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Guide Outside Cover



**ELUVIA™ Drug-Eluting Vascular Stent
Magnetic Resonance Conditional**

A patient with this device can be scanned safely only under specific conditions. Failure to follow the conditions may result in severe injury. Non-clinical testing has demonstrated the Eluvia™ Stents are MR Conditional for single stents up to 120 mm and overlapping lengths up to 200 mm. A patient with this stent can be scanned safely, immediately after placement, under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Highest spatial gradient magnetic field of 40 Tesla/m (4,000 Gauss/cm) or less
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of:
 - ≤2 W/kg for landmarks (i.e. center of RF coil) above the umbilicus
 - ≤1 W/kg for landmarks below the umbilicus and above the mid-thigh
 - ≤0.5 W/kg for landmarks below the mid-thigh

RF Heating

Under the scan conditions defined above, the Eluvia Stent is expected to produce a maximum in-vivo temperature rise of 4 °C after 15 minutes of continuous scanning. A 5 minute cool down period is recommended after scanning continuously at the maximum permissible SAR.

Image Artifact

In non-clinical testing, the image artifact caused by the device extends approximately 12 mm from the stent when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artifact does obscure the device lumen.



Advancing science for life™

Peripheral Interventions

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300 Boston Scientific Way
Marlborough, MA 01752 USA
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To order product or for more information
contact customer service at 1.888.272.1001.

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For more information about indications, contraindications, warnings and instructions for the Eluvia™ Drug-Eluting Vascular Stent System, or for copies of the Directions for Use, visit **www.bostonscientific.com**.

You may also call Boston Scientific customer service at **1.888.272.1001** for more information.



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Patient Information Guide

Understanding Peripheral Artery Disease

ELUVIA™ Drug-Eluting Vascular Stent System

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Glossary

Angioplasty

A minimally invasive treatment of the arteries that opens blocked arteries.

Anticoagulant and Antiplatelet

Medicines that slow down the clotting of blood.

Artery

A blood vessel that carries oxygen-rich blood away from the heart to the rest of the body.

Atherosclerosis

A disease in which the flow of blood is slowed down by plaque in the arteries.

Balloon Angioplasty

Inflating a balloon catheter in the blood vessel to open a blocked artery.

Balloon Catheter

A thin tube with a balloon attached to the tip that can be inflated to open blocked arteries.

Blood Vessel

Any of the veins and arteries that carry blood to and from the heart.

Bypass

A surgical procedure used to create an alternate route for blood to flow to the legs around narrowed or blocked arteries.

Catheter

A long, flexible tube that can be passed through the blood vessels.

Contrast Dye

X-ray dye used in diagnostic tests.

Drug-eluting Stent

A drug-eluting stent is a bare metal stent that has been coated with a drug and a polymer. Drug-eluting stents are designed to release a drug locally, over a period of time. This slows down the re-narrowing of the vessel by limiting the overgrowth of tissue within the stent.

Endarterectomy

A surgical procedure that removes plaque from the walls of the arteries.

Lumen

The inner channel or cavity of a vessel or tube.

Glossary continued

Minimally Invasive Procedure

A procedure that uses small instruments or devices to reduce the size of the insertion site and cause a smaller amount of trauma.

MRI (Magnetic Resonance Imaging)

A method of using a magnetic field and radio waves to produce detailed images of the inside of the human body.

Occlusion

Blockage of blood flow in the artery.

Paclitaxel

A drug that prevents vessel re-narrowing.

Peripheral

Related to areas of the body outside the heart and brain.

Peripheral Artery Disease (PAD)

Peripheral Artery Disease (also called Peripheral Arterial Disease) is a circulatory problem in which narrowed arteries reduce blood flow to the limbs.

Plaque

A buildup of cholesterol, fat, calcium and collagen in a vessel.

Polymer

The polymer carries and protects the drug before and during the procedure. Once the stent is implanted, it helps control drug release into the wall of the artery. This contributes to even and consistent distribution of the drug from the stent

Proximal Popliteal Artery

The upper portion of the vessels that passes through your knees.

Restenosis

Re-narrowing of the artery after treatment.

Sedative

A type of medication that makes you relaxed and sleepy. Also called sedation.

Stenosis

A narrowing of the artery.

Stent

A metal tube that supports the blood vessel wall and maintains blood flow through the opened vessel.

Superficial Femoral Arteries

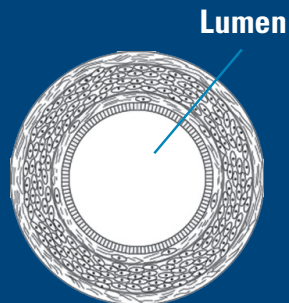
The blood vessels in the thighs that supply blood to the legs.

What is Peripheral Artery Disease?

