

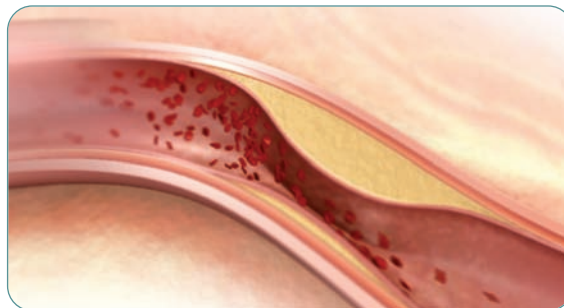
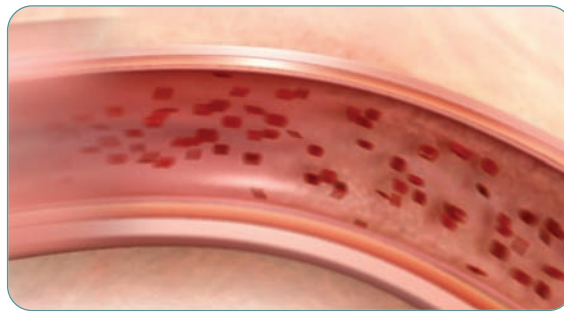
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Coronary Stent

Understanding
CORONARY ARTERY DISEASE
and how to treat it.
An open discussion

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WHAT CAUSES CORONARY ARTERY DISEASE?

- Arteries that supply blood to the heart can become clogged with cholesterol, which is a fatty substance
- When cholesterol accumulates in the arteries, it forms plaque. If this happens, the heart does not get enough oxygen-rich blood, which may lead to chest pain (this is also called angina)
- When left untreated, plaque build-up may lead to a heart attack or even death



Several risk factors can contribute to plaque building up in arteries

Coronary artery disease (CAD) can progress slowly, often without warning. Some risk factors, like family history, age, and gender, are uncontrollable.

Other risk factors, like the ones shown below, may be caused by a person's lifestyle choices:

- Smoking
- High cholesterol
- High blood pressure
- Diabetes
- Obesity/lack of physical activity

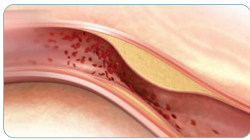
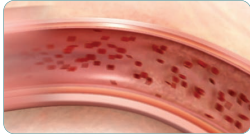
It is important to recognize these risk factors so you can prevent CAD and we can start treatment as early as possible if needed.

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SMOKING

- Smoking tobacco can speed up hardening of the arteries
- Fatty deposits form on the artery walls and can partially block blood flow to the heart
- Because nicotine constricts coronary arteries, smoking also increases the chances of a blood clot forming in the narrowed artery

HIGH CHOLESTEROL

- Having high cholesterol increases the likelihood of developing CAD, and therefore increases your risk for heart attack or stroke
- If you have high cholesterol, every 1% reduction in total blood cholesterol lowers your risk for a heart attack by 2%
- Cut your blood cholesterol level by 15%, and your risk of developing CAD drops by 30%

HIGH BLOOD PRESSURE

- High blood pressure can damage the delicate lining of your blood vessels
- Left untreated, it can cause a thickening of your artery walls and lead to serious, even fatal, complications

DIABETES

- Diabetes can lead to many other conditions that affect your cardiovascular health
- Diabetes can damage blood vessels, raise "bad" cholesterol levels, lower "good" cholesterol levels, and raise blood pressure

OBESITY/LACK OF PHYSICAL ACTIVITY

- Excess weight can lead to the development of several other CAD risk factors, such as high cholesterol, high blood pressure, and diabetes
- People who exercise less than 20 to 30 minutes a day, 3 times a week, have a greater risk for obesity and high cholesterol, which are factors that can contribute to CAD, than people who are more active

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HOW CAN HEART DISEASE BE TREATED?

Most patients with heart disease receive medication to help prevent a heart attack. Controlled exercise and a low-fat diet are also recommended.

When medication and lifestyle changes aren't enough, heart disease may also be treated with coronary artery bypass graft (CABG) surgery or with the use of balloon angioplasty and stenting.

