Cobalt-chromium sirolimus-eluting coronary bifurcation stent
with delivery system, Rapid Exchange

BIOSS LIM C®

PATIENT INFORMATION GUIDE

Cardiovascular

BALTON®

This guidebook is designed to help you and your family understand coronary artery disease and its treatment with *Cobalt-chromium sirolimus-eluting coronary bifurcation stent BiOSS LIM C® with a delivery system, Rapid Exchange.*

For your convenience, a glossary of medical terms is included at the end of this booklet.

This booklet is only a guideline. It is not intended to diagnose a medical condition. The treatment of coronary artery disease may vary according to everyone's unique needs and doctor assessments. As with any medical procedure, the best source for information and advice is your doctor.

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BiOSS LIM C® – Cobalt-chromium sirolimus-eluting coronary bifurcation stent with delivery system, Rapid Exchange

INTRODUCTION

This guidebook is designed to help you and your family understand the coronary arteries' vascular disease and treatment with a vascular **stent**. If you have any questions as you read, please write them down and discuss them with your doctor.

CORONARY ARTERY DISEASE

Coronary artery disease occurs when fatty deposits (**plaques**) clog the blood vessels that supply oxygen-rich blood to the heart muscle (**coronary arteries**).

THE HEART AND CORONARY ARTERIES

The heart is a muscle that pumps blood throughout the body. Therefore, it needs a constant supply of oxygen-rich blood to be able to function properly. The coronary arteries are the blood vessels that carry oxygen-rich blood to the heart muscle. The coronary arteries wrap around the entire heart.

FUNCTION

The coronary arteries supply essential oxygenated blood to the heart. The blood carries oxygen and nutrients that your body needs to work correctly.

CORONARY ARTERY STENOSIS

When coronary artery disease (CAD) is present, blood flow through the arteries can be reduced. When this happens, the heart muscle may not receive enough oxygen, and you may feel chest pain (called angina).

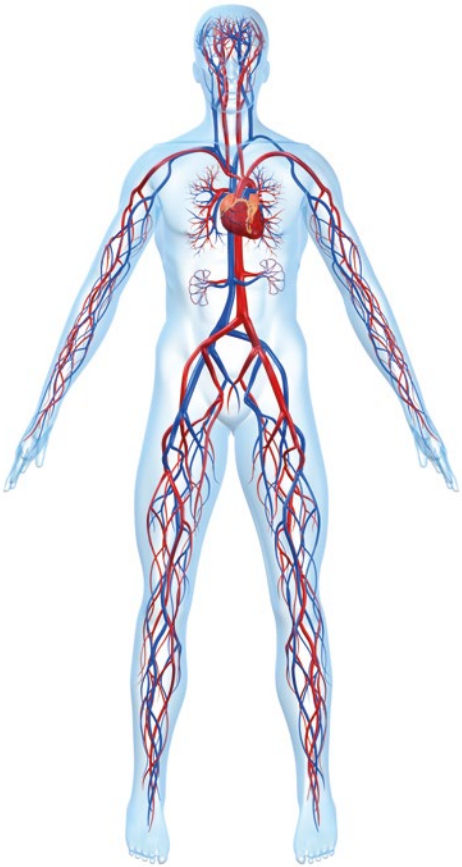


Fig. 1. Circulatory system

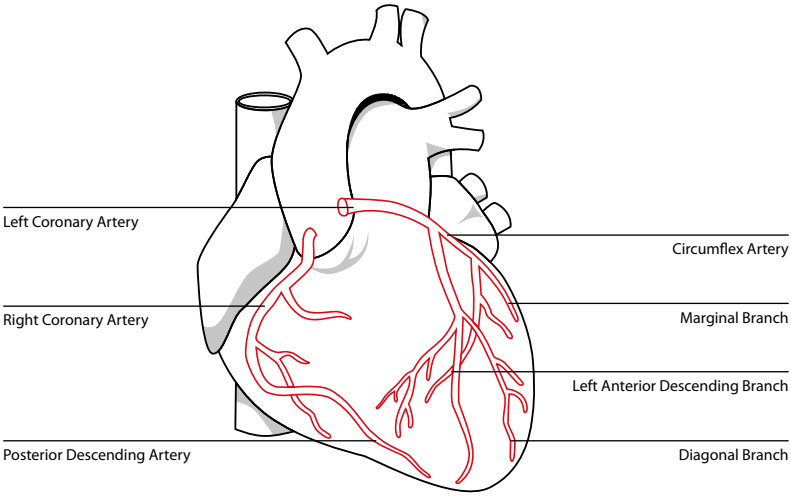


Fig. 2. Coronary artery

Coronary artery disease is caused by the build-up of fatty substances, such as cholesterol, that accumulate along the lining of the coronary arteries in a process known as atherosclerosis. You may hear this referred to as a "plaque," "lesion," "blockage," or "stenosis." This means a narrowing in the artery caused by a build-up of substances that may eventually block the blood flow.