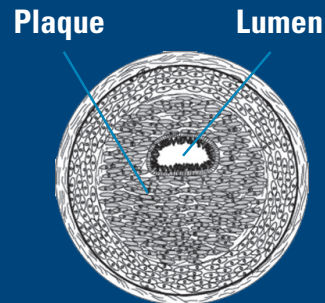
Peripheral Artery Disease (PAD) is caused by the narrowing of the arteries in the limbs. This narrowing can also be called a stenosis. It is usually caused by a buildup of fat, cholesterol, collagen or calcium deposits called plaque. Over time, this plaque can build to a total blockage of the artery.

When the limbs do not receive enough blood flow because of a blockage in an artery, it can cause pain, often during movement. In severe cases, low blood flow can cause tissue loss.

Healthy Artery



Narrowed Artery



Treating Peripheral Artery Disease

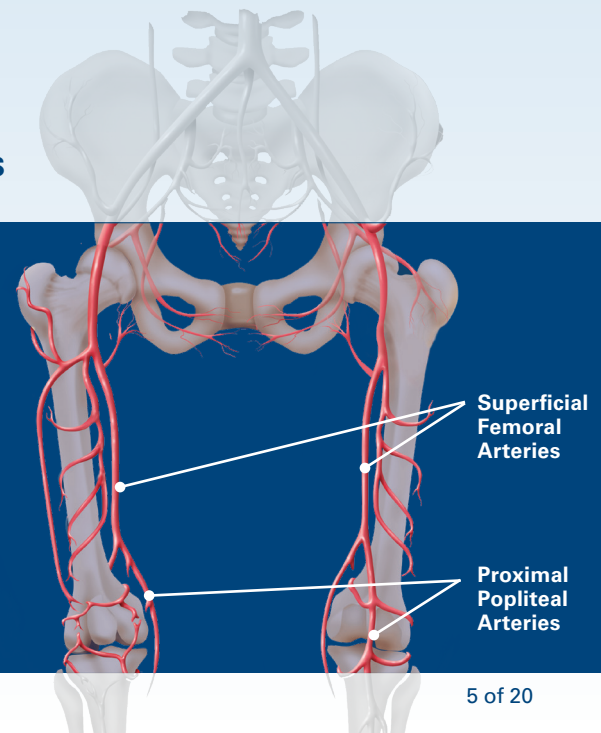
Your doctor wants you to have a stent placed in your superficial femoral or proximal popliteal artery to treat your PAD. The stent may improve blood flow in your legs to reduce leg and resting pain, and improve quality of life and your ability to walk and move around.

This guide explains the procedure and what you can expect from start to finish. A glossary at the beginning of this guide defines common medical terms about this procedure.

You will also learn steps you can take to live a healthier life with PAD.

Superficial femoral and proximal popliteal arteries

You have two superficial femoral and proximal popliteal arteries, one located within each thigh. The superficial femoral arteries start at the groin, just above each hip, and extend to just above the knees. The superficial femoral arteries connect with the popliteal arteries, which run across the knees and branch into smaller arteries that supply blood to the lower legs and feet.



Peripheral Artery Disease treatment options

There are four different treatment options for Peripheral Artery Disease. All four treatment options focus on increasing blood flow to the lower leg. The type of treatment your doctor recommends depends on your symptoms.

1

Medical therapy

For patients with mild to medium symptoms, doctors often choose medical therapy. This can include medications, exercise, and regular checkups. Doctors also say to stop smoking. The doctor may prescribe medications to decrease clotting, lower blood pressure, and reduce cholesterol. Regular checkups can help determine if more treatment is needed.

2

Angioplasty

In an angioplasty procedure, a thin tube known as a catheter is inserted into the artery. A small balloon located on the tip of a catheter is moved to the site of the narrowing and inflated to expand the artery and reduce the blockage. The balloon is deflated and removed with the catheter after the angioplasty is done. Angioplasty is less invasive than surgery, and the patient remains awake while the doctor performs the procedure.

3

Stenting

During this procedure, a small mesh tube, called a stent, is placed in the artery to keep the artery open and help prevent re-narrowing.

To further help prevent re-narrowing, "drug-eluting" stents, such as the Eluvia™ Drug-Eluting Vascular Stent System, have been developed. These stents provide the same structural support as uncoated stents, but they are coated with a drug/polymer matrix. The polymer carries and protects the drug before and during the procedure. The drug is released over time, helping to slow down the re-narrowing of the vessel by limiting the overgrowth of tissue within the stent.

4

Surgery

For patients with severe narrowing that is blocking blood flow in the legs, bypass surgery may be needed. In a bypass procedure, a healthy vein is removed from your leg. This vein is used to make a new path around the narrowed or blocked artery, or alternatively, a synthetic (plastic) artery may be used. Patients are also in the hospital for a few days after this surgery.

