

# Patient Information Guide

A photograph of a male doctor with grey hair, wearing a white lab coat and a blue stethoscope, looking down at a clipboard held by an elderly female patient with short grey hair. The patient is wearing a white top. They are in a clinical setting with a light blue background.

**LIFESTENT<sup>®</sup>**

Vascular Stent System

**LIFESTENT<sup>®</sup> XL**

Vascular Stent System

**LIFESTENT<sup>®</sup> SOLO<sup>™</sup>**

Vascular Stent System

**LIFESTENT<sup>®</sup> | 5F**

Vascular Stent System

**BARD**





If you or a member of your family has been diagnosed with peripheral arterial disease (PAD), you may have questions about the disease and treatment options, specifically if your doctor is considering treating a narrowed artery in your leg with the LIFEStENT® Vascular Stent.

This guidebook is designed to help you and your family understand the different treatment options available to you, including treatment of a narrowed leg artery with a LIFEStENT® Vascular Stent.

While this guidebook answers some of the questions patients with PAD often ask, if you have any questions as you read this guidebook, please write them down and discuss them with your doctor or nurse.

This patient brochure only addresses treatment with a LIFEStENT® Vascular Stent. Please consult with your doctor on the best treatment options available to you.

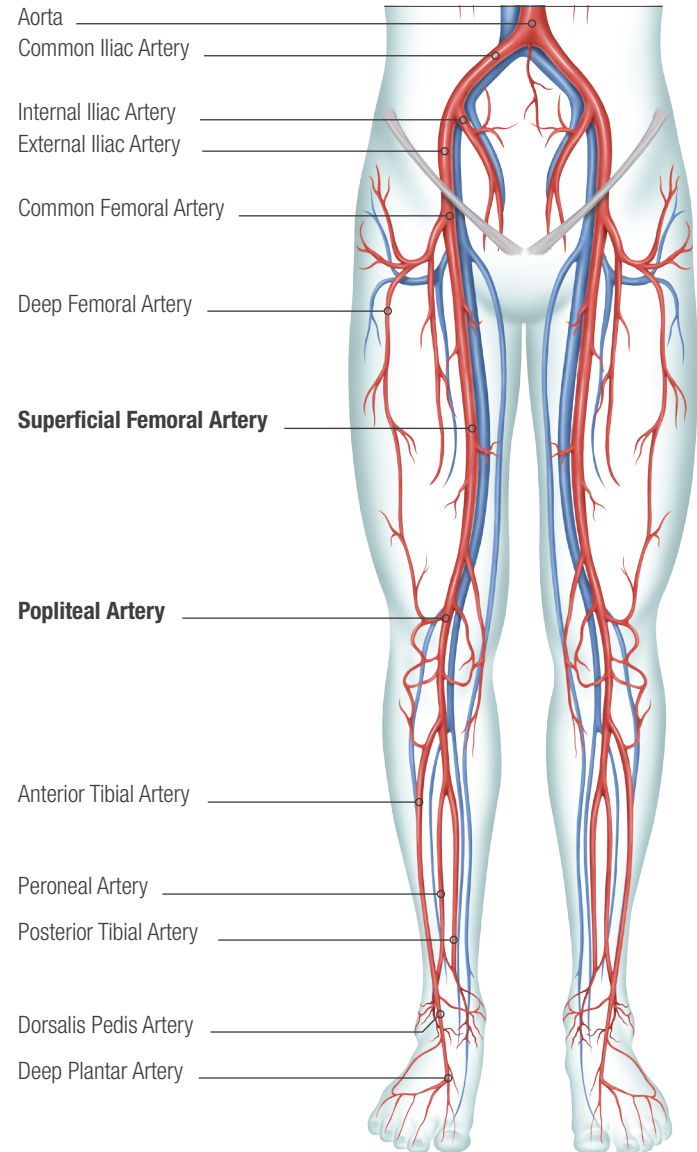
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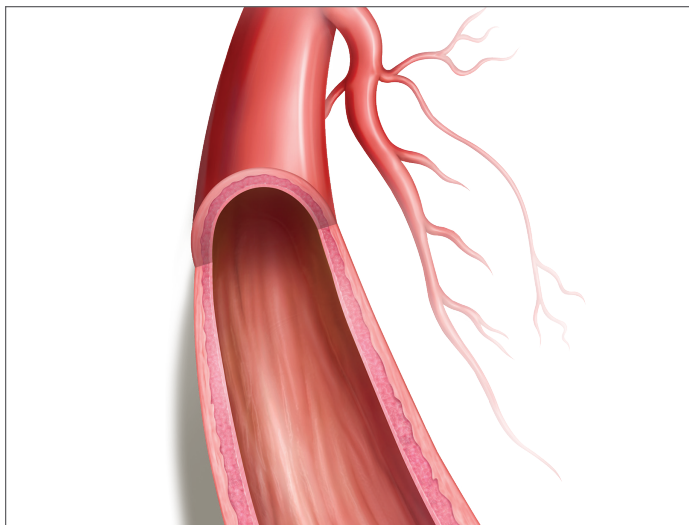
# Understanding Peripheral Arterial Disease (PAD)

