

## **Bard® LifeStent FlexStar™ and LifeStent FlexStar™ XL Vascular Stent**

### **Patient Information**

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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 FlexStar™** or **LifeStent FlexStar™ XL 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.

\* Please see glossary for definition

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\* Please see glossary for definition

## INTRODUCTION

### What Are The Superficial Femoral and Proximal Popliteal Arteries\*?

**Arteries\*** are **blood vessels\*** that carry blood away from the heart. The superficial femoral and popliteal arteries extend from the arteries in the pelvic region down to your knee. The superficial femoral arteries therefore carry oxygen-rich blood through the legs.

### 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 those which 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:

- A dull, cramping 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\***
- **High cholesterol\***
- Smoking, or are a current smoker

You may also be at risk for PAOD if you are overweight, are relatively inactive or if you have a family history of PAOD.

\* Please see glossary for definition

### How is PAOD Diagnosed?

Patients should be screened for superficial femoral artery blockages if they have:

- Pain in legs with activity or walking which is relieved with rest;

The following diagnostic tests may be performed if superficial femoral artery disease is suspected.

**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 at rest. Measurements are usually repeated at the ankle and the arm after 5 minutes of walking on a treadmill.

The result of the ankle-brachial index (ABI) test is used to predict the severity of PAOD. A slight drop in your ABI with exercise means that you probably have PAOD. This drop may be important because PAOD can be linked to a higher risk of heart attack or stroke.

**Superficial femoral artery ultrasound\*:** A sound-wave test that projects an image of the superficial femoral arteries onto a screen. This test allows the size of the vessel to be measured and the flow of blood to the legs to be tracked. This can be helpful in identifying narrowing in the superficial femoral arteries. 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 injecting dye through a small tube (catheter\*) inserted into an artery in the groin or arm. This procedure will determine exactly where the narrowing is located and will help to guide further treatments.

\* Please see glossary for definition

## TREATMENT OPTIONS

There are four basic treatment options for patients with superficial femoral artery stenosis.

### Diet Modification and Exercise

Decreasing the amount of fat and **cholesterol\*** in your diet in combination with walking exercises are the cornerstones of treating superficial femoral artery stenosis. Your doctor will make specific dietary and exercise recommendations for you. Other life style changes may also need to be made, especially the discontinuation of smoking.

### Medical Management

Medicine can be prescribed to help dilate the **blood vessels\*** in your legs in order to improve blood flow. Additionally, medications that help to lower your cholesterol and fats may be prescribed. If you have diabetes, your physician may recommend modifications to medications to help reduce your blood sugar levels.

### Superficial Femoral Artery Bypass Surgery

A man-made **graft\*** or one of your own **veins\*** could be used to act as a detour to create new channels to carry blood to and through the legs.

### Superficial Femoral Artery Balloon Angioplasty and Stenting

This procedure uses a small tube (catheter) with a small balloon on the end to open the narrowed superficial femoral artery or popliteal artery by compressing the **plaque\*** against the **lumen\*** wall. This process is designed to reduce the narrowing until it no longer interferes with blood flow. The balloon is deflated and removed from the artery.

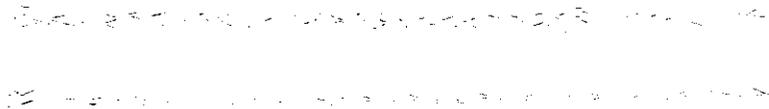
If necessary, a **stent\***, which is a metallic wire-mesh tube, is then placed into the opened artery. When expanded, the stent acts as a brace or support to keep the artery open, restoring normal blood flow. Over time, the artery wall will heal around the stent as it continues to support the vessel.

\* Please see glossary for definition

## WHAT IS THE LIFESTENT FLEXSTAR™ & LIFESTENT FLEXSTAR™ XL VASCULAR STENT (DEVICE DESCRIPTION)?

The LifeStent FlexStar™ & LifeStent FlexStar™ XL Vascular Stent is a flexible mesh tube made from **Nitinol\***. Nitinol is a metal designed to expand to a predetermined size once it is warmed by the heat of your body. The stent is contained in a delivery system for passage through the body and to the superficial femoral arteries. The stent is shown in Figure 1.

Figure 1



### When can the device be used (Indication for Use\*)?

The LifeStent FlexStar™ & LifeStent FlexStar™ XL Vascular Stent is indicated to improve luminal diameter in the treatment of symptomatic **de-novo\*** or **restenotic\*** lesion up to 160 mm in length in native superficial femoral artery (SFA) and/or proximal popliteal artery with reference vessel diameters ranging from 4.0 – 6.5 mm. In other words, the device can be used to support or prop 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 you should 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 anticoagulants).
- If the physician decides that the blockage will not allow complete inflation of the angioplasty balloon or proper placement of the stent.

