Boston Scientific

SYNERGY MEGATRON™

Everolimus-Eluting Platinum Chromium Coronary Stent System

Patient Information Guide

SYNERGY MEGATRON™

Everolimus-Eluting Platinum Chromium Coronary Stent System

PATIENT INFORMATION GUIDE

You have recently had a SYNERGY MEGATRON drug-coated stent implanted in the coronary arteries of your heart. This patient guide contains important information for you to know. This includes, possible risks with having a stent implant, medication recommendations, and questions you may have about your stent.

SYNERGY MEGATRON Drug-Eluting Stent

The SYNERGY MEGATRON Stent is a metal stent that helps reduce blockage of a coronary artery. The stent props the artery open and allows blood to reach all areas of the heart. The stent also has a special coating containing the drug everolimus. Everolimus is added to help reduce the chance of the artery becoming blocked again in patients with symptomatic coronary artery disease. This includes patients with diabetes, kidney disease, or who are at high risk for bleeding. The drug is released from the stent over time to prevent re-blockage. Re-blockage is most likely to occur in the first 3 months. The drug is released during that time. The stent was designed to be very flexible, allowing it to fit the shape of your artery. The SYNERGY MEGATRON Stent is made to last for the rest of your life. Testing shows the SYNERGY MEGATRON Stent can resist cracking or breaking for at least 10 years. The SYNERGY MEGATRON Stent is made of a Platinum Chromium Alloy, which consists of platinum, chromium, iron, nickel, and molybdenum.

The SYNERGY MEGATRON Stent is placed in the artery using the SYNERGY MEGATRON Balloon Delivery Catheter. Together, the Stent and the Balloon Delivery Catheter make up the SYNERGY MEGATRON Stent System.

Polymer Coating

The SYNERGY MEGATRON Stent is coated with a bioabsorbable polymer (coating that dissolves). This coating is on the outside surface of the stent (side in contact with the coronary artery wall). 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 artery wall. The polymer on the SYNERGY MEGATRON Stent dissolves and testing has shown that it should be absorbed by your body in about four months.

Drug Release

The SYNERGY MEGATRON Stent is coated with a polymer that contains the drug (everolimus). This coating has been designed to allow for a consistent and controlled release of the drug from the stent surface into the artery walls. The drug released from the stent coating prevents re-blockage during the time re-blockage is most likely to occur. This lowers the risk that the stented area will need to be treated again.

Possible adverse events (harmful effects) that may happen with the use of stents in arteries include but are not limited to:

- Abnormal heart beats
- Allergic reaction to medications prescribed to prevent blood clots
- Allergic reaction to the contrast dye or other medicines used during stent placement
- Allergic reaction to the materials used to make the stent
- An abnormal particle (air, blood clots, device, or device material) floating in the blood stream, including stent movement from the location where it is placed
- Bleeding, possibly life threatening
- Blood clot inside the stent which blocks blood flow
- Blood vessel damage due to puncture, tear, or burst that may need more treatment
- Build-up of blood in the lining around the heart that prevents the heart from pumping
- Death due to any cause, whether related to the heart or not
- Failure of the heart to pump enough blood to the body
- Fever or infection in your blood or other parts of the body
- Heart attack, coronary artery blood clot
- High or low blood pressure
- Injury to your skin caused by radiation used during the implant procedure
- Low blood flow to organs or lack of oxygen to the body due to fluid on the lungs that prevents breathing
- Pain in the chest or incision site
- Re-narrowing of the treated blockage or weakening of the blood vessel at the treated area
- Stroke, a blood clot or bleeding in the brain
- Worsening or failure of kidney function
- Worsening or failure of lung function that may require use of a mechanical ventilator

Contact your doctor with any questions about potential adverse events (harmful effects).

Clinical Data Summary

The main safety and effectiveness information for the SYNERGY MEGATRON Stent System comes from the EVOLVE Clinical Trials, in which the very similar SYNERGY Stent System was evaluated. The safety and performance of the SYNERGY Stent were first studied in the EVOLVE Clinical Trial which included 291 patients with follow-up to 5 years.

The safety and effectiveness of the SYNERGY Stent was then studied in the EVOLVE II Clinical Trial. A brief description of the EVOLVE II Trial and an overview of the EVOLVE II QCA Study are listed below.

The EVOLVE II randomized controlled trial, compared the SYNERGY Stent to the PROMUS Element Plus Stent in 1684 patients with a five-year clinical follow-up. The study results showed that at one year, the combined occurrence of heart-related death, heart attack, bypass surgery and repeat procedure related to the lesion where the stent was placed was similar after implantation of a SYNERGY (6.7%) vs. PROMUS Element Plus (6.5%) Stent. Patients who received a SYNERGY Stent had a similar rate of bypass surgery or repeat procedure in the lesion where the stent was placed when compared to patients who received a PROMUS Element Plus Stent.

