BARD® LIFESTENT®

Vascular Stent System

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If you or a member of your family has been diagnosed with **peripheral arterial occlusive disease (PAOD)*** or **claudication***, you may have questions about the disease and its treatment, especially if your doctor has treated you using the **LIFESTENT® Vascular Stent***.

This guidebook is designed to help you and your family understand PAOD and the treatment with a vascular stent.

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

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** See glossary for definition*

GLOSSARY

Term	Definition
Angiogram	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 non¬invasive test used to determine the degree of peripheral arterial occlusive disease within a patient's legs.
Artery	A blood vessel that carries blood from the heart and lungs through the body. Blood in arteries is full of oxygen.
Atherosclerosis	The process of fatty deposits and/or calcium build-up (plaque) on the inside of the arteries.
Balloon Angioplasty	A procedure whereby a small tube containing a balloon is passed through to the blocked area of an artery. Once the balloon is inflated, the catheter opens the blocked area in the artery. Also called Percutaneous Transluminal Angioplasty (PTA).
Blood Clot	A clump of blood cells that blocks or prevents normal blood flow.
Blood Vessel	An artery or vein
Catheter	A hollow tube used for gaining access to a blood vessel.
Catheterization	A procedure that involves passing a tube (catheter) through blood vessels and injecting dye to detect blockages.
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	Pain in the leg that occurs with work or exercise, but may also occur when resting.
Contraindications	A condition that makes a specific treatment or procedure improper or undesirable.
Contrast	X-ray dye used to view the arteries during an angiogram.
Coronary artery disease	A condition where the arteries that supply blood to the heart muscles narrow.
De-Novo Lesion	A lesion identified within your own artery that has not been previously treated via percutaneous intervention or surgical means.
Diabetes	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.
Dilation	The widening or stretching of an opening or a hollow structure in the body
Dilation Catheter	A catheter (or tube) with a balloon on the end that can be inflated.
Fluoroscopy	An x-ray procedure in which contrast dye is injected into the arteries to find narrowing or blockage of the artery.
Graft	A portion of one of your veins or a man-made synthetic tube that your surgeon connects above and below a blockage to allow blood to pass through it and around the blockage.
Guiding Catheter	A hollow-tube through which fluids or objects can be introduced or removed from the body.

Term	Definition
High Blood Pressure	Called hypertension. A condition where there is too much pressure inside your blood vessels. Blood is pushed too hard by the heart against the blood vessel walls.
High Cholesterol	A medical condition where there is too much cholesterol circulating in the blood stream.
Indication for Use	When a device or procedure can be used
Lesion	A blockage in a blood vessel. Also known as a plaque or stenosis.
LIFESTENT® Vascular Stent	A thin, flexible metal mesh tube that can be implanted in the arteries that supply blood to the thigh and knee.
Local Anesthetic	A substance used to numb the area to which it is applied.
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.
Percutaneous	Performed through a small opening in the skin.
Peripheral Artery Occlusive Disease	Vascular disease, which affects the blood vessels, especially those of the extremities.
Plaque	An accumulation or build-up of fatty deposits, calcium and/or cell debris in an artery that leads to narrowing of the lumen.
Platelet Inhibitors	Medications to prevent blood cells called platelets from sticking together and blocking the artery.
Popliteal Arteries	The arteries that pass through your knee.
Restenosis	The recurrence of a narrowing or blockage in an artery after treatment.
Stenosis	A narrowing of any canal, especially one of the superficial femoral vessels.
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.
Thrombus	A blood clot.
Transluminal	Through the inside opening of an artery.
Triglycerides	Substances in the blood that are a component of the "bad" type of cholesterol.
Ultrasound	A test, outside the body, using sound waves to determine the presence of arterial narrowing.
Vein	A blood vessel that carries blood from the organs of the body back to your heart.

UNDERSTANDING PAOD AND YOUR TREATMENT

What Are The Superficial Femoral and Popliteal Arteries*?

Arteries* are **blood vessels*** (or pipes) that carry blood away from the heart. The superficial femoral and popliteal arteries extend from the arteries in the hip region down to your knee. The superficial femoral arteries carry blood containing oxygen through the legs down to the foot.

What Is Peripheral Arterial Occlusive Disease (PAOD)?

PAOD is caused by the build-up of fatty substances 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 PAOD 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 The PAOD Risk Factors?

