

# LIFESTREAM<sup>®</sup>

Balloon Expandable Vascular Covered Stent

## Patient Brochure

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# LIFESTREAM®

Balloon Expandable Vascular Covered Stent

## LIFESTREAM® Patient Brochure

If you or a member of your family has been diagnosed with peripheral arterial disease (PAD)\* or claudication\* in your iliac arteries, you may have questions about the disease and its treatment, especially if your doctor has treated you using the LIFESTREAM® Balloon Expandable Vascular Covered Stent\*.

This guidebook is designed to help you and your family understand PAD and the treatment of atherosclerosis\* in the iliac artery\* with the LIFESTREAM® Balloon Expandable Vascular Covered Stent\*.

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

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## **UNDERSTANDING PERIPHERAL ARTERIAL DISEASE (PAD) AND YOUR TREATMENT**

### **What are iliac arteries?**

Arteries\* are blood vessels that carry blood away from the heart. The iliac arteries are in your hip region and connect the aorta in your stomach area to the femoral arteries in your legs. These arteries carry oxygen through the legs down to the feet.

### **What is Peripheral Arterial Disease (PAD)?**

PAD is caused by the build-up of fatty substances and/or calcium build up (plaque\*) within the arteries, in a process known as atherosclerosis\*. This causes a narrowing or blockage called a stenosis\* that limits blood flow. Some of the more commonly affected arteries by PAD are located in the legs, arms, neck and abdomen. Some of the symptoms you may experience due to blockages located in the arteries of the leg are:

- Pain in the hips, thighs, buttock or calf muscles (claudication\*);
- Numbness/tingling in the leg, foot, or toes;
- Changes in skin color such as paleness or bluish color in leg, foot, or toe;
- Changes in skin temperature of leg, foot, or toes.

### **What are risk factors for PAD?**

Based on clinical studies, it has been determined that you are at the greatest risk for PAD if you have a history of:

- Diabetes\*
- Coronary artery disease\*
- High blood pressure
- High cholesterol
- Smoking, or are a current smoker

You may also be at risk for PAD if you are overweight, do not exercise, or if people in your family have had 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.

## 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.

**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.

## 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.

## LIFESTREAM® BALLOON EXPANDABLE VASCULAR COVERED STENT

### What is the LIFESTREAM® Balloon Expandable Vascular Covered Stent?

The LIFESTREAM® Balloon Expandable Vascular Covered Stent is a stainless steel metal tube that is covered with a special plastic called ePTFE\*. The covered stent comes attached to a delivery system that allows your physician to move it through your body to the specific place where your artery is blocked. The expanded covered stent is shown in Figure 1.

Figure 1

LIFESTREAM® Balloon Expandable Vascular Covered Stent (Implant)



### When can the device be used (indications for use)?

The LIFESTREAM® Balloon Expandable Vascular Covered Stent is indicated for the treatment of atherosclerotic lesions in common and external iliac arteries. In other words, the device can be used to help open a blocked area of the iliac artery located in the hip region of your body.

### When should the device not be used (contraindications)?

- If you cannot take aspirin or blood-thinning medications (also called antiplatelets or anti-coagulants).
- If the physician decides that the blockage will not allow complete inflation of the angioplasty balloon or proper placement of the covered stent.
- If the location of the blockage would cause the LIFESTREAM® Balloon Expandable Vascular Covered Stent to be compressed through movement of your body.

## YOUR PROCEDURE

### What is an iliac artery angioplasty and covered stent procedure?

When your doctor performs a procedure with a LIFESTREAM® Balloon Expandable Vascular Covered Stent, he/she will start by entering a needle into your Femoral Artery\*. Your doctor may then use a small tube (catheter) with a small balloon on the end that inflates to widen the narrow sections of the artery. As the balloon inflates it squeezes the plaque\* against the inside wall of the artery. This process is designed to expand the blood vessel so that it doesn't slow blood flow anymore. If used, this balloon is deflated and removed from the artery.

A covered stent\*, which is a stainless steel wire-mesh tube covered with a special plastic called ePTFE, is then placed into your artery. The covered stent is attached to a balloon that is then expanded to place the covered stent into the artery. The covered stent continually pushes against the inside of the artery wall to keep the artery open. The covered stent is used to help blood flow through your legs more easily. Over time, the artery wall will heal around the covered stent as it continues to support the vessel.

### **Warnings associated with stent implantation**

- It is important to tell your physician about all allergies you know about.
- Tell your physician about any reasons why you cannot take blood thinning medications (also called anticoagulants or antiplatelets).
- Be sure to show the stent implant card on all future physician visits or medical tests you may be receiving, even if it seems unrelated to that particular visit.

### **What are the risks of the procedure?**

Your doctor should have discussed the procedure in detail with you and explained the possible risks and potential benefits of the device. Please make sure that your doctor has answered all of your questions.