The EVOLVE II diabetic sub-study was done to test the safety and effectiveness of the SYNERGY Stent in patients with medically treated diabetes.

The EVOLVE II QCA study was done to test the amount of re-narrowing that was seen in vessels treated with the SYNERGY Stent. The EVOLVE II QCA study included 100 patients with 12-month follow-up. There was similar re-narrowing in the SYNERGY Stent when compared to results from prior clinical trials using other drug-eluting stents.

The EVOLVE Short DAPT Study was done to test the safety of a shorter duration of dual-antiplatelet medication (3-months) after getting a SYNERGY Stent compared to a longer duration (12-months) in patients that have a high risk of bleeding. Dual-antiplatelet therapy includes aspirin and blood-thinning drugs such as clopidogrel (Plavix®), ticlopidine (Ticlid®), prasugrel (Effient®) or ticagrelor (Brilinta®). The study included 2,009 high bleeding risk patients, of which 1,487 were eligible to stop taking clopidogrel, ticlopidine, prasugrel or ticagrelor at 3-months. Patients that stopped blood-thinner at 3-months continued to take aspirin indefinitely. The study showed similar rates of heart attack or death when comparing the 3-month duration (5.6%) to a 12-month duration of dual antiplatelet medication (5.7%). The risk of stent thrombosis (blood clot) was also very low with 3-months of dual antiplatelet therapy (0.2%).

Please consult with your doctor for further information on the SYNERGY MEGATRON Stent System.

INFORMATION ON SAFE USE

Medications

Your cardiologist has prescribed medications to thin the blood and prevent blood clots from forming and sticking to the surface of the stent. These medications include aspirin and blood-thinning drugs such as clopidogrel (Plavix®), ticlopidine (Ticlid®), prasugrel (Effient®) or ticagrelor (Brilinta®). **It is extremely important to follow your medication plan. 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.**

Do not stop taking these medications early without talking to your doctor. Possible reasons for stopping medications early include surgery or dental work. You and your doctors should talk about the risks of stopping these medications too soon.

If you need to stop taking these medications early because of side effects such as significant bleeding, then your cardiologist will carefully monitor you for possible complications. Once your condition has stabilized, your cardiologist will probably put you back on these medications.

A study with the SYNERGY Stent has shown that if you are at a high risk of bleeding you may be eligible to stop taking blood thinning medications early. Your doctor will determine when it is appropriate to stop taking these medications.

After the Procedure

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

Recovery after stent placement is expected to be uneventful. If you develop any symptoms, especially chest pain or access site pain or bleeding, it is important to contact your health care team right away. You may require emergency evaluation.

Implant Card

Your doctor should provide you with a Stent Implant Card that identifies your implant. You should carry your implant card with you at all times. You should show your implant card to all your health care providers (doctors, dentists, technicians). The implant card lets them know that you have an implanted device and may be taking blood thinning medication. Please refer to your Stent Implant Card for the Reference number (catalog number) of your implant.

MRI Safety Information

If you need a magnetic resonance imaging (MRI) scan, tell your doctor or MRI staff that you have a stent implant. Non-clinical testing has shown that the SYNERGY MEGATRON Stent is MR Conditional. A patient with the SYNERGY MEGATRON Stent can typically be safely scanned right after placement of this stent. Your doctor will determine the correct MR conditions for scanning. Your doctor can access additional information in the SYNERGY MEGATRON Stent Instructions for Use available at IFU-BSCI.com.

Activity

- Follow your doctor's guidelines.
- Return to normal activities slowly. Return to activity slowly as you feel better. Check with your doctor about heavy physical activities. Remember that you are at increased risk of bleeding while you take blood thinning medication.
- 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, bleeding, shortness of breath or rash.
- Do not stop taking your medications unless you are asked to stop by the doctor who implanted your stent.
- Report any serious incident that occurs in relation to this device to your doctor. Additionally, report any serious incident that occurs in relation to this device to Boston Scientific and to the relevant local regulatory authority for medical devices in your country.
- 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 go to an emergency room, show your Stent Implant Card. Please contact the doctor who implanted your stent if you have any questions about your Stent Implant Card.

FREQUENTLY ASKED QUESTIONS

Can the stent move or rust?

Once positioned by your doctor, the stent does not move on its own. It is made 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?

Most 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 have MRI or scanner testing with a stent?

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

Can I play sports?

Your doctor will tell you what sports you can play and when you can start them. Remember that you will be at increased risk of bleeding or bruising while you take blood thinning medication.

What should I change in my diet?

Your doctor may recommend changes to your diet to reduce your risk of future cardiac events.

Does everolimus (the drug delivered by the SYNERGY MEGATRON Stent) have any drug interactions that I should be concerned about?