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

- **Diabetes***
- **Coronary artery disease***
- **High blood pressure***, also known as heart disease
- **High cholesterol***
- **Smoking, or are a current smoker**

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

How is PAOD Diagnosed?

You should be screened for superficial femoral artery blockages if you have:

- Pain in your legs when you are moving around or walking that stops when you are resting

The following diagnostic tests may be performed if superficial femoral artery disease 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*: The Ankle-Brachial Index (ABI) is a test done by measuring blood pressure at the ankle and the arm while a person is sitting or laying still. Blood pressures are then taken again at the ankle and the arm after 5 minutes of walking on a treadmill. A slight drop in your ABI score with exercise means that you probably have PAOD. Knowing if you have PAOD is important. Often, people with PAOD are also at risk of other blood flow problems like heart attack and stroke.

Superficial femoral artery ultrasound*: A sound-wave test that shows an image of the superficial femoral arteries on a screen. This test allows the size of the vessel to be measured and looks at how the blood is moving through your legs. This can help to show areas of the artery that may be narrow. This test is painless and does not require the use of needles, dye, or x-rays.

Fluoroscopy*/Angiogram*: An x-ray based image obtained by putting dye through a small tube (**catheter***) inserted into an artery in the groin or arm. This test will determine exactly where the artery may be more narrow and will provide important information to the doctor or medical team.

Superficial Femoral Artery Balloon Angioplasty and Stenting

When your doctor performs this procedure, he/she will start with needle entry in your **Femoral Artery***. Your doctor will 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 reduce the narrowing until it doesn't slow the blood flow anymore. The balloon is deflated and removed from the artery.

A **stent***, which is a wire-mesh tube made of special metal, is then placed into your artery. The metal stent is then expanded and continually pushes against the inside of the artery wall to keep the artery open. The stent is used to help blood flow through your legs easier. Over time, the artery wall will heal around the stent as it continues to support the vessel.

WHAT IS THE LIFESTENT® VASCULAR STENT (DEVICE DESCRIPTION)?

The LIFESTENT® Vascular Stent is a flexible mesh tube made from **Nitinol***. Nitinol is a metal designed to expand to a given size once it is warmed by the heat of your body. The stent comes inside a delivery system which allows your physician to move it through the body to the specific narrow place in the artery. The expanded stent is shown in Figure 1.

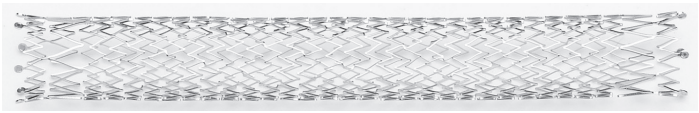

Figure 1

When Can The Device Be Used (Indication for Use*)?

The LIFESTENT® Vascular Stent is indicated to improve luminal diameter in the treatment of symptomatic **de-novo*** or **restenotic*** lesion up to 240 mm in length in native superficial femoral artery (SFA) and popliteal artery with reference vessel diameters ranging from 4.0 – 6.5 mm. In other words, the device has been proven safe and effective by the FDA to help open a blocked area of the artery in your leg.

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

- If you have an allergy to Nitinol (nickel, titanium), and/or tantalum. If you have had a skin reaction to metal jewelry or belt buckles you may be allergic to the metal used to make this stent and it is important to discuss with your doctor whether the potential benefits of implanting a stent outweigh the risks.
- 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 stent.

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.

YOUR PROCEDURE

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.

Specific risks associated with vascular stents like the LIFESTENT® Vascular Stents include:

- Placement of the device in the wrong spot;
- Movement of the device once it is placed in your body causing reduced blood flow;
- Allergic reaction to the metal of the stent, which includes nickel, titanium, and tantalum;
- Breakage of the flexible mesh tube (i.e., fracture), occurred at a rate of 3.1% at 12 months in the RESILIENT Trial on LIFESTENT® Vascular Stent.

The above device related events might result in additional procedures and/or the placement of additional vascular stents.

