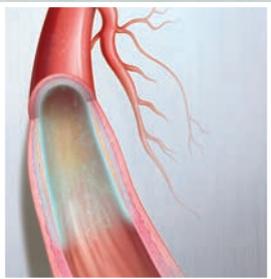
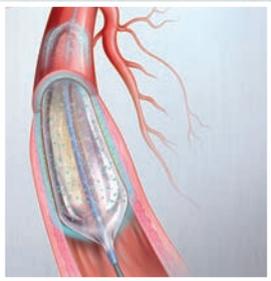
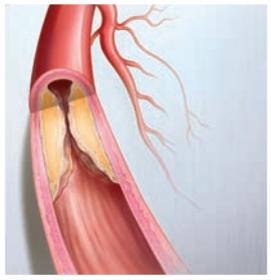


Patient Information

Peripheral Arterial Disease and
the LUTONIX® 035 Balloon



LUTONIX® 035
Drug Coated Balloon PTA Catheter



Peripheral Arterial Disease (PAD)

- What is peripheral arterial disease?
- Who is at risk?
- What are the symptoms?
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Treatment of PAD

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LUTONIX® 035 Drug Coated Balloon PTA Catheter

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The LUTONIX® 035 Procedure

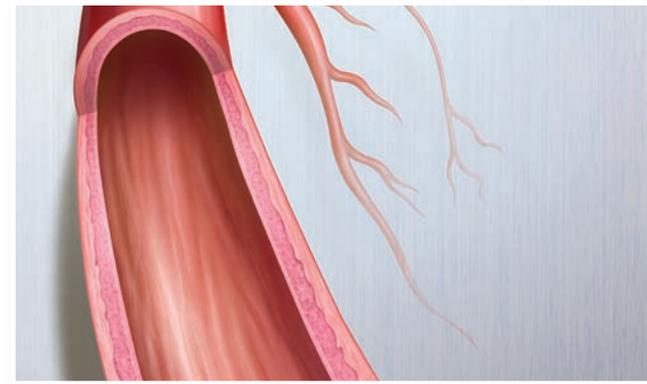
- Before the procedure
- During the procedure
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Glossary

Peripheral Arterial Disease (PAD)

Between 8 to 10 million Americans are estimated to suffer from poor blood flow to the legs and feet potentially leading to vascular disease, amputation, or worse.

Healthy Vessel



Diseased Vessel



Peripheral Arterial Disease (PAD)

What is peripheral arterial disease?

Peripheral arterial disease (PAD) develops when cholesterol levels and scar tissue build up, causing the arteries to narrow and restrict blood flow. PAD in the leg can lead to difficulty in walking and, in its most severe stage, gangrene leading to leg amputation.

Who is at risk?

Individuals may be at increased risk for PAD, if they are or have any of the following:

- Smoker
- Diabetic
- African-American
- High blood pressure
- High cholesterol
- Over 50 years of age
- Family history of PAD

What are the symptoms?

Symptoms of PAD include the following:

- Painful leg cramping
- Numbness, weakness or heaviness in the legs
- Burning or aching in feet and toes
- Cooling of skin on legs or feet
- Loss of hair on legs or feet
- Diabetic foot (foot ulcers)
- Chronic foot sores
- Gangrene (blackened dead tissue)

Peripheral Arterial Disease (PAD)

How is PAD diagnosed?

Health History

Your doctor may have assessed any symptoms, past medical history, family medical history, and risk factors you may have for coronary artery disease and PAD.

Physical Exam

Your doctor may have checked pulses in your legs and feet, checked your blood pressure, and any color changes, ulcers, infections or injuries to your legs and feet.

Blood Flow Measurements

Your doctor may have recommended tests that measure blood flow such as the ABI (ankle-brachial index). The ABI is a common non-invasive test for detecting PAD because it can help diagnose PAD whether or not you have symptoms.

Angiogram

Your doctor may have performed a contrast angiography, which is a medical procedure that takes pictures of your blood vessels so the doctor can observe any narrowing or blockage.

Treatment of PAD

What do I do if I have PAD?

You have real options. Dedicate yourself to loving your limbs, and follow your doctor's recommendations. These may vary greatly depending on your case and may include:

Lifestyle Changes:

These may include a healthier diet, exercise routine, and a plan for losing weight.

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 anti-platelet or anticoagulant medication.

Treatment of PAD

Minimally Invasive Endovascular Procedures:

Conventional Balloon Angioplasty

The most common technique for opening a narrowed vessel. These small balloons are inflated in a narrowed vessel and push the plaque against the wall to restore blood flow.

Drug Coated Balloon Angioplasty

A small balloon that is coated with a drug is used to open a blocked vessel. The balloon mechanically opens the blockage and simultaneously delivers a therapeutic dose of drug intended to keep the vessel open longer.