\* Please see glossary for definition

## 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.

The procedure used to place the LifeStent FlexStar™ & LifeStent FlexStar™ XL Vascular Stent may involve certain risks. These risks include, but are not limited to:

- Abnormal blood-filled **dilation**\* 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 dye (**contrast**\* media) 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 passageway between two areas of the body (fistulization)
- Damage to the superficial femoral artery
- Death
- Decreased or increased 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, possibly life threatening
- Nerve damage (peripheral neuropathy)
- Persistent vessel spasm
- Plaque dislodgment
- Recurrence of the blockage (**restenosis**\*)
- Re-narrowing of the artery
- Rupture of the superficial femoral artery (dissection)
- Stroke
- Unexpected limb loss

Specific risks associated with vascular stents like the LifeStent FlexStar™ & LifeStent FlexStar™ XL 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)

\* Please see glossary for definition

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

**What Is The Potential Benefit Of Using The LifeStent FlexStar™ & LifeStent FlexStar™ XL 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. All patients were followed for 1 year. The study results showed that patients who received a LifeStent had a significantly higher patency rate at one year, when compared to balloon inflation alone, (79.5% for LifeStent, 37.4% for balloon angioplasty). The combined occurrence of Major Adverse Clinical Events which is comprised of death, stroke, heart attacks, clot blocking the artery, emergency surgical repair, and/or worsening leg pain was 14.4% for LifeStent patients and 14.1% for balloon angioplasty patients. The study therefore showed the risks associated with the LifeStent are equivalent to the risks associated with balloon inflation alone.

Additionally, the safety and effectiveness of the LifeStent FlexStar™ and FlexStar™ XL Vascular Stent Systems were confirmed in the E-TAGIUSS trial that included 37 patients. All patients were followed for 30-days. The study results showed that the LifeStent FlexStar™ and FlexStar™ XL Vascular Stents were able to be accurately deployed and demonstrated minimal length change (deployment success 100.0%).

Long term risks and benefits (i.e., greater than one year) associated with the LifeStent are currently unknown.

## AFTER YOUR LIFESTENT FLEXSTAR™ or LIFESTENT FLEXSTAR™ XL VASCULAR STENTING PROCEDURE

### What To Expect During Your Recovery

Before you leave the hospital, your doctor will give you guidelines for activity, diet and medications. You will be advised when you can resume normal activity 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. Please notify your doctor if these medications cause unpleasant reactions. Do not stop taking them unless your doctor advises you to do so. Different medications may be prescribed that suit you better.

The healthy lining of the vessel should slowly grow over the stent, permanently incorporating it into the vessel wall. 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, you are encouraged to make important diet, exercise, and lifestyle changes. Some patients may need few modifications while others may need to make many changes. 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. Choosing to eat healthy foods in the right proportions will also help you to achieve and maintain a healthy weight.

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 implanted your stent for routine follow-up examinations. During these visits, your doctor will monitor your progress and evaluate your medications, the clinical 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. This card identifies you as a patient who has a stent implanted.

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.

\* Please see glossary for definition

### Safety During Magnetic Resonance Imaging (MRI\*)

After placement of your LifeStent FlexStar™ or LifeStent FlexStar™ XL 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 a MRI. Your LifeStent FlexStar™ or LifeStent FlexStar™ XL 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 provided below.

#### Conditions for All Stents

Non-clinical testing has demonstrated that the LifeStent Vascular stent is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5-Tesla or 3-Tesla.
- Spatial gradient field of 1000 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

In an analysis based on non-clinical testing and computer modeling of a patient, the 80 mm length LifeStent FlexStar™ Stent was determined to produce a potential worst-case temperature rise of 3.2°C for a whole body averaged specific absorption rate (SAR) of 1 W/kg for 15 minutes of MR scanning in a 3.0 Tesla, whole body MR system for a landmark in the legs. Temperature rises can be twice as high at a whole body averaged SAR of 2 W/kg for landmarks below the umbilicus. Temperature rises were reduced for landmarks above the umbilicus. Temperature rises of stents were measured in a non-clinical configuration using a GE Signa HDX Whole Body active shield MR scanner using software version 14/LX/MR and a phantom designed to simulate human tissue. The phantom average SAR calculated using calorimetry was 2.8 W/kg. When the stent was placed in a worst-case location within the phantom, the maximal temperature rise was 1.9°C when the local SAR was scaled to 2 W/kg.

\* Please see glossary for definition

### 1.5 Tesla Temperature Rise

In an analysis based on non-clinical testing and computer modeling of a patient, the 170 mm length LifeStent FlexStar™ XL Stent was determined to produce a potential worst-case temperature rise of 3.9°C for a whole body averaged specific absorption rate (SAR) of 1 W/kg for 15 minutes of MR scanning in a 1.5 Tesla, whole body MR system for a landmark in the legs. Temperature rises can be twice as high at a whole body averaged SAR of 2 W/kg for landmarks below the umbilicus. Temperature rises were reduced for landmarks above the umbilicus. Temperature rises of stents were measured in a non-clinical configuration using a GE Signa whole body coil and a phantom designed to simulate human tissue. The phantom average SAR calculated using calorimetry was 2.2 W/kg. When the stent was placed in a worst-case location within the phantom, the maximal temperature rise was 3.5°C when the local SAR was scaled to 2 W/kg.