Because the coronary arteries supply oxygen-rich blood to the heart, untreated blockages can be very serious and can lead to a heart attack (myocardial infarction) or even death.

Over the lifetime, many factors can cause one or more of your coronary arteries to become narrowed or blocked.

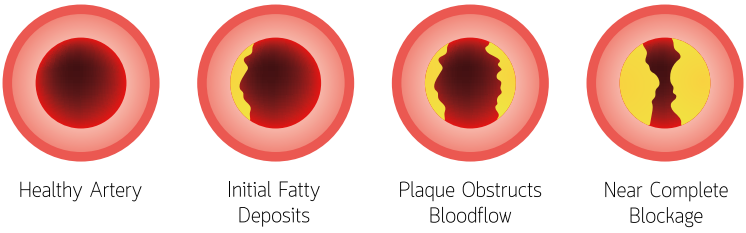


Fig. 3. Coronary artery disease

DIAGNOSIS

Coronary artery disease can progress very slowly, often without symptoms. Most people do not realize that they have heart disease. In fact, the first sign that something may be wrong could be an episode of angina or even a heart attack.

Typical angina symptoms are feelings of pressure, tightness, or pain in the chest, arm, back, neck, or jaw.

Symptoms also include heartburn, nausea, vomiting, excessive sweating, fatigue, or shortness of breath. Angina may occur as only one or many of these symptoms.

Although the exact cause of CAD is unknown, certain risk factors are often seen in patients with coronary artery disease.

These factors include:

- high blood pressure,
- high cholesterol and/or triglycerides in your blood,
- diabetes,
- smoking,
- excessive weight,
- lack of a regular exercise program,
- having a close relative with heart disease

Males are more likely to develop coronary artery disease than females.

In addition, menopausal status in women may play a role in coronary artery disease.

Males are more likely to develop coronary artery disease than females.

In addition, menopausal status in women may play a role in coronary artery disease.

You are at greatest risk for CAD if you:

- have high blood pressure
- are diabetic
- smoke cigarettes
- are overweight and/ or inactive
- have a relative with the disease

If you have experienced symptoms or have an increased risk of heart disease, your doctor may recommend you to have an exercise stress test, an electrocardiogram (ECG), chest X-ray, and blood tests.

Stress tests measure changes in the electrical activity of your heart as you perform controlled exercise and may show if the heart muscle is at risk of dying or if there was any damage to your heart.

These results may indicate a need for further testing. Your doctor may then recommend a cardiac catheterization or coronary angiogram.

It is one of the most useful methods to diagnose coronary artery disease because it allows the doctor, under X-ray, to see exactly where the coronary arteries are narrowed or blocked.

TREATMENT OPTIONS

Treatment of coronary artery disease aims to prevent a heart attack in the future.

It is important to inform your doctor about your entire medical history. Follow your doctor's recommendations. These may vary greatly depending on your case and may include:

MEDICATION

Your doctor may prescribe medications to help you reduce your cholesterol, lower blood pressure, manage your diabetes, or help you stop smoking. You may also be prescribed an antiplatelet or anticoagulant medication.

Both above options do not require any surgery, but each of them may not be enough to manage your disease completely. If neither of the above options is sufficient to manage your disease, one of the following interventional options, which consist of restoration or widening of the artery, may be recommended.

SURGICAL PROCEDURE

Coronary artery bypass grafting (CABG) is a common surgical procedure that removes a section of the artery or vein from another part of your body. This vessel is then connected (grafted) to the coronary artery at the blockage site. This creates a new path for blood to flow around (bypass) the blocked artery and to your heart. Most coronary bypass patients remain in the hospital for about a week, followed by a recovery period at home.

MINIMALLY INVASIVE ENDOVASCULAR PROCEDURES

BALLOON ANGIOPLASTY

This procedure may be done immediately following your catheterization, or you may be sent home and instructed to return for the procedure. You will be asked not to eat or drink anything after midnight on the night before your procedure.

Fig. 4. Catheterization laboratory

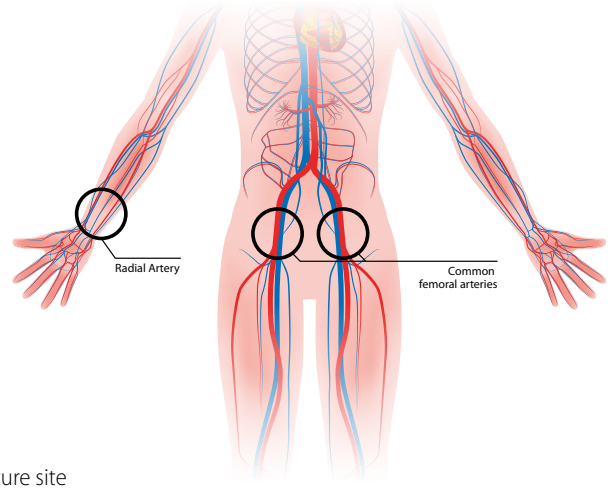


Fig. 5. Artery puncture site

You must follow these and any other instructions carefully.