Stenting

A stent, a small wire mesh tube, is placed in the vessel and remains in the body after the procedure and acts to keep the blood vessel open.

Atherectomy

Atherectomy is a mechanical device that moves (rotational, laser, orbital) inside the vessel to cut the plaque build-up from a large blood vessel within the body. The device is removed after the procedure.

Surgical Procedure

Vascular Bypass Surgery

A surgical procedure where your doctor reroutes the blood flow by attaching an artificial graft (or one of your own veins) above and below the blockage.



LUTONIX® 035 Drug Coated Balloon PTA Catheter

What is the LUTONIX® 035 Drug Coated Balloon?

LUTONIX® 035 Drug Coated Balloon is a balloon catheter with the drug paclitaxel applied to the balloon. With exception of the drug coating, the LUTONIX® 035 Drug Coated Balloon is similar to other conventional balloon catheters. The clinical data demonstrates that the LUTONIX® 035 Drug Coated Balloon is as safe and is superior in preventing re-narrowing of the artery as compared to conventional balloon catheters for treatment of patients who suffer from PAD.

What is paclitaxel?

Paclitaxel is the active drug component of the LUTONIX® 035 Drug Coated Balloon. Paclitaxel is used for cancer treatment and may help prevent re-narrowing of the artery. The LUTONIX® 035 Drug Coated Balloon uses a small amount of paclitaxel (around 2% of a single cancer treatment) and the drug is applied directly to the vessel wall.



Who should not receive a LUTONIX® 035 Drug Coated Balloon?

- Women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children.
- Patients with known hypersensitivity to paclitaxel or structurally related compounds.
- Patients who cannot receive recommended anti-platelet and/or anticoagulant therapy.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system.

LUTONIX® 035 Drug Coated Balloon PTA Catheter

What are the potential adverse events associated with the LUTONIX® 035 Drug Coated Balloon?

Potential adverse events which may be associated with an angioplasty procedure such as when using the LUTONIX® 035 Drug Coated Balloon include:

- Additional intervention
- Allergic reaction to drugs or contrast medium
- Amputation/loss of limb
- Aneurysm or pseudoaneurysm
- Arrhythmias
- Embolization
- Hematoma
- Hemorrhage, including bleeding at the puncture site
- Hypotension/hypertension
- Inflammation
- Occlusion
- Pain or tenderness
- Pneumothorax or hemothorax
- Sepsis/infection
- Shock
- Stroke
- Thrombosis
- Vessel dissection, perforation, rupture, or spasm

Potential adverse events, not described in the above source, which may be unique to the paclitaxel drug coating include:

- Allergic/immunologic reaction to the drug coating (paclitaxel)
- Alopecia
- Anemia
- Blood product transfusion
- Gastrointestinal symptoms
- Hematologic dyscrasia (including leukopenia, neutropenia, thrombocytopenia)
- Hepatic enzyme changes
- Histologic changes in vessel wall, including inflammation, cellular damage, or necrosis
- Myalgia/Arthralgia
- Myelosuppression
- Peripheral neuropathy

The LUTONIX® 035 Procedure

Before the procedure

Your doctor will explain how to prepare for your angioplasty procedure before you are admitted to the hospital. You may be asked to avoid eating or drinking anything after midnight on the night before the procedure. You may also be asked to take aspirin or other medication for a few days prior to the procedure to thin your blood and prevent clots from forming.

During the procedure

Your angioplasty procedure will take place in the hospital or in a catheterization lab. Although you may be given a sedative to help you relax, you will be awake during the procedure. This will allow you to follow your doctor's instructions to move, cough or breathe as needed.

Your doctor will be accessing your artery through your groin. The access area will first be shaved, swabbed with antiseptic and numbed with a local anesthetic. Your doctor will then make a small incision in your skin and gain access to your artery with a needle.

A wire guide will be inserted through the needle and advanced to the part of your artery that contains the blockage. The doctor will then insert an introducer sheath over the wire guide into your artery, and the LUTONIX® 035 Drug Coated Balloon will be advanced through the introducer sheath to the site of the blockage. The balloon will be inflated briefly, widening the blocked artery.

The introducer sheath may also be left in place for a few hours while you are monitored.

After the procedure

When your procedure is finished, you will be moved to a recovery area. You may feel some discomfort, which can be relieved with pain medicine. Your blood pressure and heart rate will be monitored closely. Your doctor and the standard protocol of the facility where your procedure was performed will determine when you are allowed to go home.

