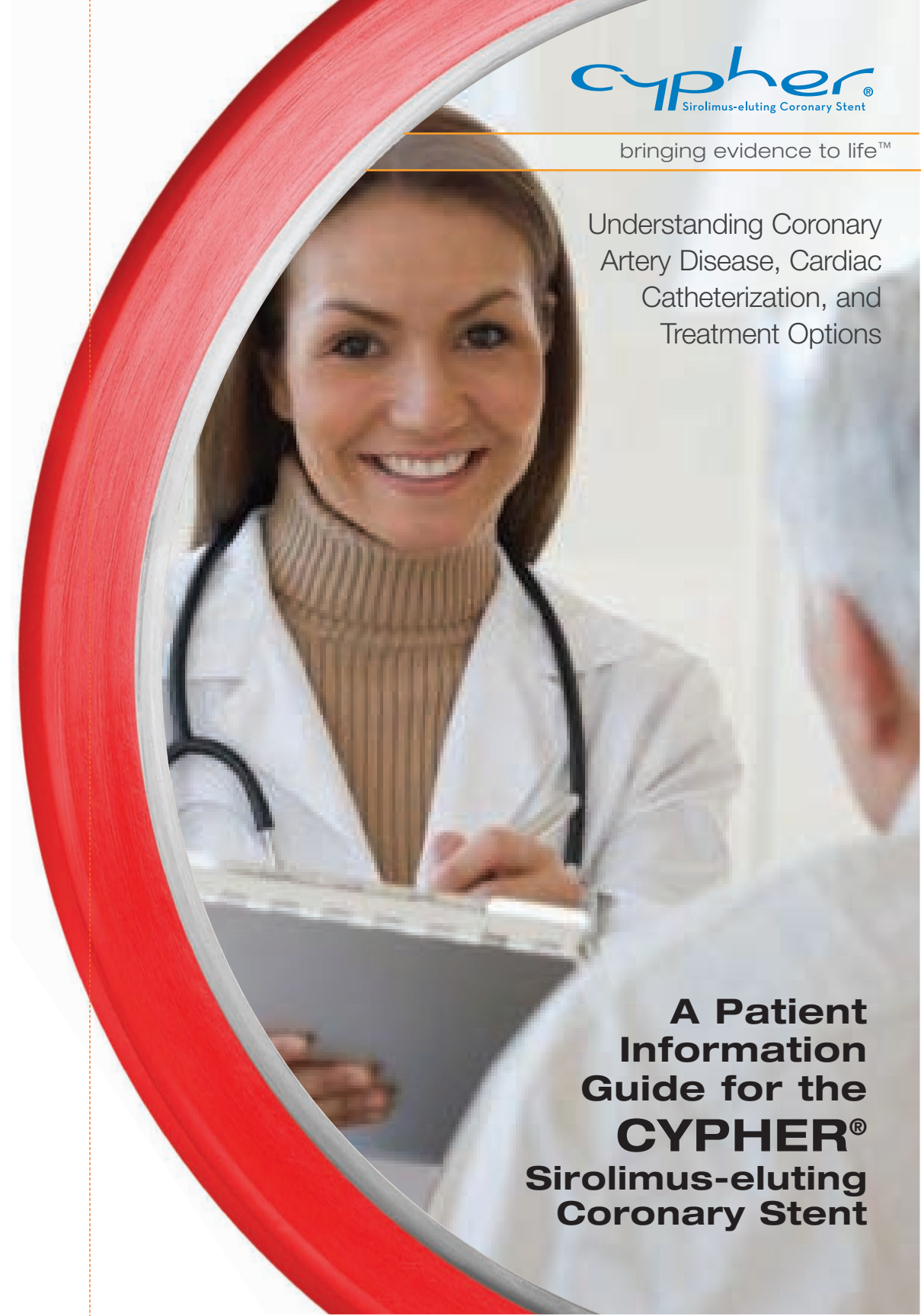


cypher[®]
Sirolimus-eluting Coronary Stent

bringing evidence to life™

Understanding Coronary
Artery Disease, Cardiac
Catheterization, and
Treatment Options



**A Patient
Information
Guide for the
CYPHER[®]
Sirolimus-eluting
Coronary Stent**

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Introduction

You have an important role to play in order to ensure that your procedure will be successful. Thoroughly read this booklet, cooperate with your physician and follow through with your responsibilities as part of the patient/medical team.

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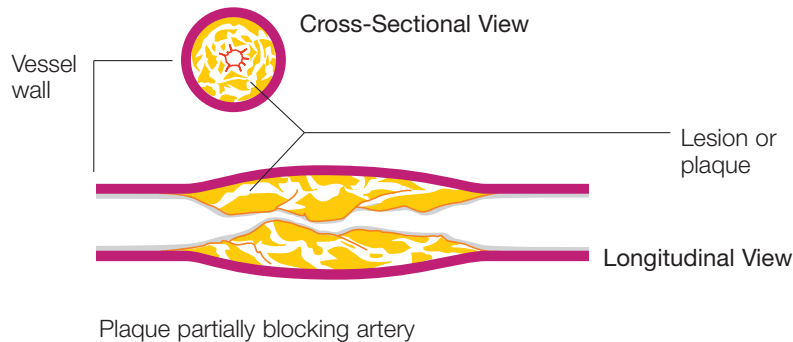
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Coronary Artery Disease

If you or a member of your family has been diagnosed with coronary artery disease (CAD), you may have questions about the disease and its treatment, especially if your doctor has recommended angioplasty followed by implantation of a drug-eluting coronary stent. This booklet answers some of the questions patients with coronary artery disease often ask.

- **Angioplasty** - A balloon procedure to open an obstruction or narrowing of a blood vessel. Also known as percutaneous transluminal coronary angioplasty (PTCA).
- **Stent** - An expandable, slotted metal tube, inserted into a vessel. A stent acts as a scaffold to provide structural support for a vessel. A drug-*eluting* stent allows for the active release of that particular drug at the stent implantation site.



Atherosclerosis A disease process in which fatty substances (plaque), such as cholesterol, are deposited on the inner lining of blood vessels.