Medical therapy

- After diagnosing CAD, physicians may prescribe nitrates, calcium channel blockers, statins, beta blockers, or aspirin to help ease symptoms

Coronary artery bypass graft surgery

- This surgery creates new pathways around narrowed or blocked arteries to allow for enough blood flow to deliver oxygen to the heart

Balloon angioplasty and stenting

- In balloon angioplasty, a very small balloon is inserted into the clogged artery and inflated to push the plaque build-up against the wall of the artery
- A device called a stent may also be used during this procedure

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HOW CAN HEART DISEASE BE TREATED?

- Blocked arteries are the number one cause of CAD
- CAD can progress slowly, often without warning
- This year, an estimated 1.1 million Americans will have new or recurrent heart attacks, and for more than 45% of these people, the attacks will be fatal

MEDICAL THERAPY

- Medication may be prescribed on its own or used in combination with a procedure such as CABG or balloon angioplasty and stenting

CABG

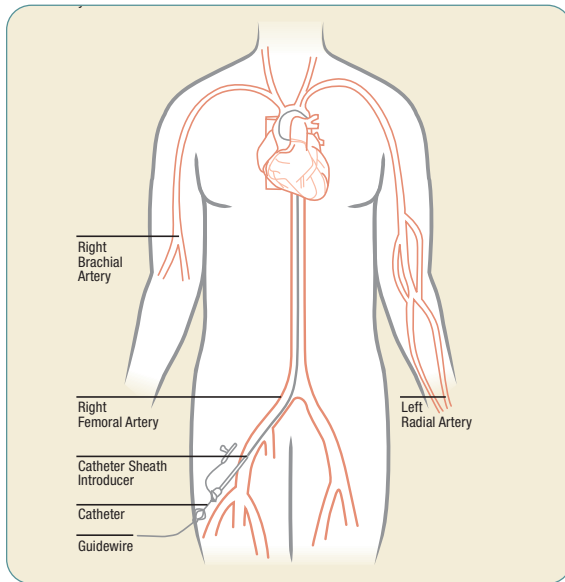
- CABG is an invasive procedure that is associated with longer recovery time than balloon angioplasty and balloon angioplasty with the implantation of a stent

BALLOON ANGIOPLASTY AND STENTING

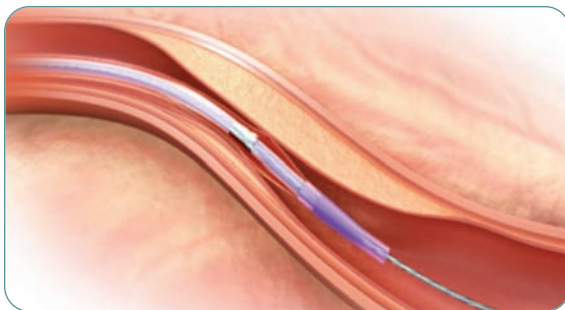
- The first part of a balloon angioplasty is very similar to a diagnostic coronary catheterization

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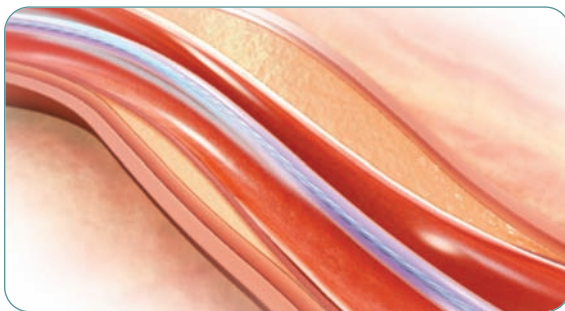
WHAT IS BALLOON ANGIOPLASTY?