If you had a cardiac catheterization procedure, angioplasty is similar in many ways. Your heart rhythm will be monitored, an intravenous line will be inserted in your arm, your wrist or groin area will be shaved and cleaned. And the procedure will be performed through that area.

As with cardiac catheterization, you need to follow your doctor's instructions during the procedure.

- After a local anesthetic is given, a small incision is made in your wrist or groin, and a catheter sheath introducer is inserted into the artery.

Then, a narrower and longer tube, called a guiding catheter, is passed through the sheath to the heart.

- A contrast medium (X-ray dye) is injected through the guiding catheter to allow the doctor to see the arteries of your heart on an X-ray machine called a fluoroscope.
- While observing the arteries on the X-ray screen, the doctor inserts a guidewire through the guiding catheter and advances it to the diseased artery.
- A balloon catheter is inserted over the guidewire and positioned at the site of the blockage.
- Once the balloon catheter is in place, the balloon is expanded. As the balloon expands, it compresses the fatty deposits (plaque) against the lining of the artery. The balloon may be expanded one or several times before it is removed.

- Once the balloon catheter is removed, the fatty deposits remain compressed, and blood flow is restored to your heart.

The balloon procedure may last from 30 to 90 minutes but varies from patient to patient.

It is not uncommon to experience some discomfort or a pressure sensation in your chest when the balloon is inflated. During the procedure, you will be asked to remain very still. You will be asked how you are feeling. Please, be sure to let your doctor know if you experience any discomfort.

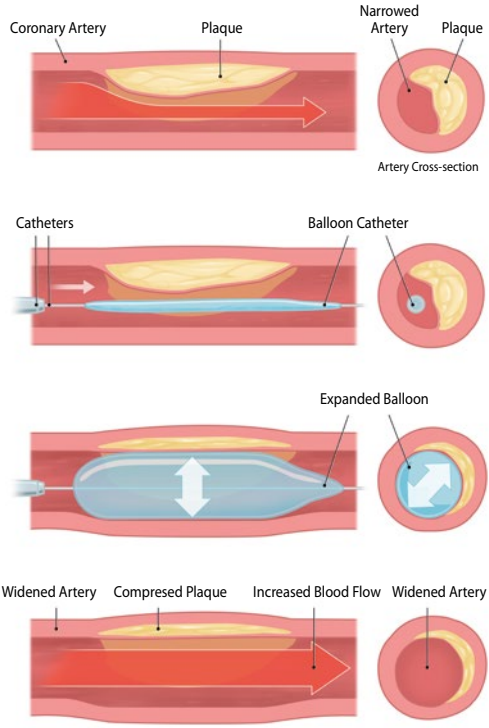


Fig. 6. Balloon angioplasty

ARTERY RE-NARROWING AFTER BALLOON ANGIOPLASTY

It is not uncommon for patients to develop a re-narrowing in the same site as the initial balloon procedure.

In fact, one-third to one-half of patients who have successful balloon angioplasty will return in the first 4-6 months after the balloon procedure.

This kind of narrowing is called "restenosis" and is due to a type of scar tissue formation.

To lower the risk for restenosis, your doctor may recommend a procedure called coronary stent implantation.

Clinical studies have shown that using a coronary balloon-expandable stent reduces the rate of restenosis and improves outcomes.

STENT IMPLANTATION

A coronary stent is a small, slotted metal tube that is mounted on a balloon catheter. It is inserted into your artery after a wider channel has been created by a balloon and positioned at the site of the blockage.

When the balloon is inflated, the stent expands and is pressed into the artery's inner wall. The balloon is then deflated and removed with the stent remaining in place. The stent acts as a scaffold that helps to hold the artery open, which improves blood flow and relieves symptoms caused by the blockage.

A coronary stent may be placed after the initial balloon procedure, which is done to create a wider opening for the stent.

You will have the same feelings when the stent is put in place as when the balloon was expanded during the procedure.

The stent, which is mounted on a balloon catheter, is inserted into the artery and placed at the site of the initial blockage.