** See glossary for definition*

The procedure used to place the LIFESTENT® Vascular Stent may involve certain risks. These risks are uncommon, but are important to be aware of:

- Abnormal blood-filled **dilation*** (or pocket) of a weakened artery wall (aneurysm)
- Air, pieces of devices, or fragments of clot blocking the artery, which could cause your toe to turn blue.
- Allergic reaction to the dye (**contrast***) which could include kidney failure
- Bleeding at the access (puncture) site in your groin or arm
- Bruising, swelling at the puncture site
- Creation of an abnormal pathway between two areas of the body (fistulization)
- Damage to the superficial femoral artery
- Death
- Decrease or increase in blood pressure
- Excessive bleeding (hemorrhage)
- Expansion of one or more layers of the vessel wall (pseudoaneurysm)
- Heart attack (myocardial ischemia/infarction)
- Infection/fever
- Irregular heartbeats, which could be life threatening
- Nerve damage (peripheral neuropathy)
- Pain
- Persistent vessel spasm
- Plaque that was previously stuck in one place could be allowed to move freely, which could lead to a new clot
- Recurrence of the blockage (restenosis*)
- Re-narrowing of the artery
- Rupture of the superficial femoral artery (dissection)
- Stroke
- Unexpected limb loss (amputation)

RESILIENT Trial Adverse Event Summary

Event	RESILIENT Randomized		RESILIENT Feasibility
	LIFESTENT® (N=134) % (N pts) [N events]	PTA (N=72) % (N pts) [N events]	LIFESTENT® (N=20) % (N pts) [N events]
In-Hospital Events			
Major Adverse Events	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Death	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Myocardial Infarction	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Target Limb Loss / Amputation	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
TVR	0 (0/134) [0]	41.7 (30/72) [31]	5.0 (1/20) [1]
TLR	0 (0/134) [0]	41.7 (30/72) [30]	0 (0/20) [0]
Non-TLR	0 (0/134) [0]	1.4 (1/72) [1]	5.0 (1/20) [1]
Stroke/CVA	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Distal Embolization	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Access Site Bleeding / Hematoma	0.7 (1/134) [1]	0 (0/72) [0]	5.0 (1/20) [1]
Blood Loss requiring Transfusion	1.5 (2/134) [2]	1.4 (1/72) [1]	0 (0/20) [0]
Vessel Perforation	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Vessel Aneurysm	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Vessel Pseudo-Aneurysm	0 (0/134) [0]	1.4 (1/72) [1]	5.0 (1/20) [1]
Vessel Dissection	4.5 (6/134) [6]	20.8 (15/72) [16]	5.0 (1/20) [1]
Thrombosis	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]

RESILIENT Trial Adverse Event Summary

Event	RESILIENT Randomized		RESILIENT Feasibility
	LIFESTENT® (N=134) % (N pts) [N events]	PTA (N=72) % (N pts) [N events]	LIFESTENT® (N=20) % (N pts) [N events]
Events at 30-Days			
Major Adverse Events	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Death	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Myocardial Infarction	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Target Limb Loss / Amputation	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
TVR	0.7 (1/134) [2]	41.7 (30/72) [31]	5.0 (1/20) [1]
TLR	0.7 (1/134) [1]	41.7 (30/72) [30]	0 (0/20) [0]
Non-TLR	0.7 (1/134) [1]	1.4 (1/72) [1]	5.0 (1/20) [1]
Stroke/CVA	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Distal Embolization	0 (0/134) [0]	1.4 (1/72) [1]	0 (0/20) [0]
Access Site Bleeding / Hematoma	0.7 (1/134) [1]	1.4 (1/72) [1]	5.0 (1/20) [1]
Blood Loss requiring Transfusion	1.5 (2/134) [2]	2.8 (2/72) [2]	0 (0/20) [0]
Vessel Perforation	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Vessel Aneurysm	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Vessel Pseudo-Aneurysm	0 (0/134) [0]	1.4 (1/72) [1]	5.0 (1/20) [1]
Vessel Dissection	4.5 (6/134) [6]	20.8 (15/72) [16]	5.0 (1/20) [1]
Thrombosis (24 Hrs - 30 Days Only)	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]

The table above shows the adverse events (complaints) that were reported during the time of the stent procedure and 30 days after the stent procedure. These events were part of the RESILIENT stent trial with the LIFESTENT® Vascular Stent.

- The first column shows the type of complaint observed or reported.
- The second and fourth columns show you how many people treated with the LIFESTENT® Vascular Stent had that type of complaint. The first number is the percentage or frequency of the complaint. The numbers in the "( )" show the actual number of patients in the group of 134 (second column) or group of 20 (fourth column) who actually had an adverse event.
- The third column called "PTA" shows the complaints that happened with the patients who did not get treated with the LIFESTENT® Vascular Stent, and only with a balloon.