The procedure used to place the LIFESTREAM® Balloon Expandable Vascular Covered Stent may involve certain risks. These risks are uncommon, but are important to be aware of. Potential patient adverse effects that may occur include, but are not limited to, the following:

- Abnormal vein to artery connection (fistula)
- Abscess
- Allergic reaction
- Amputation
- Aneurysm or pseudoaneurysm (thinning and ballooning of the vessel wall)
- Angina/coronary ischemia
- Arrhythmias (irregular heart beat)
- Bypass surgery
- Death
- Difficult or unable to breathe
- Distal embolization (downstream complications)
- Drug reaction
- Edema
- Fever
- Hematoma and/or bleeding at the puncture (access) site
- Hemorrhage/bleeding
- Hypotension/hypertension
- Incorrect stent position
- Infection
- Inflammation
- Kidney damage or failure
- Pain
- Radiation injury
- Restenosis in the treatment area / covered stent edge (narrowing of the vessel)
- Sepsis
- Shock
- Stroke/Transient Ischemic Attack (TIA)
- Thrombotic event / thrombosis (blood clots)
- Vasospasm (vessel spasm)
- Vessel wall trauma, perforation / dissection / rupture

Please ask your doctor for clarification if you do not understand any of these potential serious adverse effects.

### **What is the potential benefit of using the LIFESTREAM® Balloon Expandable Vascular Covered Stent?**

The safety and effectiveness of the LIFESTREAM® Balloon Expandable Vascular Covered Stent was evaluated in the BOLSTER clinical trial. The BOLSTER study measured the rate of death, heart attack, limb amputation, re-intervention\*, and restenosis\* for those patients treated with the LIFESTREAM® Balloon Expandable Vascular Covered Stent. In comparison to historical studies performed for treating PAD in the iliac arteries, patients treated with the LIFESTREAM® Balloon Expandable Vascular Covered Stent in the BOLSTER study had similar safety and efficacy results.

Please ask your doctor for more information about the results of these studies.

## **AFTER YOUR PROCEDURE**

### **What to Expect During Your Recovery**

Before you leave the hospital, your doctor will speak to you about what kind of movement 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 doctor will prescribe medications for you to take to prevent blood clots\* from forming in your newly opened blood vessel. It is very important you tell your doctor if these medicines make you feel bad or you have any kind of allergic reaction. Medications may also be provided that can help lower your cholesterol. If you have diabetes, your physician may recommend modifications to medications to help reduce your blood sugar levels.

The artery that has been treated with the covered stent will begin to slowly grow around the covered stent and it will become permanent. You will not feel the stent and your daily activities will not be affected. Since you now have a vascular covered stent implanted in your leg, you should tell this to any doctor who treats you in the future.

### **Follow-Up Examinations**

You will need to see the doctor who put in your covered stent for routine follow-up examinations. During these visits, your doctor will monitor your progress and evaluate your medications, the status of your disease, and how the stent is working for you.

### **Keep Your Patient Implant Card**

Show your implant card if you report to an emergency room. The implant card will let your doctor or health care providers know that you have a covered stent in your leg.

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

If you require a magnetic resonance imaging (MRI) scan, tell your doctor or MRI technician that you have a covered 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 LIFESTREAM® Balloon Expandable Vascular Covered 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 LIFESTREAM® Balloon Expandable Vascular Covered 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 a MRI. A copy of the information located on the card is also provided below.

The LIFESTREAM® Balloon Expandable Vascular Covered Stent is a permanent implant and can be safely scanned under the following conditions:

- Static magnetic field of 3-Tesla or 1.5-Tesla only
- Spatial gradient magnetic field of 3000-Gauss/cm (30 T/m) or less
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of < 2 W/kg in the normal operating mode.

<b>GLOSSARY</b>	
<b>Term</b>	<b>Definition</b>
<b>Arteries</b>	Blood vessels that carry blood from the heart and lungs through to the body. Blood in the arteries is full of oxygen.
<b>Atherosclerosis</b>	The process of fatty deposits and/or calcium build-up (plaque) on the inside of the arteries.
<b>Blood clots</b>	Clumps of blood cells that block or prevent normal blood flow.
<b>Claudication</b>	Pain in the leg that occurs with work or exercise, but may also occur when resting.
<b>Coronary artery disease</b>	A condition where the arteries that supply blood to the heart muscles narrow.
<b>Covered stent</b>	An expandable, metallic tubular shaped device covered with a special plastic coating that provides structural support for a vessel.
<b>Diabetes</b>	A disease affecting one's metabolism of glucose (sugar) which causes changes in the blood vessels. These changes may aid in the development of peripheral artery disease.
<b>ePTFE</b>	A special plastic used to provide coverage on a bare metal stent.
<b>Femoral artery</b>	A large vessel in the thigh that supplies blood to the leg.
<b>Iliac artery</b>	Large vessels near the hip that supply blood to the pelvis and legs.
<b>Patency</b>	When a blood vessel is open, expanded or unobstructed.
<b>Peripheral artery disease</b>	Vascular disease, which affects the blood vessels, especially those of the extremities.
<b>Plaque</b>	An accumulation or build-up of fatty deposits, calcium and/or cell debris in an artery that leads to narrowing of the vessel.
<b>Re-intervention</b>	An additional procedure that becomes necessary due to the recurrence of disease after initial treatment.
<b>Restenosis</b>	The recurrence of a narrowing or blockage in an artery after treatment.
<b>Stenosis</b>	A narrowing of any canal, especially one of the superficial femoral vessels.

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