

Peripheral Artery Disease
and the **Stellarex™** Drug-coated
Angioplasty Balloon

**A Patient
Resource
Guide**

 **Spectranetics®**
Always Reaching Farther

What is Peripheral Artery Disease (PAD)?

PAD is the hardening or narrowing of the arteries in the leg, caused by fatty deposits or calcium which accumulates in the blood vessels of the buttocks, legs and feet blocking normal blood flow.¹

Symptoms of PAD include:

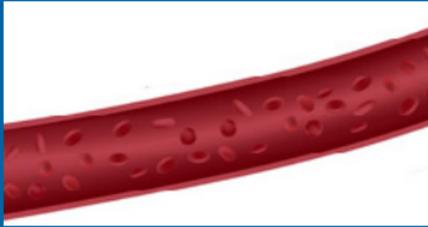
- Leg pain
- Wounds on the foot or toe that will not heal
- Gangrene
- Noticeable decrease in temperature of your leg or foot

The most common symptom of Peripheral Artery Disease (PAD) is a painful cramping in the hips, thighs or calves when walking, climbing stairs or exercising.²

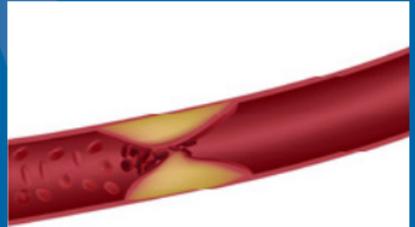
Risk factors for PAD:

- Smoking
- Diabetes
- High blood pressure
- High cholesterol
- History of heart or vascular disease

PAD affects 17 million Americans.²



Healthy Vessel



Diseased Vessel

Diagnosing PAD can include the following:

A physical exam

Your physician will check for weak pulses in the legs. Checking for weak pulses is usually performed by checking the pulse at your hips, knees and feet.



An Ankle-Brachial Index (ABI) test

The Ankle-Brachial Index (ABI) test measures the ratio of blood pressure in the ankle compared to the blood pressure in the arms. Compared to the arm, lower blood pressure in the ankle is a symptom of blocked arteries (peripheral vascular disease). Sometimes PAD can be present even if the ABI is relatively normal.³

A non-invasive Doppler Ultrasound test

The test involves a non-invasive method that visualizes the artery with sound waves and measures the blood flow in an artery to indicate the presence of a blockage.

Managing PAD

Depending on the severity, PAD can be treated through changes in lifestyle, medication or minimally invasive procedures or surgery.





Lifestyle Changes

Many risk factors can be managed by making some lifestyle changes, such as:

- Quitting smoking
- Controlling your diabetes
- Exercising
- Watching your cholesterol
- Keeping your blood pressure under control

Medications

When lifestyle changes are not enough, your doctor may prescribe medications to help lower cholesterol, manage blood sugar levels, or prevent clots with antiplatelet or anticoagulant therapies.

Managing PAD

Continued

Minimally Invasive Procedures

There are non-surgical procedures available to improve blood flow in the leg arteries.

These procedures are performed in a cath lab under local anesthesia.

Atherectomy

A variety of mechanical devices, or atherectomy, are available to cut, ablate or remove plaque build-up from the artery. Your doctor will choose the most appropriate version depending on the type of blockage.

Balloon Angioplasty

A balloon is inserted into the artery and inflated at the site of the blockage pushing the plaque to the artery wall to improve blood flow.

Drug-coated Balloon Angioplasty

A balloon that is coated with a therapeutic drug dose that adheres to the vessel wall after balloon inflation and may aid in preventing the artery from re-narrowing.

Stenting

A stent is a small mesh tube made of metal that expands and is placed permanently to help keep the vessel wall open to improve blood flow.

Surgical Procedures

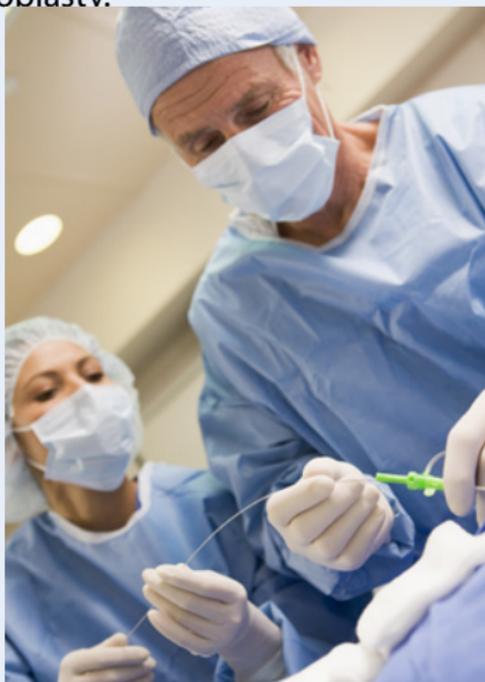
Vascular Surgery

Your doctor may choose to perform a vascular surgery, or bypass, depending on the severity of PAD. These surgeries are performed under general anesthesia and involve incisions into the artery to remove plaque or reroute blood flow through a graft placed above and below the blocked artery.

