Xience™

Everolimus Eluting Coronary Stent System

PATIENT INFORMATION GUIDE

Abbott

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YOUR CONTACT AND DEVICE INFORMATION

Have your doctor or nurse help you complete the information below.

Doctor name: _____

Phone number: _____

Address: _____

Hospital name: _____

Phone number: _____

Address: _____

Catalogue number: _____

Lot number: _____

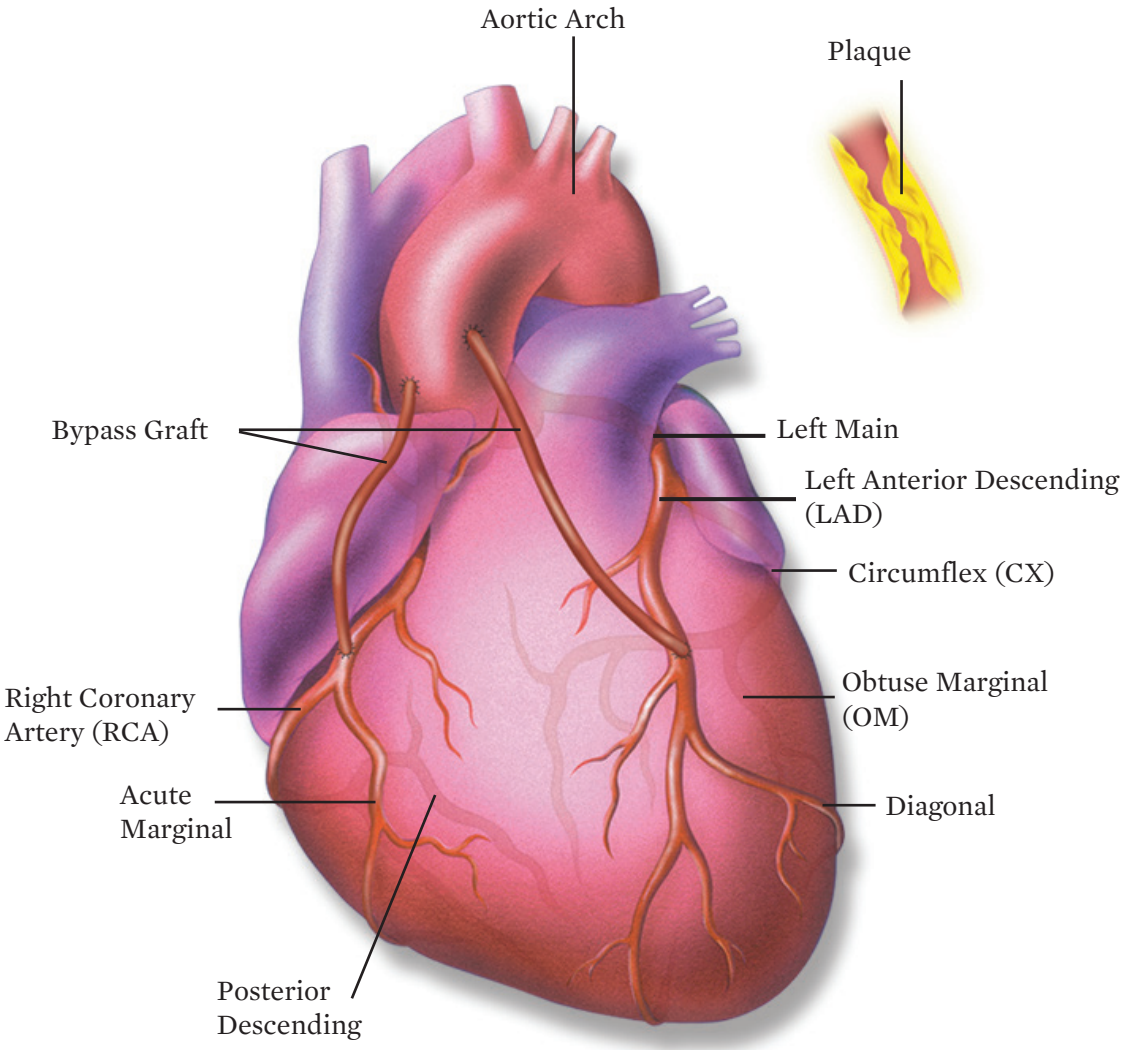
Unique device identifier (UDI) number: _____