Everolimus is delivered to the wall of your coronary artery from your SYNERGY MEGATRON Stent. It is estimated that the everolimus drug will be released into the surrounding artery tissue for about 3 months following stent implantation. However, it is highly unlikely that the levels of everolimus in your blood will be measurable after one week or will have effects anywhere other than in your heart. Formal drug interaction studies with everolimus-based stents have not been conducted. Be sure to discuss with your doctor any drugs or supplements you are taking or plan 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.

Where does the polymer coating go once it's absorbed?

The coating is eliminated from the body as carbon dioxide and water.

REF Catalog Number

This document applies to the following products:

H7493942808350	H7493942812500	H7493942820450	H7493942828400
H7493942808400	H7493942816350	H7493942820500	H7493942828450
H7493942808450	H7493942816400	H7493942824350	H7493942828500
H7493942808500	H7493942816450	H7493942824400	H7493942832350
H7493942812350	H7493942816500	H7493942824450	H7493942832400
H7493942812400	H7493942820350	H7493942824500	H7493942832450
H7493942812450	H7493942820400	H7493942828350	H7493942832500

SYMBOL DEFINITIONS

The following symbols are used for patient information:

REF Catalog Number	LOT Lot Number	Indicates the date the device must be implanted by.
UDI Unique Device Identifier	MR MR Conditional	

Information in this patient guide relates to the health care professional *SYNERGY MEGATRON Instructions for Use* for this device. See IFU-BSCI.com for the health care professional Instructions for Use.

Stent Identification Information

Product Name: _____

Product Lot Number: _____

Stent Location: _____

Stent Identification Information

Product Name: _____

Product Lot Number: _____

Stent Location: _____

SYNERGY MEGATRON™

Everolimus-Eluting Platinum Chromium Coronary Stent System

MR

Non-clinical testing has demonstrated that the SYNERGY MEGATRON Stent is MR Conditional for single and overlapped conditions up to 66 mm. A patient with this device can be safely scanned in a MR system meeting the following conditions. Failure to follow these conditions may result in injury to the patient. Full MRI safety information is available in the SYNERGY MEGATRON Instructions for Use, which can be obtained at IFU-BSCI.com or by calling 888-272-1001.

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only
- Maximum spatial gradient magnetic field of 2000 gauss/cm (20 T/m) for 1.5 Tesla systems and 1060 gauss/cm (10.6 T/m) for 3.0 Tesla systems
- Maximum MR system reported, whole body averaged SAR of ≤ 2 W/kg (Normal Operating Mode)
- Scan Duration: Up to 15 minutes of continuous RF (a sequence of back-to-back series/scan without breaks), followed by 5 minutes of cooling

Under the conditions defined above, the stent is expected to produce a maximum temperature rise of 5.7 °C after 15 minutes of continuous RF.

The presence of this stent may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact. In non-clinical testing, the image artifact extends approximately 10 mm from the stent when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

Please contact 888-272-1001 for more information about MR image artifact.

PLEASE CARRY YOUR CARD AT ALL TIMES.

Your cardiologist has prescribed medications to thin the blood and prevent blood clots after your implant. It is extremely important to follow the medication plan as prescribed by your cardiologist. Before considering any surgery or dental work that would require you to stop taking these medicines early, you and your doctors should consider the risks from stopping these medications too soon. **For questions about 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 Lot Number: _____

Stent Location: _____

Product Name: _____

Product Lot Number: _____

Stent Location: _____

Stent Implant Location

Boston Scientific

Manufacturer

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA
USA Customer Service +1-888-272-1001

www.bostonscientific.com

2022-05

51477768-02A

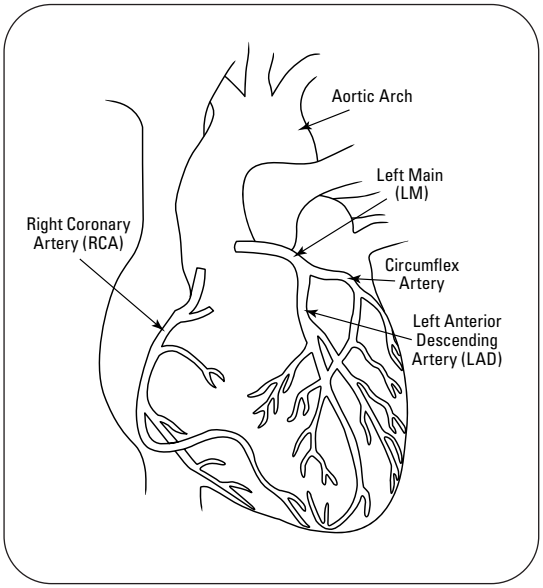
Boston Scientific

SYNERGY MEGATRON™

Everolimus-Eluting Platinum Chromium Coronary Stent System

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.

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



Boston Scientific

Manufacturer

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA
USA Customer Service +1-888-272-1001

www.bostonscientific.com

2022-05

51477768-02