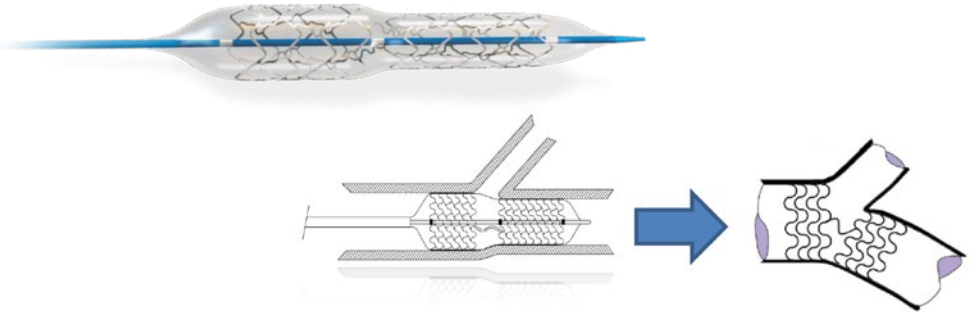
- When the balloon and stent are positioned, the balloon is inflated. The stent expands and becomes firmly pressed into the inner wall of the artery. One or more stents may be used at the site that was narrowed or blocked.
- X-ray pictures are taken so that the doctor can see the stent in your artery. Additional balloon inflations may be needed to expand the stent fully.
- The balloon catheter is deflated and removed along with the guidewire and the guiding catheter.
- The stent will remain in place permanently. Over the next weeks, your cells will form a natural covering that will hold the stent securely in place.

Persons allergic to Co Cr, polymers, or sirolimus may suffer an allergic response to this implant. It is important to notify your physician if you have any known metal, plastic, or drug allergies.

ARTERY RE-NARROWING AFTER STENTING (IN-STENT RESTENOSIS)

Occasionally some patients develop a re-narrowing within the stent which may lead to a recurrence of symptoms such as the feeling of pressure, tightness, or pain in the chest, arm, back, neck, or jaw. This kind of narrowing is called "in-stent restenosis" and is due to forming a new atherosclerotic plaque.

In fact, a small percentage of patients who have successful stent implantation develop in-stent restenosis over a period of few years.

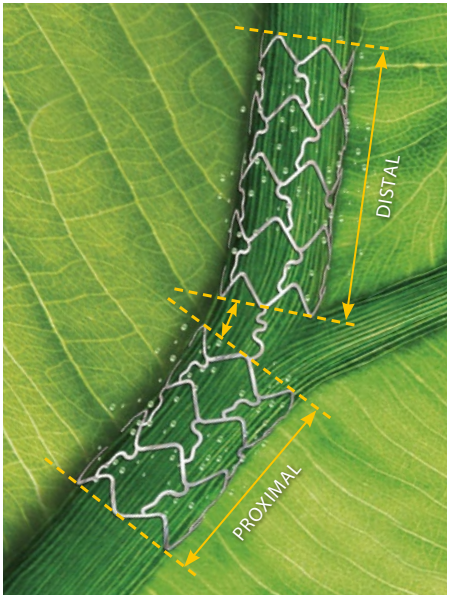


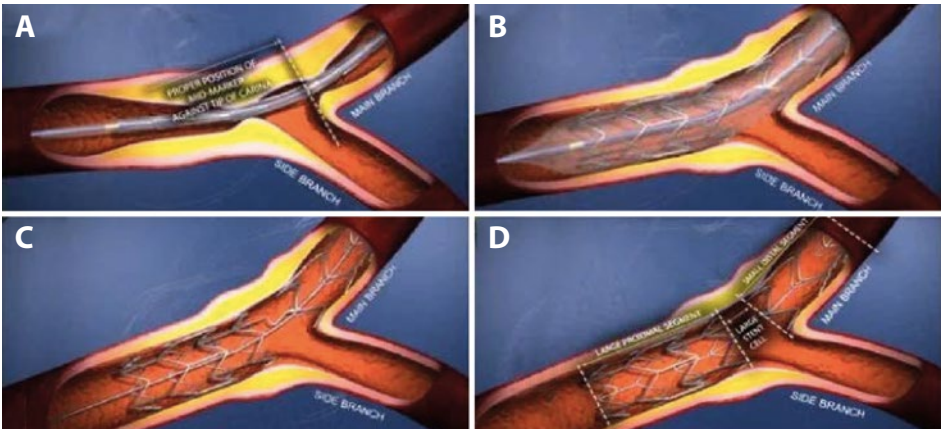
COBALT-CHROMIUM SIROLIMUS-ELUTING CORONARY BIFURCATION STENT BIOSS LIM C® WITH DELIVERY SYSTEM, RX

The BiOSS LIM C® stent is uniquely designed to be implanted in a region where one artery divides into two smaller arteries (the main branch and a side branch), i.e., a place called a coronary bifurcation. The physician may choose to implant another drug-eluting stent such as ALEX® PLUS in the side branch depending on the result of using BiOSS LIM C® in the main branch. Sometimes one stent may not be adequate to achieve good results.

