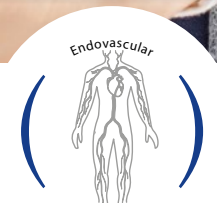


Self-expanding stent JAGUAR
with delivery system



PATIENT INFORMATION LEAFLET



This guidebook is designed to help you and your family understand peripheral artery disease and its treatment with *Self-expanding stent Jaguar with delivery system*.

For your convenience, a glossary of medical terms is included at the end of this booklet. Words that are in bold throughout the text are defined in the glossary.

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

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JAGUAR – Self-expanding stent

with delivery system

INTRODUCTION

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

PERIPHERAL ARTERY DISEASE

Arteries are blood vessels that carry blood away from the heart. Peripheral artery disease involves the build-up of fatty deposits (**plaque**) in the inner lining of arteries in a process called atherosclerosis.

rosis. This process commonly occurs in arteries throughout the body over time.

PERIPHERAL ARTERIES

The most common locations of peripheral vascular disease are the legs, arms, the neck, and kidneys. The pulse in the legs can be easily palpated in the groin, under the knee, and at the foot.

FUNCTION

Lower limb peripheral arteries (e.g., iliac, femoral, and popliteal arteries) carry oxygen through the legs down to the feet. The proper blood flow is crucial for proper lower limb functioning, especially when walking.

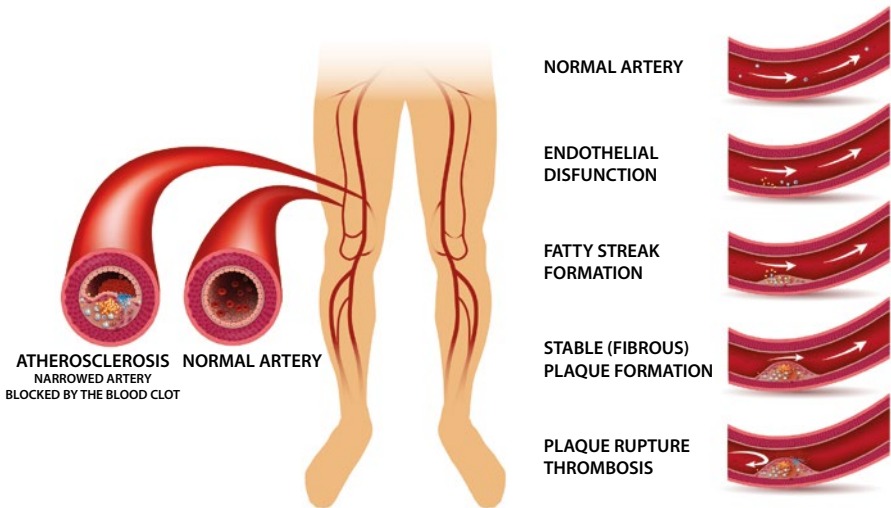


Fig. 1. Leg artery disease atherosclerosis and blood clot

PERIPHERAL ARTERY STENOSIS

The term stenosis describes a lesion in the artery in which blood flow is partially blocked; a lesion in which the artery is completely blocked is called an occlusion. When the blood flow becomes severely limited, the muscles surrounding the artery do not receive enough oxygen, and you start feeling pain. During the early stages of peripheral artery disease, symptoms are usually rare; however, as the build-up of **plaque** progresses, it blocks blood flow through the artery to tissues and organs. The symptoms resulting from peripheral artery disease depend on the location and extent of the disease. Over time, symptoms may stabilize or may become worse, requiring intervention to open the blockage.

CAUSES AND RISK FACTORS

The causes of peripheral artery disease are not entirely understood, but many factors increasing the likelihood of peripheral artery disease have been identified such, as:

- smoking
- diabetes
- high cholesterol level
- high blood pressure level
- obesity and
- positive family history.

Also, you should remember that atherosclerosis in one vasculature bed (e.g., in coronary arteries) increases the risk of atherosclerosis in the others (e.g., co-existence with peripheral artery disease).

DIAGNOSIS

Depending on the location of the disease, one or more of the following symptoms may be present. You should be screened for peripheral artery stenosis if you have:

intermittent claudication (dull pain in the buttocks, thighs, calves, or feet during physical activity such as walking);

numbness or tingling in the leg, foot, or toe;

changes in the skin color (i.e., pale/bluish) or skin temperature in the leg, foot, or toe;

difficulty in feeling the pulse in the groin, under the knee, or on foot;

the appearance of ulcers (sores) on the foot or toe that heal with difficulty.

Sometimes, patients are screened for peripheral artery stenosis if the doctor knows the patient has vascular disease elsewhere in the body.

