Cobalt-chromium stent
for renal vessels Nefro C
with delivery system

Nefro C

PATIENT INFORMATION LEAFLET

Endovascular

BALTON®

This guidebook is designed to help you and your family understand renal artery disease and its treatment with *Cobalt-chromium stent for renal vessels Nefro C with a 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 renal artery disease may vary according to your individual 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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INTRODUCTION

This guidebook is designed to help you and your family understand the vascular disease of **renal arteries** 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.

RENAL ARTERY DISEASE

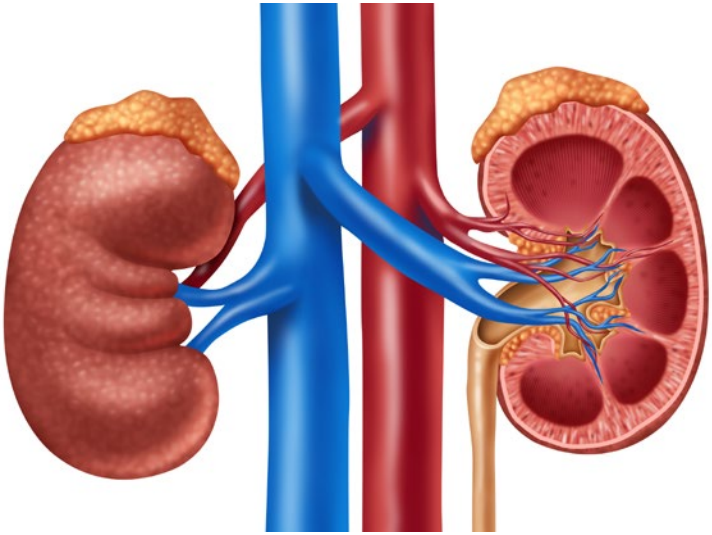
Renal artery disease involves the build-up of fatty deposits (**plaque**) in the inner lining of arteries in a process called atherosclerosis. This process commonly occurs in arteries throughout the body over time. Renal artery disease might be clinically significant when renal artery **stenosis** is ≥60%, although additional factors are taken into consideration, including functional assessment. The prevalence of renal artery disease increases with age and may be present in 5–10% of the general population, with a higher prevalence in high-risk patients.

RENAL ARTERIES

Arteries are blood vessels that carry blood away from the heart. Renal arteries are blood vessels joining the aorta with kidneys.

FUNCTION

Renal arteries carry oxygen to the kidneys. The proper blood flow is crucial for



proper kidney functioning, i.e., organism clearance from metabolic toxins, preserving water-ion hemostasis, and controlling blood pressure.

RENAL ARTERY STENOSIS

The term stenosis describes a lesion in the artery which partially blocks the blood flow; a lesion that completely blocks the blood flow is called an occlusion. When the blood flow becomes severely limited, the kidneys started to be ischemic, and in consequence, toxin clearance or blood pressure control might be impaired. During the early stages of renal artery disease, symptoms are usually absent; however, as the build-up of plaque progresses, it blocks the blood flow, and over time, symptoms may stabilize or may become worse, requiring intervention to open the blockage.

CAUSES AND RISK FACTORS

The causes of renal artery disease are not completely understood, but many factors have been identified that increase the likelihood of renal artery disease such, as:

- male gender
- smoking
- diabetes
- high cholesterol level
- high blood pressure level
- chronic kidney disease, and
- positive family history.

Also, you should remember that atherosclerosis in one vasculature bed (e.g., coronary artery disease or aorto-iliac occlusive disease) increases the risk of atherosclerosis in others (e.g., co-existence with renal 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 renal artery stenosis if you have:

the onset of hypertension before the age of 30 years;

the onset of severe hypertension after the age of 55 years, when associated with chronic kidney disease of heart failure;

hypertension and abdominal bruit;

rapid and persistent worsening of previously controlled hypertension;

resistant hypertension (i.e., other secondary forms unlikely, and the target not achieved despite four drug classes including a diuretic and a mineralocorticoid-receptor antagonist in appropriate doses);

hypertensive crisis (i.e., acute renal failure, acute heart failure, hypertensive encephalopathy, or grade 3-4 retinopathy);

new azotemia or worsening of renal function after treatment with ACE inhibitors/angiotensin receptor blockers;

unexplained atrophic kidney or discrepancy in kidney size, or unexplained renal failure;

flash pulmonary edema.

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

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

Renal artery ultrasound, which uses sound waves to produce pictures of the renal arteries.

Renal artery angiography (invasive or noninvasive with computed tomography or magnetic resonance) is a diagnostic imaging tool that uses a contrast medium and a special X-ray machine to study the health of veins, arteries, and blood flow.

