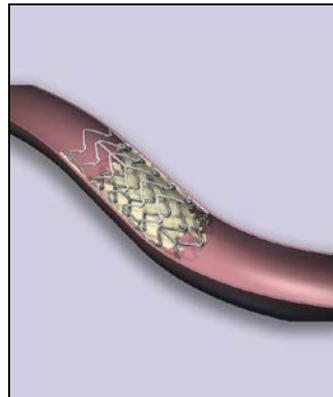
Step 1



Step 2



Step 3

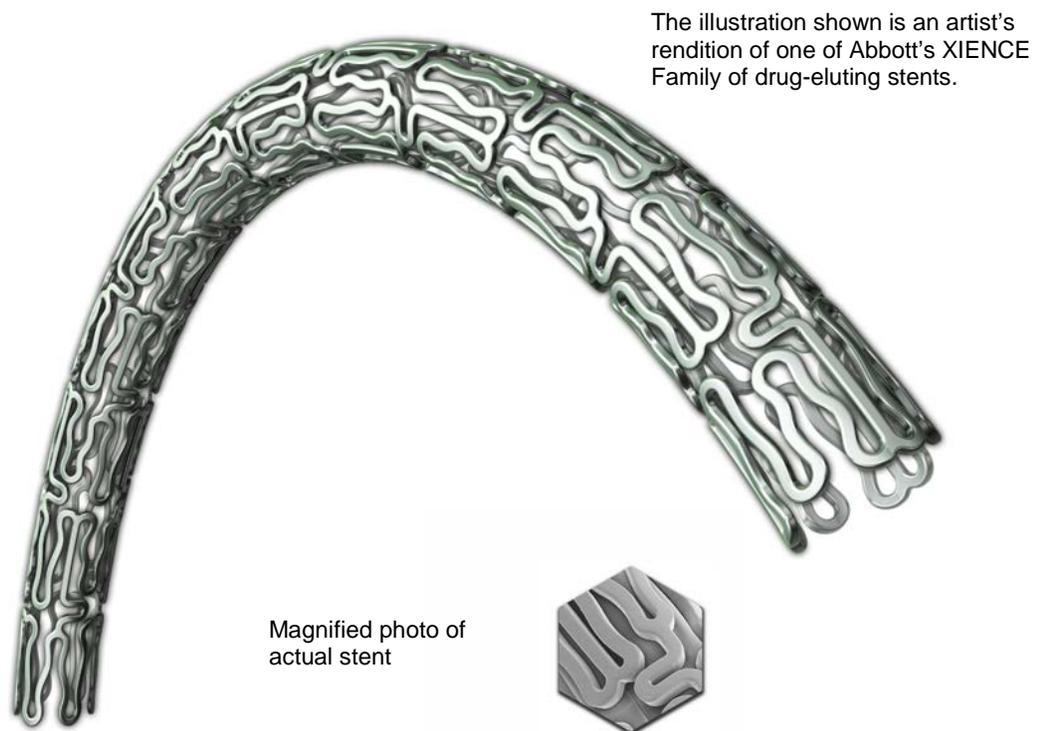


Coronary artery stents are less invasive than bypass surgery. Stenting involves a shorter hospital stay – usually one to three days – and faster recovery than surgery. However, restenosis can also occur in some patients who receive stents (in-stent restenosis), due to the build-up of scar tissue within 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 are coated with a drug and provide the same structural support as uncoated stents. The drug is released over time, helping to prevent restenosis by limiting the overgrowth of normal tissue within the stent.

XIENCE Family of Coronary Stents



The XIENCE Family of Coronary Stents is intended for use by or under the direction of a physician.