You will see that the frequency of adverse events at the time of the procedure was very low.

What Is The Potential Benefit Of Using The LIFESTENT® Vascular Stent?

The safety and effectiveness of the LIFESTENT® Vascular Stent was compared to balloon inflation alone in the RESILIENT trial that included 206 patients. 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 balloon inflation alone, (81.5% for LIFESTENT® Vascular Stent, 36.7% for balloon angioplasty). When looking at the two groups at three years, Major Adverse Clinical Events, which includes death within 30 days, stroke, heart attacks, clot blocking the artery, emergency surgery, and/or worse leg pain, was 24.8% for LIFESTENT® Vascular Stent patients and 24.8% for balloon angioplasty patients. This means that the study showed the risks associated with the LIFESTENT® Vascular Stent are similar to the risks associated with balloon inflation alone.

Additionally, the safety and effectiveness of the LIFESTENT® Vascular Stent System was confirmed in the BARD® LIFESTENT® Vascular Stent Delivery System Study which included 76 patients. All patients in the study were followed for 30 days. The study results showed that the LIFESTENT® Vascular Stents were able to be accurately put in patients' legs and had very little change in stent length when being implanted.

** See glossary for definition*

Also, an analysis of four sources of existing data: (1) the RESILIENT trial (2) the ELODIE trial which was conducted in Europe, (3) information reported by a United States (U.S.) physician, and (4) information reported by a European Union (EU) physician was included. In total, two-hundred-eighty-five (285) patients with one or more implanted LIFESTENT® Vascular Stent devices were identified and included in the analysis. In total, there were 46 lesions in this analysis with lesion lengths beyond 160 mm. The safety and effectiveness of the LifeStent® Vascular Stent System when used behind the knee (popliteal arteries) was additionally evaluated in the ETAP study, conducted in Europe. The results generally followed those of the RESILIENT and ELODIE trials and it was noted that stenting behind the knee resulted in a lower recurrence of blockage than balloon inflation.

The results show that LIFESTENT® Vascular Stent can be safely implanted in patients and can provide an effective solution to the treatment of long segment lesions.

Long term risks and benefits (i.e., greater than three years) associated with the LIFESTENT® Vascular Stent are currently unknown.

AFTER YOUR LIFESTENT® VASCULAR STENTING 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. Do not stop taking them unless your doctor advises you to do so. Your doctor may be able to provide you other medications that you may be able to take more easily. Also, medications that help to lower your cholesterol and fats may be provided. 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 stent will begin to slowly grow around the 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 stent implanted in your leg, you should tell this to any doctor who treats you in the future.

To help yourself stay healthy in the future, it is recommended you change your diet, continually exercise, and live an active life. Those patients who are able to reduce the fats and cholesterol in their diets are less likely to redevelop blockages in the stent. A low-fat, low-cholesterol diet can lower the levels of fat in your blood and reduce your risk. Eating healthy foods in the right size meals will also help you to achieve and maintain a healthy weight.

Necessary Life Style Changes

Decreasing the amount of fat and **cholesterol*** in your diet together with walking exercises are important ways of treating superficial femoral artery stenosis. Your doctor will make specific dietary and exercise suggestions for you. Complete guidance can be found at the American Heart Association website: www.heart.org.

In addition to a healthy diet, it is extremely important to avoid smoking. If you need help quitting, please notify your healthcare provider.

Follow-Up Examinations

You will need to see the doctor who put in your 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 Implant Card Handy

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 stent in your leg.

Furthermore, it is recommended to register the stent implant under MedicAlert Foundation (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 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 a MRI. A copy of the information located on the card is also provided below.

Conditions for All Stents

Non-clinical testing has demonstrated that the LifeStent® Vascular Stent is MR Conditional for vascular placement in lesions up to a length of 240 mm. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5-Tesla or 3-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 F2182-11a. Maximum artifact extended 3 mm beyond the stent for the spin echo sequence and 10 mm for the gradient echo sequence. 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. The presence of other implants or the health state of the patient may require reduction of the MRI limits listed above.

** See glossary for definition*

BARD® LIFESTENT®

Vascular Stent System

CONTACT INFORMATION

Your doctor or nurse will review this material with you. We encourage you to ask them any questions regarding your treatment and recovery.

Additionally, your doctor may recommend that you join a support group to speak with others who have undergone similar procedures. Ask your doctor for contact information about these groups and possible web site addresses.

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