## What are the Superficial Femoral and Popliteal Arteries?

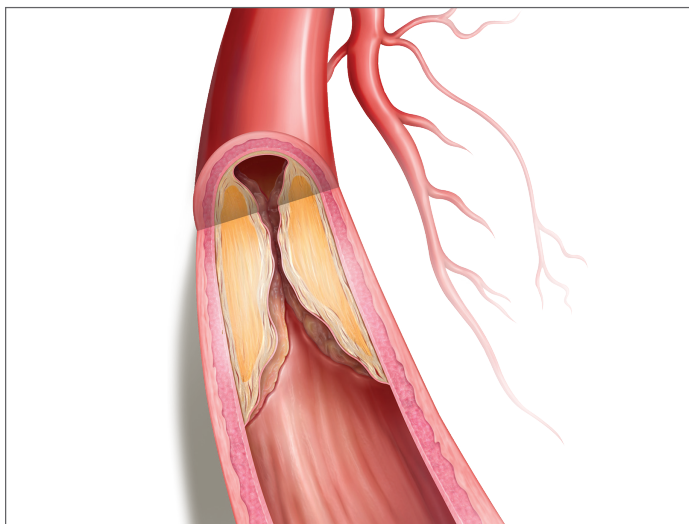
Arteries are blood vessels that carry blood away from the heart. The superficial femoral and popliteal arteries extend from the hip region down through the knee. These arteries carry blood containing oxygen through the legs down to the feet.







Healthy Artery



Diseased Artery

## What is Peripheral Arterial Disease (PAD)?

Peripheral arterial disease develops when the arteries to the arms and legs become narrowed, limiting blood flow, oxygen, and nutrients. Arteries become narrowed when plaque; consisting of fat, cholesterol, calcium and fibrous tissue; builds up inside of the arteries during a process known as atherosclerosis. The area of narrowing or blockage in an artery may also be called a stenosis.

Symptoms of PAD in the arteries of the leg include:

- ▶ Fatigue, pain, or discomfort in leg muscles during exercise (claudication)
- ▶ Numbness or tingling
- ▶ Changes in skin color
- ▶ Changes in skin temperature
- ▶ Loss of hair on the legs or feet
- ▶ Non-healing wounds or ulcers

## What are the risk factors for PAD?

Factors that increase the risk of developing PAD include:

- ▶ Smoking
- ▶ Diabetes
- ▶ Obesity
- ▶ African-American ethnicity
- ▶ High blood pressure
- ▶ High cholesterol
- ▶ Coronary artery disease
- ▶ Over 50 years of age
- ▶ Family history of PAD, heart disease or stroke

## How is PAD diagnosed?

PAD is diagnosed based on medical and family history, a physical exam, and diagnostic test results.

The following diagnostic tests may be performed if PAD is suspected. These tests can be used to diagnose where blockages might be and how narrow your arteries are in areas of your leg.

