The Safety of Coronary Stenting
What Causes Coronary Artery Disease?

• Arteries that supply blood to the heart can become clogged with fatty substances (like cholesterol).
• When cholesterol accumulates to form plaque (a process called atherosclerosis), the heart does not get enough oxygen-rich blood and you may eventually have chest pain (this is also called angina).
• When left untreated, atherosclerosis may lead to a heart attack (myocardial infarction) or even death.

Heart Disease Can Be Treated in the Following Ways:

• Medical Therapy: Most patients with heart disease receive medication to help prevent a heart attack, and doctors usually recommend controlled exercise and a low-fat diet.
• Balloon Angioplasty and Stenting: In this procedure, a very small balloon is inserted into the clogged artery and inflated to push the plaque build-up against the wall of the artery. The stent procedure may involve the use of a drug-eluting stent (DES) or an uncoated stent.
• Coronary Artery Bypass Graft (CABG): This surgery creates new pathways around narrowed or blocked arteries to allow for enough blood flow to deliver oxygen to the heart.

Your doctor can discuss these treatments with you to determine which option is best for you.
What Is Angioplasty?

Angioplasty is very similar to your initial cardiac catheterization procedure.

- Following the insertion of the catheter sheath introducer, a long tube called a guiding catheter is inserted and guided toward the heart.
- Just as in the diagnostic procedure, contrast dye is injected through the arteries of your heart to allow the doctor to identify possible blockages in the arteries.

In coronary angiography, a catheter is inserted into an artery and then guided to your heart.
A balloon catheter is inserted into the heart and positioned at the site of the blockage. Once it is in place, the balloon is expanded to push the plaque back against the wall. This creates an opening in the artery to improve blood flow.

In some cases, your doctor may stop the procedure after balloon angioplasty.

Another common option is to place a coronary artery stent. A coronary artery stent is a small, slotted, metal tube that is mounted on a balloon catheter.

This stent is inserted into your artery after a wider channel has been created by the balloon, and 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. This improves blood flow and relieves symptoms caused by the blockage.
A stent is a permanent implant that remains in your artery. Over the coming weeks, your cells will form a natural covering that will hold the stent securely in place. It is important to notify your doctor if you have any known metal, plastic or drug allergies.

There are currently two types of stents available:

- **Uncoated stents** – An expandable, slotted metal tube that acts as a mechanical scaffold in a vessel.
- **Drug-eluting stents** – A drug-eluting stent allows for the release of a particular drug at the stent implantation site. The CYPHER® Sirolimus-eluting Coronary Stent is an example of a drug-eluting stent. It contains a drug called sirolimus. Sirolimus is intended to limit the over-growth of tissue as the healing process occurs following coronary stent implantation.

### Benefits of Drug-eluting Stents (DES)

The safety and efficacy of the CYPHER® Stent was compared to the Bx VELOCITY® Stent (an uncoated stent) in four clinical trials. The benefit of the CYPHER® Stent can be seen in the graph where the rate of re-intervention, or the number of people that required another procedure due to reblockage at the treatment site, is much lower than those who received an uncoated stent. In fact, four years after the procedure, for every 100 patients treated with the CYPHER® Stent, approximately eight patients required a re-intervention compared to 24 re-interventions for every 100 patients who received an uncoated stent.
Important Safety Information

You may have read recently about thrombosis complications with stents in the newspaper and online. While stents have proven to be a safe and effective treatment, their use may, on rare occasions, result in what is known as stent thrombosis or the formation of a blood clot.

Recently, the FDA convened a panel of experts to consider the risks and benefits of drug-eluting stents. During this meeting the panelists agreed that the benefits of drug-eluting stents outweigh the risks when they are used according to their label instructions.

Although rare, a stent thrombosis can lead to a heart attack, which can be fatal. The risk of thrombosis with any stent, uncoated or drug-eluting, remains low. Our four clinical trials following patients over a five-year period indicate a similar overall risk of thrombosis between the CYPHER® Stent and uncoated stents. Please speak to your doctor to better understand the risks and benefits associated with the use of stents in your specific case.

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.

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. The safety and efficacy of the CYPHER® Stent in patients with brachy-therapy of the target lesion has not been established.

Taking Your Medication Is Important

When you leave the hospital, your cardiologist may prescribe a number of medications to thin your blood in order to 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 an additional antiplatelet medication (such as ticlopidine or clopidogrel) after stent implantation for a period of time, which should be determined by your doctor. It is extremely important to follow your medication regimen. If you stop taking these medications earlier than instructed by your cardiologist, you increase your chances of experiencing a blood clot, a heart attack, or even death. If you plan to have any type of surgery or dental work that may require you to stop taking antiplatelet medications early, you and your cardiologist should discuss whether the placement of a drug-eluting stent is the right treatment choice for you.

It is very important that you take your medications exactly as prescribed, without missing any doses. Call your doctor if you feel that you cannot tolerate your medications or if you develop any side effects such as bleeding, upset stomach or rash formation.
Prior to Your Procedure, 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 allergies to metal (i.e., 316L stainless steel)
- If you are allergic to the drug Rapamune (this is the drug sirolimus in tablet and/or liquid form), its derivatives, or a certain category of polymers known as polymethacrylates 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 CYPHERTM Stent procedure while you are on antiplatelet medication
It Is Very Important to Follow These Instructions

1. Follow your medication schedule exactly as prescribed to avoid possible complications related to stent implantation.

2. Do not stop taking any of the prescribed medications unless you or your doctor has consulted with the doctor who performed the procedure.

3. Notify your doctor immediately if you experience chest pain, also known as angina, or notice any changes such as more severe or frequent chest discomfort, particularly 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 from the medications, such as nausea, vomiting, bleeding, or rash formation.

5. If you report to an emergency department, show the card that identifies you as a CYPHER® Stent implant patient.

6. Keep all appointments for follow-up care – including your blood tests.

7. Magnetic Resonance Imaging (MRI) of a single CYPHER® Stent or two overlapping CYPHER® Stents has been shown to be safe in MRI units with a magnetic strength of three Tesla or less. Notify your doctor that you have a CYPHER® Stent before you have an MRI medical scan.

8. Notify your cardiologist or family doctor if you are scheduled to see your dentist or gastroenterologist while on antiplatelet medication.
You have a very important role to play in ensuring 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 maximum benefit from your treatment and join the thousands of patients with coronary artery disease who are leading healthy, productive lives.

For more information on patient education, please visit our website at www.CYPHERUSA.com. If you would like to speak to us, please call us at 1-800-781-0282.

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