Device description: _____

_____

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

CORONARY VASCULATURE



CORONARY ARTERY DISEASE (CAD)

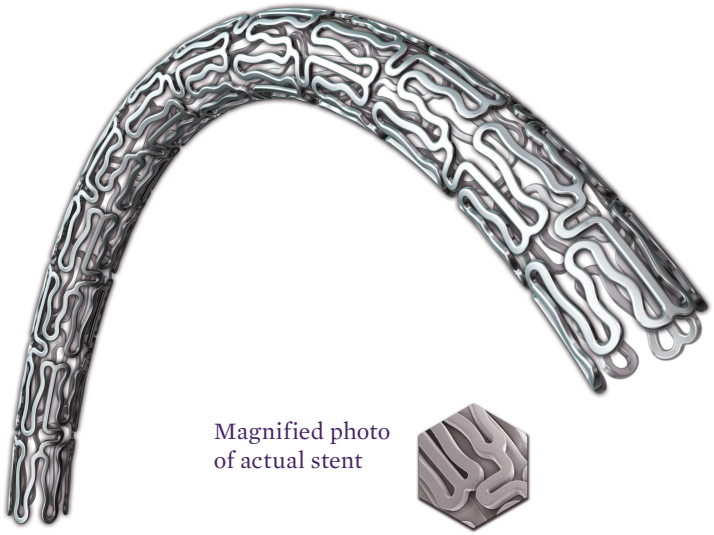
The main blood vessels that supply blood and nutrients to your heart are called coronary arteries. Your doctor has determined or suspects that at least one of your coronary arteries has a significant narrowing due to gradual build-up of “plaque” that is causing reduced blood flow to your heart. This can cause you to have pain in your chest, shortness of breath either on exercise or at rest, limitation of daily activities and / or other symptoms.

DRUG-ELUTING STENTS (DES)

You can be treated by placing one or more flexible metal mesh tubes coated with medication (called drug-eluting stent) inside the artery to keep it open. The drug is released over time helping to prevent renarrowing of the coronary arteries after your procedure. This renarrowing process is called restenosis, and it is caused by the growth of scar tissue within the coronary artery where the stent was placed. The stents are implanted to improve blood flow to the heart.

XIENCE™ FAMILY OF CORONARY STENTS

The illustration shown is an artist's rendition of one of Abbott's XIENCE Family of drug-eluting stents.



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

The XIENCE Family of Coronary Stents includes the following: Everolimus Eluting Coronary Stent Systems – XIENCE Skypoint™, XIENCE PRO™S, and XIENCE PRO™ 48.

The differences between the various members of the XIENCE Family of Stents 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 Skypoint, XIENCE PROS, and XIENCE PRO 48 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 are made of medical grade cobalt chromium. The stent provides support to the artery. The stent is coated with 2 polymers (a type of plastic). The first polymer called poly n-butyl methacrylate (PBMA) is inactive and adheres to the stent and the polymer containing the drug everolimus. The second polymer called poly vinylidene fluoride-co-hexafluoropropylene (PVDF-HFP) is inactive and it contains the drug, everolimus. 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. Everolimus is a drug which slows or stops the growth of new cells. It is released over time, helping to prevent overgrowth of cells or tissue within the stent.

The information contained in this guide covers the XIENCE Family of Everolimus Eluting Coronary Stent Catalogue Numbers. The exact stent, catalogue number(s), and size(s) that you received can be located on the Patient Implant Card that was provided to you upon your discharge.

XIENCE™ FAMILY OF CORONARY STENTS

(continued)