**Ankle-Brachial Index (ABI):** ABI is a common non-invasive test for detecting PAD by comparing the blood pressure in the ankles to the blood pressure in the arms. A lower ABI result may indicate presence of PAD.

**Doppler Ultrasound:** A Doppler Ultrasound is a non-invasive test that looks at blood flow in the major arteries of the leg. During this test, a handheld device is placed on your body and passed back and forth over the affected area sending out sound waves. A computer measures how the sound waves reflect back, and converts sound waves into a picture of blood flow in the arteries.

**Angiography/Fluoroscopy:** Angiography with Fluoroscopy is a minimally invasive technique used to obtain an x-ray based image by injecting dye through a catheter that is inserted into an artery in the groin. This procedure allows the physician to determine exactly where the narrowing or blockage is located in the artery.

A photograph of a doctor in a white lab coat and stethoscope, seen from the side, holding the hand of a patient. The patient is an older man with a mustache, lying in a hospital bed with light blue bedding, wearing a white hospital gown with a small blue pattern. The background shows a hospital room with a metal stand and a window with blinds.

## Understanding Your Stent Procedure

Treatment with a LIFESTENT® Vascular Stent is one of the many methods for treating the vessels affected by PAD. Please consult with your doctor to learn more about the best treatment options for you.

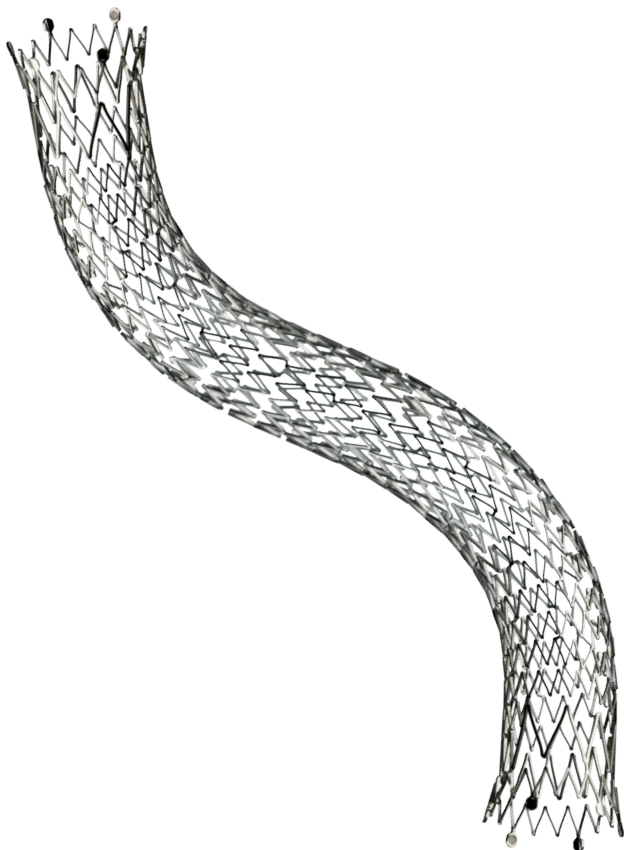
### **Percutaneous Transluminal Angioplasty and Stenting**

During a percutaneous transluminal angioplasty (PTA) and stenting procedure, your physician will begin with needle entry in your femoral artery in your groin. Your physician will then insert a catheter (thin tube) with a small balloon at the tip into the blocked artery. As the balloon is inflated it pushes plaque outward against the artery wall. This widens the artery and restores blood flow. The balloon is deflated and removed from your body.

Then, a stent, which is a small metal wire mesh tube, is expanded inside of your artery to help keep the artery open. Over time, your artery wall will heal around the stent as it continues to support the vessel.

## What is the LIFEStENT® Vascular Stent?

The LIFEStENT® Vascular Stent is a flexible mesh tube made from nitinol. Nitinol is a nickel titanium alloy that has shape memory and is designed to expand to a specified size when warmed to body temperature. The stent comes inside a delivery system catheter which allows the doctor to advance it through your body to the specific narrowing in the artery.



