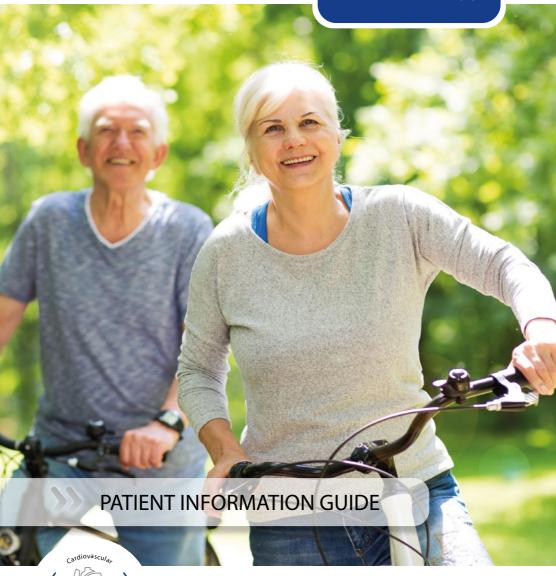
Cobalt-chromium sirolimus-eluting coronary stent with delivery system, Rapid Exchange











This guidebook is designed to help you and your family understand coronary artery disease and its treatment with Cobalt-chromium sirolimus-eluting coronary stent ALEX® PLUS 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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ALEX® PLUS – Cobalt-chromium sirolimus-eluting coronary stent with delivery system, Rapid Exchange

INTRODUCTION

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

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 **ARTFRIFS**

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.

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 chest pain (called angina) may be felt.

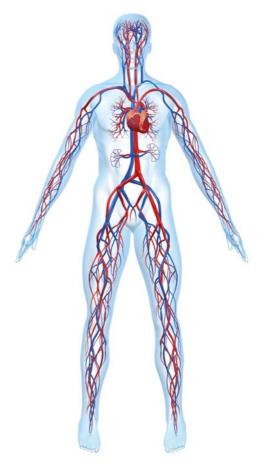


Fig. 1. Circulatory system





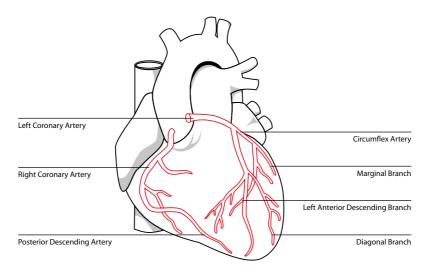


Fig. 2. Coronary artery

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 that there is a narrowing in the artery caused by a build-up of substances that may eventually block 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 feeling 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 risk 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 a 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.

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

To prevent a heart attack in the future, coronary artery disease can be managed in several ways.

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, such as reducing cholesterol, regulating blood pressure and diabetes, or an antiplatelet or anticoagulant.





ery Stenting

Nitroglycerin may be given to relieve chest discomfort due to coronary blockage. However, it does not treat the blockage itself.

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 is a minimally invasive procedure used to open blocked arteries.

It is performed in the catheterization laboratory.

This procedure may be done immediately following your catheterization, or

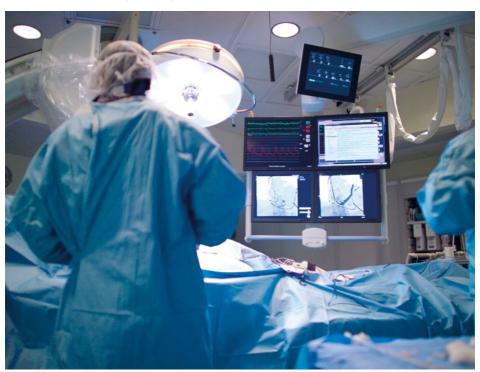


Fig. 4. Catheterization laboratory





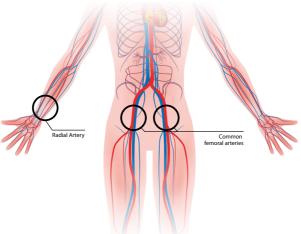


Fig. 5. Artery puncture site

you may be sent home and instructed to return for the procedure.

If you have had a cardiac catheterization procedure, angioplasty is similar in many ways. First, your heart rhythm will be monitored. An intravenous line will be inserted into 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 catheter, is passed through the sheath to the heart

- Contrast agent (X-ray dye) is injected through the guiding catheter to allow the doctor to see the arteries of your heart on an X-ray fluoroscope machine.
- 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.



Patient's Guide to Coronary Artery Stenting

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

It is not uncommon to experience 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.

In many cases, balloon angioplasty alone may not be successful in an effective opening of your blocked artery. Instead, your doctor may recommend placing a coronary stent in the site of the artery blockage.

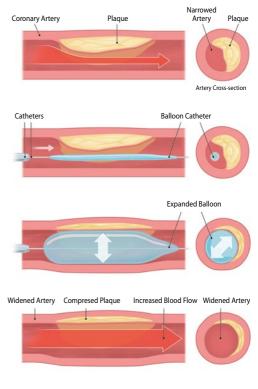


Fig. 6. Balloon angioplasty

WHAT IS A STENT?

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 blockage site.





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.

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. Therefore, it is essential to notify your physician if you have any known metal, plastic, or drug allergies.