### Additional Information

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. 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 overlapped or fractured stents is not known.

## GLOSSARY

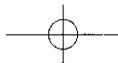
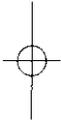
Term	Definition
<b>Angiogram</b>	An x-ray procedure in which contrast dye is injected into the arteries to diagnose a narrowing or blockage of the artery.
<b>Ankle-Brachial Index (ABI)</b>	A non-invasive test used to determine the degree of peripheral arterial occlusive disease within the subjects limbs.
<b>Artery</b>	A blood vessel that carries blood from the heart and lungs through the body. Blood in 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>Balloon Angioplasty</b>	A procedure whereby a dilation catheter 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).
<b>Blood Clot</b>	A clump of blood cells that blocks or prevents normal blood flow.
<b>Blood Vessel</b>	An artery or vein
<b>Catheter</b>	A hollow tube used for gaining access to a blood vessel.
<b>Catheterization</b>	A procedure that involves passing a tube (catheter) through blood vessels and injecting dye to detect blockages.
<b>Cholesterol</b>	A substance that circulates in the blood and plays a role in the formation of blockages. Cholesterol originates in foods that are rich in animal fat.
<b>Claudication</b>	Pain in the leg that occurs with work or exercise, but may also occur when resting.
<b>Contraindications</b>	A condition that makes a specific treatment or procedure improper or undesirable.
<b>Contrast</b>	X-ray dye used to view the arteries during an angiogram.
<b>Coronary artery disease</b>	A condition where the arteries that supply blood to the heart muscles progressively narrow.
<b>De-Novo Lesion</b>	A lesion identified within your own artery that has not been previously treated via percutaneous intervention or surgical means.
<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>Dilation</b>	The widening or stretching of an opening or a hollow structure in the body
<b>Dilation Catheter</b>	A catheter with a balloon on the end that can be inflated.
<b>Fluoroscopy</b>	An x-ray procedure in which contrast dye is injected into the arteries to diagnose a narrowing or blockage of the artery.
<b>Graft</b>	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.
<b>Guiding Catheter</b>	A hollow-tube through which fluids or objects can be introduced or removed from the body.

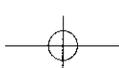
Term	Definition
High Blood Pressure	Called hypertension. A condition where there is too much pressure inside your blood vessels. Blood is pushed too hard by the heart against the blood vessel walls.
High Cholesterol	A medical condition where there is too much cholesterol circulating in the blood stream.
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 FlexStar™ 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 Reso- nance 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 non-invasive test 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.

## 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.





## Bard® LifeStent FlexStar™ Stent and Delivery System Vascular Application

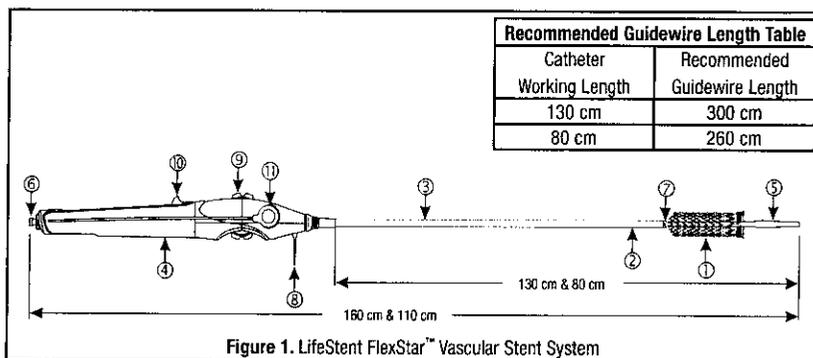


Figure 1. LifeStent FlexStar™ Vascular Stent System

**CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).**

***This device is supplied in sterile condition. All materials inside the sterile barrier pouch (the delivery system and stent, as shown in Figure 1, as well as the tray and pouch liner) are sterile. The external surface of the sterile barrier pouch, as well as the product carton, should not be considered sterile.***

### A. Device Description

The LifeStent FlexStar™ Vascular Stent System is designed to deliver a self-expanding stent to the peripheral vasculature via a sheathed delivery system. The LifeStent FlexStar™ Vascular Stent System is comprised of the following:

An implantable self-expanding nickel-titanium alloy (nitinol) stent (1), as shown in Figure 1 and Figure 2. The stent is a flexible, fine tubular mesh prosthesis, with a helical design, which achieves its unconstrained diameter upon deployment into the target vessel. Upon deployment, the stent imparts an outward radial

force on the luminal surface of the vessel to establish patency. The stent has a total of 12 tantalum radio-opaque markers (Figure 2, items 1A & 1B) located on the ends of the stent (i.e., 6 at each end).