## When Can The Device Be Used (Indication)?

The LIFEStENT® Vascular Stent is used to help expand a narrowed artery in your leg from the upper thigh to just behind the knee. Your doctor will know how to best choose the correct stent size.

## When Should The Device Not Be Used (Contraindications)?

- ▶ If you have a known hypersensitivity or allergy to nitinol, nickel, titanium, or tantalum metals
- ▶ If you cannot take aspirin or blood-thinning medications (also known as anticoagulants or antiplatelets)
- ▶ If the doctor determined that the blocked artery will not allow complete inflation of the angioplasty balloon or proper placement of the stent



## What are the risks of the LIFEStENT® Vascular Stent implantation procedure?

As with any procedure, there is a chance that complications may occur. The following are some of the risks that may be associated with your stent implantation procedure. Be sure to discuss any questions you may have with your doctor.

- ▶ Abnormal blood pressure (hypotension/hypertension)
- ▶ Abnormal connection between an artery and vein
- ▶ Additional surgical procedures
- ▶ Air, pieces of the plaque, pieces of the device, or fragments of blood clots that can block the artery
- ▶ Allergic reactions
- ▶ Bleeding at procedure site
- ▶ Breakage/fracture of the stent
- ▶ Bruising/swelling at procedure site
- ▶ Chest pain or discomfort
- ▶ Damage to organs including kidneys, pancreas, liver, or lungs
- ▶ Damage to the artery
- ▶ Death
- ▶ Excessive bleeding requiring transfusion
- ▶ Formation of blood clots in arteries or veins
- ▶ Heart attack
- ▶ Incorrect placement of the stent
- ▶ Infection/Fever
- ▶ Irregular heart beat (arrhythmia)
- ▶ Limb loss (amputation)
- ▶ Movement of the stent after implantation
- ▶ Pain
- ▶ Recurrence of the narrowing/blockage (restenosis)
- ▶ Reduction of blood flow to tissue/organs
- ▶ Spasm of artery
- ▶ Stroke
- ▶ Weakening of the artery wall (aneurysm)



## Clinical evidence for the LIFESTENT® Vascular Stent

The safety and effectiveness of the LIFESTENT® Vascular Stent was originally established in the RESILIENT clinical study, which included 206 patients with three year follow-up data. The RESILIENT clinical study compared patients that received the LIFESTENT® Vascular Stent to patients that received percutaneous transluminal angioplasty (PTA) alone, a well established treatment. The study results showed that patients who received a LIFESTENT® Vascular Stent had a significantly higher patency rate (normal blood flow) at one year, when compared to PTA alone (81.5% for LIFESTENT® Vascular Stent, 36.7% for PTA). Patients that received the LIFESTENT® Vascular Stent demonstrated a significantly lower re-intervention rate out to three years compared to the PTA patients.

At three years, the incidence of Major Adverse Clinical Events, which included death within 30 days, stroke, heart attacks, clot blocking the artery, emergency surgery, and/or worsened leg pain, was 24.8% for both patients that received the LIFESTENT® Vascular Stent and PTA alone. This means that the study showed the risks associated with the LIFESTENT® Vascular Stent are similar to the risks associated with PTA alone. In patients that received the LIFESTENT® Vascular Stent, no deaths occurred within 30 days and no amputations occurred within 12 months.

The safety and effectiveness of the LIFESTENT® Vascular Stent is further supported by additional clinical studies. For more information on the LIFESTENT® Vascular Stent please visit [www.BardPV.com](http://www.BardPV.com).

# After Your LIFESTENT® Vascular Stent Implantation Procedure

## What to expect during your recovery

Before you leave the hospital, your doctor will speak to you about what kind of activities you can do, what you should eat, and what medicine you will need to take. You will be told when you can start to return to normal activities and return to work. Your physician may prescribe medications for you to take to prevent blood clots from forming in your newly opened blood vessel. It is important to follow your doctor's instructions and to keep all follow-up appointments. During these follow-up appointments, your doctor will monitor your progress and evaluate your medications and the status of your disease.