BiOSS LIM C® has a patented design to cover the larger and the smaller diameters of the bifurcation area and prevents narrowing within the stent (in-stent restenosis). The stent is made of cobalt-chromium alloy L605. The outline of the stent was obtained using laser work.

The stent is mounted onto a specially dedicated balloon. After balloon deflation, the BIOSS LIM C® stent copies the bifurcation configuration matching proximal-distal vessel size requirements. It fits all parts of coronary bifurcation according to principles of optimal energy distribution. The unique stent construction ensures its proper and reliable implantation into arterial walls. Thanks to the connections between stent segments, its capabilities of adjustment to the shape of the artery increase.





The BiOSS LIM C® stent has a thin coating of a drug (sirolimus) on its surface. The drug is located within a biodegradable polymer coating. The polymer layers release sirolimus in a process of their slow biodegradation (lasting ca 8 weeks). The stent is designed to provide mechanical support in the artery while the drug (sirolimus) is slowly released into the artery wall around the stent. The drug's action (sirolimus) is intended to limit the overgrowth of normal tissue as the healing process occurs following coronary stent implantation.

Overgrowth of normal tissue is thought to be a major factor responsible for re-narrowing the artery after stenting.

PREPARING FOR YOUR PROCEDURE

The benefit of implantation of the cobalt-chromium sirolimus-eluting coronary bifurcation stent BiOSS LIM C® is the reduction of **coronary artery stenosis**. However, as with any intervention, the implantation procedure involves some risks and contraindications.

CONTRAINDICATIONS:

The use of coronary vessel stents is usually contraindicated in the following groups:

- Patients with contraindication(s) for antiplatelet and/or anticoagulant treatment.
- Patients with stenosis which prevents from the effective filling of the angioplasty balloon.
- Patients with 0,0,1 type of lesion in the bifurcation segment according to the Medina classification.
- Patients with excessively tortuous vessels, which, in opinion of attend-

ing physicians, would make impossible the insertion of the balloon stent.

- Contraction of coronary vessels.
- Patients with a known hypersensitivity to cobalt-chromium alloy, a polymer of lactic acid or sirolimus.
- Women during pregnant or lactation.

BEFORE YOUR CORONARY ARTERY STENTING PROCEDURE

Upon adission to the hospital, you may undergo angiography, intravascular ultrasound imaging, and blood tests. Remember to tell your doctor about all the medications you are currently taking and any allergies you may have. You may be asked not to drink or eat from midnight before the procedure.

Your doctor should have discussed the procedure in detail with you and explained the device's possible risks and potential benefits. Please do not hesitate to ask any questions. As with any intervention, the **angioplasty** and stenting procedure involves some risks. These risks are uncommon but are important to be aware of.

POTENTIAL ADVERSE REACTIONS

Adverse events that may be associated with PCI, treatment procedures and the use of a coronary stent in coronary arteries include the following, but are not limited to:

- Allergic reaction or hypersensitivity to administered anticoagulation or antiplatelet drugs, anesthesia, contrast agent, or stent materials: Co-Cr, polymer, sirolimus)
- Cardiac ischemic conditions
  - myocardial infarction
  - prolonged chest pain
  - the need for urgent CABG
- Cardiac arrhythmias
- Cardiac failure/shock
- Coronary artery complications
  - abrupt closure
  - dissection
  - embolism (air, atherosclerotic plaque, thrombotic material or device)
  - perforation
  - restenosis
  - spasm
  - thrombosis (acute, subacute, late, very late)
- Death
- Fever
- Hypotension/hypertension
- Infection
- Nausea and vomiting
- Pain
- Palpitations, dizziness, syncope
- Pericardial complications
  - cardiac tamponade
  - pericardial effusion
  - pericarditis

- Renal insufficiency/failure
- Stroke/TIA
- Vascular access complications which may require blood transfusion or vessel repair:
  - bleeding (ecchymosis, hematoma, hemorrhage, retroperitoneal hemorrhage)
  - embolism (air, atherosclerotic plaque, thrombotic material or device)
  - peripheral ischemia
  - peripheral nerve injury
  - pseudoaneurysm, dissection, perforation, arteriovenous fistula

Make sure you understand the possible risks and benefits of your coronary stent procedure.

STENT IMPLANTATION PROCEDURE

Coronary artery stenting is a procedure performed in the cardiac catheterization laboratory. You will enter the room equipped with special instruments and will be lying on the X-ray table. You will be covered with sterile sheets, and the area where the catheter will be inserted will be shaved and washed with antiseptic solution to prevent infection.