Angina (Pectoris) Chest discomfort, pain, tightness or pressure. May also have associated pain in neck, jaw, back or arm. May include profuse sweating, nausea, or shortness of breath. Angina may be a single symptom or a combination of these symptoms.

What Causes Coronary Artery Disease?

The heart is a muscle that acts like a pump to move blood throughout the body. To function properly, the heart must receive oxygen. Oxygen is supplied to the heart by the coronary (heart) arteries that wrap around the surface of the heart. When coronary artery disease (CAD) is present, blood flow through the arteries can be reduced. When this happens, the heart muscle may not receive enough oxygen, and chest pain (called angina) may be felt.

CAD is caused by the build-up of fatty substances, such as cholesterol, that collect along the lining of the coronary arteries, in a process known as atherosclerosis. You may hear this referred to as a "plaque," "lesion," "blockage" or "stenosis." This means that there is a narrowing in the artery caused by a build-up of substances which may eventually block the flow of blood. Because the coronary arteries supply oxygen-rich blood to the heart, untreated blockages can be very serious and can lead to a heart attack (myocardial infarction) or even death. Over the course of a person's lifetime many influences can cause one or more of your coronary arteries to become narrowed or blocked.

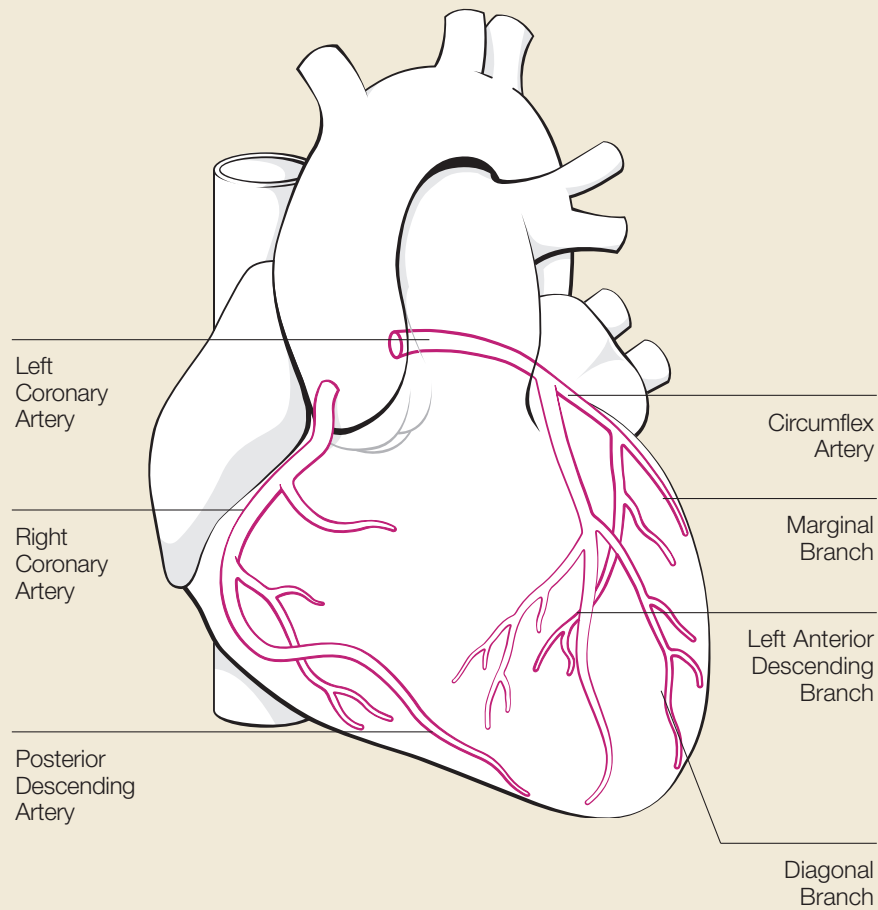
Note: The underlined words throughout this patient guide are referenced to definitions at the bottom of the respective page.

Coronary Arteries The coronary arteries are special blood vessels which supply the heart with necessary oxygen and nutrients. The heart does not function properly without enough oxygen.

Coronary Artery Disease Atherosclerosis of the coronary arteries.

Myocardial Infarction Commonly called a "heart attack." Involves irreversible damage to heart tissue/muscle. Insufficient oxygen reaching the heart muscle via the coronary arteries may cause angina, heart attack (myocardial infarction), or even death to the affected area of the heart.

The Heart and Its Coronary Arteries



Symptoms of Heart Disease

Coronary artery disease can progress very slowly, often without symptoms. Most people do not realize that they have heart disease. In fact, the first sign that something may be wrong could be an episode of angina, or even a heart attack. Typical angina symptoms are feelings of pressure, tightness, or pain in the chest, arm, back, neck or jaw. Symptoms also include heartburn, nausea, vomiting, excessive sweating, fatigue or shortness of breath. Angina may occur as only one or many of these symptoms.

Although the exact cause of CAD is not known, there are certain risk factors that are often seen in patients with coronary artery disease. These factors include: high blood pressure, having a close relative with heart disease, high cholesterol and/or triglycerides in your blood, diabetes, smoking, excessive weight, and lack of a regular exercise program. Males are more likely to develop coronary artery disease than females. In addition, menopausal status in women may play a role in coronary artery disease.

Risk Factors for CAD

You are at greatest risk for CAD if you:

- have high blood pressure
- are diabetic
- smoke cigarettes
- are overweight and/or inactive
- have a relative with the disease

Cholesterol A substance that circulates in the blood and plays a role in the formation of blockages. Cholesterol originates in foods that are rich in animal fats.

Diabetes A disease affecting one's metabolism of glucose (sugar) which causes changes in blood vessels. These changes may aid in the development of coronary artery disease.

Triglycerides Substances in the blood that are a component of the "bad" type of cholesterol.

How is Heart Disease Diagnosed?