TREATMENT OPTIONS

Treatment of renal artery disease aims to improve quality of life, preserve kidney function, improve blood pressure control, and improve life expectancy. Therefore, it is important to inform your doctor about your entire medical history. Then, please, 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.

If pharmacotherapy is insufficient to manage your disease, one of the following interventional options may be recommended:

SURGICAL PROCEDURE

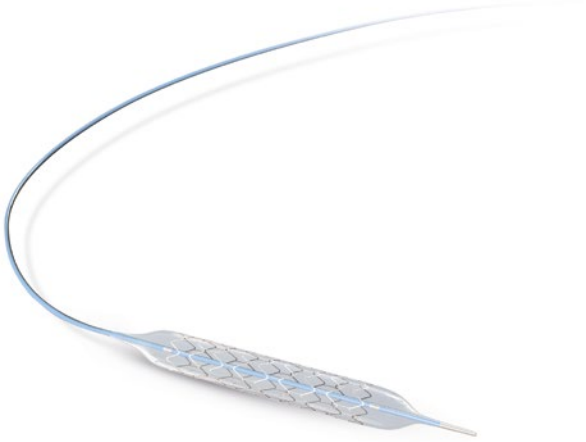
Renal artery disease may be treated with conventional surgery. However, this option is only reserved for patients with complex anatomy of renal arteries, after a failed endovascular procedure or during open aortic surgery. **Vascular bypass surgery** is an open surgery operation. You are usually put to sleep for this procedure using general anesthesia. Then, 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

This is the mainstay of renal artery stenosis revascularization (if indicated). 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 renal artery. 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.

COBALT-CHROMIUM STENT FOR RENAL VESSELS NEFRO C WITH DELIVERY SYSTEM

Balloon-expandable NEFRO C stent manufactured by Balton Company is made of cobalt-chromium alloy. First, the outline of the stent was obtained by means of laser working. Next, a stent is mounted on the balloon at the end of the delivery system for passage into the body to the **renal arteries**. After balloon inflation, 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.



PREPARING FOR YOUR PROCEDURE

The Balloon-Expandable NEFRO C Stent is indicated for the treatment of atherosclerotic lesions in **renal arteries**. In other words, the device can be used to help open a blocked area of the **renal arteries**.

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 cobalt-chromium 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, renal artery ultrasound, and blood tests. Remember to tell your doctor about all the medications you are cur-

rently taking and any allergies you may have. In addition, 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

Stent Implantation Contraindications

- Insufficient blood flow below the potential stent implant spot.
- Impossibility of a guidewire and balloon catheter to pass through the stenosed/occluded artery.
- Hypercoagulability reported in anamnesis.
- Possibility of closing side branches with a stent.
- Fresh thrombus.
- Contraindications to taking antithrombotic medicines (e.g., active bleeding from the digestive tract, recent cerebral stroke).
- Allergy to contrast medium.
- Allergy to cobalt-chromium alloy.

POTENTIAL ADVERSE REACTIONS

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 cobalt-chromium)
- Cardiac arrhythmias
- Cardiac failure/shock
- Death
- Dialysis
- Emergent surgery to correct vascular complications
- Fever
- Hypotension/hypertension
- Infection
- Myocardial ischemia/infarction
- Nausea and vomiting
- Nephrectomy
- Pain
- Palpitations, dizziness, syncope
- Peripheral artery complications:
  - abrupt closure
  - dissection
  - embolism (air, atherosclerotic plaque, thrombotic material, or device)