Table 1: XIENCE Skypoint Everolimus Eluting Coronary Stent

Catalogue Number	Stent Size (Diameter x Length)	Catalogue Number	Stent Size (Diameter x Length)
1800200-08	2.0 x 8 mm	1800300-33	3.0 x 33 mm
1800200-12	2.0 x 12 mm	1800300-38	3.0 x 38 mm
1800200-15	2.0 x 15 mm	1800300-48	3.0 x 48 mm
1800200-18	2.0 x 18 mm	1800325-08	3.25 x 8 mm
1800200-23	2.0 x 23 mm	1800325-12	3.25 x 12 mm
1800200-28	2.0 x 28 mm	1800325-15	3.25 x 15 mm
1800200-33	2.0 x 33 mm	1800325-18	3.25 x 18 mm
1800200-38	2.0 x 38 mm	1800325-23	3.25 x 23 mm
1800225-08	2.25 x 8 mm	1800325-28	3.25 x 28 mm
1800225-12	2.25 x 12 mm	1800325-33	3.25 x 33 mm
1800225-15	2.25 x 15 mm	1800325-38	3.25 x 38 mm
1800225-18	2.25 x 18 mm	1800350-08	3.5 x 8 mm
1800225-23	2.25 x 23 mm	1800350-12	3.5 x 12 mm
1800225-28	2.25 x 28 mm	1800350-15	3.5 x 15 mm
1800225-33	2.25 x 33 mm	1800350-18	3.5 x 18 mm
1800225-38	2.25 x 38 mm	1800350-23	3.5 x 23 mm
1800250-08	2.5 x 8 mm	1800350-28	3.5 x 28 mm
1800250-12	2.5 x 12 mm	1800350-33	3.5 x 33 mm
1800250-15	2.5 x 15 mm	1800350-38	3.5 x 38 mm
1800250-18	2.5 x 18 mm	1800350-48	3.5 x 48 mm
1800250-23	2.5 x 23 mm	1800400-08	4.0 x 8 mm
1800250-28	2.5 x 28 mm	1800400-12	4.0 x 12 mm
1800250-33	2.5 x 33 mm	1800400-15	4.0 x 15 mm
1800250-38	2.5 x 38 mm	1800400-18	4.0 x 18 mm
1800250-48	2.5 x 48 mm	1800400-23	4.0 x 23 mm
1800275-08	2.75 x 8 mm	1800400-28	4.0 x 28 mm
1800275-12	2.75 x 12 mm	1800400-33	4.0 x 33 mm
1800275-15	2.75 x 15 mm	1800400-38	4.0 x 38 mm
1800275-18	2.75 x 18 mm	1800400-48	4.0 x 48 mm
1800275-23	2.75 x 23 mm	1800450-12	4.5 x 12 mm
1800275-28	2.75 x 28 mm	1800450-15	4.5 x 15 mm
1800275-33	2.75 x 33 mm	1800450-18	4.5 x 18 mm
1800275-38	2.75 x 38 mm	1800450-23	4.5 x 23 mm
1800275-48	2.75 x 48 mm	1800450-28	4.5 x 28 mm
1800300-08	3.0 x 8 mm	1800450-33	4.5 x 33 mm
1800300-12	3.0 x 12 mm	1800500-12	5.0 x 12 mm
1800300-15	3.0 x 15 mm	1800500-15	5.0 x 15 mm
1800300-18	3.0 x 18 mm	1800500-18	5.0 x 18 mm
1800300-23	3.0 x 23 mm	1800500-23	5.0 x 23 mm
1800300-28	3.0 x 28 mm	1800500-28	5.0 x 28 mm
		1800500-33	5.0 x 33 mm