You may have experienced symptoms of heart disease which caused you to seek your doctor's attention. If you have experienced symptoms or have an increased risk of heart disease, your doctor may recommend that you have an exercise stress test, an electrocardiogram (EKG), chest x-ray, and blood tests. Stress tests measure changes in the electrical activity of your heart as you perform controlled exercise, and may show if heart muscle is at risk of dying or if there has been damage to your heart. These results may indicate a need for further testing. Your doctor may then recommend a cardiac catheterization or coronary angiogram. It is one of the most useful methods to diagnose coronary artery disease because it allows the doctor, under x-ray, to see exactly where the coronary arteries are narrowed or blocked.

- **Cardiac** - Relating to the heart.
- **Catheterization** - A procedure that involves passing a tube (catheter) through blood vessels and injecting dye to detect blockages.
- **Coronary Angiogram** - A test used to diagnose CAD using the catheterization procedure. Contrast dye is injected into the coronary arteries via a catheter, and this allows the doctor to see, on an x-ray screen, the exact site where the artery is narrowed or blocked.

Catheter A tube used for gaining access to one of the body's cavities or blood vessels. In angioplasty, a catheter provides access to the heart's arteries.

Electrocardiogram (EKG) A test that measures and shows the electrical activity of the heart muscle.

Stress Test A test that measures electrical changes in the patient's heart (EKG) while the patient is doing controlled exercise. The stress test can show if there has been damage to the heart or if there is decreased blood flow to areas of the heart.

Cardiac Catheterization

Cardiac catheterization is performed in a specialized area in the hospital called a Cardiac Catheterization Laboratory. The night prior to the test, you may not be allowed to eat or drink anything after midnight. Before the catheterization, a doctor will explain the procedure to you and ask certain questions about your health. While you are discussing this test, you should ask any questions or mention any concerns or worries that you have about the procedure. After the procedure has been explained, you will be asked to sign a consent form, which gives your permission for the test to be performed.

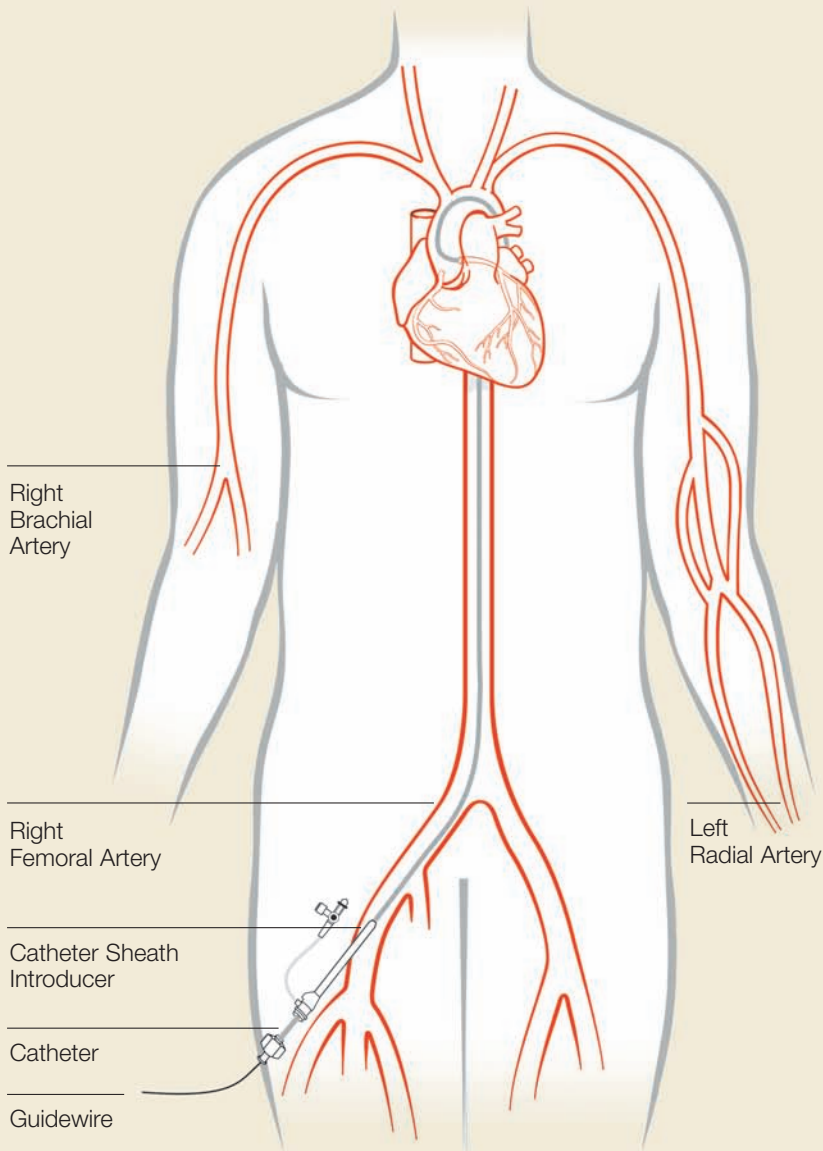
Before your procedure begins, you will be taken to the room where the cardiac catheterization will be done. Your heart rhythm will be monitored and an intravenous line (IV) will be placed to provide you with fluids and to make it easier to administer any needed medication.

Your arm or groin will be shaved and cleaned with an antiseptic solution and sterile drapes will be placed in this area. Before the procedure begins, you will receive local anesthetic to numb the area. You may feel some pressure and a burning sensation at the site, but it will only last a few seconds.

During the procedure you will not need general anesthesia, but a sedative may be given to help you relax. It is important for you to remain awake so that you can move or breathe deeply when asked to do so by the doctor. Following these instructions may improve the quality of the x-ray pictures.

During this procedure a long tube called a catheter is placed through another small tube, (called a catheter sheath introducer) that is inserted in your arm or groin. The catheter is guided to your heart and then into the opening of the arteries. The catheter provides a pathway for a special liquid dye to flow into the arteries. This liquid dye allows the doctor to see the shape and size of your arteries as well as the function of your heart muscle on an x-ray screen.

In coronary angiography, a catheter is inserted into an artery and then guided to your heart.