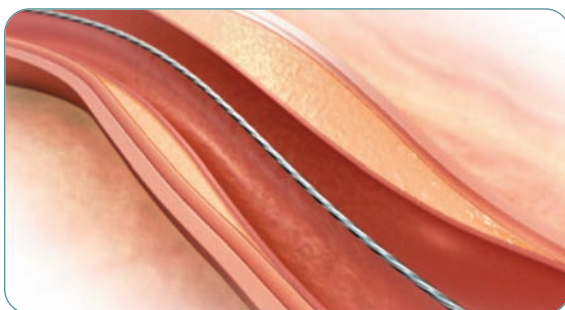
- A long tube, which is called a guiding catheter, is inserted into an artery and moved toward the heart
- Dye is injected through the arteries of the heart to help identify possible blockages in the arteries



- A balloon catheter is moved into the heart and is positioned at the site of the blockage



- Once it is in place, the balloon is inflated with air to push the plaque against the wall of the artery

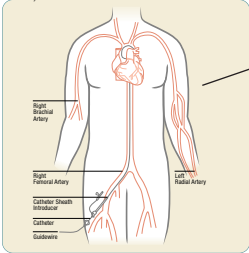


- This creates an opening in the artery to improve blood flow

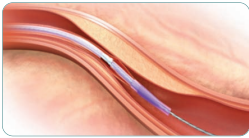
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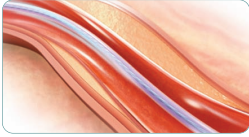
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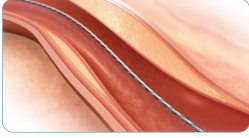
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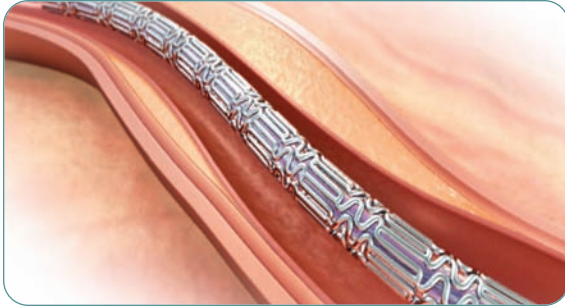
WHAT IS BALLOON ANGIOPLASTY?

- The whole procedure takes between 30 and 90 minutes
- Patients are awake, but may be given a sedative to help them relax
- An area of the groin or arm will be shaved and cleaned in preparation for the procedure. Patients are given a local anesthetic to numb the area.

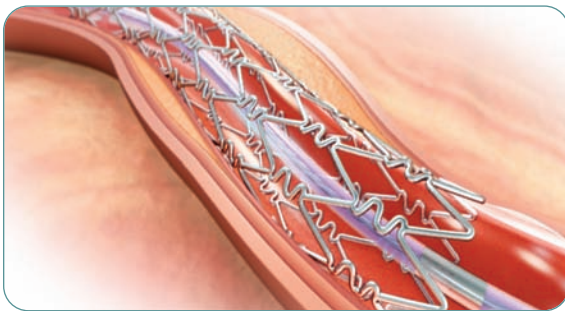
WHAT IS A CORONARY ARTERY STENT?

A coronary artery stent may also be used during a balloon angioplasty procedure to help keep the artery open.

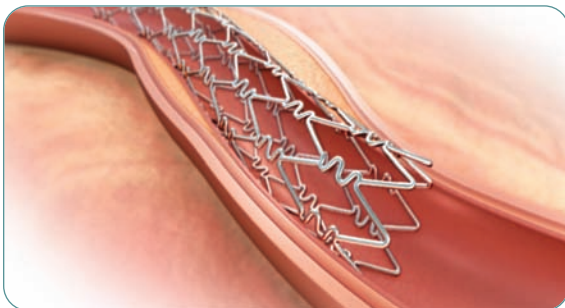
- A coronary artery stent is a small, mesh, metal tube that is mounted on a balloon catheter



- A stent is inserted into an artery after a wider opening has been created by the balloon; the stent is then 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

There are currently 2 types of stents available:

- **Uncoated stents**
 - Also known as bare metal stents
- **Drug-eluting stents**
 - A drug-eluting stent (DES), like the CYPHER® Stent shown above, is coated with a drug that is designed to be gradually released into surrounding tissue
 - The intention of this “time-release” process is to slow down the growth of unwanted cells and allow the vessel to heal

