

Patient Information Guide

Understanding Peripheral Artery Disease

Ranger™ Paclitaxel-Coated PTA Balloon Catheter

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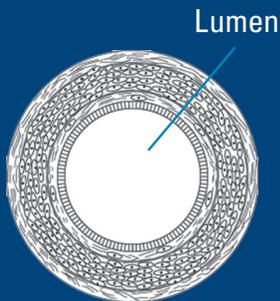
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What is Peripheral Artery Disease?

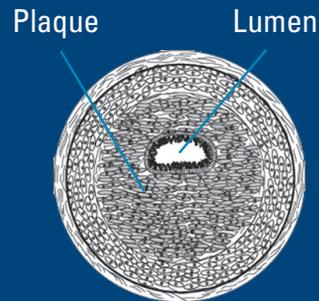
Peripheral Artery Disease (PAD) is caused by the narrowing of the arteries in the limbs. This narrowing can also be called a stenosis. It is usually caused by a buildup of fat, cholesterol, collagen, or calcium deposits called plaque. Over time, this plaque can build to a total blockage of the artery.

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

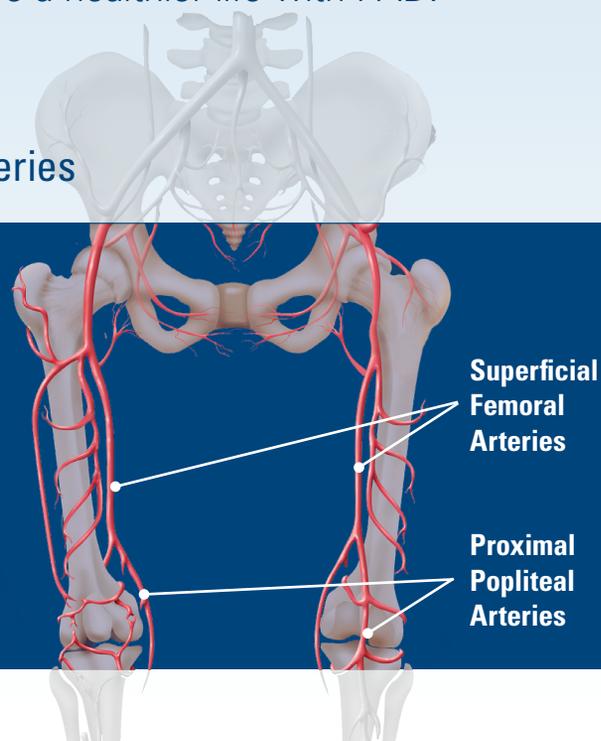
Your doctor wants to use a drug-coated balloon in your superficial femoral or proximal popliteal artery to treat your PAD. This procedure may improve blood flow in your legs to reduce leg and resting pain, and improve your quality of life and your ability to walk and move around.

This guide explains the procedure and what you can expect from start to finish. A glossary at the end of this guide defines common medical terms relevant to 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 different treatment options for Peripheral Artery Disease focusing on increasing blood flow to the lower leg. The type of treatment your doctor recommends depends on your symptoms.

Medical Therapy

For patients with mild to medium symptoms, doctors often choose medical therapy. This can include medications, exercise, and regular checkups. Regular checkups can help determine if more treatment is needed.

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.

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 the catheter is moved to where the artery narrows and inflated to expand the artery and reduce the blockage. The balloon is deflated and removed with the catheter after the angioplasty is done. The balloon may either be uncoated, or coated with a drug.

Surgery

For patients with severe narrowing of the artery 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 and is used to make a new path around the narrowed or blocked artery.

What is the Ranger™ Paclitaxel-Coated PTA Balloon Catheter?

The Ranger Paclitaxel-Coated PTA Balloon Catheter is a balloon catheter with the drug paclitaxel applied to the balloon. Drug-coated balloons are inflated inside blood vessels to treat blockages and prevent re-narrowing.

What is paclitaxel?

Paclitaxel is the active drug component of the Ranger drug-coated balloon. Paclitaxel may help prevent re-narrowing of the artery. The Ranger drug-coated balloon is coated with a small amount of paclitaxel which is applied directly to the vessel wall when the balloon is inflated.

Risks

Your doctor may not consider you to be a good candidate for a drug-coated balloon if you have a sensitivity or risk of an allergic reaction to the drug used on the Ranger™ Paclitaxel-Coated PTA Balloon Catheter (paclitaxel). If you are at risk, your doctor will choose another therapy for your PAD treatment.

Note: It is very common for your doctor to prescribe specific medications before, during, and after your procedure. 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.

A study published in December 2018 in the Journal of the American Heart Association reported an increased risk of death starting at 2 years and up to 5 years after treatment with paclitaxel-coated devices in the upper leg compared to treatment with uncoated devices. The U.S. Food and Drug Administration also observed this increased risk of death associated with paclitaxel-coated devices that are approved in the U.S. Additional studies are being conducted to better understand this risk. Although so far the cause for this increased risk of death is unknown, this is important information for you to have when making a decision about treatment options. Your doctor can explain the risks and benefits of paclitaxel-coated devices that are specific to you.