Table 2: XIENCE PROS Everolimus Eluting Coronary Stent

Catalogue Number	Stent Size (Diameter x Length)	Catalogue Number	Stent Size (Diameter x Length)
1508200-08	2.0 x 8 mm	1508300-08	3.0 x 8 mm
1508200-12	2.0 x 12 mm	1508300-12	3.0 x 12 mm
1508200-15	2.0 x 15 mm	1508300-15	3.0 x 15 mm
1508200-18	2.0 x 18 mm	1508300-18	3.0 x 18 mm
1508200-23	2.0 x 23 mm	1508300-23	3.0 x 23 mm
1508200-28	2.0 x 28 mm	1508300-28	3.0 x 28 mm
1508200-33	2.0 x 33 mm	1508300-33	3.0 x 33 mm
1508200-38	2.0 x 38 mm	1508300-38	3.0 x 38 mm
1508225-08	2.25 x 8 mm	1508325-08	3.25 x 8 mm
1508225-12	2.25 x 12 mm	1508325-12	3.25 x 12 mm
1508225-15	2.25 x 15 mm	1508325-15	3.25 x 15 mm
1508225-18	2.25 x 18 mm	1508325-18	3.25 x 18 mm
1508225-23	2.25 x 23 mm	1508325-23	3.25 x 23 mm
1508225-28	2.25 x 28 mm	1508325-28	3.25 x 28 mm
1508225-33	2.25 x 33 mm	1508325-33	3.25 x 33 mm
1508225-38	2.25 x 38 mm	1508325-38	3.25 x 38 mm
1508250-08	2.5 x 8 mm	1508350-08	3.5 x 8 mm
1508250-12	2.5 x 12 mm	1508350-12	3.5 x 12 mm
1508250-15	2.5 x 15 mm	1508350-15	3.5 x 15 mm
1508250-18	2.5 x 18 mm	1508350-18	3.5 x 18 mm
1508250-23	2.5 x 23 mm	1508350-23	3.5 x 23 mm
1508250-28	2.5 x 28 mm	1508350-28	3.5 x 28 mm
1508250-33	2.5 x 33 mm	1508350-33	3.5 x 33 mm
1508250-38	2.5 x 38 mm	1508350-38	3.5 x 38 mm
1508275-08	2.75 x 8 mm	1508400-08	4.0 x 8 mm
1508275-12	2.75 x 12 mm	1508400-12	4.0 x 12 mm
1508275-15	2.75 x 15 mm	1508400-15	4.0 x 15 mm
1508275-18	2.75 x 18 mm	1508400-18	4.0 x 18 mm
1508275-23	2.75 x 23 mm	1508400-23	4.0 x 23 mm
1508275-28	2.75 x 28 mm	1508400-28	4.0 x 28 mm
1508275-33	2.75 x 33 mm	1508400-33	4.0 x 33 mm
1508275-38	2.75 x 38 mm	1508400-38	4.0 x 38 mm

XIENCE™ FAMILY OF CORONARY STENTS

(continued)

Table 3:
XIENCE PRO 48 Everolimus Eluting Coronary Stent

Catalogue Number	Stent Size (Diameter x Length)	Catalogue Number	Stent Size (Diameter x Length)
1017250-48	2.5 x 48 mm	1017300-48	3.0 x 48 mm
1017275-48	2.75 x 48 mm	1017350-48	3.5 x 48 mm

WHAT ARE THE CONTRAINDICATIONS OR SITUATIONS IN WHICH YOU SHOULD NOT BE IMPLANTED WITH A XIENCE™ STENT?

- If you have a known hypersensitivity (allergy) or any other condition not advisable to exposure to everolimus, sirolimus or other sirolimus-derivative drugs, metallic stent components (cobalt, chromium, nickel, tungsten, methacrylic polymer, and fluoropolymers), or radiocontrast agents sensitivity
- If you cannot take aspirin or blood-thinning medications (also called antiplatelet or anticoagulant therapy)

WHAT ARE THE WARNINGS ABOUT USE OF THE XIENCE™ STENT IN YOU?

After the stent is placed inside you, you will have to take medicine that prevents your blood from clotting. An example of medicine that prevents blood clotting is aspirin. Take this medicine as instructed by your doctor. If instructed by your doctor, you may also have to take medicine that thins your blood. Make sure to take all medicine(s) as instructed by your doctor.

POTENTIAL ADVERSE EVENTS (SIDE EFFECTS) ASSOCIATED WITH THE XIENCE™ FAMILY OF CORONARY STENTS AND EVEROLIMUS

The risk of using the XIENCE Stent is the same as standard stent procedures for a narrowed heart vessel. If a blood clot forms inside the stent, you may need to get treated with the same procedure. This may also lead to a heart attack, the need for urgent heart surgery, or death. Even with the successful placement of a stent, there is a chance of the heart vessel narrowing again. This may need more treatment, like placement of another stent or heart surgery. These additional treatments will most likely increase blood flow to your heart. A second balloon catheter may be used after the stent is placed. The balloon catheter will fully expand the stent. The risks from using balloon catheters to expand the stent is similar to the risks for placement of your first stent. The most serious of these risks are emergency surgery, or death.

Some problems associated with the treatment of your narrowed artery and the placement of a stent are listed below. There may be other risks that are not in this list.