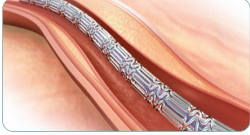
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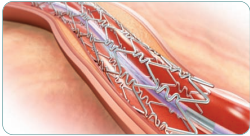
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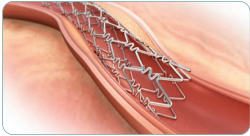
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HOW A STENT IS IMPLANTED INTO A VESSEL

- A stent is a permanent implant that remains in your artery
- The stent acts as a scaffold that helps to hold the artery open
- This improves blood flow and relieves symptoms caused by the blockage
- In the weeks following implantation, cells will form a natural covering that will hold the stent securely in place

UNCOATED STENTS

- Uncoated stents were the first stents, also known as bare metal stents
- This expandable, mesh, metal tube acts as a mechanical scaffold in a vessel

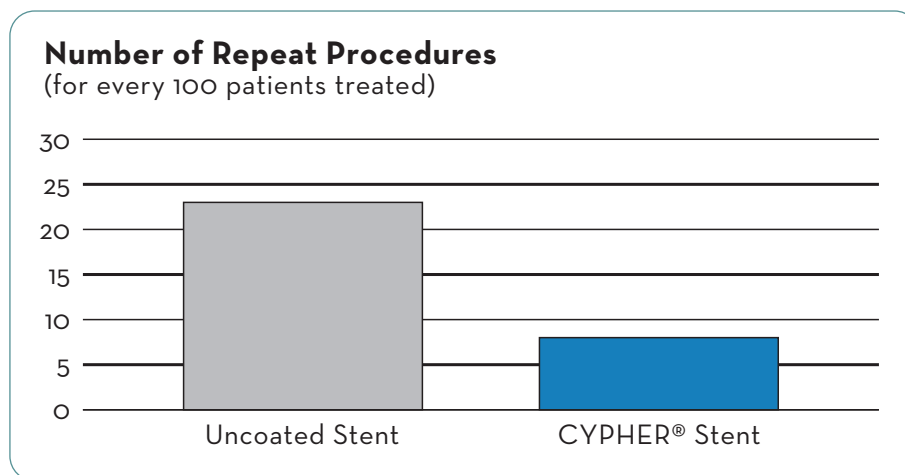
DRUG-ELUTING STENTS

- The CYPHER® Sirolimus-eluting Coronary Stent is an example of a drug-eluting stent

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WHAT ARE THE BENEFITS OF DRUG-ELUTING STENTS?

- The safety and efficacy of the CYPHER® Stent was compared to an uncoated stent in 4 clinical trials
- The benefits of the CYPHER® Stent can be seen in the graph below, where the rate of re-intervention, or the number of people that required another procedure due to re-blockage at the treatment site, is much lower than for those who received an uncoated stent



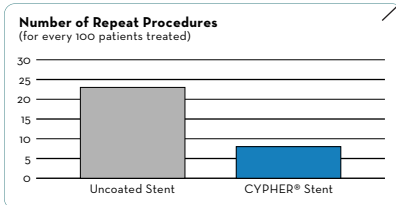
- In fact, 4 years after the procedure, for every 100 patients treated with the **CYPHER® Stent**, only **8** patients required a re-intervention, compared to **24** re-interventions needed for every 100 patients who received an **uncoated stent**
- Late-term risks and benefits (beyond 5 years after stent implantation) associated with the CYPHER® Stent are presently unknown but are currently under investigation.