Risks (Continued)

There is a chance that complications can occur, including but not limited to those listed below. Ask your doctor to discuss the risk of these complications, as some are extremely rare.

- Allergic reactions
- Amputation
- Bleeding
- Blockage of the vessel by an air bubble, a clot, or loose tissue in the vessel.
- Blood clots
- Bruising at your groin area
- Death
- Infection
- Injury to the wall of the artery
- Kidney damage or failure
- Restenosis or re-narrowing of the artery
- Spasm of the vessel wall
- Temporary change in blood pressure during the procedure
- Total blockage (occlusion) of the vessel

Potential complications which may be unique to the paclitaxel drug coating include:

- Abnormal liver values
- Allergic or immunologic reaction
- 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 additional treatment.

During a Typical Drug-Coated Balloon 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

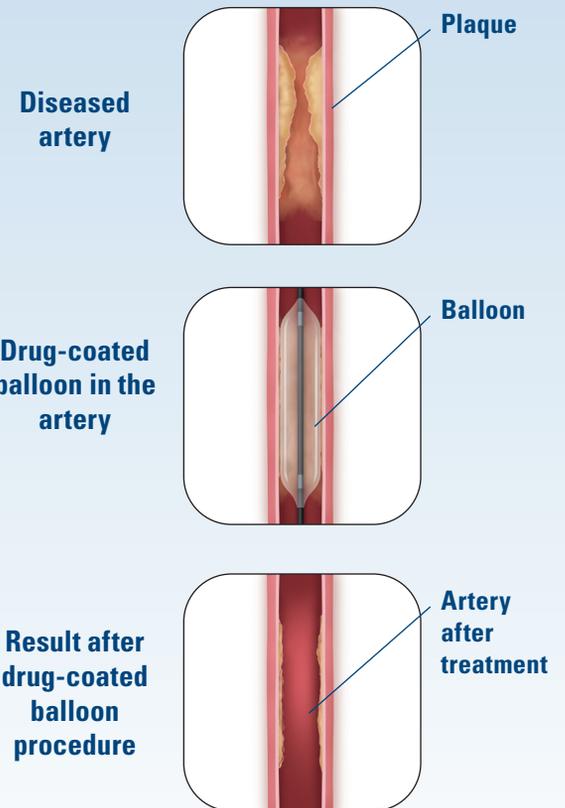
The narrowed section of the artery may need to be enlarged to make room for the drug-coated balloon. To do this, the doctor may use other devices to push the plaque to the side or remove plaque buildup inside the artery.

3

When the physician is satisfied with the size of the lumen, the drug-coated balloon will be inserted.

4

After the drug-coated balloon is inserted, it is inflated to make contact with the artery wall, allowing the drug to be released. The devices are removed and the puncture site in your groin is closed. The drug from the balloon is absorbed into the artery and is designed to help keep the artery open and prevent future narrowing of the artery.



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

After a Typical Drug-Coated Balloon 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, brain function, 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 follow your doctor's instructions regarding your activity level.
- You should keep all follow-up appointments requested by your doctor and bring your medications with you.

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.

Clinical Data Summary

The Ranger™ Paclitaxel-Coated PTA Balloon Catheter was evaluated in a clinical trial called the RANGER II SFA study. The study enrolled 376 patients to determine if Ranger showed acceptable performance in long-term (12-month) safety and effectiveness.

The RANGER II SFA study demonstrated that the Ranger Paclitaxel-Coated PTA Balloon Catheter provided better clinical benefits compared to non-drug coated balloons. The results also confirmed Ranger is safe and effective for treating *de novo* or restenotic blockages in the superficial femoral artery and the proximal popliteal artery of the upper leg.

Glossary

Angioplasty

A minimally invasive treatment to open blocked arteries

Artery

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

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-Coated Balloon

A balloon that mechanically opens the blockage and simultaneously delivers a therapeutic dose of drug intended to keep the vessel open longer

Lumen

The inner channel or cavity of a vessel or tube

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

Occlusion

Blockage of blood flow in the artery

Paclitaxel

A drug that prevents vessel re-narrowing

Percutaneous Transluminal Angioplasty (PTA)

A procedure that can open up a blocked blood vessel using a small, flexible plastic tube, or catheter, with a balloon at the end of it. When the tube is in place, it inflates to open the blood vessel, or artery, so that normal blood flow is restored

Glossary (continued)

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

Proximal Popliteal Artery

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

Restenosis

Re-narrowing of the artery after treatment

Sedative

A type of medication that makes you relaxed and sleepy

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 upper thighs that supply blood to the legs

For more information about indications, contraindications, warnings and instructions for the Ranger™ Paclitaxel-Coated PTA Balloon Catheter, or for copies of the Directions for Use or Patient Guide, visit www.bostonscientific.com.

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



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