Once the catheter is positioned, the doctor will take pictures of your heart. With the catheter in the main pumping chamber of the heart (left ventricle), some dye will be injected through the catheter and a picture will be taken. The dye makes it easier for the doctor to see the shape and overall function of your heart. You may be asked to take a deep breath and hold it, which allows the doctor to have a clearer view of your heart on the x-ray screen. You may also feel a hot flush when the dye is injected. This feeling is to be expected and normally passes in 15 to 30 seconds.

Pictures will also be taken of your coronary arteries from several different angles. Once all these pictures have been developed and your doctor has been able to review them, he or she will be able to discuss the final results with you. If the cardiac catheterization showed that there were one or more blockages in your coronary arteries, then further treatment may be recommended.

Can Heart Disease Be Treated?

Most patients with heart disease receive medication to help prevent a heart attack, and doctors usually recommend controlled exercise and a low-fat diet. Medication may also be prescribed to help lower cholesterol levels in the blood. However, there are no drugs available to eliminate blockages within the heart arteries. If heart disease is present, you may be at risk of having a heart attack if the disease is not treated. Until several years ago, the only treatment for blockages of heart arteries was Coronary Artery Bypass Graft (CABG) surgery.

Today, there are several options available to you. Your doctor can discuss these with you to determine which option is best for you.

Balloon Angioplasty

This procedure may be done immediately following your catheterization or you may be sent home and instructed to return for the procedure. You will be asked not to eat or drink anything after midnight on the night before your procedure. It is important that you follow these and any other instructions carefully.

If you have had a cardiac catheterization procedure, angioplasty is similar in many ways. Your heart rhythm will be monitored, an intravenous line will be inserted in your arm, your arm or groin area will be shaved and cleaned and the procedure will be performed through that area. As with cardiac catheterization, it is important for you to follow your doctor's instructions during the procedure.

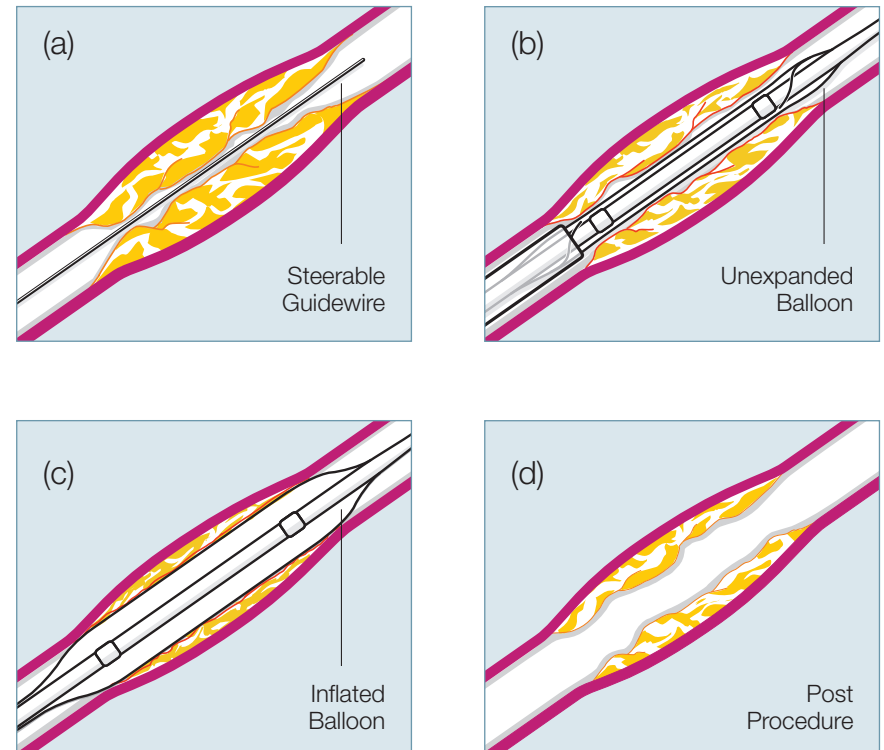
Balloon Angioplasty Step-by-Step

- After local anesthetic is given, a small incision is made in your arm or groin and a catheter sheath introducer is inserted into the artery. Then, a narrower and longer tube, called a guiding catheter, is passed through the sheath to the heart.
- Contrast dye (x-ray dye) is injected through the guiding catheter to allow the doctor to see the arteries of your heart on an x-ray machine called a fluoroscope.
- While observing the arteries on the x-ray screen, (a) the doctor threads a guidewire through the guiding catheter and advances it to the diseased artery.
- A balloon catheter is inserted over the guidewire (b) and positioned at the site of the blockage.
- Once the balloon catheter is in place, the balloon is expanded (c). As the balloon expands, it compresses the fatty deposits (plaque) against the lining of the artery. The balloon may be expanded one or more times before it is removed. X-ray pictures are taken so that the doctor can monitor your artery as the blood flow is improved.

- Once the balloon catheter is removed, the fatty deposits remain compressed, and blood flow is restored to your heart (d). The balloon procedure may last from 30 to 90 minutes, but varies from patient to patient.

It is not uncommon to experience some discomfort or a pressure sensation in your chest when the balloon is inflated. During the procedure you will be asked to remain very still. You will be asked how you are feeling; be sure to let your doctor know if you experience any discomfort.

Balloon Angioplasty of partially blocked artery.



Coronary Artery Re-narrowing May Occur After Balloon Angioplasty

It is not uncommon for patients to develop a re-narrowing in the same site as the initial balloon procedure. In fact, one-third to one-half of patients who have successful balloon angioplasty will return in the first 4-6 months after the balloon procedure. This kind of narrowing is called “restenosis” and is due to a type of scar tissue formation.

In order to lower the risk for restenosis, your doctor may recommend a procedure called coronary stent implantation. Experience has shown that use of a coronary balloon-expandable stent reduces the rate of restenosis and improves the success rate of balloon angioplasty.

What is a Coronary Artery Stent?