## Living with PAD

Living a healthy, active lifestyle can greatly improve your quality of life and reduce the risk of developing new blockages and narrowing in your peripheral arteries.

The following lifestyle changes may improve your overall health:

- ▶ Lose excess weight and maintain a healthy weight
- ▶ Exercise regularly
- ▶ Avoid smoking
- ▶ Decrease fats and cholesterol in your diet
- ▶ Eat proper portion sized meals

You should talk to your doctor about these lifestyle changes and how to increase your chances for a healthier outcome and a more rewarding life.





## **Keep your stent implant card handy**

Your stent implant card contains important information about the stent you had implanted. Be sure to show your implant card to any health care providers that treat you in the future.

It is recommended to register the stent implant under MedicAlert Foundation ([www.medicalert.org](http://www.medicalert.org)) or an equivalent organization.

If you require a magnetic resonance imaging (MRI) scan, tell your doctor or MRI technician that you have a stent implant and direct them to follow the instructions written on the implant card or included in this booklet.

## Safety during Magnetic Resonance Imaging (MRI)

After placement of your LIFEStENT® Vascular Stent, your doctor may request a special test that uses electrical waves from a magnet to obtain images of the inside of your body, called an MRI. Your LIFEStENT® Vascular Stent has been classified as MR Conditional. This means that an MRI can be done safely if specific testing conditions are followed. These conditions are outlined on the implant card that was provided to you as part of your procedure. Please provide this information to anyone assisting you with an MRI. A copy of the information located on the card is also provided below.

Non-clinical testing has demonstrated that the LIFEStENT® Vascular Stent is MR Conditional. The LIFEStENT® Vascular Stent can be scanned safely, immediately after placement of this implant, under the following conditions:

- ▶ Static magnetic field of 1.5 Tesla or 3.0 Tesla.
- ▶ Spatial gradient field of 2500 Gauss/cm or less.
- ▶ Maximum whole-body-averaged specific absorption rate (SAR) of 1 W/kg for 15 minutes of scanning. For landmarks superior of the umbilicus, a whole body SAR up to 2 W/kg may be applied.
- ▶ In a configuration where the patients legs are not in contact with each other.

## 3.0 Tesla Temperature Rise

Under the scan conditions defined above, the LIFEStENT® Vascular Stent is expected to produce a maximum temperature rise in the patient of 2.7 °C after 15 minutes of continuous scanning.

## 1.5 Tesla Temperature Rise

Under the scan conditions defined above, the LIFEStENT® Vascular Stent is expected to produce a maximum temperature rise in the patient of 3.0 °C after 15 minutes of continuous scanning.

## Image Artifact

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent. Artifact tests were performed according to ASTM F2119-07. In non-clinical testing, the image artifact caused by the device extends approximately 3 mm from the LIFEStENT® Vascular Stent when imaged with a spin echo sequence and 8 mm when imaged with a gradient echo sequence in a 3.0 Tesla MRI system. The lumen was obscured.

## Additional Information

The LIFEStENT® Vascular Stent has not been evaluated in MRI systems other than 1.5 or 3.0 Tesla. The heating effect in the MRI environment for fractured stents is not known.

# Glossary

## **Amputation**

Surgical removal of the leg.

## **Aneurysm**

An excessive localized enlargement of an artery caused by a weakening of the artery wall.

## **Angiography**

An x-ray procedure in which contrast dye is injected into the arteries to diagnose a narrowing or blockage of the artery.

## **Ankle-Brachial Index (ABI)**

A common non-invasive test for detecting PAD by comparing the blood pressure in the ankles to the blood pressure in the arms.

## **Anticoagulant**

Medications that prevent blood clots from forming.

## **Antiplatelet**

Medications that prevent blood clots from forming.

## **Arrhythmia**

Irregular or abnormal heartbeat.

## **Artery**

A blood vessel that carries blood from the heart and lungs through the body. Blood in arteries is full of oxygen.