Potential Risks

Below are the possible risks that may occur to you with use of the XIENCE Stent. These risks are not specific to the XIENCE Stent and may happen with any stent for heart vessels:

- Allergic reactions or hypersensitivity to rubber, contrast agent, anesthesia, device materials (cobalt, chromium, nickel, tungsten, methacrylic polymer and fluoropolymers), and drug reactions to everolimus, anticoagulation, or antiplatelet drugs

POTENTIAL ADVERSE EVENTS (SIDE EFFECTS) ASSOCIATED WITH THE XIENCE™ FAMILY OF CORONARY STENTS AND EVEROLIMUS *(continued)*

- Vascular complications in arteries used to access the coronary artery which may require blood transfusion or surgical artery repair, including:
  - Complications at the groin or arm access site
  - Bleeding
  - Formation of an abnormal connection between an artery and the vein next to it
  - Leaking of blood from an artery to the surrounding tissue (usually as a result of a puncture to the artery)
  - Weakness in wall of artery (causing possible serious bleeding complications)
  - Partial or complete tear of the wall of the artery
  - Vessel puncture or rupture
  - Movement of air, tissue, plaque, blood clot, or device material (stent or catheter parts) downstream in the arteries resulting in blockage in blood flow
  - Nerve damage caused by compression of the nerves, injury to the nerve, or interruption of blood supply to the nerves
  - Decreased blood supply to the arms and / or legs which may cause cramping or pain
- Complications at the heart arteries which may require additional treatment or surgery, including:
  - Complete blockage of the coronary artery, which may require a repeat procedure or emergency surgery to reopen the coronary artery
  - Formation of an abnormal connection between a heart artery and the vein next to it
  - Leaking of blood from a heart artery to the surrounding tissue (usually as a result of a puncture to the artery)
  - Weakness in wall of the heart artery (causing possible serious bleeding complications)
  - Partial or complete tear of the wall of the artery supplying the heart muscle
  - Puncture or rupture of the wall of the artery supplying the heart muscle
  - Movement of air, tissue, plaque, blood clot, or device material (stent or catheter parts) that partially or completely blocks the heart artery and / or implanted stent
  - Development of blood clots partially or completely blocking blood flow within the artery and / or the implanted stent
  - Narrowing or renarrowing of the treated heart artery
- Complications in the sac around the heart which may require additional treatment, including:
  - Rapid accumulation of blood in the sac around the heart resulting in compression of the heart so it cannot pump out blood to the rest of the body which may require additional treatment or emergency surgery
  - An abnormal accumulation of blood around the heart
  - Inflammation of the tissue around the heart (causing possible chest pain)
- Irregular heartbeats (caused by abnormal electrical activity in the heart from the upper or lower heart chambers)
  - Rapid, irregular beating of the heart's upper chambers. Blood may pool and clot inside the heart, increasing the risk for heart attack and stroke.
  - Rapid, irregular beating of the heart's lower chambers.

POTENTIAL ADVERSE EVENTS (SIDE EFFECTS) ASSOCIATED WITH THE XIENCE™ FAMILY OF CORONARY STENTS AND EVEROLIMUS *(continued)*

- Decreased blood and / or oxygen supply to part of the heart muscle which may cause:
  - Decreased blood supply to heart muscles
  - Heart attack (permanent damage of an area of the heart tissue, due to interruption in the blood flow to the heart muscle)
  - Temporary spasm of the heart arteries
  - Chest pain (which may radiate to jaw or arm) or discomfort caused by inadequate supply of blood to the heart
- Stroke or temporary stroke symptoms as a result of decreased oxygen to the brain causing blurred vision, dizziness, faintness, and numbness
- Abnormal organ function in very ill patients including:
  - Stoppage of the heart
  - Heart function failure (potentially leading to the development of fluid in the lungs and severe breathing difficulty)
  - Lung function failure (potentially leading to severe breathing difficulty)
  - Kidney failure
  - Shock (a life-threatening condition in which blood pressure is too low to maintain adequate-blood flow to your organs)
- Bleeding
- Blood count abnormalities
- Low or high blood pressure
- Infection
- Nausea and vomiting
- Feeling of the heart beating rapidly (palpitations), dizziness, or fainting
- Chest pain
- Fever
- Pain
- Death

Afinitor‡ is the brand name of everolimus developed by Novartis Europharm Limited. It is also marketed as Votubia‡. It is approved in the European Union (EU) to treat adult patients with advanced kidney (renal) cancer, and other advanced tumors when other treatments cannot keep the disease under control. Afinitor‡ is sold under the brand name Zortress‡ or Certican‡ in more than 65 other countries, and it is used in adults to keep the body from rejecting a transplanted kidney, heart, or liver.

The possible side effects of taking everolimus by mouth[1] are listed below. The amount of the drug released in your blood from the stent is several times lower than taking doses of 1.5 milligrams to 10 milligrams daily by mouth.

