Boston Scientific

REBEL™

Platinum Chromium Coronary Stent System

Patient Information Guide

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PATIENT INFORMATION GUIDE

You have recently had a REBEL bare metal stent implanted in the coronary arteries of your heart. The following information is important for you to know, including the possible risks associated with having a stent implant along with medication recommendations and questions you may have about your stent.

REBEL Platinum Chromium Stent

The REBEL Stent is a bare metal stent made from a platinum chromium (PtCr) alloy. Platinum Chromium is a biocompatible metal specifically developed by Boston Scientific for coronary stents. The stent was designed to be very strong and flexible, allowing it to fit the shape of your artery and keep the vessel open.

The REBEL Stent is delivered to the artery using the REBEL balloon delivery catheter. Together, the REBEL Stent and the REBEL balloon delivery catheter make up the REBEL Stent System.

Coronary Artery Disease

Coronary artery disease (CAD) is the narrowing of the arteries in the heart. This narrowing can also be called stenosis. It is usually caused by a build up of fat or calcium deposits called plaque. Over time, this plaque can build to a total blockage of the artery. This process is called atherosclerosis.

Coronary Artery Stenting

During this procedure the REBEL stent is delivered into your coronary arteries. Once positioned within the stenosis, it is expanded with the inflation of the REBEL balloon delivery catheter. The REBEL Stent is left in the artery to keep it open and help prevent further narrowing of the coronary artery. Over time, the artery wall will heal around the stent as it continues to support the artery.

Potential adverse events (in alphabetical order) which may be associated with the use of coronary stent in native coronary arteries include but are not limited to:

- Abrupt closure
- Allergic reaction (including to medications, contrast, stent materials)
- Aneurysm (coronary)
- Angina
- Arrhythmias, including ventricular fibrillation and ventricular tachycardia
- Arteriovenous fistula
- Bleeding
- Cardiac tamponade
- Cardiogenic shock
- Cardiomyopathy
- Death
- Emboli (including air, tissue, thrombus, plaque or device materials)
- Heart failure
- Hematoma
- Hemorrhage
- Hypotension/hypertension
- Infection, local and/or systemic
- Ischemia, myocardial
- Myocardial infarction
- Pain
- Pericardial effusion
- Pseudoaneurysm, femoral
- Pulmonary edema
- Renal insufficiency or failure
- Respiratory failure
- Restenosis of stented segment
- Shock
- Stent embolization
- Stent fracture
- Stent migration
- Stent thrombosis and/or vessel occlusion
- Stroke/cerebrovascular accident/transient ischemic attack
- Total occlusion of coronary artery
- Vessel spasm
- Vessel injury (including dissection, perforation, rupture or trauma)

There may be other potential adverse events that are unforeseen at this time.

Clinical Data Summary

The principal safety and effectiveness for the REBEL Stent System is derived from the global OMEGA Clinical Trial, a clinical trial conducted on the OMEGA™ Stent System. The REBEL and OMEGA stents utilizes the same platinum chromium alloy. The REBEL Stent System has supplementary proximal stent connectors for increased axial strength, a short flexible stent delivery system tip, and a PTFE coated proximal hypotube for improved stent deliverability. Given the similarities between the OMEGA and REBEL Stent Systems and supportive bench and animal study information, the findings from the OMEGA Clinical Trial are applicable to the REBEL Stent System.

The OMEGA Clinical Trial included 328 patients with planned follow-up 30 days, 9 months and 12 months after the procedure. The combined occurrence of death, heart attack, bypass surgery and repeat angioplasty was 12.9% for the OMEGA stent at 9 months. The study results showed that the OMEGA Stent was as safe and effective as other approved bare metal coronary stents.

MEDICATIONS

Your cardiologist has prescribed a number of medications to thin the blood and prevent blood clots from forming and adhering to the surface of the stent. These medications include aspirin and blood-thinning drugs such as clopidogrel (Plavix®), ticlopidine (Ticlid®), or prasugrel (Effient®). It is extremely important to follow your medication regimen. **If you stop taking these medications before being instructed to do so by your cardiologist, the chances of blood clot formation on the stent, subsequent heart attack or even death are increased.**

If surgery or dental work is recommended which would require you to stop taking these medications prematurely, you and your doctors should carefully consider the risks and benefits of this additional surgery or dental work versus the possible risks from early discontinuation of these medications.

If you do require premature discontinuation of these medications because of significant bleeding, then your cardiologist will be carefully monitoring you for possible complications. Once your condition has stabilized, your cardiologist will probably put you back on these medications.

AFTER THE PROCEDURE

After the stent is implanted, you will rest in a cardiology ward for a short period where you can be monitored closely as you begin to recover. It may be one or more days before you are discharged from the hospital.

ACTIVITY

- Follow your doctor's guidelines.
- Return to normal activities gradually, pacing your return to activity as you feel better. Check with your doctor about strenuous activities.
- Let your doctor know about any changes in lifestyle you make during your recovery period.
- Report side effects from medications immediately. These may include headaches, nausea, vomiting or rash.
- Do not stop taking your medications unless you are asked to stop by the doctor who implanted your stent.
- Keep all follow-up appointments, including laboratory blood testing.
- Carry your Stent Implant Card at all times. If you receive dental or medical care or report to an emergency room/center, show your Stent Implant Card.