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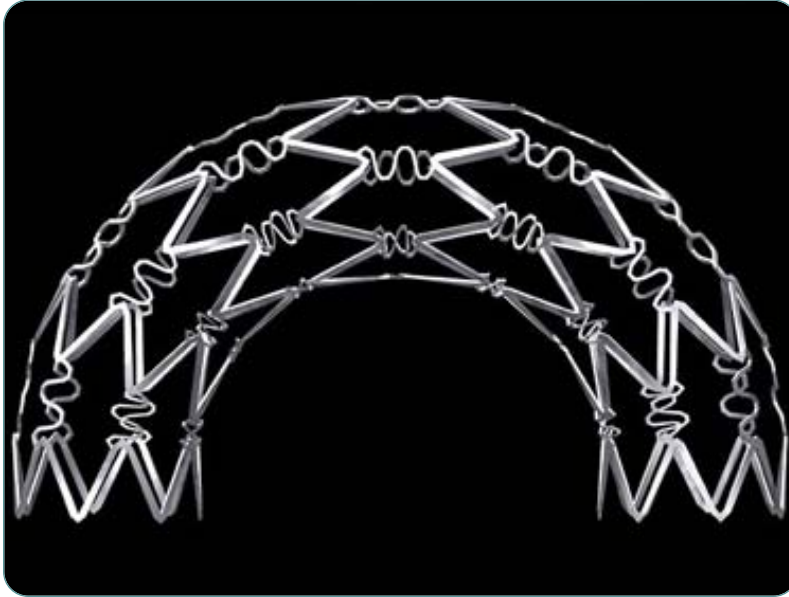
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WHAT ARE THE BENEFITS OF DRUG-ELUTING STENTS?

- Unlike an uncoated stent, the CYPHER® Stent provides a unique medication, sirolimus, which is slowly released into the artery wall around the stent
- This helps to slow down the growth of unwanted cells and reduce the risk of re-blockage in the artery, and allows the vessels to heal and stay open
- All of these benefits reduce the chances of needing another procedure to keep the artery open, compared to an uncoated stent

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WHAT IS THE CYPHER® STENT?



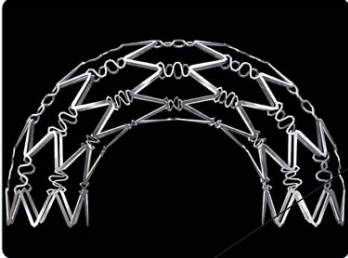
The CYPHER® Stent has 2 parts:

- The stent
- The anti-rejection-type medication (sirolimus)

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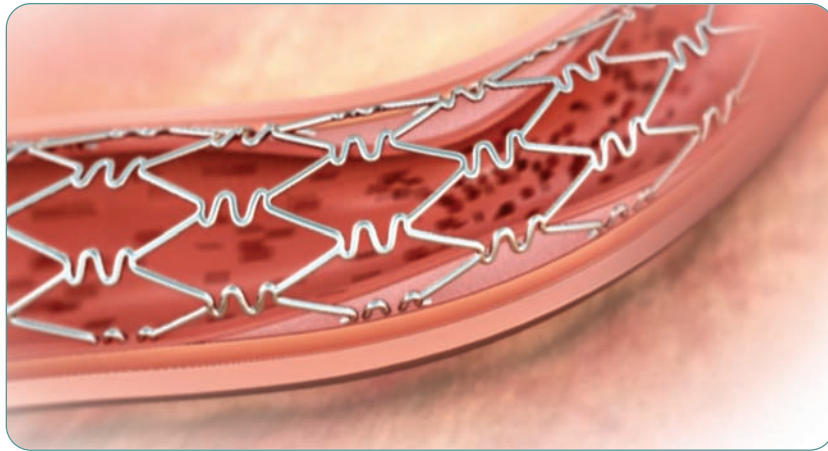
THE STENT

- The stent is a small, expandable, mesh, metal tube that is inserted into a coronary artery
- The stent acts as a scaffold that helps hold the artery open, which improves blood flow to the heart and relieves symptoms caused by the blockage

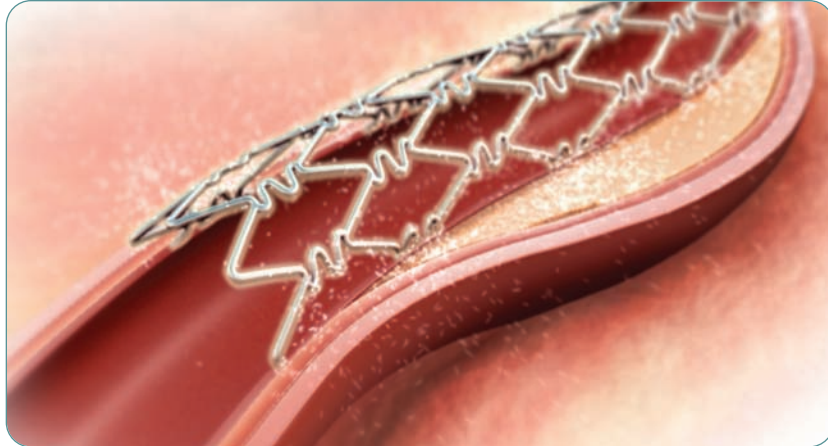
THE ANTI-REJECTION-TYPE MEDICATION (SIROLIMUS)