The XIENCE Family of Coronary Stents includes the following: Everolimus Eluting Coronary Stent Systems – XIENCE V, XIENCE nano, XIENCE PRIME, XIENCE PRIME LL, XIENCE Xpedition SV, XIENCE Xpedition, XIENCE Xpedition LL, and XIENCE Alpine. The differences between the various XIENCE systems involve differences in sizes (diameter and length) as well as differences in the stent design and delivery system. Going forward in this document, the XIENCE V, XIENCE nano, XIENCE PRIME, XIENCE PRIME LL, XIENCE Xpedition SV, XIENCE Xpedition, XIENCE Xpedition LL, and XIENCE Alpine systems will be referred to as the “XIENCE Family of Coronary Stents” or as “XIENCE stents.” The XIENCE Family of Coronary Stents is designed to prevent re-narrowing within the stent (in-stent restenosis). These stents consist of a medical grade cobalt

chromium stent with a thin coating of a drug called everolimus on its surface. This stent 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 XIENCE stents 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 XIENCE Family of Coronary Stents is available in various diameters and lengths (reference **Table 1** below).

Table 1: XIENCE Family Size Matrix

	Available Stent Diameters	Available Stent Lengths
XIENCE V	2.5, 2.75, 3.0, 3.5, 4.0 mm	8, 12, 15, 18, 23, 28 mm
XIENCE nano	2.25 mm	8, 12, 15, 18, 23, 28 mm
XIENCE PRIME	2.25, 2.5, 2.75, 3.0, 3.5, 4.0 mm	8, 12, 15, 18, 23 mm
XIENCE PRIME LL	2.25*, 2.5, 2.75, 3.0, 3.5, 4.0 mm	28, 33, 38 mm
XIENCE Xpedition SV	2.25 mm	8, 12, 15, 18, 23, 28 mm
XIENCE Xpedition	2.5, 2.75, 3.0, 3.25, 3.5, 4.0 mm	8, 12, 15, 18, 23, 28 mm
XIENCE Xpedition LL	2.5, 2.75, 3.0, 3.25, 3.5, 4.0 mm	33 and 38 mm
XIENCE Alpine	2.25**, 2.5, 2.75, 3.0, 3.25, 3.5, 4.0 mm	8, 12, 15, 18, 23, 28, 33, 38 mm

* The 2.25 mm stent diameter for XIENCE PRIME LL is only available in the 28 mm stent length.

** The 2.25 mm stent diameter for XIENCE Alpine is not available in the 33 and 38 mm stent lengths.

Contraindications

- If you have a known hypersensitivity (allergy) or contraindication to everolimus or structurally-related compounds cobalt, chromium, nickel, tungsten, acrylic, and 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 XIENCE Family of Coronary Stents

The risk of using the XIENCE 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:

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
- 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, and fluoropolymer)

- 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 of drug in your blood from the XIENCE V 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 collection of a clear fluid containing white blood cells
- Acne
- Blood clot in the vein
- Constipation
- Cough
- Decreased functioning of sexual organs in men
- Decreased platelet cell count
- Decreased red or white blood cells
- Decreased sense of taste
- Destruction of red blood cells
- Destruction of the kidney tubules
- Diarrhea
- Dry or itchy skin
- Fatigue
- Fever
- Headache
- Higher levels of potassium and lower levels of magnesium and phosphorus in the blood

- Increased blood cholesterol
- Increased blood pressure
- Increased blood sugar
- Increased fat and triglyceride fats in the blood
- Infection of the lungs
- Infections
- Inflammation of the lining of the digestive system
- Insomnia
- Kidney function test abnormality
- Lack or loss of strength
- Liver function test abnormality
- Loss of appetite
- Loss of blood supply to the bone
- Mouth ulcers or sores
- Muscle pain
- Nausea
- Nose bleeds
- Pain in the arms and legs
- Painful urination
- Presence of red blood cells in the urine
- Rash
- Shortness of breath and lung or breathing problems
- Surgical wound complication
- Tremor
- Vomiting
- Water retention in the body

Exposure to drug and polymer on the XIENCE Family of Coronary Stents is directly related to the number and lengths of the stents implanted. The use of multiple XIENCE stents will result in you 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 XIENCE 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