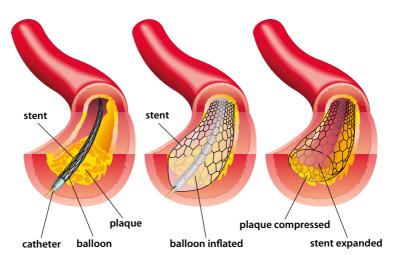


Fig. 7. Stenting



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

Occasionally some patients develop a re-narrowing within the stent which may lead to the 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 the formation of new atherosclerotic plaque.

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

FOLLOW UP CARE

You will be discharged and referred to your cardiologist or family doctor.

If you experience chest pain or notice any changes such as chest discomfort, please, notify your doctor.

COBALT-CHROMIUM SIROLIMUS-ELUTING CORONARY STENT ALEX® PLUS WITH DELIVERY SYSTEM, RX

The ALEX® PLUS stent is designed to prevent re-narrowing within the stent (instent restenosis). The stent is made of cobalt-chromium alloy L605 using the most modern laser technology, which provides mechanical support in the artery. The alloy used for its production has been widely applied for years in implantology.

The stent is mounted onto a tiny balloon. The 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 ALEX® PLUS stent has a thin coating composed of a biodegradable polymer and anti-restenotic drug (sirolimus) on its surface. Sirolimus prevents overgrowth of arterial tissue as the healing process occurs following coronary stent implantation. Unfortunately, this process can also lead to in-stent restenosis. The polymer is designed to release sirolimus in a process during its slow biodegradation (lasting approximately eight weeks).

ALEX® PLUS is available in various diameters and lengths.





PREPARING FOR YOUR PROCEDURE

The benefit of implantation of the cobalt-chromium sirolimus-eluting coronary stent ALEX® PLUS 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 excessively tortuous vessels, which, in the opinion of doctors, would make it impossible to insert the balloon or the stent
- Contraction of coronary vessels
- Pregnant women or during lactation
- Patients with a known hypersensitivity to cobalt-chromium alloy, a polymer, or sirolimus.

BEFORE YOUR CORONARY ARTERY STENTING PROCEDURE

Upon admission 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.

Tell your doctor if you cannot take any aspirin or blood-thinning medicines. These medications are usually prescribed before and after your 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 essential to be aware of

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

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)







Patient's Guide to Coronary Artery Stenting

- 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 through the catheter will visualize 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.







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, and the puncture site. 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 normal 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

ALEX PLUS

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

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

(**UA**) Стент коронарний кобальто-хромовий з сиролімусом алекс плюс з системою доставки

(**КZ**) Коронарлық қан тамырларына арналған сиролимусы бар кобальт-хромды стент

(TR) Hizli değişim salim sistemine sahip, kobalt-krom sirolimus salinimli koroner stent the sticker from the product label here

BALTON sp. z o.o. Nowy Świat 7/14, 00-496 Warszawa, Poland Tel. (+48) 22 597 44 00, fax (+48) 22 597 44 44 email: balton@balton.pl, www.balton.pl



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www.balton.pl

MD

ALEX PLUS

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

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

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

(IT) Stent coronarico in lega cromo-cobalto a rilascio di farmaco sirolimus con polimero bioriassorbibile con sistema di introduzione a scambio rapido

(ES) Stent coronario cromo cobalto recubierto de sirolimus con sistema de liberación de intercambio rápido

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

EXPLANATION OF SYMBOLS

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MDD (BN) Medical device name/ IPU Nazwa wyrotou medycnego' IPU Nazwa wyrotou medycnego' IPU Nazwa wyrotou medycnego' IPU Name dei fispositivo medico' IPU Name dei fispositivo medico' IPU Name dei Medizinorodukto' IPU Name dei Medizinorodukto' IPU Hasaawie Medizinorodukto

EXPLANATION OF SYMBOLS

EXPLANATION OF SYMBOLY

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[PL] Unikalia Identificacion/
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[PL] Unikalia Identificacion
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(ES) Vinitaria Identificacion
[PL] Vinitaria Identificacion

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(PL) Global Trade Item Number/
(PL) Global Trade Item Carbon

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(ES) Numero de articulo comercial

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comercial (RD) Indobansial Homeo

pregament opporania (UA) Homeo

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EXPLANATION OF SYMBOLS

REF [KN] Catalogue Number (PL) Numer (atalogow) [FR] Numero de catalogue (IT) Numero de catalogo (ES) Número de catalogo (DE) Katalognummer (PT) Catalogo de número (RU) Karanoxi-isi nomero (RU) Ka

(EN) Manufacturer/ (PL) Producent/ (FR) Fabricant/ (IT) Productore/ (ES) Fabricante/ (BD) Hersteller/ PT) Fabricante/ (RU) Производитель/ (UA) Виробник/ (KZ) ӨнДіруші/ (TR) Uretici

(TRI Vietic)

[RI) Information website for patient/
PIL) Strona internetowa
2: Informaciarrientowa
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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 Alex® Plus 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 a 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. 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.
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 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.



Balton Sp. z o.o., ul. Nowy Świat 7/14, 00-496 Warszawa, Poland

Manufacturing site: ul. Modlińska 294, 03-152 Warszawa, Poland

tel.: (+48) 22 597 44 00, fax: (+48) 22 597 44 44 e-mail: balton@balton.pl, **www.balton.pl**



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ALEX°PWS