The following tests may be performed if peripheral artery disease is suspected.

Ankle-brachial index (ABI) – your doctor may recommend measuring blood flow by assessing the blood pressure at the arm and the ankle. The value below 0.9 is inappropriate.

Peripheral artery ultrasound, which uses sound waves to produce pictures of the peripheral arteries in the leg.

Peripheral artery angiography is a diagnostic imaging tool that uses a contrast medium and a special X-ray machine to study the condition of veins, arteries, and blood flow.

TREATMENT OPTIONS

Treatment of peripheral artery disease aims to improve physical activity, quality of life and prevent leg amputation. 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 anti-coagulant medication.

If pharmacotherapy is insufficient to manage your disease, one of the following interventional options, which consist of restoration or widening the artery, may be recommended.

SURGICAL PROCEDURE

Peripheral artery disease may be treated with conventional surgery. **Vascular bypass surgery** is an open surgery operation. You are usually put to sleep for this procedure using general anesthesia. The doctor reroutes the blood flow by attaching an artificial graft (or one of your own veins) above and below the blockage (occlusion).

MINIMALLY INVASIVE ENDOVASCULAR PROCEDURE

Conventional balloon angioplasty or artery stenting are endovascular treatment options which means they are performed through a blood vessel, mostly under the local anesthetic. During this procedure interventional radiologist, angiologist, or vascular surgeon opens up a narrowed or blocked artery to improve blood flow. A small incision is made in your groin or arm, and small tubes or **catheters** containing the medical devices used for the procedure are introduced to the peripheral artery in your leg. A **balloon catheter** is then inflated to open the blockage. If the result is not satisfactory, the **stent** (a small wire tube) is introduced. The **stent** is placed at the area of your blockage. The stent holds the artery open to allow normal blood flow to the rest of the leg.

SELF-EXPANDING STENT JAGUAR WITH DELIVERY SYSTEM

Self-expanding Jaguar stent manufactured by Balton Company is made of nitinol alloy. The stent is made in one-wire technology, without any welds or solders. The stent is placed inside the delivery system for passage into the body

to the peripheral arteries. After being released from the delivery system, the stent opens up, taking the form of a cylinder. Thanks to its properties, it restores the desired shape of the lumen of the vessel.



Fig. 2. Jaguar stent

PREPARING FOR YOUR PROCEDURE

The Self-Expanding Stent Jaguar is indicated for the treatment of atherosclerotic lesions in peripheral arteries. In other words, the device can be used to help open a blocked area of the peripheral arteries of the leg.

The device should not be used:

- If you cannot take aspirin or blood-thinning medications (also called antiplatelets or anticoagulants).
- If you have hypersensitivity to nickel-titanium or contrast medium
- If the physician decides that the blockage or vascular anatomy will not allow proper placement of the stent.

Upon admission to the hospital, you may undergo tests such as angiography, peripheral artery ultrasound, 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 possible risks and potential benefits of the device. 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.

CONTRAINDICATIONS

- unsatisfactory blood flow below the possible stent implantation location,
- impossibility of passing through the stenosis or occlusion site with the guidewire and a balloon catheter,
- hypercoagulability in a patient's anamnesis,
- a risk of closing with a stent significant vessels in the collateral circulation system,
- an exceptionally calcified atherosclerotic plaque that may damage the stent,
- contraindications to taking antithrombotic medicines (e.g., current bleeding from the gastrointestinal tract, recent hemorrhagic stroke)
- allergy to contrast medium,
- allergy to nitinol,
- pregnant women or during lactation.

POTENTIAL COMPLICATIONS

(in alphabetic order)

Adverse reactions (in alphabetic order), which may result from this procedure include:

- Allergic reaction or hypersensitivity to administered anticoagulation or antiplatelet drugs, anesthesia, contrast agent, or stent materials)
- Cardiac arrhythmias
- Cardiac failure/shock
- Death
- Fever
- Stent fracture or stent loss
- Hypotension/hypertension
- Infection
- Lower limb artery complications
 - abrupt closure
 - dissection
 - embolism (air, atherosclerotic plaque, thrombotic material, or device)
 - perforation
 - restenosis
 - spasm
 - thrombosis (acute, subacute, late, very late)
- Myocardial infarction
- Nausea and vomiting
- Pain
- Palpitations, dizziness, syncope
- 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

STENT IMPLANTATION PROCEDURE

The **peripheral artery** stenting is a procedure performed in the catheterization laboratory or a radiology suite. 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 of catheter insertion 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 into

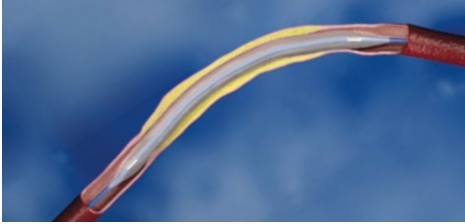
the groin or arm (it depends on the decision of your operator). When the medication takes effect, you should only feel dull pressure where the operator is working with the catheter. The operator will insert a fine tube (introducer) into the artery. It will provide a passageway through which the doctor can insert catheters with necessary devices and a contrast medium. A contrast medium injected through the catheter will allow seeing the area of blockage in your artery.