ELUVIA™ Drug-Eluting Vascular Stent System

The ELUVIA Drug-Eluting Vascular Stent System consists of a delivery system and a stent coated with a drug/polymer matrix used to treat PAD.

Using the delivery system to navigate to the blockage, the ELUVIA stent, a mixture of nickel and titanium called nitinol, is placed in the artery. Once placed, the stent expands to the vessel wall as a reaction to body heat, to provide a mechanical scaffolding to keep the artery open.

The coating matrix consists of a base primer layer of PBMA (poly (n-butyl methacrylate)) polymer, and an active layer which elutes paclitaxel, a drug that inhibits cellular growth, from a PVDF/HFP (copolymer of vinylidene fluoride and hexafluoropropylene) polymer coating. The polymer carries and protects the drug before and during the procedure. The drug is released over time, helping to slow down re-narrowing, or restenosis, of the artery that can sometimes occur.

ELUVIA™ Clinical Summary

The ELUVIA Drug-Eluting Vascular Stent System was evaluated in the IMPERIAL Trial. The IMPERIAL Trial enrolled 465 patients. After one year, it was determined that the outcome of the procedure was successful in most cases, both in effectiveness and safety. The IMPERIAL clinical trial demonstrated that ELUVIA provides clinical benefits that, at a minimum, are non-inferior to those observed for similar devices.

The results of this study showed that the ELUVIA Drug-Eluting Vascular Stent System is safe and effective for treating *de novo* or restenotic lesions in the native superficial femoral artery and/or proximal-popliteal artery. Your doctor can explain the risks and benefits that are specific to you.

Risks

Your doctor may not consider you to be a good candidate for stenting if you have any of the following conditions:

- You are unable to take medications, such as Aspirin or Plavix, that make it more difficult for your blood to clot.
- You are allergic to nickel or titanium. These are the metals used to make up the ELUVIA™ Drug-Eluting Vascular Stent System. Discuss the potential for allergy with your doctor if you have ever experienced a skin rash to jewelry, watches, or belt buckles.
- You have poor kidney function.
- You are allergic to the drug, paclitaxel, or related drugs.
- You are allergic to the polymer or related compounds. The ELUVIA polymer is made from PBMA - poly (n-butylmethacrylate) and PVDF/HFP (copolymer of vinylidene fluoride and hexafluoropropylene).
- You are trying to conceive or are pregnant.

Note: It is very common for your doctor to prescribe specific medications before, during and after your stent placement. These medications are intended to help decrease the risk of forming a blood clot in your artery. Please check with your doctor to find the right medication for you.

The placement of stents in blood vessels is done to treat blockages and to try to prevent re-narrowing.

As with any stent procedure, there is a chance that complications may occur, including but not limited to those listed below. Ask your doctor to discuss the risk of these complications, as some are extremely rare.

- Air bubble(s), tissue, or clots, which can block the vessel (emboli)
- Allergic reactions
- Amputation
- Bleeding
- Blood clot(s)
- Bruising at your groin area
- Death
- Infection
- Injury or damage to your artery or wall of the artery. This could require emergency surgery.
- Kidney damage or failure
- Restenosis or re-narrowing of the artery around or within the stent
- Spasm of the vessel wall
- Temporary change in blood pressure during the procedure
- Total blockage (occlusion) of the vessel

Potential adverse events related to the drug paclitaxel (based on studies of patients who used the drug for a prolonged period of time) or the polymer include:

- Allergic or immunologic reaction to the drug (paclitaxel)
- Allergic reaction to the polymer or polymers with similar chemical structures
- Abnormal liver values
- Anemia (which may require a blood transfusion)
- Changes in blood profile (decrease of white and red blood cells and platelets)
- Changes of the tissue in the vessel wall including inflammation, cell injury and cell death
- Disturbances of the gastrointestinal (GI) tract and stomach
- Loss of hair
- Muscle pain/joint pain
- Nerve disease in arms and legs

Your doctor and the medical staff will monitor you during and after the procedure for complications. If a complication does occur, your doctor will decide if you require treatment. In the event of complications, surgical removal of the stent may be required.

Before your procedure

Below is a typical checklist. Your doctor may ask you to go through this before your procedure.

- ☐ Tell your doctor about any medications you are taking, and bring the medications to your appointments.
- ☐ Let your doctor know if you are trying to conceive or are pregnant.
- ☐ Let your doctor know about any allergies you have. It is important he or she knows about allergies to contrast dye, iodine, cobalt, chromium, nickel, titanium, stainless steel or polymers.
- ☐ Tell your doctor if you cannot take aspirin or blood thinning medicines. These medications are usually prescribed before and after your procedure.
- ☐ Do not eat or drink anything after midnight on the night before your procedure.

