Product Information for Patients

SYNERGY™ SHIELD

Everolimus-Eluting Platinum Chromium Coronary Stent System

Coronary Stent

Device Information

The SYNERGY SHIELD Stent is a metal stent with a special coating containing the drug everolimus. Everolimus is added to help reduce the chance of the blood vessel 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 a period of time to prevent re-blockage. The stent is made to be very flexible so it fits the shape of your blood vessel.

The SYNERGY SHIELD Stent is placed in the blocked vessel using the SYNERGY SHIELD Balloon Delivery Catheter. Together the SYNERGY SHIELD Stent and the SYNERGY SHIELD Balloon Delivery Catheter make up the SYNERGY SHIELD Stent System.

Your doctor should provide you with a Patient Implant Card that identifies your particular 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 Patient Implant Card for the Reference number (model number) of your implant.

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

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- 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

Information on Safe Use

Your doctor has ordered a number of medications to thin the blood and prevent blood clots after your implant. **It is extremely important to follow the medication plan ordered by your doctor.** 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.

Recovery after stent placement is expected to be uneventful. If you develop any symptoms post-procedure, 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.

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 SHIELD Stent is MR Conditional. A patient with the SYNERGY SHIELD 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 SHIELD Stent Instructions for Use available at www.bostonscientific.com.

Warnings and/or Precautions

See Information on Safe Use section.

Expected Lifetime and Follow-up

- The SYNERGY SHIELD Stent is made to last for the rest of your life. Testing shows the SYNERGY SHIELD Stent can resist cracking or breaking for at least 10 years. The delivery device is removed after the stent is placed and does not stay in the patient.
- Follow your doctor's instructions about medications needed after placement of the stent.
- Return to normal activities slowly. Return to activity slowly as you feel better. Check with your doctor about heavy physical activities.
- Let your doctor know about any changes in lifestyle you make during your recovery period.
- Report side effects from blood thinning medications right away. These may include headaches, nausea, vomiting, rash or difficulty breathing.
- Do not stop taking your medications without an agreement from the doctor who placed your stent.
- Keep all follow-up appointments, including lab blood testing.

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.

For customers in Australia, report any serious incident that occurs in relation to this device to Boston Scientific and to the Therapeutic Goods Administration (https://www.tga.gov.au).

Patient Contacting Materials

The following patient contacting materials are present in the SYNERGY SHIELD Stent. Tell your doctor if you think you are allergic or sensitive to any of these materials.

Material	Amount(s)
Everolimus	≤ 0.000364 g
Poly(DL-Lactide-co-Glycolide) (PLGA)	≤ 0.000444 g
Platinum	≤ 0.022198 g

Material	Amount(s)
Chromium	≤ 0.012108 g
Iron	≤ 0.024889 g
Nickel	≤ 0.006054 g
Molybdenum	≤ 0.001769 g

Symbol Definitions

The following symbols are used for patient information:

31	Date		Health care center or doctor		Patient identification
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 literature relates to information in the physician's literature for the device: 51496007-01A.

REF

H7493966608220	H7493966608250	H7493966608270	H7493966608300	H7493966608350
H7493966608400	H7493966612220	H7493966612250	H7493966612270	H7493966612300
H7493966612350	H7493966612400	H7493966612450	H7493966612500	H7493966616220
H7493966616250	H7493966616270	H7493966616300	H7493966616350	H7493966616400
H7493966616450	H7493966616500	H7493966620220	H7493966620250	H7493966620270
H7493966620300	H7493966620350	H7493966620400	H7493966620450	H7493966620500
H7493966624220	H7493966624250	H7493966624270	H7493966624300	H7493966624350
H7493966624400	H7493966624450	H7493966624500	H7493966628220	H7493966628250
H7493966628270	H7493966628300	H7493966628350	H7493966628400	H7493966628450
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EC REP

Boston Scientific Limited
Ballybrit Business Park
Galway IRELAND

AUS **Australian Sponsor Address**

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY NSW 1455 Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

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

bostonscientific.com

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