Fig. 3. Catheterization laboratory



Artery narrowed by the plaque.

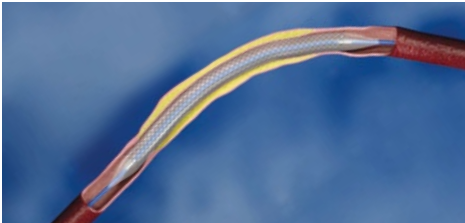


The operator may insert a balloon to prepare the artery for **stent** implantation.



Then the stent is advanced into the peripheral artery in a delivery system and deployed to the blocked area of the artery.

The stent will be placed in the proper position in your artery.



The delivery system is withdrawn from your body. Once again, the doctor may insert the balloon to ensure the stent is in full contact with the artery wall.



The Jaguar 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 it is necessary, the introducer 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 access to the procedure were through the arm, it would be stitched closed, and you may be allowed to sit up afterward.

Once you return to the ward, you will have regular observations of your con-

scious 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 on medications, diet, and physical 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 staying in health in the future you should pay attention on the healthy diet and exercises. It will be easier and safer if you get help from a professional dietician and physiotherapist. It is extremely important 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.

<p>MD</p> <p>JAGUAR</p> <p>(UA) Саморозширний стент джегар з системою доставки (KZ) Енгузу жүйесі бар, өздігінен кеңейтін стент (TR) Salım sisteminde sahip, kendiliğinden genişleyen stent</p>	<p>05/2021</p> <p>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</p> <p> Put the sticker from the product label here</p>	<p>BALTON®</p> <p>INTERNATIONAL IMPLANT CARD</p> <p> _____</p> <p> _____</p> <p> _____</p> <p> _____</p> <p> www.balton.pl</p>	<p>MD</p> <p>JAGUAR</p> <p>(EN) Self-expanding stent with delivery system (PL) Stent samorozprężalny z systemem wprowadzającym (FR) Stent auto-éxpansible avec système de pose (IT) Stent auto-espandibile in nitinolo con sistema di rilascio (ES) Stent periférico autoexpandible de nitinol con sistema de liberación (DE) Selbstexpanderender stent mit Katheter (PT) Stent auto-expansível com sistema de colocação (RU) Стент саморасширяющийся с системой доставки</p>
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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 парты/ (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) İmplantasyon tarihi

SN (EN) Serial number/ (PL) Numer sejniwy/ (FR) Numéro de série/ (IT) Numero di serie/ (ES) Número de serie/ (DE) Originalnummer/ (PT) Número de série/ (RU) Серийный номер/ (UA) Серійний номер/ (KZ) Сериялық нөмірі/ (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 идентификациясы/ (TR) Benzersiz Cihaz Kimliği)

GTIN (EN) Global Trade Item Number/ (PL) Globalny Numer Jednostki Handlowej/ (FR) Numéro d'article du commerce mondial/ (IT) Numero articolo commercio globale/ (ES) Numero de artículo comercial global/ (DE) Globalen Artikelnummer/ (PT) Número global de item comercial/ (RU) Глобальный номер предмета торговли/ (UA) Номер глобальної торгової позиції/ (KZ) Сәуат-сәттықтiң 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) Каталогный 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) Өндiрушi/ (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 pacientes/ (RU) Информационный веб-сайт для пациента/ (UA) Інформаційний веб-сайт для пацієнта/ (KZ) Ташкентке арналған ақпараттық веб-сайт/ (TR) Hasta için bilgi web sitesi)

SAFETY DURING MAGNETIC RESONANCE IMAGING (MRI)

If you require MRI after carotid artery stenting, tell your health care providers that you have a stent.

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.



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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 whereby a balloon 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. It is also called PTA (Percutaneous Transluminal 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.
Peripheral Arteries	Arteries are vessels that carry blood away from the heart. The most common locations of peripheral vascular disease are the legs, arms, neck, and kidneys.
Catheter	A long hollow tube used to introduce a device, drug, or contrast medium into a blood vessel.

GLOSSARY

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 in food that is 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.

Jaguar