During the procedure, you will be awake, and medical and nursing staff will be monitoring you closely. A local anesthetic will be injected through the skin. When the medication takes effect, you should only feel dull pressure where the operator is working with the catheter. The operator will insert a fine tube (introducer) into the artery. It will provide a passageway through which the doctor can insert catheters with necessary devices and a contrast medium. The contrast medium injected throw the catheter will allow seeing the area of blockage in your artery. The operator may insert a balloon to prepare the artery for **stent** implantation. Then the stent, which is mounted on a balloon catheter, is advanced into the **coronary artery** and deployed to the blocked area of the artery. When the balloon and stent are positioned, the balloon is inflated. The stent expands and becomes firmly pressed into the inner wall of the artery. One or more stents may be used at the site that was narrowed or blocked. The delivery system is withdrawn from your body. Once again, the doctor may insert a balloon to ensure the stent is in full contact with the artery wall. The stent stays in place permanently, holding the artery open. The introducer is usually removed at the end of the procedure, but if the physician feels the necessity, it may sometimes be left in place temporarily.

The procedure takes approximately 60 to 90 minutes.

AFTER YOUR PROCEDURE

Once the procedure is finished, you will be moved to the special care unit, where you will be closely monitored by hospital staff. Your heart rhythm and blood pressure will be monitored continuously.

If the groin were used as an access site for the procedure, you would have to lie flat in bed and not move your leg for up to six hours, and a sandbag may be placed over the puncture site to keep pressure on it. In some cases, the puncture site may be closed with a closure device that will be described to you by your doctor.

If the access to the procedure were through the wrist, it would be closed by compression dressing, and you may be allowed to sit up afterward.

Once you return to the ward, you will have regular observations of your conscious level, heart rate, blood pressure, puncture site, and pulses in your feet. You may also have a drip to make sure you are not getting dehydrated. When the drip is removed, you should drink around 2 liters of water to help to wash out the contrast (dye) used during the procedure.

Notify hospital staff if you feel anything disturbing like trouble with seeing, swallowing, feeling lightheaded or dizzy, weakness, tingling, or numbness in limbs, face, or side of your body.

Mostly after 1 – 3 days after the procedure, you will be allowed to go home. Before you leave the hospital, your doctor will give you information about medications, diet, and activity.

YOUR RECOVERY

You will be informed when you can resume regular activity and return to work. You should avoid strenuous activities like lifting for at least a week. Remember to take all prescribed medications as your doctor tells you to do. Notify your doctor if these medications cause unpleasant reactions.

To help yourself stay healthy in the future, you should pay attention to a healthy diet and exercise. It will be easier and safer if you get help from a professional dietician and physiotherapist. In addition, it is essential to avoid smoking. If you need help quitting, please notify your healthcare provider.

PATIENT IMPLANT CARD

Be sure your doctor gives you a completed Patient Implant Card that you can keep as a record of your procedure. Carry the card with you always and show it to any doctors or health care workers who may be treating you. The card will have the date of the **stent** procedure, the location of the **stent** in your body, the name of the doctor who performed the procedure, and other important information.

MD

BIOSS LIM C

(**PT**) Stent de bifurcação coronária em cromo-cobalto com eluição de sirolimus com sistema de colocação Rapid Exchange

(**RU**) Стент кобальтово–хромовый с сиролимусом для бифуркации коронарных сосудов с системой доставки Rapid Exchange

(**UA**) Стент коронарний кобальто-хромовий з сиролімусом для бифуркації коронарних судин біосс лім сі з системою доставки

(**KZ**) Жеткізу жүйесі бар коронарлық қан тамырларының бифуркациясына арналған сиролимусы бар кобальт -хромды стент

(**TR**) Hizli değişim salimi sistemine sahip, kobalt-krom sirolimus salinimli koroner bifurkasyon stent

05/2021

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BALTON®

INTERNATIONAL IMPLANT CARD

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MD

BIOSS LIM C

(**EN**) Cobalt-chromium sirolimus eluting coronary bifurcation stent with delivery system Rapid Exchange

(**PL**) Stent kobaltowo-chromowy do bifurkacji naczyń wieńcowych uwalniający sirolimus z systemem wprowadzającym Rapid Exchange

(**FR**) Stent coronaire de bifurcation à élution de sirolimus au cobalt-chrome avec système de pose à Échange Rapide

(**IT**) Stent per biforcazione coronarica in lega cromo-cobalto a rilascio di sirolimus con polimero bioriassorbibile con sistema di introduzione a scambio rapido

(**ES**) Stent coronario recubierto de sirolimus para bifurcación de cromo-cobalto con sistema de liberación de intercambio rápido