- Abdominal pain
- Low number of red blood cells that can cause tiredness and shortness of breath. May require a blood transfusion.
- Swelling that happens just below the surface of the skin, most often around the lips and eyes
- Development of blood clots that may block arteries
- Bleeding and clotting disorders (including abnormal early destruction of red blood cells and platelets which may eventually cause kidney failure and blood clots to form in small blood vessels)
- Difficulty passing stool
- Coughing

[1] 1.5 mg to 10 mg/day

POTENTIAL ADVERSE EVENTS (SIDE EFFECTS) ASSOCIATED WITH THE XIENCE™ FAMILY OF CORONARY STENTS AND EVEROLIMUS *(continued)*

- Diabetes (high blood sugar)
- Diarrhea (frequent, loose, watery stools), which can cause dehydration and may require hospitalization and treatment with intravenous fluids
- Shortness of breath
- Fetal injury or death
- Redness of the skin
- Inflammatory skin disease with redness of the skin
- Headache
- Blood clot formation that causes obstruction of the arteries in the liver
- Liver disorders (including inflammation of the liver, yellowing of the skin and eyes, and darkened urine)
- Allergic reaction to everolimus
- High blood pressure
- Infection (symptoms of infection may include fever, pain, redness, and / or difficulty breathing)
- Blood clot formation that causes obstruction of the arteries and / or veins in the kidneys
- Abnormal blood and urine laboratory test results (increases in waste molecules generated from muscle metabolism; abnormal amount of protein in urine; low or high blood potassium concentrations; changes in blood cholesterol and fat parameters; liver function test abnormalities; decreases in red and / or white blood cells and platelets)
- Cancer of the lymph nodes and skin cancer
- Inability to father children (for men)
- Irregular menses (for women)
- Feeling sick to the stomach (nausea)
- Drug interactions resulting in decreased kidney function (and possible kidney failure)
- Inflammation of the lungs caused by autoimmune diseases, chemical burns, or drug reactions, which can cause shortness of breath
- Mouth blisters or sores
- Pain
- Inflammation of the pancreas causing pain in the upper abdomen. This could become severe and cause nausea, vomiting, fever, and rapid heart rate.
- An abnormal accumulation of blood around the heart
- Swelling of arms or legs
- Collection of fluid around the lungs in the chest cavity, which can cause shortness of breath and may require treatment
- Lung infection
- Fever
- Skin rash
- Kidney dysfunction
- Infection of sinuses, nose and throat
- Infection of the urinary system
- Formation of a blood clot that blocks or partially blocks a vein
- Vomiting
- Wound healing complications (including wound infection and an abnormal collection of lymph fluid)

Please tell your doctor about any medicines you are taking. Everolimus may react with these medicines.

POTENTIAL ADVERSE EVENTS (SIDE EFFECTS) ASSOCIATED WITH THE XIENCE™ FAMILY OF CORONARY STENTS AND EVEROLIMUS *(continued)*

If You Experience Adverse Events or Unwanted Effects from Your XIENCE Stent

If you experience any of these adverse events (side effects) or any other unexpected effects because of the XIENCE Stent, please report this to your doctor as soon as possible.

PATIENT EXPOSURE TO MATERIALS AND SUBSTANCES

A patient receiving a XIENCE™ Stent can be exposed to everolimus or structurally related compounds (sirolimus and other sirolimus-derivative drugs) and / or metallic stent and system components (cobalt, chromium, nickel, tungsten, methacrylic polymer and fluoropolymers). Exposure to the stent materials, the drug (everolimus), and the polymers (PVDF-HFP and PBMA) on the XIENCE stents is related to the number and lengths of the stents placed in you. Use of two or more stents will expose you to larger amounts of the stent materials, drug and polymers.

The weight of the cobalt chromium stent and the amount of everolimus, PVDF-HFP and PBMA on the stent varies by the size of the stent. The XIENCE Skypoint™ Everolimus Eluting Coronary Stent that is 4.0 millimeters in diameter and 48 millimeters long is the largest XIENCE Stent and contains the most amount of the cobalt chromium, everolimus, PVDF-HFP and PBMA of all the XIENCE Stents. The XIENCE Skypoint cobalt chromium stent, that is 4.0 millimeters in diameter and 48 millimeters long without any coating, weighs 60.3 milligrams. The amount of everolimus in the polymer coating is 0.3 milligrams. The amount of PVDF-HFP is 1.47 milligrams and PBMA is 0.33 milligrams. For all other XIENCE Stent sizes, the weight of the cobalt chromium stent and the quantities of everolimus, PVDF-HFP and PBMA on the stent that you would be exposed to, are less.