There have been five clinical trials that together shown the safety and effectiveness of the XIENCE Family of Coronary Stents in patients with coronary artery disease. A short description of some of these 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 XIENCE V stent had fewer major adverse cardiac events (16.7%) compared to patients who received the metallic stent (28.0%). (Major adverse cardiac events included death due to cardiac causes, heart attack, or the need for coronary artery 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 five years, patients who had received the XIENCE V stent had a rate of major adverse cardiac events of 8.9% compared to a rate of 20.3% 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 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 five years, patients who had received the XIENCE V stent had a rate of major adverse cardiac events of 14.4% compared to a rate of 22.0% 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 bypass surgery or repeat angioplasty at the site of the lesion where the stent was placed. The occurrence of target lesion failure (which is comprised of cardiac death, heart attacks, bypass surgery or repeat angioplasty at the site of the treated lesion) was significantly lower in patients treated with XIENCE V stents (9.5%) compared to TAXUS stents (11.9%) at three years.

SPIRIT Small Vessel

The SPIRIT Small Vessel clinical study was conducted in the United States to evaluate the performance of the 2.25 mm diameter XIENCE stent (XIENCE nano) in small coronary arteries. There were 144 patients who received the XIENCE nano stent.

After three years, the rate of target lesion failure (which is comprised of cardiac death, heart attacks, bypass surgery, or repeat angioplasty at the site of the lesion, was 12.1% with the XIENCE nano stent.

SPIRIT PRIME

The SPIRIT PRIME clinical study was conducted globally to evaluate the performance of the XIENCE PRIME family of stent systems. There were 415 patients enrolled in the Core Size Registry (stent diameters 2.25, 2.5, 3.0, 3.5, 4.0 mm with stent lengths 8, 18, and 28 mm) and 110 patients enrolled in the Long Lesion Registry (stent diameters 2.5, 3.0, 3.5, 4.0 mm, with stent lengths 33 and 38 mm) at up to 75 global sites.

After three years, the rate of target lesion failure (which is comprised of cardiac death, heart attacks, bypass surgery, or repeat angioplasty at the site of the treated lesion) was 8.5% in the Core Size Registry patients and 9.6% in the Long Lesion Registry patients.

For patients treated with the XIENCE Family of Coronary Stents in ways not studied in these clinical trials, clinical results may vary.

Other Key Clinical Trials and Studies

XIENCE V USA

After the XIENCE V stent was approved for use in the United States, the XIENCE V USA clinical study was conducted to evaluate the continued safety and effectiveness of the XIENCE V stent in a wide range of patients. A total of 8,040 patients were enrolled from 191 sites in the United States.

At four years, 1.56% of patients experienced a stent-associated blood clot. In addition, the occurrence of cardiac deaths or heart attacks was 14.9% at four years with the XIENCE V stent.

DIABETES MELLITUS STUDY

The safety and effectiveness of treatment with XIENCE stents in patients with diabetes was evaluated using one-year data from diabetic patients enrolled in selected Abbott Vascular studies (SPIRIT IV, SPIRIT PRIME and XIENCE V USA) plus data from diabetic patients followed in hospital registry studies maintained at the Cleveland Clinic and Wake Forest University . A total of 1239 diabetic patients treated with at least one XIENCE stent were evaluated (949 from Abbott Vascular trials and 290 from the hospital databases). The rate of target vessel failure (which is comprised of cardiac death, target-vessel myocardial infarction or ischemia driven target vessel revascularization) was 8.0%.

EXPERT CTO

The EXPERT CTO clinical study was designed to evaluate the safety and performance of the XIENCE stent systems in completely blocked coronary arteries. There were 250 patients enrolled in the study at 20 sites across the United States. At one year, the rate of major adverse cardiac events (which is comprised of death, heart attacks, bypass surgery, or repeat angioplasty at the site of the lesion) was 18.5% in patients treated with the XIENCE stent.

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. Firstly, 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.