A coronary stent is a small, slotted, metal tube that is mounted on a balloon catheter. It is inserted into your artery after a wider channel has been created by a balloon, and is positioned at the site of the blockage. When the balloon is inflated, the stent expands and is pressed into the inner wall of the artery. The balloon is then deflated and removed with the stent remaining in place. The stent acts as a scaffold that helps to hold the artery open, which improves blood flow and relieves symptoms caused by the blockage.

Magnetic Resonance Imaging (MRI) A diagnostic study similar to a CT or CAT scan which creates an image using electromagnetic waves instead of x-ray.

Restenosis A re-narrowing or blockage of an artery at the same site where angioplasty was previously done.

Tesla A unit measure of magnetic strength.

A stent is a permanent implant that remains in your artery. Over the next weeks, your cells will form a natural covering that will hold the stent securely in place. Persons allergic to 316L stainless steel, polymers (plastics) or sirolimus may suffer an allergic response to this implant. It is important to notify your physician if you have any known metal, plastic or drug allergies. Magnetic Resonance Imaging (MRI) of single or two overlapping CYPHER® Sirolimus-eluting Coronary Stents has been shown to be safe in MRI units with a magnetic strength of three Tesla or less. Metal detectors found in airports and appliances such as microwave ovens also will not affect the stent or make it move.

Some of the currently available stents are:

- **Uncoated stents** - An expandable, slotted metal tube that acts as a mechanical scaffold in a vessel. The BX VELOCITY® Coronary Stent is an example of an uncoated stent.
- **Coated stents** - A stent with a thin surface covering.
- **Drug-eluting stents** - The CYPHER® Stent is an example of a drug-eluting stent. The CYPHER® Stent contains a drug called sirolimus. A drug-eluting stent allows for the release of that particular drug at the stent implantation site. The action of the drug (sirolimus) is intended to limit the over-growth of normal tissue as the healing process occurs following coronary stent implantation.

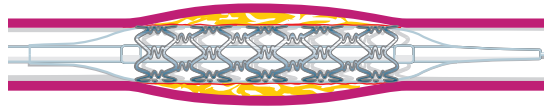
How is a Coronary Stent Implanted?

A coronary stent may be placed after the initial balloon procedure, which is done to create a wider opening for the stent. You will have the same feelings when the stent is put in place as when the balloon was expanded during the procedure.

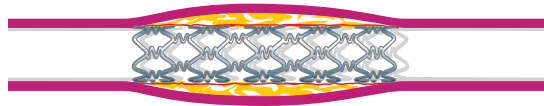
A stent is mounted on a balloon catheter.



The balloon is inflated and the stent is expanded.



The balloon is removed and the stent is implanted in the vessel.



- The stent, which is mounted on a balloon catheter, is inserted into the artery and placed at the site of the initial blockage.
- When the balloon and stent are positioned, the balloon is inflated. The stent expands and becomes firmly pressed into the inner wall of the artery. One or more stents may be used at the site that was narrowed or blocked.
- X-ray pictures are taken so that the doctor can see the stent in your artery. Additional balloon inflations may be needed to fully expand the stent.
- The balloon catheter is deflated and removed along with the guidewire and guiding catheter.
- The stent will remain in place permanently.

Coronary Stent Re-narrowing (In-stent Restenosis) May Occur After Coronary Stenting

Occasionally some patients develop a re-narrowing within the stent which may lead to recurrence of symptoms such as feelings of pressure, tightness, or pain in the chest, arm, back, neck or jaw (see also “Symptoms of Heart Disease”). This kind of narrowing is called

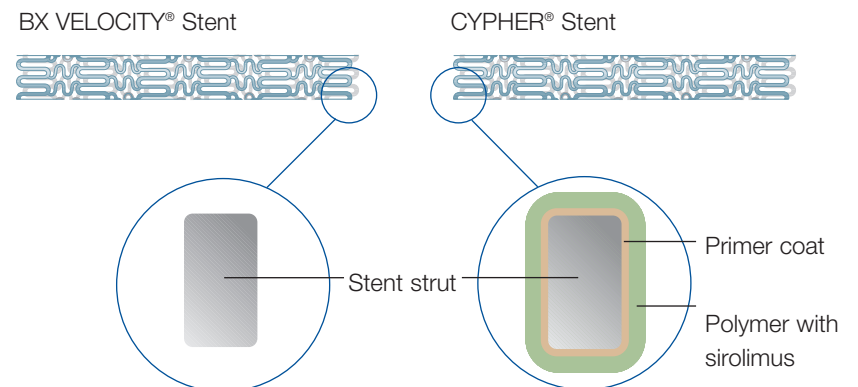
“in-stent restenosis” and is due to a type of scar tissue formation. In fact, 10 to 20 percent of patients who have successful stent implantation develop in-stent restenosis over a period of 4-6 months.

To lower the risk of in-stent restenosis, your doctor may recommend implantation of a CYPHER® Stent. Experience has shown that use of the CYPHER® Stent can reduce the rate of in-stent restenosis and repeat cardiac intervention.

What is the CYPHER® Sirolimus-eluting Coronary Stent and How Does It Work?

The CYPHER® Stent is designed to prevent re-narrowing from occurring within the stent (in-stent restenosis). It consists of a stainless steel BX VELOCITY® Stent with a thin coating of drug (sirolimus) on its surfaces. The drug is located within a polymer (plastic) coating. The BX VELOCITY® Stent is designed to provide mechanical support in the artery, while the drug (sirolimus) is slowly released into the artery wall around the stent. The action of the drug (sirolimus) is intended to limit the overgrowth of normal tissue as the healing process occurs following coronary stent implantation. Overgrowth of normal tissue is thought to be a major factor responsible for re-narrowing of the artery after stenting.

Cross-sectional view of a coated stent to show how coating conforms to the surface of the bare metal stent



When Should the CYPHER® Stent **Not** Be Used (Contraindications)?

- If you cannot take aspirin or blood-thinning medications (also called antiplatelets or anticoagulants).
- If you are unwilling or unlikely to comply with antiplatelet or anticoagulant therapy.
- If you cannot receive recommended antiplatelet and/or anticoagulation therapy.
- If you have an allergy to the drug sirolimus, structurally-related drugs or a certain category of polymers known as poly methacrylates or polyolefin.
- If the physician decided that the blockage will not allow complete inflation of the angioplasty balloon or proper placement of the stent or delivery balloon.

