

Promus ELITE™

*Everolimus-Eluting Platinum Chromium
Coronary Stent System*

Patient Information Guide

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PATIENT INFORMATION GUIDE

You have recently had a Promus ELITE drug-coated 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.

Promus ELITE Drug-Eluting Stent

The Promus ELITE Stent is a bare-metal stent with a special drug coating added to help reduce the chance of the artery becoming blocked again. The drug is released from the stent over the period of time during which re-blockage is most likely to occur. The stent was designed to be very flexible, allowing it to fit the shape of your artery.

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

Polymer Coating

The stent is coated with a polymer which was developed specifically for drug-eluting stents. The polymer carries and protects the drug before and during the procedure. Once the stent is implanted, it helps control drug release into the coronary arterial wall. This contributes to even and consistent distribution of the drug from the stent.

Drug Release

The Promus ELITE drug-eluting stent is coated with a drug and polymer and has been designed to allow for a consistent and controlled release of the drug from the stent surface into the artery walls. Both the amount of drug and release rate have been selected so that healing can occur while minimizing the processes leading to restenosis (recurrent blockage of the artery), thus reducing the need for additional treatment in the stented area.

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 stent closure
- Acute myocardial infarction
- Allergic reaction to anti-coagulant and/or antiplatelet therapy, contrast medium, or stent materials such as stainless steel, platinum, chromium, iron, nickel or molybdenum
- Angina
- Arrhythmias, including ventricular fibrillation and ventricular tachycardia
- Arteriovenous fistula
- Bleeding
- Cardiac tamponade
- Cardiogenic shock/pulmonary edema
- Coronary aneurysm
- Death
- Dissection
- Emboli, distal (air, tissue or thrombotic material or material from device(s) used in the procedure)
- Heart failure
- Hematoma
- Hemorrhage, which may require transfusion
- Hypotension/hypertension
- Infection, local or systemic
- Ischemia, myocardial
- Pain, access site
- Perforation or rupture of coronary artery
- Pericardial effusion
- Pseudoaneurysm, femoral
- Renal insufficiency or failure

- Respiratory failure
- Restenosis of stented segment
- Stent embolization or migration
- Stent deformation, collapse, or fracture
- Stent thrombosis/occlusion
- Stroke/cerebrovascular accident/transient ischemic attack
- Total occlusion of coronary artery
- Vessel spasm
- Vessel trauma requiring surgical repair or reintervention

Adverse events associated with daily oral administration of everolimus to organ transplant patients include but are not limited to:

- Abdominal pain
- Abnormal laboratory tests which may include:
 - Increased levels of creatinine in the blood (which reflect reduced kidney function)
 - Increased or decreased levels of potassium in the blood
 - Decreased levels of magnesium or phosphorous in the blood
 - Increased sugar (glucose) levels in the blood (possible new-onset diabetes)
 - Increased cholesterol levels in the blood
 - Increased levels of fats and triglycerides in the blood
- Back pain
- Blood in the urine
- Constipation
- Cough
- Decrease or changes in sense of taste
- Decreased red blood cell, white blood cell, or platelet cell counts (platelet cells help the blood clot)
- Decrease or loss of sperm count in men
- Delayed wound healing/fluid accumulation (may include surgical wounds)
- Diarrhea
- Dry or itchy skin
- Fatigue
- Fever
- Headache
- Increased blood pressure
- Indigestion
- Infections: increased risks of bacterial, viral, fungal, or protozoal infections (may include herpes virus infections, BK virus infection, polyoma virus infection, opportunistic infections, or a combination of the above)
- Inflammation of the lining of the digestive system and mucous membranes
- Inflammation of the lung (not due to infections)
- Infection of the lungs and upper airways
- Insomnia
- Interactions with medications that are influenced by the CYP3A4 metabolic pathway (consult your doctor for more information)
- Loss of appetite
- Lymphoma and other malignancies (may include skin cancers)
- Mouth ulcers or sores
- Nosebleeds
- Nausea
- Pain in the arms, chest, legs, incision site or related to the procedure
- Pain or difficulty with urination
- Presence of protein in the urine
- Rash
- Reactive swelling, usually in the face

- Shortness of breath, and lung or breathing problems
- Swelling in the body (usually in the legs) caused by water retention
- Tremor
- Urinary tract infection
- Vomiting
- Weakness

Live vaccines and close contact with people that have received them should also be avoided. There is also potential harm to a fetus for pregnant women.

When used with cyclosporine medication, there may be an increased risk of the following:

- Blood clots in the small blood vessels
- Bleeding that appears as purple patches or spots on the skin
- Blood clotting in the smallest blood vessels of the body that may affect the kidneys

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

Clinical Data Summary

The principal safety and effectiveness information for the Promus ELITE™ Stent System is derived from the NG PROMUS Clinical Trial, which evaluated the Promus PREMIER™ Stent System, and the global PLATINUM Clinical Trial Program, a series of clinical trials conducted on the PROMUS Element™ Stent System. The PROMUS Element, Promus PREMIER, and Promus ELITE Stents utilize the same platinum chromium alloy and the same everolimus and PVDF-HFP coating, resulting in the same kinetic release profile. Given the similarities between the PROMUS Element, Promus PREMIER and Promus ELITE Stent Systems and supportive bench and animal study information, the findings from the PLATINUM and NG PROMUS clinical studies are applicable to the Promus ELITE Stent System.

The safety and effectiveness of the Promus PREMIER Stent System was studied in the NG PROMUS Clinical Trial that included 100 patients with planned 30-day follow-up. The study results showed that the Promus PREMIER Stent System had similar acute performance when compared to results from prior clinical trials using other drug-eluting stents.