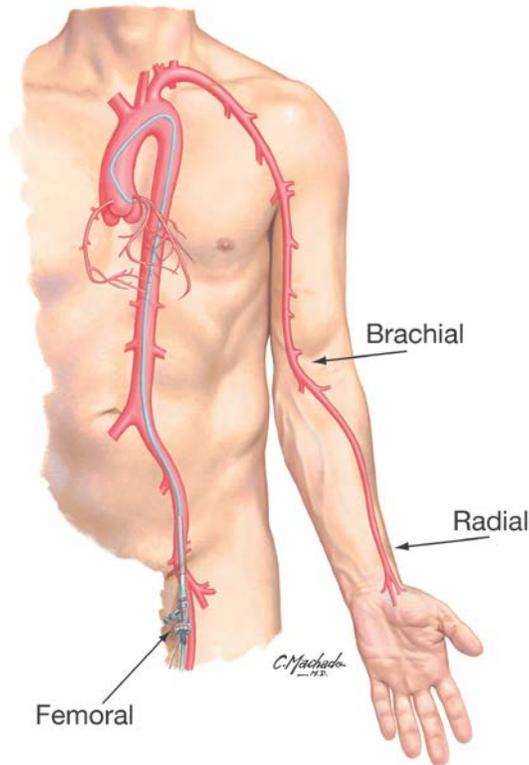
The procedure usually lasts about 90 minutes, during which time your doctor will ask you to remain very still. For the most part, you will be comfortable, but you may feel some pressure or chest pain when the balloon is inflated. This is normal and will quickly fade when the balloon is deflated.

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.

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).



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

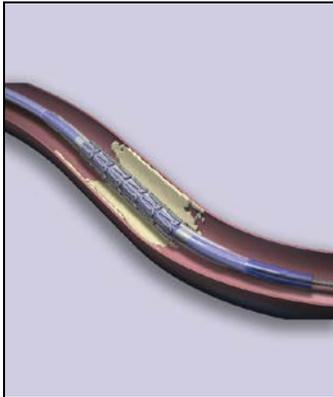
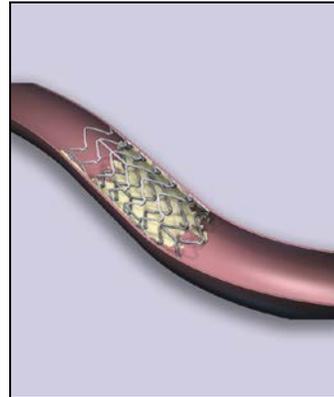
After the catheters are inserted, your doctor will inject a contrast dye through the guiding catheter into your artery to view the narrowing. Your doctor will watch the injection on an X-ray monitor, much like a TV screen. While these X-rays are being taken, your doctor may ask you to take a deep breath 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 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 3: Once in place, the XIENCE stent will remain as a permanent implant in your coronary artery.

Step 1**Step 2****Step 3**

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 other blood thinning medications (such as Plavix, Effient, or Brilinta) 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 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, Effient, or Brilinta. 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 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.

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.

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 XIENCE stents are MR conditional. Patients with single or overlapped XIENCE 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 15 minutes of scanning for each sequence.

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

Control you blood pressure and cholesterol. Discuss with your doctor the ways you can control you blood pressure and cholesterol to reduce your risk of cardiac problems.

Manage your diabetes. If you have diabetes, keep your sugar and glucose levels within target levels to help reduce the risk of coronary artery disease.

Manage your medications. Continue to take your medication as prescribed, whether for high blood pressure, elevated cholesterol levels and/or anti-platelet management post procedure.

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. Please confirm with your physician.

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.

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. If you experience chest pain symptoms similar to those you had when you presented with angina or heart attack, please notify your physician.

How can I help prevent a recurrence of symptoms?

While there is no sure way to prevent a recurrence of symptoms, you can reduce your risk through exercise, not smoking, controlling your blood pressure and cholesterol, taking prescribed medications, 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): 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 by thinning the 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) and scar tissue within the artery wall. The build-up is sometimes referred to as “plaque.”

Brachial artery: The site at the arm for insertion of the catheter to perform angiogram and/or angioplasty.

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. 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 (CABG) Surgery: Open-heart surgery to treat CAD.

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. Often used as an access site to perform coronary angioplasty.

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.

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 without requiring a deep incision.

Plaque: An accumulation or build-up of fatty deposits, calcium, inflammatory cells, and scar tissue in the artery wall 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.

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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