The LUTONIX® 035 Procedure

Summary of Clinical Information

The LUTONIX® 035 Drug Coated Balloon was evaluated in the LEVANT 2 Clinical Study. The LEVANT 2 Clinical Study enrolled 476 patients. After one year, it was determined that the procedure was successful in most patients and that the LUTONIX® 035 Drug Coated Balloon was more successful at preventing renarrowing of the arteries than conventional balloon catheters. Although there is limited information for the female population, the treatment effect was reduced in women as compared to men. Additional data is needed to determine whether different outcomes are expected in women. The safety of using a LUTONIX® Drug Coated Balloon was comparable to using a conventional balloon catheter.

The results of this study showed that the LUTONIX® 035 Drug Coated Balloon is safe and effective for treating superficial femoral or popliteal artery stenoses. Your doctor can explain the risks and benefits that are specific to you.



Glossary

Alopecia

Hair loss.

Aneurysm

A sac formed by the expansion of the wall of an artery, a vein or the heart.

Arrhythmias

Irregular heartbeat rhythm.

Embolization

The sudden obstruction of an artery by a clot or any foreign material formed or introduced elsewhere in the circulatory system and carried to the site of blockage by the bloodstream.

Hematologic Dyscrasia

Blood disorder such as decrease in blood cell counts or platelets.

Hematoma

A collection of blood, usually clotted, in an organ, space or tissue outside a vessel.

Hemorrhage

Excessive bleeding either internally or externally.

Hepatic Enzyme

Liver enzyme.

Hypotension

Low blood pressure.

Hypertension

High blood pressure.

Inflammation

Redness or swelling of tissue in response to pathogens or irritants.

Myalgia / Arthralgia

Joint and muscle pain.

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Glossary

Myelosuppression

Decrease in bone marrow activity resulting in fewer red blood cells, white blood cells, and platelets.

Necrosis

Cell death.

Occlusion

Blockage of the artery vessel.

Peripheral Neuropathy

Numbness in hands or feet.

Pneumothorax

Abnormal collection of air between the lungs and the chest wall.

Hemothorax

Collection of blood between the lungs and the chest wall.

Introducer Sheath

A tube that is inserted into the body to provide access and allow delivery of other devices.

Pseudoaneurysm

A collection of blood from a ruptured vessel that gives the appearance of an aneurysm; also known as a false aneurysm.

Sepsis

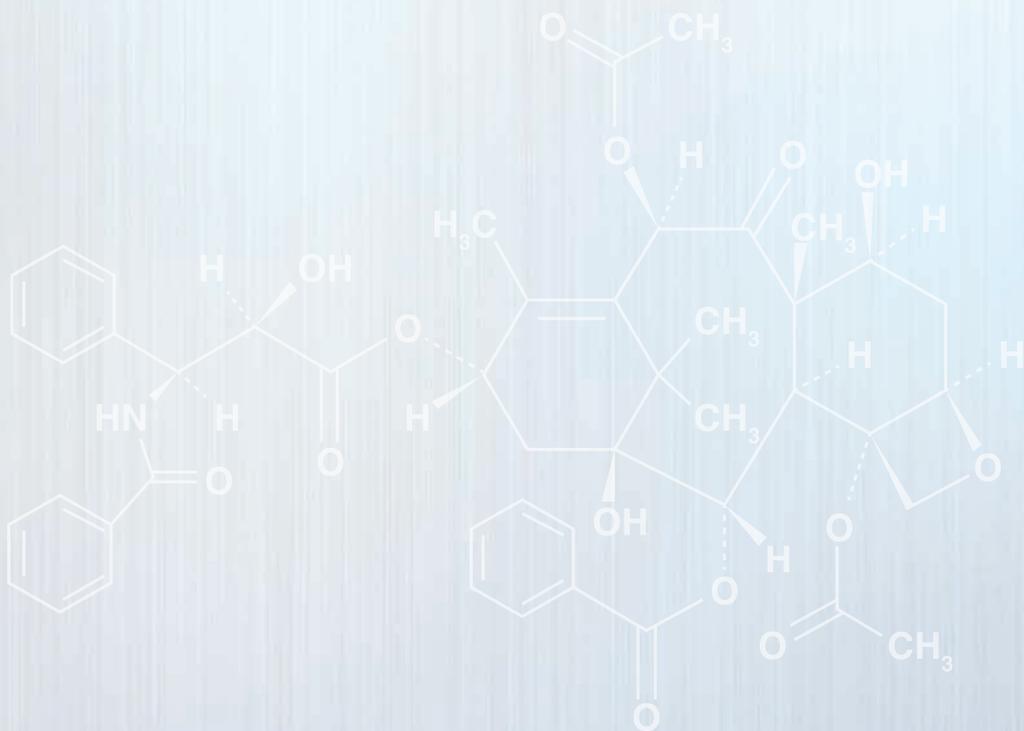
Whole body inflammation due to severe infection.

Thrombosis

Formation of blood clot in the blood vessel.

For more information about peripheral arterial disease visit our website at LoveYourLimbs.com.





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