Cobalt is present as part of a cobalt alloy in the XIENCE Stent. Scientific information shows that medical devices made with metal alloys containing cobalt do not cause an increased risk of cancer or problems with reproduction.

YOUR DRUG-ELUTING STENT PLACEMENT PROCEDURE

Your procedure was performed in a cardiac catheterization laboratory (cath lab). While you were lying on the X-ray table, an X-ray camera moved over your chest during the procedure. The staff monitored your heart by attaching several small sticky patches to your chest and used a specialized electrocardiogram (ECG / EKG) recorder and monitor.

Cardiac Catheterization Laboratory

Most likely, the catheter to access your heart vessels was introduced through your groin and required a very small skin incision on the inside of your upper thigh. The area was shaved and cleaned with an antiseptic, and you were given a local anesthetic to numb the area. This incision allowed 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 then inserted a guiding catheter (long, flexible tube) into the introducer sheath and advanced it to where the coronary arteries branched off to the heart. A guide wire was then advanced through the guiding catheter to the narrowing in the coronary artery. This helped carry all the necessary devices required during your 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).

YOUR DRUG-ELUTING STENT PLACEMENT PROCEDURE

(continued)

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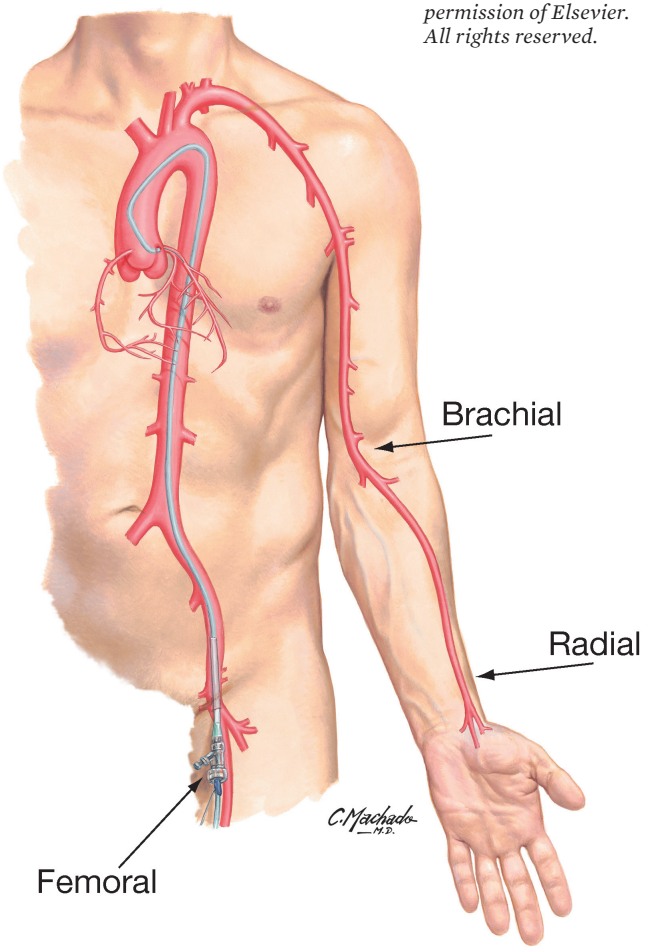


Blood vessel access for heart catheterization through the femoral, radial or brachial artery

After the catheters were inserted, your doctor injected a contrast dye through the guiding catheter into your artery to view the narrowing. Your doctor watched the injection on an X-ray monitor, much like a TV screen. While these X-rays were being taken, your doctor may have asked you to take a deep breath and hold it for a few seconds. You may also have been asked to cough after the X-ray picture was completed, to help speed the removal of the contrast dye from the arteries.