A delivery system, as shown in Figure 1, is comprised of an inner tubing assembly that contains the guidewire lumen, a stent delivery sheath (2) and a system stability sheath (3), which are linked together by means of a handle (4). The guidewire lumen terminates distally in an atraumatic catheter tip (5) and originates proximally in a luer hub (6) designed to accept a compatible guidewire. The self-expanding stent (1) is constrained in the space between the guidewire

lumen and stent delivery sheath. Unintended stent movement during sheath retraction is restricted by the delivery system. The stent delivery sheath has a radiopaque zone (7) at its distal end. Prior to deployment, the shipping lock (8) must be removed and discarded.

Refer to "Stent Deployment Procedure, Section 4. Deploy Stent" for directions on deploying the stent with the:

- Thumbwheel (9)
- Fast Track Deployment Lever (10)
- Rapid Deployment Ring (11)

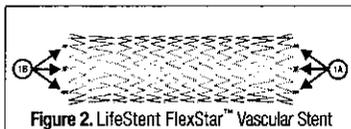


Figure 2. LifeStent FlexStar™ Vascular Stent

### B. Indication for Use

The LifeStent FlexStar™ Vascular Stent System is intended to improve luminal diameter in the treatment of symptomatic de-novo or restenotic lesions up to 160 mm in length in native superficial femoral artery (SFA) and/or proximal popliteal artery with reference vessel diameters ranging from 4.0-6.5 mm.

### C. Contraindications

The LifeStent FlexStar™ Vascular Stent System is contraindicated for use in:

- Patients with a known hypersensitivity to nitinol (nickel, titanium), and tantalum.
- Patients who cannot receive recommended anti-platelet and/or anti-coagulation therapy.
- Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system.

### D. Warnings

- DO NOT use if the temperature exposure indicator (i.e., square label found on the pouch) is black as the unconstrained stent diameter may have been compromised. The temperature exposure indicator label should be grey and must be clearly visible on the pouch.
- The LifeStent FlexStar™ Vascular Stent System is supplied sterile and is intended for single use only. DO NOT resterilize and/or reuse the device.
- DO NOT use if pouch is opened or damaged.
- DO NOT use the stent after the end of the month indicated by the "Use By" date specified on the package.
- Persons with allergic reactions to nickel titanium (nitinol) alloy may suffer an allergic response to this implant.
- DO NOT use with Ethiodol™ or Lipiodol contrast media.
- DO NOT expose the delivery system to organic solvents (e.g., alcohol).
- The stent is not designed for repositioning or recapturing.
- Stenting across a major branch could cause difficulties during future diagnostic or therapeutic procedures.
- If multiple stents are placed in an overlapping fashion, they should be of similar composition (i.e., nitinol).
- The long-term outcomes following repeat dilatation of endothelialized stents are unknown.

### E. Precautions

- The device is intended for use by physicians who have received appropriate training.
- The delivery system is not designed for use with power injection systems.
- Recrossing a partially or fully deployed stent with adjunct devices must be performed with caution.
- Prior to stent deployment, remove slack from the delivery system catheter outside the patient.

- If excessive force is felt during stent deployment, do not force the delivery system. Remove the delivery system and replace with a new unit.
- Store in a cool, dark, dry place.
- Do not attempt to break, damage, or disrupt the stent after placement.
- Stent fractures were noted to be an uncommon event in the RESILIENT trial. Stent fractures may occur with the use of overlapping stents; however there was no correlation between stent fractures and the number of stents implanted in the RESILIENT trial. Fractures may occur in SFA or popliteal segments that undergo significant motion, particularly in areas with severe angulation and tortuosity. The RESILIENT trial was not designed to show a correlation between stent fractures and the location although six (6) fractured stents were observed in areas with severe calcification, and one (1) stent placed across the point of flexion in the mid-popliteal region resulted in a fracture. Care should also be taken when deploying the stent as manipulation of the delivery system may, in rare instances, lead to stent elongation and subsequent stent fracture. The long-term clinical implications of these stent fractures have not yet been established.

## F. MRI Conditions

### Conditions for All Stents

Non-clinical testing has demonstrated that the LifeStent FlexStar™ Vascular Stent is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5-Tesla or 3-Tesla.
- Spatial gradient field of 1000 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

In an analysis based on non-clinical testing and computer modeling of a patient, the 80 mm length LifeStent FlexStar™ Stent was determined to produce a potential worst-case temperature rise of 3.2°C for a whole body averaged specific absorption rate (SAR) of 1 W/kg for 15 minutes of MR scanning in a 3.0 Tesla, whole body MR system for a landmark in the legs. Temperature rises can be twice as high at a whole body averaged SAR of 2 W/kg for landmarks below the umbilicus. Temperature rises were reduced for landmarks above the umbilicus. Temperature rises of stents were measured in a non-clinical configuration using a GE Signa HDX Whole Body active shield MR scanner using software version 14/LX/MR and a phantom designed to simulate human tissue. The phantom average SAR calculated using calorimetry was 2.8 W/kg. When the stent was placed in a worst-case location within the phantom, the maximal temperature rise was 1.9°C when the local SAR was scaled to 2 W/kg.