## **Atherosclerosis**

A build up of plaque (fat, cholesterol, calcium and fibrous tissue) that causes arteries to narrow.

## **Balloon Angioplasty**

A procedure where a small tube containing a balloon at the tip is passed through to the blocked area of an artery. The balloon is inflated and opens the blocked area in the artery. Also called Percutaneous Transluminal Angioplasty (PTA).

## **Blood Clot**

A clump of blood cells that can block or prevent normal blood flow.

## **Blood Vessel**

An artery or vein.

## **Catheter**

A small, hollow tube used for gaining access to a blood vessel and delivering treatment therapies.

## **Cholesterol**

A substance that moves through the blood and plays a role in the formation of blockages. Cholesterol originates in foods that are rich in animal fat.

## **Claudication**

Fatigue, pain, or discomfort in leg muscles during exercise.

## **Contraindications**

A condition that makes a specific treatment or procedure improper or undesirable.

## **Coronary Artery Disease**

A condition where the arteries that supply blood to the heart muscles narrow.

## **De Novo Lesion**

A lesion or stenosis identified within an artery that has not been previously treated via percutaneous intervention or surgical means.

## **Diabetes**

A disease affecting one's metabolism of glucose (sugar) which can cause changes in the blood vessels. These changes may aid in the development of peripheral arterial disease.

## **Doppler Ultrasound**

A non-invasive test to detect PAD that evaluates blood flow in the major arteries of the leg.

## **Fluoroscopy**

An x-ray procedure in which contrast dye is injected into the arteries to find narrowing or blockage of the artery.



# Glossary

## **High Blood Pressure**

A condition where the force of blood against the artery wall is too high. Also known as hypertension.

## **High Cholesterol**

A condition where there is too much cholesterol circulating in the blood stream.

## **Hypertension**

A condition where the pressure inside the blood vessels is too high. Also known as high blood pressure.

## **Hypotension**

A condition where the pressure inside the blood vessels is too low. Also known as low blood pressure.

## **Indication for Use**

When/where a device or procedure can be used.

## **Lesion**

A narrowing or blockage of an artery. Also known as a stenosis.

## **Lumen**

The inner channel or cavity of a vessel or tube.

## **MRI (Magnetic Resonance Imaging)**

A diagnostic test that uses magnetic waves to obtain images of the inside of your body.

## **Nitinol**

A special metal made of nickel and titanium that remembers its shape. Nitinol can be compressed when cold and expands back to its original shape and size when heated.

## **Patency**

Measurement of openness and blood flow in an artery.

## **Percutaneous**

Performed through a small opening in the skin.

## **Percutaneous Transluminal Angioplasty (PTA)**

A procedure where a small tube containing a balloon at the tip is passed through to the blocked area of an artery. The balloon is inflated and opens the blocked area in the artery. Also called Balloon Angioplasty.

## **Peripheral Arterial Disease (PAD)**

Vascular disease when arteries in the extremities become narrowed, limiting blood flow, oxygen, and nutrients to the extremities.

## **Plaque**

A build up of fat, cholesterol, calcium and fibrous tissue that causes arteries to narrow.

## **Popliteal Arteries**

The arteries that pass through your knee.

## **Re-intervention**

An additional interventional medical procedure performed sometime after the initial procedure.

## **Restenosis**

The recurrence of a narrowing or blockage in an artery after treatment.

## **Restenotic Lesion**

A lesion or stenosis within an artery that has previously been treated via percutaneous intervention or surgical means.

## **Stenosis**

A narrowing or blockage of an artery. Also known as a lesion.

## **Stent**

An expandable, metallic, tubular shaped device that provides structural support for a vessel.

## **Superficial Femoral Arteries**

The arteries that extend from your pelvic region down to your knee.



Bard Peripheral Vascular, Inc.  
1625 W. 3rd Street Tempe, AZ 85281 USA [www.bardpv.com](http://www.bardpv.com)  
Tel: 1 480 894 9515 / 1 800 321 4254 Fax: 1 480 966 7062 / 1 800 440 5376