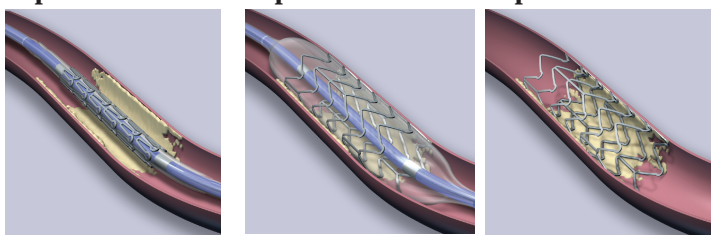
A guiding catheter was used to position a balloon catheter in the narrowing in the coronary artery and the balloon was then inflated. This compressed the plaque and widened the coronary artery. This procedure is called pre-dilatation.

Step 1: A XIENCE™ Stent mounted on a balloon catheter was delivered to the narrowing in the coronary artery by a delivery catheter.

Step 2: The balloon was then inflated and expanded the stent, pressing it against the coronary artery wall. Your doctor may have choosen to expand the stent further, by using another balloon so that the stent made better contact with the artery wall. This is known as post-dilatation.

Step 3: Once in place, the XIENCE Stent remains as a permanent implant in your coronary artery.

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



Immediately After Procedure and Follow-up Care

Following the procedure, you were asked to lie flat for four to six hours and to not bend your leg or arm, depending on which area your doctor used to insert the catheters. Pressure was also placed on the area.

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

Medications were prescribed for you before and after stent placement. Antiplatelet medications such as aspirin and other blood thinning medications (such as Clopidogrel, Prasugrel, Ticagrelor, 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 gave you instructions about your medications before you left 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 left the hospital, your cardiologist instructed you to take a daily dose of aspirin and another antiplatelet drug such as Clopidogrel, Prasugrel, Ticagrelor, Plavix‡, Effient‡, or Brilinta‡. Your doctor told you how long you should continue taking the antiplatelet drugs. It is very important that you take these medications exactly as your doctor instructed 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 blood thinner and / or 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 blood thinner and / or 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. Note that a large study, conducted in patients at high risk of bleeding and who received the

YOUR DRUG-ELUTING STENT PLACEMENT PROCEDURE

(continued)

XIENCE Stent, showed that it is safe to discontinue the second antiplatelet drug (Clopidogrel, Prasugrel, Ticagrelor, Plavix‡, Effient‡, or Brilinta‡) after one month (as short as 28 days) post-procedure.

Expected Lifetime of the Device

The XIENCE Stent is a medical device implanted into totally or partially blocked vessels. The XIENCE Stent has been shown to be safe in a human coronary artery for a minimum of 10 years. The XIENCE Stent is a permanent implant designed to remain safely in your body for the rest of your life.

Follow-up Care

You were 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 renarrowing 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.

MAGNETIC RESONANCE IMAGING (MRI) SCANNING

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
- Maximum gradient slew rate of 200 T/m/s per axis
- Maximum spatial gradient field of
  - 2500 gauss/cm (25 T/m) (XIENCE PRO™ 48)
  - 3000 gauss/cm (30 T/m) (XIENCE Skypoint™, XIENCE PRO™S)
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode).

The stent(s) should not migrate in this MRI environment, and the 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.

CONTROLLING CAD THROUGH LIFESTYLE CHOICES

CAD can be treated effectively, but it has no cure. You can help to prevent your CAD 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 CAD. Chemicals in cigarette smoke may make it easier for plaque to build up on your artery walls. Smoking also 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 your blood pressure and cholesterol. Discuss with your doctor the ways you can control your 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 CAD.

Manage your medications. Continue to take your medication as prescribed, whether for high blood pressure, elevated cholesterol levels and / or antiplatelet 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 doctor.

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 with your angina or heart attack, please notify your doctor.

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.

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."

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.

Brachial Artery: The main artery of the upper arm, supplying blood to the arm and hand. The site at the arm used as an access site to perform coronary angiography 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 angiography and 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.

DEFINITION OF MEDICAL TERMS

(continued)

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.

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.

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).

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.

DEFINITION OF SYMBOLS USED IN PATIENT LABELING

Symbol	Definition
	Rapid exchange
	Patient identification
	Manufacturer
	Authorized representative in the European Community/European Union
	UK Responsible Person
	Patient information website
	MR Conditional
	Medical device
	Catalogue number
	Batch code
	Unique device identifier
	Health care centre or doctor
	Date

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This product is intended for use by or under the direction of a physician. It is important to read thoroughly the instructions for use, warnings, and potential complications associated with the use of this device.

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