- After the placement of the stent, sirolimus, a unique anti-rejection-type medication, helps keep the artery open during and after the healing process

HOW DOES THE CYPHER® STENT WORK?



- Overgrowth of tissue is believed to be a major factor responsible for re-narrowing of the artery after stent placement

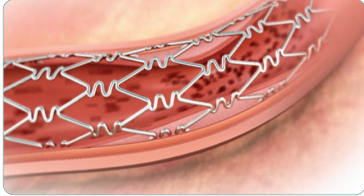


- The CYPHER® Stent limits this overgrowth of normal tissue, which significantly reduces the chance of re-blockage and the need for another procedure

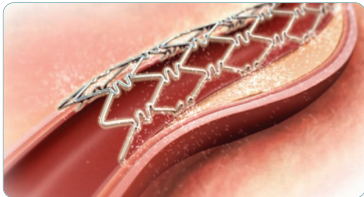
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This medication works in several ways:

- It slows the growth of unwanted cells during the healing process
- It reduces the risk of re-blockage in the artery
- It helps the vessel to heal and stay open

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IS THE CYPHER® STENT RIGHT FOR YOU?

- The risks associated with the CYPHER® Stent are comparable to the risks associated with uncoated stents

The CYPHER® Stent may not be right for you if:

- You cannot take aspirin or blood-thinning medications (also called antiplatelets or anticoagulants)
- You have an allergy to the drug sirolimus (also known as rapamycin), its derivatives, or a certain category of polymers known as polymethacrylates or polyolefin
- It is determined that the blockage will not allow complete inflation of the angioplasty balloon

Also, be sure to let me know if:

- You are taking any other medications
- You have a history of bleeding problems
- You are allergic to 316L stainless steel, polymers (plastics), or sirolimus
- You are currently taking Rapamune® (sirolimus) (Rapamune is a tablet or liquid form of sirolimus)
- You are currently or think you may be pregnant
- You are currently nursing
- A dental or surgical procedure is scheduled to follow your CYPHER® Stent procedure while you are still on antiplatelet medication

The CYPHER® Stent is not for everyone – especially those who cannot take antiplatelet medicine or have certain allergies. It carries risks, including the formation of a blood clot in the stent, heart attack, and the possible need for a repeat procedure. The CYPHER® Stent also carries the risks associated with the drug sirolimus. Talk to your doctor about these risks, and whether this or other treatments are right for you.

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WHAT ARE THE POSSIBLE SIDE EFFECTS OF THE CYPHER® STENT?

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 stent to the intended site • Fever • Fistulation • 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 • Arthralgia • 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

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SIDE EFFECTS CHART

- Exposure to sirolimus and the polymer coating is directly related to the number of implanted CYPHER® Stents
- Use of more than 2 CYPHER® Stents has not been adequately evaluated
- Use of more than 2 CYPHER® Stents will result in your exposure to a larger amount of sirolimus and polymer coating than experienced in the clinical studies

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Patient Information for the CYPHER® Sirolimus-eluting Coronary Stent (SY-fer sir-AHL-i-mus e-LUT-ing KOR-o-nair-e stent)

This summary is about the CYPHER® Sirolimus-eluting Coronary Stent, a combination product consisting of a device (stent) and an anti-rejection-type medication (sirolimus) contained in a polymer (soft plastic) coating on the stent. Please read it carefully. This information should not take the place of careful discussions with your doctor. Only your doctor can decide if the CYPHER® Stent is right for you. Contact your doctor if you have any questions.