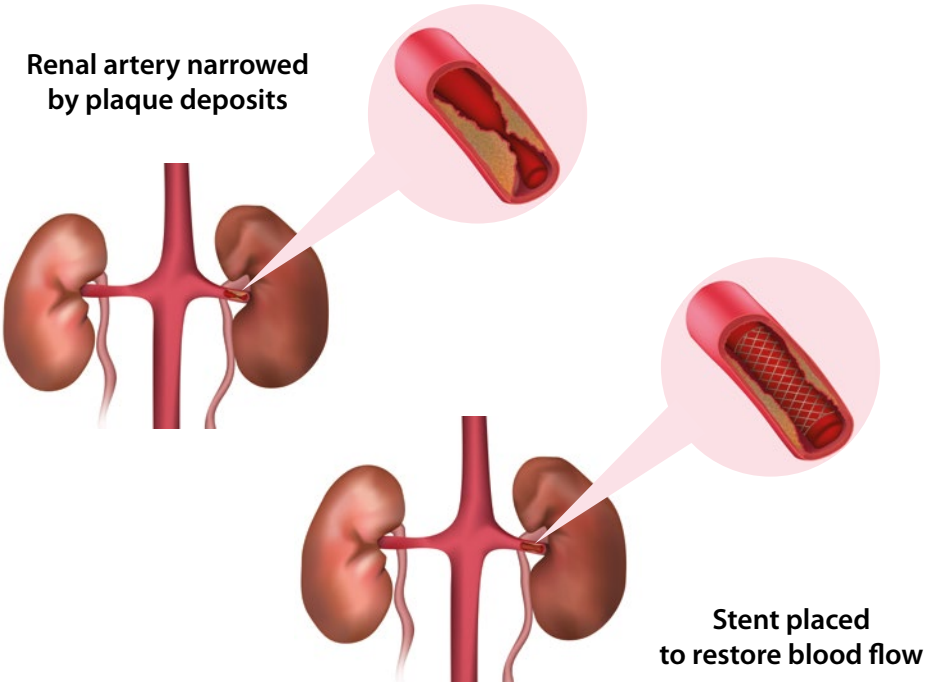
  - perforation
  - restenosis
  - spasm
- Renal artery thrombosis, aneurysm, rupture, perforation, occlusion, spasm, or restenosis
- Renal insufficiency/failure/infarct
- Stroke/TIA
- Stent migration/embolization/misplacement
- Vascular access complications which may require blood transfusion or vessel 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 **renal 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.

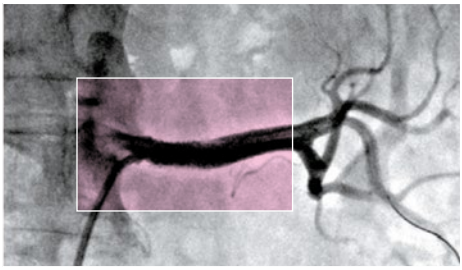
During the procedure, you will be awake, and medical and nursing staff will be monitoring you closely. First, a local anesthetic will be injected through the skin into the groin or arm (it depends on the decision of your operator). When the medication takes effect, you should only feel dull pressure where the operator is working with the catheter. Next, 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 contrast medium. The contrast medium injected through the catheter will visualize the area of blockage in your artery. Subsequently, the operator may insert a balloon to prepare the artery for **stent** implantation.

Then the stent is advanced into the **renal artery** on a delivery system and deployed to the blocked area of the artery.



The stent will be placed in the proper position in your artery. Then, the delivery system will be 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 Nefro C 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 necessary, it may sometimes be left in place temporarily.

Before stenting



After stenting

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 as well as kidney function tests will be performed.

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 closed, 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, having increasing dyspnea, or starting to urinate less and less.

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 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 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 doctor or health care worker 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

NEFRO C

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

(**UA**) Стент кобальто-хромовий для ниркових судин нефро-сі з системою доставки

(**KZ**) Бүйрек тамырларына арналған, RX енгізу жүйесі бар кобальт-хром стенті

(**TR**) RX salim sistemine sahip kobalt-krom renal stent

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INTERNATIONAL IMPLANT CARD

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MD

NEFRO C

(**EN**) Cobalt-chromium stent for renal vessels with delivery system Rapid Exchange

(**PL**) Stent kobaltowo-chromowy do naczyń nerkowych z systemem wprowadzającym RX

(**FR**) Stent au cobalt-chrome pour les vaisseaux rénaux avec système de pose à Échange Rapide

(**IT**) Stent in cromo cobalto per vasi renali con sistema di rilascio Rapid Exchange

(**ES**) Stent de cromo cobalto para vasos renales con sistema de liberación de intercambio rápido

(**DE**) Kobalt-chrom-nierenarterienstent mit Rapid-Exchange-katheter

(**PT**) Stent para vasos renais em cobalto-cromo com sistema de colocação Rapid Exchange

EXPLANATION OF SYMBOLS

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(**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**) Numero de lot/ (**IT**) Numero di lotto/ (**ES**)Número de lote/ (**DE**) Chargennummer/ (**PT**) Número do lote/ (**RU**) Номер партии/ (**UA**) Номер партії/ (**KZ**) Номер партиі/ (**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 commerce 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 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 a bsorption 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 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. 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.
Renal Arteries	Arteries are vessels that carry blood away from the heart. Renal arteries join the aorta with the 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 dye to detect blockages.
Cholesterol	A substance that circulates in the blood and when deposited in the artery, plays a role in the formation of blockages. Cholesterol originates in foods that are 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	Small clots or pieces of plaque that travel in the bloodstream and lodge in a blood vessel, blocking blood flow.
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.

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