What Are the Risks and Potential Benefits of Treatment with the CYPHER® Sirolimus-eluting Coronary Stent?

Potential adverse events which may be associated with the implantation of a coronary stent include: allergic reaction, irregular heart rhythm, death, drug reactions to blood-thinning agents (antiplatelet/anticoagulants) or contrast media, emergency bypass surgery, fever, bleeding at the puncture site, chest pain or angina and stroke.

Potential adverse events related to the drug sirolimus (based on studies of patients who used the drug for a prolonged period of time) include: infection, tumor formation, fatigue, joint pain and diarrhea.

Exposure to sirolimus and the polymer coating is directly related to the number of implanted stents. Use of more than two CYPHER® Stents has not been adequately evaluated. Use of more than two CYPHER® Stents will result in your exposure to a larger amount of sirolimus and polymer coating than experienced in the clinical studies.

There is no clinical experience on the performance of the CYPHER® Stent before or after use of brachytherapy.

The safety and effectiveness of the CYPHER® Stent was compared to BX VELOCITY® Stent (an uncoated stent) in the SIRIUS study that included 1058 patients. All patients were followed for one year. The study results showed that patients who received a CYPHER® Stent had a significantly lower incidence of repeat procedures when compared to the uncoated BX VELOCITY® Stent group. Additionally, patients treated with the CYPHER® Stent had an in-lesion restenosis rate of 8.9% while patients treated with the BX VELOCITY® Stent had an in-lesion restenosis rate of 36.3%. The combined occurrence of death, heart attacks, bypass surgery and repeat angioplasty was 8.4% for CYPHER® Stent patients and 22.9% for BX VELOCITY® Stent patients. For patients treated with the CYPHER® Stent in indications not studied in this clinical trial, clinical results may vary.

The study showed that the risks associated with the CYPHER® Stent are equivalent to the risks associated with the BX VELOCITY® (uncoated) Stent.

Late-term risks and benefits (i.e., greater than five years) associated with the CYPHER® Stent are presently unknown but are currently under investigation.

Potential adverse events associated with coronary stent placement	
<ul style="list-style-type: none"> • Allergic reaction • Aneurysm • Arrhythmias • Cardiac tamponade • Death • Dissection • Drug reactions to antiplatelet agents/ anticoagulation agents/contrast media • Emboli, distal (tissue, air, or thrombotic emboli) • Embolization, stent • Emergency CABG • Failure to deliver the stent to the intended site • Fever • Fistulization • Hemorrhage • Hypotension/Hypertension 	<ul style="list-style-type: none"> • Incomplete stent apposition • Infection and pain at the intended site • Myocardial infarction • Myocardial ischemia • Occlusion • Prolonged angina • Pseudoaneurysm • Renal failure • Restenosis of stented segment (greater than 50% obstruction) • Rupture of native and bypass graft • Stent migration • Stroke • Thrombosis (acute, subacute, late, or very late) in the stent • Ventricular fibrillation • Vessel spasm • Vessel perforation
Potential adverse events related to Sirolimus (following prolonged oral use)	
<ul style="list-style-type: none"> • Abnormal liver function tests • Anemia • Arthralgias • Diarrhea • Hypercholesterolemia • Hypersensitivity, including anaphylactic/ anaphylactoid type reactions 	<ul style="list-style-type: none"> • Hypertriglyceridemia • Hypokalemia • Infections • Interstitial lung disease • Leukopenia • Lymphoma and other malignancies • Thrombocytopenia

Other Treatment Options

Other treatment options include balloon angioplasty, placement of other stents or bypass surgery.

- **Balloon angioplasty** - See “Balloon Angioplasty” section. This may include the use of an angioplasty catheter or other devices that are intended to open the obstruction or narrowing of the blood vessel.
- **Uncoated stents** - An expandable, slotted metal tube that acts as a mechanical scaffold in a vessel. The BX VELOCITY® Stent is an example of an uncoated stent.
- **Coated stents** - A stent with a thin surface covering.
- **Bypass surgery** - An operation in which a piece of vein or artery is used to bypass a blockage in a coronary artery.

Preparation for a CYPHER® Sirolimus-eluting Coronary Stent

If you know in advance that you will be receiving a CYPHER® Stent, your doctor will ask you to follow certain instructions. For several days before the procedure, you may be asked to take aspirin and other prescribed medications.

Caution. Be sure to let your doctor know:

- If you are taking any other medications
- If you have a history of bleeding problems
- If you have any metal allergies (i.e., 316L stainless steel)
- If you are allergic to the drug Rapamune¹ (sirolimus), its derivatives or a certain category of polymers known as poly-methacrylates or polyolefin
- If you are currently taking Rapamune
- If you are currently or think you may be pregnant

- If you are currently nursing
- If a dental or surgical procedure is scheduled to follow your CYPHER® Stent procedure while on antiplatelet medication

Note: Sirolimus is also available in tablet and liquid form, known by the name Rapamune. Let your doctor know if you are currently using this drug.

How is Treatment with the CYPHER® Sirolimus-eluting Coronary Stent Performed?

Placement of a CYPHER® Stent is no different from the placement of an uncoated stent, described earlier in this booklet. You will be brought to the cardiac catheterization laboratory and prepared for your heart catheterization. The CYPHER® Stent will be placed after the initial balloon procedure, which is done to create a wider opening for the stent. You will have the same feelings when the stent is put in place as when the balloon was expanded during the procedure.

- The stent, which is mounted on a balloon catheter, is inserted into the artery and placed at the site of the initial blockage.
- When the balloon and stent are positioned, the balloon is inflated. The stent expands and becomes firmly pressed into the inner wall of the artery. One or more stents may be used at the site that was narrowed or blocked.
- X-ray pictures are taken so that the doctor can see the stent in your artery. Additional balloon inflations may be needed to fully expand the stent.
- The balloon catheter is deflated and removed along with the guidewire and guiding catheter.
- The stent will remain in place permanently.