Stellarex™ Drug-coated Angioplasty Balloon

The Stellarex Drug-coated Angioplasty Balloon is a device used to treat patients with PAD by mechanically opening the vessel; during treatment, a small dose of drug is transferred to the artery, which is intended to prevent re-narrowing. Clinical studies have shown that the Stellarex Drug Coated balloon is safe and effective, and that rates of restenosis (or re-narrowing of the artery) are improved over conventional balloon angioplasty.

This balloon is coated with EnduraCoat Technology, a formulation of the drug paclitaxel and the carrier polyethylene glycol (PEG). Upon balloon inflation, the EnduraCoat formulation is transferred to the vessel wall so the paclitaxel may aid in preventing the re-narrowing of the artery over time. Paclitaxel is commonly used to treat cancer patients at much larger doses.



Contraindications

The Stellarex™ Drug-coated Angioplasty Balloon should not be used in:

- Patients with known hypersensitivity to paclitaxel or structurally related compounds.
- Patients who cannot receive recommended anti-platelet and/or anti-coagulation therapy.
- Women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children.

Potential Complications and Adverse Events

Potential complications which may be associated with a peripheral balloon dilation procedure include, but may not be limited to, the following:

- Abrupt vessel closure
- Allergic reaction to contrast medium, anti-platelet therapy or catheter system components (drug, excipients, and materials)
- Amputation/loss of limb
- Arrhythmias
- Arterial aneurysm
- Arterio-venous fistula (AVF)
- Artery injury
- Bleeding
- Death
- Embolism/device embolism
- Fever
- Hematoma
- Hemorrhage
- Hypertension/hypotension
- Infection or pain at insertion site
- Inflammation
- Ischemia for infarction of tissue/organ
- Occlusion
- Pain or tenderness
- Peripheral adema
- Pseudoaneurysm
- Renal insufficiency or failure
- Restenosis
- Sepsis or systemic infection
- Shock
- Stroke/cerebrovascular accident
- Thrombosis
- Vessel dissection, perforation, rupture, spasm or recoil
- Vessel trauma which requires surgical repair

Potential complications which may be associated with the addition of paclitaxel to a PTA balloon catheter include, but may not be limited to, the following:

Allergic/immunologic reaction to paclitaxel

Alopecia

Anemia

Gastrointestinal symptoms (diarrhea, nausea, pain, vomiting)

Hematologic dyscrasia (including neutropenia, leucopenia, thrombocytopenia)

Hepatic enzyme changes

Histologic changes in vessel wall including inflammation, cellular damage, or necrosis

Myalgia/arthralgia

Myelosuppression

Peripheral neuropathy

The Stellarex Drug-coated Angioplasty Balloon Procedure

Before the procedure

Before your procedure, you may have additional blood tests the day before the procedure. Your doctor may prescribe medications before the procedure that will increase your blood's ability to prevent clotting during and after the procedure. You may also be asked to avoid eating or drinking for eight hours prior to the procedure.



A long, thin, white, flexible catheter with a blue handle and a blue tip. The catheter is curved and has a small, clear, cylindrical balloon at the tip. The brand name 'stellarex' is printed in black, with a stylized orange 'x' logo to its right.

stellarex™

Drug-coated
Angioplasty Balloon

During this procedure

Your angioplasty procedure is performed in a catheterization laboratory or operating room. You will receive a sedative medication in your IV before the procedure to help you relax. A local anesthetic will be injected into the skin at the insertion site in the groin area. An introducer sheath will be inserted into the groin to access the artery and a wire called a catheter will be placed into the artery and advanced to the blockage site. A dye will be sent through the catheter and into your main leg artery which allows the x-ray images to show where there is blockage in the leg arteries.

The Stellarex Drug-coated Balloon will be inserted through an introducer sheath and advanced over the wire to the blockage. The Stellarex balloon will be inflated, pushing aside the fatty tissue in the artery, making a larger opening and improving the blood flow. A small drug dose will then be transferred to the vessel wall. The balloon will then be deflated and removed from the vessel. The introducer sheath will be removed and the insertion site will be closed and bandaged.