The safety and effectiveness of the PROMUS Element Stent were compared to the PROMUS® Stent in the PLATINUM Workhorse clinical trial that included 1530 patients with a planned five-year clinical follow-up. The study results showed that patients who received a PROMUS Element Stent had a similar incidence of bypass surgery or repeat angioplasty in the lesion where the stent was placed, when compared to patients who received a PROMUS Stent (1.9% in both the PROMUS Element and PROMUS groups at 12 months). The combined occurrence of all death, heart attack, bypass surgery and repeat angioplasty, was 5.0% (PROMUS Element Stent) vs. 4.9% (PROMUS Stent) at 12 months.

There were also two sub-studies as part of the PLATINUM trial study design, which were conducted to determine the safety and effectiveness of the 2.25 mm diameter stent (Small Vessel sub-study), and the 32 and 38 mm lengths (Long Lesion sub-study). The Small Vessel sub-study included 94 patients with a planned five-year clinical follow-up. The study results showed that patients who received a PROMUS Element 2.25 mm diameter stent had a lower incidence of bypass surgery or repeat angioplasty in the lesion where the stent was placed, when compared to rates from a prior clinical trial using another drug-eluting stent. The combined occurrence of all death, heart attack, bypass surgery and repeat angioplasty was 7.8% (PROMUS Element Stent) at 12 months. The Long Lesion sub-study included 102 patients with a planned five-year clinical follow-up. The study results showed that patients who received a PROMUS Element 32 or 38 mm length Stent had a lower incidence of bypass surgery or repeat angioplasty in the lesion where the stent was placed, when compared to rates from a prior clinical trial using another drug-eluting stent. The combined occurrence of all death, heart attack, bypass surgery and repeat angioplasty was 5.2% (PROMUS Element Stent) at 12 months.

There was also a Pharmacokinetic sub-study as part of the PLATINUM trial study design, which was conducted to determine the release of the drug (everolimus) from the PROMUS Element Stent. There were 22 patients included in this sub-study with a planned five-year clinical follow-up. The drug release of the PROMUS Element Stent was found to be similar to that from other previously approved everolimus drug-eluting stents.

Finally, there was a PLATINUM QCA study, which was conducted to determine the amount of renarrowing that was observed in vessels treated with the PROMUS Element Stent. The PLATINUM QCA study included 100 patients with planned 12-month follow-up. There was similar renarrowing in the PROMUS Element Stent when compared to results from prior clinical trials using other drug-eluting stents.

Please consult with your physician for further information on the Promus ELITE Everolimus-Eluting Platinum Chromium Coronary Stent System.

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 Promus ELITE Stent is MR Conditional and that a patient with a Promus ELITE 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 Promus ELITE 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.

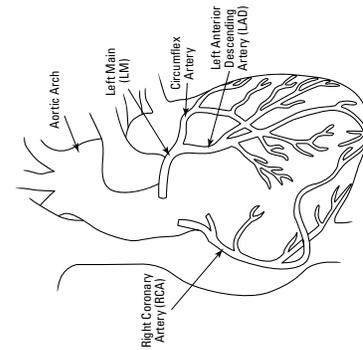
Does everolimus have any drug interactions that I should be concerned about?

Formal drug interaction studies with everolimus-based stents have not been conducted. Since some everolimus will remain on the stent, interactions at the location of the stent itself affecting the performance of the drug cannot be ruled out. Be sure to discuss with your doctor any drugs you are taking or planning to take.

What if I have taken everolimus before for cancer treatment and had a reaction to it?

Be sure to let your doctor know if you have had a previous allergic reaction to everolimus.

Stent Implant Location



Boston Scientific

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Non-clinical testing has demonstrated that the Promus ELITE 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 Promus ELITE 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 Promus ELITE Stent(s). Prior to undergoing an MRI scan, inform your doctor that you have a Promus ELITE 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

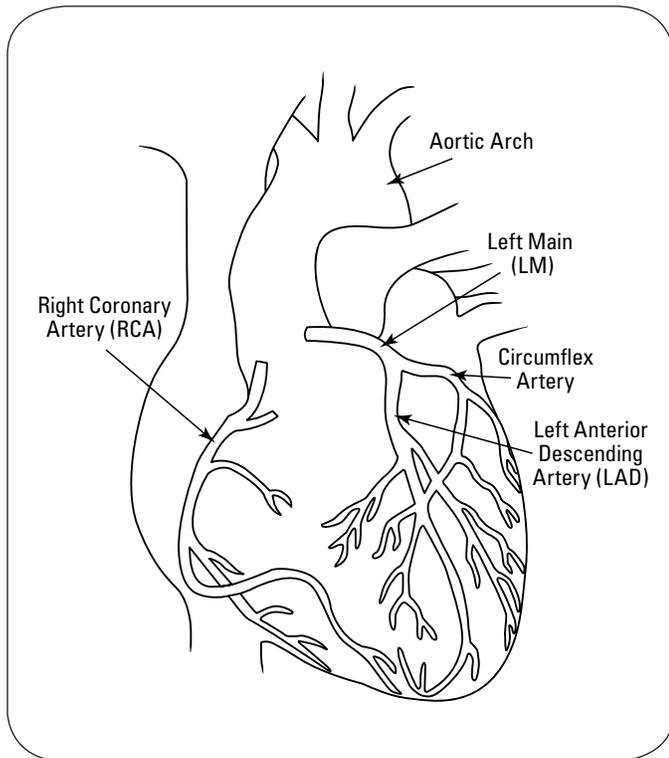
Stent Identification Information

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.

Promus ELITE™ Everolimus-Eluting Platinum Chromium Coronary Stent System is a product of Boston Scientific Corporation.



Boston Scientific

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