- ☐ Follow the instructions you receive from your doctor and nurses.
- ☐ Make sure you understand the possible risks and benefits of your stent procedure.
- ☐ You could be given a sedative to relax you before starting your stent procedure. The sedative can make you sleepy.

During a typical stenting procedure

1

A small puncture is made in your groin to gain access to the artery. A wire and catheter are inserted and moved to the narrowed section of the artery.

2

The narrowed section of the artery may need to be enlarged to make room for the stent. To do this, the doctor places a small, deflated balloon over the wire and through the catheter to the narrowed area of the artery and inflates the balloon. This pushes the plaque buildup to the side of the artery to make a larger opening for a stent to be placed.

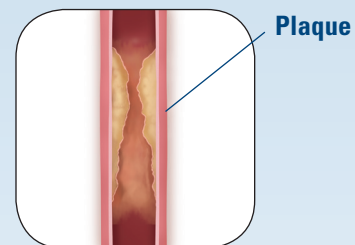
3

The balloon is deflated and removed, and a small mesh tube called a stent is placed into the same area of the artery to keep it open.

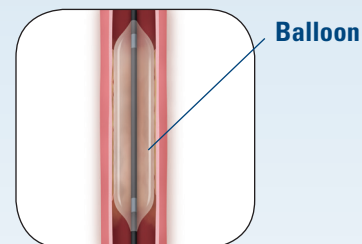
4

After the stent is implanted, the catheter and wire are removed and the puncture site in your groin is closed. The stent remains in place and is designed to help keep the artery open and prevent future narrowing of the artery. Stents that are coated with a drug/polymer matrix continue to release drug over time, helping to slow down the re-narrowing of the vessel by limiting the overgrowth of tissue within the stent.

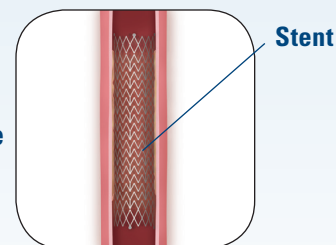
Diseased Artery



Balloon Angioplasty Procedure



Result After Stent Procedure



Images courtesy of Boston Scientific. Images are for illustration purposes only, and are not necessarily to scale.

After a typical stenting procedure

- You may feel sleepy from the sedative given to you. This will wear off over the next few hours.
- You will be taken to a unit where nurses and doctors can monitor you.
- Your heart rate, blood pressure, and the entry site in your groin will be checked frequently.
- You will be asked to drink a lot of liquids to flush the contrast dye out of your system. You will have to stay in bed for several hours. You will be asked to keep your leg straight so the entry site in your groin can heal well.
- You may need a short hospital stay.
- You should alert your doctor or nurse if you experience any of these symptoms
 - Leg or foot pain
 - Unusual coldness and/or skin discoloration in the leg or foot
 - Numbness in the leg or foot
 - Reappearance of the symptoms you had before treatment
 - Pain, bleeding or infection at the entry site in your groin
- You should avoid straining yourself or lifting "heavy" items until your doctor lets you know that it is okay to do so.
- You should keep all follow-up appointments requested by your doctor and bring your medications with you.

Stent implant card

Your stent implant card shown on the right tells health care providers that you have a stent implanted in your superficial femoral or proximal popliteal artery.

This card also has:

- The doctor who put in your stent
- The doctor’s phone number
- The date the stent was put in
- Where the stent was placed
- The size of the stent
- The manufacturer’s lot number for the stent

The card provides information that is needed if you have any special diagnostic tests such as such as an MRI.

There are also phone numbers on the card that your health care providers can call if they have any questions. Your discharge nurse will fill in the card. If he or she does not, please call the doctor who placed the stent for this information.

Patient Name	Emergency Contact Number
Implanting Physician's Name	Stent Material
Physician's Phone Number	Date of Implant

PLEASE CARRY YOUR CARD AT ALL TIMES.

Please ask your physician for a copy of the Patient Information Guide. Additionally, the Patient Information Guide for this product is available from the Eluvia™ Drug-Eluting Vascular Stent System website. To view, download or print the Patient Information Guide, go to www.bostonscientific.com

Stent Identification Information

Product Name	Product Name
Product Code	Product Code
Product Lot Number	Product Lot Number
Stent Location	Stent Location

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Living with Peripheral Artery Disease

Treatment for Peripheral Artery Disease includes controlling things that can cause the reoccurrence of symptoms. You cannot control some risk factors, such as your age, gender, ethnic background or family history. However, you can change many of the risk factors for this disease.

Your doctor may suggest the following healthy lifestyle changes:

- Lose excess weight
- Quit smoking
- Exercise regularly
- Control stress
- Decrease fat in your diet
- Limit alcohol consumption

Reducing your risk factors can also have a positive impact on the long-term success of Peripheral Artery Disease treatment. Talk to your health care providers today about how to increase your chances for a healthier outcome and a more rewarding life.

Notes

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