(**DE**) Sirolimus-freisetzender kobalt-chrom-bifurkationsstent mit Rapid-Exchange-katheter

EXPLANATION OF SYMBOLS

(**EN**) Patient name and surname/ (**PL**) Imię i nazwisko pacjenta/ (**FR**) Nom et prénom du patient/ (**IT**) Nome e cognome del paziente/ (**ES**) Nombre y apellido del paciente/ (**DE**) Patientenname und Nachname/ (**PT**) Nome e sobrenome do paciente/ (**RU**) Имя и фамилия пациента/ (**UA**) Ім'я та прізвище пацієнта/ (**KZ**) Науқастың аты-жөні/ (**TR**) Hasta adı ve soyadı

(**EN**) Name and address of the healthcare institution/ (**PL**) Nazwa i adres zakładu opieki zdrowotnej/ (**FR**) Nom et adresse de l'établissement de santé/ (**IT**) Nome e indirizzo dell'istituzione sanitaria/ (**ES**) Nombre y dirección de la institución sanitaria/ (**DE**) Name und Anschrift der Gesundheitseinrichtung/ (**PT**) Nome e endereço da instituição de saúde/ (**RU**) Название и адрес лечебного учреждения/ (**UA**) Назва та адреса закладу охорони здоров'я/ (**KZ**) Денсаулық сақтау мекемесінің атауы және мекен-жайы/ (**TR**) Sağlık kurumunun adı ve adresi

LOT (**EN**) Batch code/ (**PL**) Numer serii/ (**FR**) Numéro de lot/ (**IT**) Numero di lotto/ (**ES**)Número de lote/ (**DE**) Chargennummer/ (**PT**) Número do lote/ (**RU**) Номер партии/ (**UA**) Номер партії/ (**KZ**) Номер партии/ (**TR**) Sıra numarası

EXPLANATION OF SYMBOLS

31 (**EN**) Date of implantation/ (**PL**) Data implantacji/ (**FR**) Date d'implantation/ (**IT**) Data di impianto/ (**ES**) Fecha de implantación/ (**DE**) Datum der Implantation/ (**PT**) Data de implantação/ (**RU**) Дата имплантации/ (**UA**) Дата імплантації/ (**KZ**) Имплантация күні/ (**TR**) Implantasyon tarihi

SN (**EN**) Serial number/ (**PL**) Numer seryjny/ (**FR**) Numéro de série/ (**IT**) Numero di serie/ (**ES**) Número de serie/ (**DE**) Ordnungsnummer/ (**PT**) Número de série/ (**RU**) Серийный номер/ (**UA**) Серійний номер/ (**KZ**) Сериялық нөмір/ (**TR**) Seri numarası

MD (**EN**) Medical device name/ (**PL**) Nazwa wyrobu medycznego/ (**FR**) Nom du dispositif médical/ (**IT**) Nome del dispositivo medico/ (**ES**) Nombre del dispositivo médico/ (**DE**) Name des Medizinprodukts/ (**PT**) Nome do dispositivo médico/ (**RU**) Название медицинского устройства/ (**UA**) Назва медичного виробу/ (**KZ**) Медициналық құралдың атауы/ (**TR**) Tıbbi cihaz adı

EXPLANATION OF SYMBOLS

UDI (**EN**) Unique Device Identification/ (**PL**) Unikalna Identyfikacja Wyrobu Medycznego/ (**FR**) Identification unique de l'appareil/ (**IT**) Identificazione univoca del dispositivo/ (**ES**) Identificación de dispositivo única/ (**DE**) Eindeutige Geräteidentifikation/ (**PT**) Identificação Única de Dispositivo/ (**RU**) Уникальная идентификация устройства/ (**UA**) Унікальна ідентифікація пристрою/ (**KZ**) Құрылғының бірегей идентификаясы/ (**TR**) Benzersiz Cihaz Kimliği

GTIN (**EN**) Global Trade Item Number/ (**PL**) Globalny Numer Jednostki Handlowej/ (**FR**) Numéro d'article du commercé mondial/ (**IT**) Numero articolo commercio globale/ (**ES**) Número de artículo comercial global/ (**DE**) Globalen Artikelnummer/ (**PT**) Número global de item comercial/ (**RU**) Глобальный номер предмета торговли/ (**UA**) Номер глобальної торгової позиції/ (**KZ**) Сауда-саттықтың дүниежүзілік нөмірі/ (**TR**) Global Ticari Ürün Numarası

EXPLANATION OF SYMBOLS

REF (**EN**) Catalogue Number/ (**PL**) Numer katalogowy/ (**FR**) Numéro de catalogue/ (**IT**) Numero di catalogo/ (**ES**) Número de catálogo/ (**DE**) Katalognummer/ (**PT**) Catálogo de número/ (**RU**) Каталожный номер/ (**UA**) Номер каталогу/ (**KZ**)Каталог нөмірі/ (**TR**) Katalog numarası