After the procedure

After the procedure, you will be moved to a recovery area where your blood pressure, pulse, and breathing will be monitored. You will be required to lie flat and still for a prolonged period. You may be given pain medication for pain or discomfort related to the insertion site. You will receive detailed instructions for your discharge and recovery period. Arrangements will be made for a follow-up visit with your physician.

Stellarex Drug-coated Balloon:

A Clinical Summary

The Stellarex Drug-coated Balloon was evaluated in the **ILLUMENATE** Pivotal Trial. The ILLUMENATE Pivotal Trial enrolled 300 patients. After one year, it was determined that the outcome of the procedure was successful. The clinical trial conclusively demonstrated superior safety and effectiveness of the Stellarex Drug-coated Balloon when compared to conventional balloon catheters.

The results of this study showed that the Stellarex Drug-coated Balloon is safe and effective for treating superficial femoral or popliteal artery stenosis. Your doctor can explain the risks and benefits that are specific to you.

Glossary

Abrupt vessel closure – blockage of a blood vessel limiting blood flow

Alopecia – loss of hair

Amputation – surgical removal of a body limb

Anemia - lowered ability of the blood to carry oxygen

Aneurysm - is a localized, blood-filled balloon-like bulge in the wall of a blood vessel

Ankle Brachial Index (ABI) – compares the blood pressure measured at your arm to the blood pressure measured at your ankle

Angioplasty – a procedure to open narrowed arteries to improve blood flow

Angiography – medical imaging technique used to visualize the inside of blood vessels and organs of the body, with particular interest in the arteries, veins, and the heart chambers.

Anticoagulant medications - drugs that prevent your blood from clotting or prevent existing clots from getting larger; also known as “blood thinners”

Antiplatelet medications – drugs that keep blood clots from forming; Aspirin is a type of antiplatelet therapy

Arrhythmias – abnormal heart rhythms; the heart beats too fast, slow, or irregularly

Artery - blood vessels that carry blood away from the heart

Arterio-venous fistula - an abnormal connection or passageway between an artery and a vein

Artery injury (dissection, perforation, rupture) – a tear to the artery wall causing blood to leak from the vessel

Artery spasm – a sudden, involuntary contraction of the vessel

Atherosclerosis – build-up of plaque on the inside of the blood vessels

Arthralgia - joint pain

Bypass graft surgery - the rerouting of blood flow through a graft placed above and below the blocked artery.

Calcification – the process in which calcium builds up in the blood vessel.

Continued on next page

Glossary

Continued

Claudication – pain caused by too little blood flow. Symptoms such as pain, cramping, weakness in buttocks, thigh or calf with walking that is associated with progressive PAD

Drug Coated Balloon (DCB) - a balloon coated with a drug intended to prevent the re-narrowing of the vessel

Embolism – an obstruction in a blood vessel due to a blood clot or other foreign matter that gets stuck while traveling through the bloodstream

Hematoma – A localized collection of blood outside the blood vessels

Hemorrhage – excessive bleeding internally or externally

Hypertension – high blood pressure

Hypotension – low blood pressure

Inflammation – becomes reddened, swollen, hot, and often painful, especially as a reaction to injury or infection

Introducer Sheath – a tube inserted into the body to provide an access point and allow the insertion of other instruments

Ischemia – an insufficient supply of blood to an organ, usually due to a blocked artery

Leucopenia – condition in which the number of white blood cells in the circulating blood is lower than normal

Myalgia – muscle pain

Nausea – discomfort in the upper stomach with an involuntary urge to vomit

Neutrotenia – abnormally few neutrophils in the blood, leaving to increased susceptibility to infection

Occlusion – a blood vessel that is completely blocked preventing blood flow

Peripheral neuropathy – damage to or disease affecting nerves, which may impair sensation, movement, gland or organ function

Pseudoaneurysm – collection of blood due to a hole in the artery; gives the impression of an aneurysm

Renal failure – a medical condition of impaired kidney function in which the kidneys fail to adequately filter metabolic wastes from the blood

Restenosis – recurrent PAD in a previously treated vessel segment accompanied by re-narrowing of the artery and worsening symptoms requiring revascularization.

Sepsis – a bacterial infection in the bloodstream or body tissues

Shock – when body is not getting enough blood flow; could be life threatening

Thrombocytopenia – is a blood disease characterized by an abnormally low number of platelets in the bloodstream

Thrombosis – formation of a blood clot



REFERENCES

1. SAGE Group Report, The Real Cost of PAD.
2. American Heart Association www.americanheart.org.
3. National heart, Lung and Blood Institute www.nhlbi.nih.gov.

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