

THE CYPHER[®] SIROLIMUS-ELUTING CORONARY STENT.



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 supply 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.

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 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.cyphersusa.com

Sirolimus-eluting Stent made by Cordis Corporation pursuant to a license from Wyeth Pharmaceuticals.

Rapamune[®] is a trademark of Wyeth Pharmaceuticals.

[†]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.

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