### 1.5 Tesla Temperature Rise

In an analysis based on non-clinical testing and computer modeling of a patient, the 170 mm length LifeStent FlexStar™ XL Stent was determined to produce a potential worst-case temperature rise of 3.9°C for a whole body averaged specific absorption rate (SAR) of 1 W/kg for 15 minutes of MR scanning in a 1.5 Tesla, whole body MR system for a landmark in the legs. Temperature rises can be twice as high at a whole body averaged SAR of 2W/kg for landmarks below the umbilicus. Temperature rises were reduced for landmarks above the umbilicus. Temperature rises of stents were measured in a non-clinical configuration using a GE Signa whole body coil and a phantom designed to simulate human tissue. The phantom average SAR calculated using calorimetry was 2.2 W/kg. When the stent was placed in a worst-case location within the phantom, the maximal temperature rise was 3.5°C when the local SAR was scaled to 2 W/kg.

**Additional Information**

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. The LifeStent FlexStar™ 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 overlapped or fractured stents is not known.

**G. Overview of Clinical Studies**

Two independent clinical studies support the safety and effectiveness of the LifeStent Vascular Stent Systems.

The RESILIENT pivotal trial was a prospective, randomized, multi-center study designed to compare the safety and effectiveness of the LifeStent Vascular Stent System to PTA in the treatment of symptomatic vascular disease of the superficial femoral artery (SFA) and proximal popliteal artery. 206 subjects were randomized in a 2:1 fashion between the test and control arm at 23 U.S. and 2 European centers. In total, 134 subjects were randomized to the test arm (treatment with the LifeStent Vascular Stent System) and 72 subjects were randomized to the control arm (treatment with stand alone balloon angioplasty). The primary safety endpoint was 30-day mortality and the primary effectiveness endpoint was the 6-month re-intervention rate. 30-day data is available for 99.5% (205/206) of the randomized subjects and 6-month effectiveness data is available for 89.3% (184/206) of the randomized subjects. All subjects are being followed for a total of three years following the index procedure.

The E-TAGIUSS supporting trial was a prospective, non-randomized, multi-center study designed to assess the acute deliverability of the LifeStent FlexStar™ and FlexStar™ XL Vascular Stent Systems. 37 subjects were treated in 7 European centers. The primary safety endpoint was 30-day mortality and the primary effectiveness endpoint was the assessment of stent length following deployment. 30-day mortality data is available for 91.9% (34/37) of the treated subjects and deployed stent length

data is available for 46 deployed stents. All subjects were followed for 30 days following the index procedure.

**H. Adverse Events**

**a. Observed Adverse Events**

The following adverse events were documented during the course of the RESILIENT trial (N=226).

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]
<b>In-Hospital Events</b>			
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]	0 (0/20) [0]
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]	0 (0/20) [0]
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 (<24 Hours Only)	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
<b>Events at 30-Days</b>			
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) [1]	41.7 (30/72) [31]	0 (0/20) [0]
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]	0 (0/20) [0]
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]	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 (24 Hrs - 30 Days Only)	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]
<b>Events at 12-Months</b>			
Major Adverse Events	7.5 (10/134) [12]	6.9 (5/72) [6]	5.0 (1/20) [1]
Death	3.7 (5/134) [5]	2.8 (2/72) [2]	0 (0/20) [0]
Myocardial Infarction	3.7 (5/134) [7]	2.8 (2/72) [2]	5.0 (1/20) [1]
Target Limb Loss / Amputation	0 (0/134) [0]	2.8 (2/72) [2]	0 (0/20) [0]
TVR	15.7 (21/134) [27]	52.3 (38/72) [52]	10.0 (2/20) [2]
TLR	11.9 (16/134) [16]	52.3 (38/72) [45]	10.0 (2/20) [2]
Non-TLR	7.5 (10/134) [11]	6.9 (5/72) [7]	0 (0/20) [0]
Stroke/CVA	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]	4.2 (3/72) [3]	5.0 (1/20) [1]
Late Thrombosis (>30 Days Only)	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
<b>Latest Data Available</b>			
	12-months	12-months	24-months
Major Adverse Events	7.5 (10/134) [12]	6.9 (5/72) [6]	5.0 (1/20) [1]
Death	3.7 (5/134) [5]	2.8 (2/72) [2]	0 (0/20) [0]
Myocardial Infarction	3.7 (5/134) [7]	2.8 (2/72) [2]	5.0 (1/20) [1]
Target Limb Loss / Amputation	0 (0/134) [0]	2.8 (2/72) [2]	0 (0/20) [0]
TVR	15.7 (21/134) [27]	52.3 (38/72) [52]	10.0 (2/20) [2]
TLR	11.9 (16/134) [16]	52.3 (38/72) [45]	10.0 (2/20) [2]
Non-TLR	7.5 (10/134) [11]	6.9 (5/72) [7]	0 (0/20) [0]
Stroke/CVA	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]	4.2 (3/72) [3]	5.0 (1/20) [1]
Late Thrombosis (>30 Days Only)	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]

The following adverse events were documented during the course of the E-TAGIUS trial (N=37).