1. Rapamune is a registered trademark of Wyeth Pharmaceuticals.

How Long is the Hospital Stay?

Your hospital stay will be the same as for an angioplasty or non-drug-eluting stent procedure. Many patients are able to go home the day following the procedure. The amount of time that you may stay in the hospital will depend on several factors including any difficulties that you may have experienced during the procedure and how well the puncture site is healing. The amount of time depends on your physician's discharge orders.

What Happens After Your Angioplasty or Stent Procedure?

After your procedure, you will be moved to a special care unit where nurses will be able to monitor your heart rhythm and blood pressure very closely. At this time, the catheter sheath introducer (tube) may be removed and pressure will be applied to the puncture site, either your groin or arm, until the bleeding has stopped. Your puncture site will be watched closely for any signs of bleeding. If your leg was used to insert the catheters, you may be instructed to lie flat for several hours, and you may not be allowed to bend the leg that was used. Should you see any blood or feel warmth at the area of the puncture site, notify your nurse immediately. Your extremity will be monitored for any changes in color, temperature and sensation.

Once you have returned to your room, you may be able to eat and drink and your family may visit depending on your doctor's orders. Eat foods that are light until you are able to sit upright. Drink all of the fluids that are offered, because they will help to flush the x-ray dye through your kidneys and out of your body. Your doctor will advise you when you can get out of bed and walk.

Many patients are able to go home the day following the procedure. The amount of time that you may stay in the hospital will depend on several factors including any difficulties that you may have experienced during the procedure and how well the puncture site is healing. The amount of time depends on your physician's discharge orders.

Taking Your Medications is Important

Caution:

- After you leave the hospital you may be instructed to take medications. It is very important that you take your medications exactly as prescribed.
- Be sure not to miss any doses.
- Call your doctor if you feel that you cannot tolerate your medications or develop any side effects such as bleeding, upset stomach, rash, or have any questions.

Depending on which blood thinning medications (also called antiplatelet or anticoagulants) are prescribed, you may need to have follow-up blood tests to monitor the effects of the medicine on your blood. This can be done at your local hospital laboratory or primary care doctor's office and you may have breakfast before having the blood taken.

Your cardiologist may prescribe a number of medications to thin the blood and prevent blood clots from forming and adhering to the surface of the stent. You will be asked to take a small daily dose of aspirin indefinitely. In addition, it is recommended that you take antiplatelet medication for a period of time after stent implantation, which should be a minimum of three months. The antiplatelet medication may be extended to 12 months or longer as determined by your doctor. It is extremely important to follow your medication

Antiplatelet A medicine that reduces the clumping of platelets in the blood. An antiplatelet medicine helps thin the blood to prevent clot formation.

Anticoagulant A substance that slows, suppresses or prevents the clotting of blood.

regimen. If you stop taking these medications earlier than instructed by your cardiologist, you increase the chances of having a blood clot, heart attack or even death.

If you plan to have any type of surgery or dental work which may require you to stop taking antiplatelet medications early, 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 which would require you to stop taking antiplatelet medications early is recommended after you've 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 early discontinuation of antiplatelet medications because of significant bleeding, then your cardiologist will be carefully monitoring you for possible complications. Once your condition has stabilized, your cardiologist will possibly put you back on these medications.

Caution. It is Very Important to Follow These Instructions:

1. Follow your medication schedule exactly to avoid possible complications related to stent implantation.
2. Do not stop taking any of the prescribed medications unless you are instructed to do so by the doctor who performed the procedure.
3. 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.
4. Notify your doctor if you experience any side effects of the medications such as nausea, vomiting, and bleeding or rash.
5. Show your identification card (see also "After You Go Home" section) if you report to an emergency room. This card identifies you as a stent implant patient.
6. Keep all appointments for follow-up care including your blood tests.
7. Magnetic Resonance Imaging (MRI) of single and two overlapping CYPHER® Sirolimus-eluting Coronary Stents are MR-conditional. They can be scanned safely, immediately post implantation under the following conditions: static magnetic field of 3 Tesla; spatial gradient field of 500 Gauss/cm; and maximum whole-body-averaged specific absorption rate (SAR) of 4.0 W/kg for 15 minutes. Notify your doctor before you have an MRI Scan.
8. Notify your cardiologist or family doctor if you are scheduled to see the dentist while on antiplatelet medication. Your physician may prescribe antibiotics to avoid the potential of an infection (see also "After You Go Home" section).

You will be discharged to the care of your cardiologist or family doctor. After returning home, if you experience any pain, discomfort, bleeding of any kind, rash or itching, contact your doctor or the hospital. You should be able to return to your normal activities such as work, sports, and sex very soon. Check with your physician prior to doing anything that is physically strenuous.

After You Go Home

If you received a stent (uncoated, coated or drug-eluting) you will be given a small wallet-size identification card containing information about the location of your stent or therapy and the date it was performed, along with important doctors' names and telephone numbers. An example of the card is included in the back of this booklet; this card should be kept with you at all times. It is important to alert any doctor that is treating you that you received an uncoated, coated or drug-eluting stent.

If a surgical or dental procedure is recommended while on antiplatelet medication, ask your surgeon or dentist to contact the doctor who performed the stent procedure to discuss the possible risks of stopping your antiplatelet medication early.

Follow-up Visits

You may be instructed to return to see your cardiologist or family doctor. The first visit will usually take place within the first 2-4 weeks after your procedure and every six months for the first year. If you are doing well, the doctor may recommend yearly visits thereafter.

Diet and Lifestyle Changes

To help yourself stay healthy in the future, you are encouraged to make important diet, exercise and lifestyle changes. Some patients may need few modifications while others may need to make many changes. Those patients who are able to reduce the fats and cholesterol in their diets are less likely to redevelop blockages within the stent. A low-fat, low-cholesterol diet can lower the levels of fat in your blood and reduce your risk. Eating healthy foods in the right portions will also help you to maintain or achieve a healthy weight.