What is the CYPHER® Stent? The CYPHER® Stent has three parts:

The stent: a small, expandable, slotted metal tube that is inserted into a coronary artery (one of the blood vessels that supplies the heart with oxygen and nutrients). A stent acts as a scaffold that helps hold the artery open, which allows blood flow to the heart and relieves symptoms caused by the blockage.

The anti-rejection-type medication (sirolimus*): an anti-rejection-type medication that limits the overgrowth of tissue as the healing process occurs following coronary stent implantation.

The inactive ingredient: a polymer (soft plastic) coating on the stent that contains the medication sirolimus, and slowly elutes (releases) the medication into the artery wall around the stent.

How does the CYPHER® Stent work? Overgrowth of tissue is believed to be a major factor responsible for renarrowing of the artery after stent placement. The CYPHER® Stent limits this overgrowth of tissue, which significantly reduces the chance of reblockage and the need for another procedure.

What is the CYPHER® Stent used for? The CYPHER® Stent is used to help open coronary arteries in people who have symptoms of ischemic disease (lack of blood flow to the heart) such as heart attack or angina, due to atherosclerosis (fatty substances such as cholesterol deposited on the inner lining of blood vessels).

Placement of the CYPHER® Stent is no different than the placement of a bare-metal (uncoated) stent. The CYPHER® Stent will remain in the vessel permanently.

Who should not receive the CYPHER® Stent? Patients who:

- are allergic to the anti-rejection-type medication (sirolimus*)
- are allergic to the polymers used in the coating
- cannot take antiplatelet medication such as aspirin
- cannot take anticoagulant medication (blood thinners)
- have a blockage that the doctor decides will not allow complete inflation of the angioplasty balloon

Women of childbearing age should be using effective contraception before they receive the CYPHER® Stent, and for 12 weeks after. Women who are nursing should discuss this with their doctor before receiving the CYPHER® Stent.

The CYPHER® Stent has not been studied for use in children.

What other medical issues should I discuss with my doctor? You should tell your doctor about any other medications (prescription or nonprescription) you are taking, especially medications that affect your immune system. You should also tell your doctor if you have a history of bleeding problems.

What are the possible side effects of the CYPHER® Stent? Use of the CYPHER® Stent carries the risks associated with all coronary stent placement, including allergic reaction, irregular heart rhythm, stent thrombosis (blood clot in the stent), death, reactions to antiplatelet or anticoagulant medications or to dyes used during placement, emergency bypass surgery, fever, bleeding at the puncture site, chest pain or angina and stroke. The risk of thrombosis with any stent, uncoated or drug-eluting, remains low. Our two clinical trials following patients over a five-year period indicate a similar overall risk of thrombosis between the CYPHER® Stent and uncoated stents. However, after 1 year, a very small increased risk of stent thrombosis can be seen with the CYPHER® Stent versus uncoated stents.

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 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 orally for a prolonged period of time) include: infection, tumor formation, fatigue, joint pain and diarrhea.

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

Exposure to sirolimus and the polymer coating on the CYPHER® Stent 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.

What can I expect after I receive the CYPHER® Stent? Many patients are able to return home the day following their procedure. Your doctor will decide how long you need to stay based on your individual needs.

Your doctor will prescribe aspirin, and other antiplatelet or anticoagulant medications (blood-thinners). It is very important that you take these medications exactly as directed; 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 itching, or if another healthcare professional asks you to stop taking your medication. You may also have to have follow-up blood tests to monitor the effects of the CYPHER® Stent.

You should be able to return to your normal activities such as work, sports and sex very soon, but again, this will be determined by your doctor. Check with your doctor prior to doing anything that is physically strenuous.

You will be given a schedule for follow-up visits with your cardiologist or family doctor, and a small identification card to carry with you at all times, containing information about the CYPHER® Stent.

If you have chest pain after your procedure, see a doctor immediately.

How can I get more information about the CYPHER® Stent?

If you have any other questions, speak to your doctor, or call **1-800-781-0282** or visit **www.cypherusa.com**

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Please see Essential Prescribing Information.
For full Instructions for Use, go to cordislabeling.com.