E-TAGIUS Trial Adverse Event Summary		
Event	In-Hospital	30 Day
Major Adverse Event	0% (0/37)	0% (0/37)
Death	0% (0/37)	0% (0/37)
Myocardial Infarction	0% (0/37)	0% (0/37)
Target Limb Loss	2.7% (1/37)	2.7% (1/37)
Target Lesion Revascularization (TLR)	0% (0/37)	0% (0/37)
Stent Thrombosis	0% (0/37)	0% (0/37)
Distal Embolization	2.7% (1/37)	2.7% (1/37)
Access Site Bleeding	2.7% (1/37)	2.7% (1/37)
Non-Access Site Bleeding	0% (0/37)	0% (0/37)
Vessel Perforation	0% (0/37)	0% (0/37)
Vessel Aneurysm	0% (0/37)	0% (0/37)
Vessel Pseudo-Aneurysm	0% (0/37)	0% (0/37)
Vessel Dissection	0% (0/37)	0% (0/37)

**b. Potential Adverse Events**

Potential adverse events that may occur include, but are not limited to, the following:

- Allergic/anaphylactoid reaction
- Amputation
- Aneurysm
- Angina/coronary ischemia
- Arterial occlusion/thrombus, near the puncture site
- Arterial occlusion/thrombus, remote from puncture site
- Arterial occlusion/restenosis of the treated vessel
- Arteriovenous fistula
- Arrhythmia
- By-pass Surgery
- Death related to procedure
- Death unrelated to procedure
- Embolization, arterial
- Embolization, stent
- Fever
- Hemorrhage/bleeding requiring a blood transfusion
- Hematoma bleed, remote site
- Hematoma bleed at needle, device path: non-vascular procedure
- Hematoma bleed, puncture site: vascular procedure
- Hypotension/hypertension
- Incorrect positioning of the stent requiring further stenting or surgery
- Intimal injury/dissection
- Ischemia/infarction of tissue/organ
- Liver failure
- Local infection
- Malposition (failure to deliver the stent to the intended site)
- Open surgical repair
- Pain
- Pancreatitis
- Pulmonary embolism/edema
- Pneumothorax
- Pseudoaneurysm
- Renal failure
- Respiratory arrest
- Restenosis
- Septicemia/bacteremia
- Stent Fracture
- Stent Migration

- Stroke
- Vasospasm
- Venous occlusion/thrombosis, remote from puncture site
- Venous occlusion/thrombosis, near the puncture site

## I. Clinical Studies

### a. RESILIENT FEASIBILITY STUDY

The RESILIENT study included a feasibility study to assess the safety of the LifeStent Vascular Stent System. This feasibility study enrolled 20 subjects at six US investigative sites. Results from this study provided justification for initiation of a pivotal study to assess the safety and effectiveness LifeStent Vascular Stent System

### b. RESILIENT RANDOMIZED STUDY

#### Design

The RESILIENT trial was a prospective, multi-center, randomized clinical investigation to evaluate the superiority of the LifeStent Vascular Stent System compared to PTA in the treatment of symptomatic vascular disease of the SFA and/or proximal popliteal artery. A total of 226 subjects were treated at 23 US and 2 European investigative sites. Each site not participating in the feasibility study was required to perform one roll-in case. A total of 20 roll-in cases were performed and 206 randomized cases were performed. Seventy-two (72) subjects were randomized to the PTA arm and 134 subjects were randomized to treatment with the LifeStent Vascular Stent System.

Subjects eligible to be enrolled in this study had stenotic or occluded lesions of the SFA and/or proximal popliteal artery and suffered from lifestyle limiting claudication (Rutherford Category 1 – 3). Lesions could be either de novo or restenotic. Subjects with previously stented lesions or target limb vascular bypass were excluded. Reference vessel diameter (RVD) of the treated subjects was to be 4.0 – 6.5 mm

in diameter and the collective length of the treated segment was to be less than 150 mm. Subjects underwent angiographic analysis of the lesion prior to and immediately following treatment. Subjects were followed at 30 days, 6 months and annually thereafter with follow-up planned out to 36 months. Office visits were coupled with duplex ultrasound assessments of the treated segments. X-ray evaluation of the stented lesions was also performed.