In addition to a healthy diet, it is extremely important to avoid smoking. Smoking not only increases the risk of worsening coronary artery disease, but it increases the chance that your PTCA or stent site will close. If you need help with quitting, notify your health care provider.

Other factors that can contribute to heart disease such as stress and lack of exercise should also be evaluated. Steps can be taken to reduce stress in your life and your physician can help you develop a controlled exercise program.

Even after your full recovery, your doctor may want to check your progress from time to time. You can reduce your risk of developing future disease by making healthy lifestyle choices. Be sure to contact your doctor or health care provider if you have any questions or need assistance regarding your lifestyle modifications.

Summary

You have a very important role to play in order to ensure that your procedure will be successful. It is essential that you cooperate with your physician and follow through with your responsibilities as part of the patient/medical team. If you have any questions or concerns, please contact your physician to discuss them. It is important that you get the most benefit from your treatment and join the thousands of people with coronary artery disease who are leading healthy, productive lives.

For more information on patient education, please visit our website: www.CYPHERSTENT.com or www.CYPHERLABELING.com.

Glossary

Angina (Pectoris) - Chest discomfort, pain, tightness or pressure. May also have associated pain in neck, jaw, back or arm. May include profuse sweating, nausea, or shortness of breath. Angina may be a single symptom or a combination of these symptoms.

Angioplasty - A balloon procedure to open an obstruction or narrowing of a blood vessel. Also known as percutaneous transluminal coronary angioplasty (PTCA).

Anticoagulant - A substance that slows, suppresses or prevents the clotting of blood.

Antiplatelet - A medicine that reduces the clumping of platelets in the blood. An antiplatelet medicine helps thin the blood to prevent clot formation.

Atherosclerosis - A disease process in which fatty substances (plaque), such as cholesterol, are deposited on the inner lining of blood vessels.

Brachytherapy - *See Intravascular Brachytherapy.*

Coronary Artery Bypass Graft (CABG) Surgery - An operation in which a piece of vein or artery is used to bypass a blockage in a coronary artery; performed to prevent myocardial infarction and relieve angina pectoris.

CAD - Coronary Artery Disease.

Cardiac - Relating to the heart.

Cardiac Catheterization - *See Coronary Angiogram.*

CAT Scanning - *See Computered Tomography Scanning.*

Catheter - A tube used for gaining access to one of the body's cavities or blood vessels. In angioplasty, a catheter provides access to the heart's arteries.

Catheterization - A procedure that involves passing a tube (catheter) through blood vessels and injecting dye to detect blockages.

Cholesterol - A substance that circulates in the blood and plays a role in the formation of blockages. Cholesterol originates in foods that are rich in animal fats.

Computered Tomography Scanning - A technique for producing cross-sectional images of the body in which x-rays are passed through the body at different angles and analyzed by a computer; also called CT scanning or CAT scanning.

Coronary - Related to the arteries that supply blood to the heart.

Coronary Angiogram - A test used to diagnose CAD using the catheterization procedure. Contrast dye is injected into the coronary arteries via a catheter, and this allows the doctor to see, on a x-ray screen, the exact site where the artery is narrowed or blocked.

Coronary Arteries - The coronary arteries are special blood vessels which supply the heart with necessary oxygen and nutrients. The heart does not function properly without enough oxygen.

Coronary Artery Disease - Atherosclerosis of the coronary arteries.

CT Scanning - *See Computer Tomography Scanning.*

Diabetes - A disease affecting one's metabolism of glucose (sugar) which causes changes in blood vessels. These changes may aid in the development of coronary artery disease.

EKG - Electrocardiogram. A test that measures and shows the electrical activity of the heart muscle.

Exercise Electrocardiogram - *See Stress Test.*

Fluoroscope - Equipment used in a cardiac catheterization procedure which captures a "motion picture" x-ray image of the heart and coronary arteries.

In-stent Restenosis - A re-narrowing or blockage of an artery within a stent.

Intravascular Brachytherapy - The administration of a therapeutic dose of radiation from within a vessel to a specific area of vascular disease to prevent the reoccurrence of an obstruction or narrowing.

Ischemia - Lack of or insufficient oxygen to the tissue, in this case, to the heart muscle. Ischemia is a reversible condition if normal blood flow is restored.

Left Ventricle - The largest chamber of the heart which is responsible for pumping blood throughout the body.

Lesion - A blockage in a blood vessel. It is also known as a plaque or stenosis.

MRI - Magnetic Resonance Imaging. A diagnostic study similar to a CT or CAT scan which creates an image using electromagnetic waves instead of x-ray.

Myocardial Infarction - Commonly called a “heart attack.” Involves irreversible damage to heart tissue/muscle. Insufficient oxygen reaching the heart muscle via the coronary arteries may cause angina, heart attack (myocardial infarction), or even death to the affected area of the heart.

Percutaneous - Performed through a small opening in the skin.

Percutaneous Transluminal Coronary Angioplasty -
See Angioplasty.

Plaque - The accumulated material that causes a blockage in a blood vessel. Also known as a lesion or stenosis.

Platelets - Blood cells that are involved in the formation of a clot.

PTCA - Percutaneous Transluminal Coronary Angioplasty.
See Angioplasty.

Restenosis - A re-narrowing or blockage of an artery at the same site where angioplasty was previously done.

Stenosis - A narrowing of any canal, especially one of the cardiac vessels.

Stent - An expandable, slotted metal tube, inserted into a vessel. A stent acts as a scaffold to provide structural support for a vessel.

Stress Test - A test that measures electrical changes in the patient's heart (EKG) while the patient is doing controlled exercise. The stress test can show if there has been damage to the heart or if there is decreased blood flow to areas of the heart.

Tesla - A unit measure of magnetic strength.

Thrombosis/Late Thrombosis/Very Late Thrombosis - A blockage caused by clumping of cells. Late Thrombosis occurs after 30 days of stent implantation. Very late thrombosis occurs after one year of stent implantation.

Transluminal - Through the inside opening of an artery.

Triglycerides - Substances in the blood that are a component of the “bad” type of cholesterol.

Vessel - Any channel for carrying a fluid, such as an artery or vein.

Notes