FREQUENTLY ASKED QUESTIONS

Can the stent move or rust?

Once positioned by your physician, the stent does not move on its own. It is manufactured so it will not rust.

Can I walk through metal detectors with a stent?

Yes, without any fear of setting them off.

How soon can I go back to work?

The majority of people return to work within a few days following the procedure.

What if I still have pain?

If you experience pain, immediately inform your cardiologist or the center where the procedure was performed.

Can I undergo MRI or scanner testing with a stent?

MRI safety testing has shown that the REBEL™ Stent is MR Conditional and that a patient with a REBEL Stent may safely undergo an MRI scan under certain conditions listed on the Stent Implant Card. Prior to undergoing an MRI scan, inform your doctor or MR technologist that you have a REBEL Stent.

Can I play sports?

Your doctor will tell you what sports you can play and when you can start them.

What should I change in my diet?

Your doctor may prescribe a low-fat, low-cholesterol diet to help reduce the levels of fat in your blood and reduce your risk.

MORE INFORMATION

For more information about the REBEL Stent System, please go to www.stent.com or call Coronary Stent Support at: 1-877-829-8741

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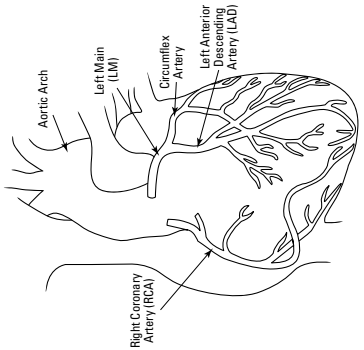
Stent Implant Location



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Non-clinical testing has demonstrated that the REBEL Stent is MR Conditional for single and overlapped conditions up to 74 mm. A patient with this device can be safely scanned in a Magnetic Resonance system meeting the following conditions:

- Static magnetic field of 3.0 and 1.5 Tesla only
- Maximum spatial gradient magnetic field of 2200 gauss/cm (22 T/m)
- Maximum Magnetic Resonance system reported, whole body averaged specific absorption rate (SAR) of <2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the REBEL Stent is expected to produce a maximum temperature rise of 2.6°C after 15 minutes of continuous scanning.

The stent(s) should not migrate in this MRI environment and MRI may be performed immediately following the implantation of a REBEL Stent(s). Prior to undergoing an MRI scan, inform your doctor that you have a REBEL Stent. MR image quality will be compromised if the area of interest is in the same area or relatively close to the position of the stent.

Please contact 1.888.272.1001 for more information about MR image artifact.

PLEASE CARRY YOUR CARD AT ALL TIMES.

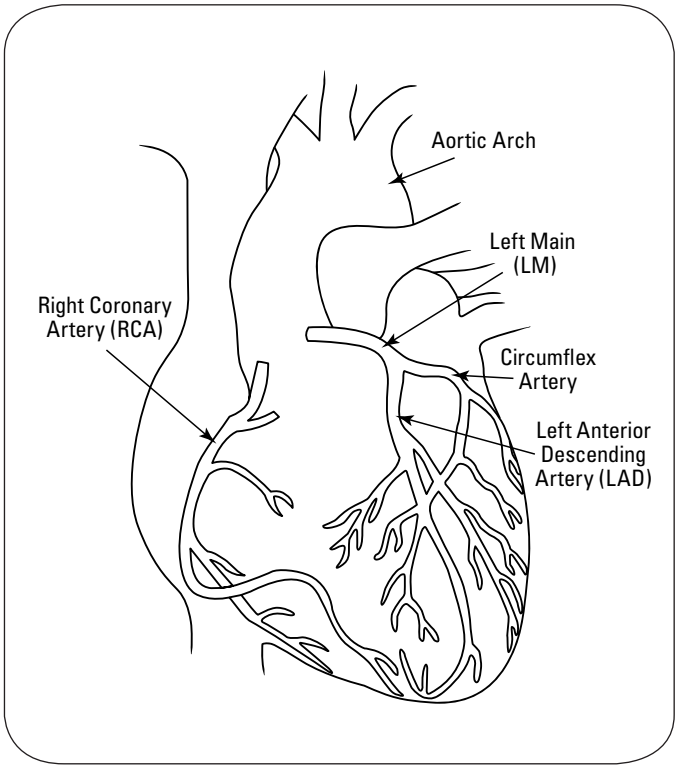
Your cardiologist has prescribed a number of medications to thin the blood and prevent blood clots after your implant. It is extremely important to follow the medication regimen as prescribed by your cardiologist. Before considering any surgery or dental work which would require you to stop taking these medicines early, you and your doctors should consider the risks from premature discontinuation of these medications. **For questions regarding your Coronary Stent System or other procedures (e.g., MRI), please contact your implanting cardiologist.**

Patient Name	Implanting Physician's Name
Date of Birth	Hospital
Date of Implant	City/State
	Phone Number

Stent Identification Information

Product Name:	Product Name:
Product Lot Number:	Product Lot Number:
Stent Location:	Stent Location:
Product Name:	Product Name:
Product Lot Number:	Product Lot Number:
Stent Location:	Stent Location:

Indications, contraindications, warnings and instructions for use can be found in the labeling supplied with each product. CAUTION: Federal (U.S.A.) law restricts these products to sale by or on the order of a physician.
REBEL™ Platinum Chromium Coronary Stent System is a product of Boston Scientific Corporation.



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