The RESILIENT trial utilized a Frequentist approach with its statistical plan. The primary objectives were to show the following:

- that the probability of the occurrence of Target Lesion Revascularization (TLR) or Target Vessel Revascularization (TVR) at 6-months post-procedure for the subjects treated with LifeStent NT (test arm) was significantly lower than (and therefore superior to) that for the subjects treated with PTA-alone (control arm); and,
- that the death rates at 30-days post-procedure were not significantly different between the test arm and the control arm.

Continuous variables were compared using an independent samples t-test. Dichotomous variables were compared using Fisher's exact test. Ordinal variables were compared using a Chi-square test. Time to event was compared using a log-rank test. Interval censored data were analyzed using the Kaplan-Meier method as the primary analysis. A sensitivity analysis for interval censored data was performed using the Weibull distribution. Effectiveness endpoints were analyzed as one-sided tests. Safety endpoints were analyzed as two-sided tests.

The results were evaluated using an Intent-to-Treat (ITT) analysis. In particular, control subjects requiring stent placement to salvage a failed angioplasty remained in the cohort to which they were randomized.

**Demographics**

Characteristics of the subjects enrolled in the study including age, gender, medical history as well as lesion characteristics are provided in the tables below.

RESILIENT Trial Subject Demographics			
Variable	Category	Test	Control
Age at Procedure (Yrs)	N, Mean ± SD	134, 66.4 ± 9.9	72, 66.1 ± 9.2
Gender, % (n/N)	Female	29.1 (39/134)	33.3 (24/72)
	Male	70.9 (95/134)	66.7 (48/72)
Race, % (n/N)	African American	9.0 (12/134)	9.7 (7/72)
	Caucasian	89.5 (120/134)	84.7 (61/72)
	Other	1.5 (2/134)	5.6 (4/72)
Hypertension, % (n/N)		83.6 (112/134)	91.7 (66/72)
Hypercholesterolemia, % (n/N)		78.4 (105/134)	73.5 (53/72)
Diabetes, % (n/N)		38.1 (51/134)	38.9 (28/72)
Smoking, % (n/N)		71.6 (96/134)	83.3 (60/72)
Coronary Artery Disease, % (n/N)		56.0 (75/134)	54.2 (39/72)
Myocardial Infarction, % (n/N)		20.1 (27/134)	26.4 (19/72)
Target Limb Rutherford Category, % (n/N)	Class 1	3.0 (4/134)	6.5 (5/72)
	Class 2	35.8 (49/134)	41.7 (30/72)
	Class 3	61.2 (82/134)	50.0 (36/72)
	Class 5		1.4 (1/72)
Target Limb ABI (mm Hg)	N, Mean ± SD	124, 0.71 ± 0.19	66, 0.72 ± 0.19
Contralateral Limb ABI (mm Hg)	N, Mean ± SD	120, 0.88 ± 0.21	64, 0.84 ± 0.21

RESILIENT Trial Lesion Characteristics			
Variable	Category	Test	Control
Number of Lesions, % (n/N)	1 Lesion(s)	85.8 (115/134)	87.5 (63/72)
	2 Lesion(s)	14.2 (19/134)	12.5 (9/72)
Target Side, % (n/N)	Left	47.7 (73/153)	54.3 (44/81)
	Right	52.3 (80/153)	45.7 (37/81)
Lesion Location, % (n/N)	Proximal 1/3 of SFA	50.3 (77/153)	45.7 (37/81)
	Middle 1/3 of SFA	32.0 (49/153)	38.3 (31/81)
	Distal 1/3 of SFA	13.1 (20/153)	14.8 (12/81)
	Proximal Popliteal	4.6 (7/153)	1.2 (1/81)
Lesion Classification, % (n/N)	De Novo/Stenosed	80.4 (123/153)	79.0 (64/81)
	Occlusion	17.0 (26/153)	18.5 (15/81)
	Restenosed	2.6 (4/153)	2.5 (2/81)
Target Vessel RVD (mm)	N, Mean ± SD	153, 5.2 ± 0.8	81, 5.2 ± 0.8
Lesion % Diameter Stenosis	N, Mean ± SD	153, 86.3 ± 12.5	80, 87.8 ± 11.5
Lesion Length (mm)	N, Mean ± SD	153, 61.8 ± 42.5	81, 57.2 ± 36.8

**Methods**

Subjects underwent either PTA or PTA plus LifeStent Vascular Stent System placement in the target lesion(s). In cases where the PTA only result was sub-optimal, stent placement was performed. This occurred in 40% (29/72) of the subjects that were randomized to the PTA-only treatment arm. Post procedure medication

was suggested as aspirin for 6 months and clopidogrel for 12 weeks.

All data were collected on case report forms at investigative sites. Adverse events were adjudicated by the clinical events committee and the data safety monitoring board routinely reviewed the study outcomes to ensure that the benefits of continuing the study outweighed any potential risks. Independent core laboratories were utilized to analyze angiographic, x-ray and duplex imaging.