(**EN**) Manufacturer/ (**PL**) Producent/ (**FR**) Fabricant/ (**IT**) Produttore/ (**ES**) Fabricante/ (**DE**) Hersteller/ (**PT**) Fabricante/ (**RU**) Производитель/ (**UA**) Виробник/ (**KZ**) Өндіруші/ (**TR**) Üretici

(**EN**) Information website for patient/ (**PL**) Strona internetowa z informacjami dla pacjenta/ (**FR**) Site d'informations pour le patient/ (**IT**) Sito web con le informazioni per i pazienti/ (**ES**) Sitio web con información para el paciente/ (**DE**) Webseite mit Informationen für Patienten/ (**PT**) Site de informações para paciente/ (**RU**) Информационный веб-сайт для пациента/ (**UA**) Інформаційний веб-сайт для пацієнта/ (**KZ**) Пациентке арналған ақпараттық веб-сайт/ (**TR**) Hasta için bilgi web sitesi

SAFETY DURING MAGNETIC RESONANCE IMAGING (MRI)

If you require **MRI** after coronary artery stenting, tell your healthcare providers that you have a **stent**.

MRI safety testing has shown that the Bioss Lim C stent is MR Conditional and that a patient with a coronary stent may safely undergo an MRI scan under certain conditions listed below.

MRI SAFETY INFORMATION:

A patient with this device can be safely scanned in an MRI system meeting the following conditions:

- Static magnetic field of 3.0 T or 1.5 T
- Maximum spatial field gradient of 1900 gauss/cm (19 T/m)
- Maximum MRI system reported, whole body averaged specific absorption rate (SAR) of 1.0 W/kg

CONCLUSION

You have a very important role to play to ensure that your **stent** implantation is successful. You must cooperate with your doctor and follow through with your responsibilities as part of the patient/medical team. You will need to see the doctor who implanted your stent for routine follow-up examinations. During these visits, your doctor will monitor your progress and evaluate your medications, the status of your disease, and how the stent is working for you. If you have any questions or concerns, please contact your doctor to discuss them.

GLOSSARY

Term	Definition
Angiogram	A procedure in which contrast medium is injected into the arteries to diagnose a narrowing or blockage of the artery.
Angioplasty	A procedure where a balloon dilation catheter is passed through the blood vessel to the blocked area of an artery. Once the balloon on the tip of the catheter is inflated, the blocked area in the artery is opened. Also called PTCA (Percutaneous Transluminal Coronary Angioplasty).
Anticoagulant	A medicine that slows or prevents the clotting of blood.
Atherosclerosis	The process of fatty deposits and/or calcium build-up (plaque) on the inside of the arteries.
Balloon Catheter	A long tube that passes through your arteries with a tiny balloon on its tip. The balloon is inflated after it is in place to open a blockage and press the stent against the artery wall.
Bifurcation	A division into two branches, such as a blood vessel.
Coronary Arteries	Coronary arteries are special blood vessels that supply the heart with necessary oxygen and nutrients. The heart does not function properly without enough oxygen.
Coronary Artery Disease	Atherosclerosis of the coronary arteries.

GLOSSARY

Catheter	A long hollow tube used to introduce a device. drug. or contrast medium into a blood vessel.
Catheterization	A procedure that involves passing a tube (catheter) through blood vessels and injecting a contrast medium to detect blockages.
Cholesterol	A substance that circulates in the blood and, when deposited in the artery, plays a role in forming blockages. Cholesterol originates from food rich in animal fat
Embolic material	Small clots or pieces of plaque that travel in the bloodstream and lodge in a blood vessel, blocking blood flow.
MRI (Magnetic Resonance Imaging)	A diagnostic test that uses magnetic waves to obtain images of the inside of your body.
Plaque	An accumulation or build-up of fatty deposits, calcium, and/or cell debris in an artery that leads to narrowing of the artery.
Restenosis	The recurrence of a narrowing or blockage in an artery after treatment.
Stent	An expandable, metallic, tubular-shaped device that provides structural support for a vessel.
Stenosis	A narrowing in your arteries caused by plaque build-up, which restricts blood flow.
Ultrasound	A non-invasive test using sound waves to determine the presence of arterial narrowing.

CONTACT INFORMATION

Your doctor or nurse will review this material with you. We encourage you to ask them any questions regarding your treatment and recovery.

Additionally, your doctor may recommend that you join a support group to speak with others who have undergone similar procedures. Ask your doctor for contact information about these groups and possible website addresses.

Please be informed that the BIOSS LIM C® stent is not currently approved by Therapeutic Goods Administration, Department of Health.

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