**Results**

As shown in the principal Safety and Effectiveness table (Section J) the LifeStent Vascular Stent System demonstrated a significantly lower re-intervention rate at both 6 (94.6% (LifeStent) vs. 54.1% (control),  $p < 0.0001$ ) and 12-months (83.2% (LifeStent) vs. 46.2% (control),  $p < 0.0001$ ). Additionally, as expected, there was no difference in the 30-day mortality rate between the two study arms.

**c. E-TAGIUSS CONFIRMATORY STUDY**

**Design**

The E-TAGIUSS trial was a prospective, multi-center, confirmatory clinical investigation to evaluate the LifeStent FlexStar™ and FlexStar™ XL Vascular Stent Systems in the treatment of symptomatic vascular disease of the SFA and proximal popliteal artery. A total of 37 subjects were treated at 7 European investigative sites.

Subjects eligible to be enrolled in this study had to demonstrate Trans-Atlantic Inter-Society Consensus (TASC) A, B or C lesions. Reference vessel diameter (RVD) of the treated subjects was to be 4.0 – 6.5 mm in diameter and the collective length of the treated segment was to be less than 200 mm. Subjects underwent angiographic analysis of the lesion prior to and immediately following treatment. Subjects were followed at 30 days with an office visit.

**Demographics**

Characteristics of the subjects enrolled in the study including age, gender, medical history as well as lesion characteristics are provided in the tables below.

E-TAGIUSS Trial Subject Demographics		
Variable	Category	Total
Age at Procedure (Yrs)	Mean ± SD (N)	37, 71.1 ± 7.8
	Female	29.7 (11/37)
Gender, % (n/N)	Male	70.3 (26/37)
	Caucasian	97.3 (36/37)
Race, % (n/N)	Other	2.7 (1/37)
	Hypertension, % (n/N)	83.8 (31/37)
Hypercholesterolemia, % (n/N)	56.8 (21/37)	
Smoking, % (n/N)	49.6 (18/37)	
Coronary Artery Disease, % (n/N)	32.4 (12/37)	
Diabetes, % (n/N)	24.3 (9/37)	
Myocardial infarction, % (n/N)	13.5 (5/37)	
Target Limb Rutherford Category, % (n/N)	Class 1	5.4 (2/37)
	Class 2	35.1 (13/37)
	Class 3	45.9 (17/37)
	Class 4	5.4 (2/37)
	Class 5	8.1 (3/37)
Target Limb ABI (mm Hg)	Mean ± SD (N)	35, 0.6 ± 0.2
Contra-lateral Limb ABI (mm Hg)	Mean ± SD (N)	31, 0.9 ± 0.2

E-TAGIUSS Trial Lesion Characteristics		
Variable	Category	Total
Number of Lesions, % (n/N)	1	86.5 (32/37)
	2	13.5 (5/37)
Target Side, % (n/N)	Left	47.6 (20/42)
	Right	52.4 (22/42)
Lesion Location, % (n/N)	Popliteal	2.4 (1/42)
	SFA	95.2 (40/42)
	SFA & Popliteal	2.4 (1/42)
Lesion Classification, % (n/N)	Occlusion	42.9 (18/42)
	Reoccluded	7.1 (3/42)
	Restenosed	2.4 (1/42)
Lesion Severity/TASC Grade, % (n/N)	Stenosed	47.6 (20/42)
	TASC A	45.9 (17/37)
	TASC B	24.3 (9/37)
	TASC C	29.7 (11/37)
Target Vessel RVD (mm)	N, Mean ± SD	42, 5.3 ± 0.6
Lesion % Diameter Stenosis	N, Mean ± SD	42, 89.3 ± 15.1
Lesion Length (mm)	N, Mean ± SD	42, 89.2 ± 69.8

**Methods**

Subjects underwent PTA plus LifeStent FlexStar™ and/or FlexStar™ XL Vascular Stent placement in the target lesion(s). Post procedure medication was suggested as aspirin and clopidogrel for a minimum of 30 days.

All data were collected on case report forms at investigative sites. Adverse events were adjudicated by the clinical events committee and the data safety monitoring board reviewed the study outcomes.

Independent core laboratories were utilized to analyze angiographic data.

**Results**

As shown in the principal Safety and Effectiveness table (Section J) the LifeStent FlexStar™ and FlexStar™ XL Vascular Stent Systems were able to accurately deploy the stent and demonstrated minimal length change (deployment success 100.0%). Additionally, the acute safety and effectiveness measures demonstrated positive results.

**J. Principal Safety and Effectiveness Tables**

**a. RESILIENT RANDOMIZED STUDY**

RESILIENT Principal Safety and Effectiveness Table			
Variable	Test	Control	p-value
MACE @ 30 Days, % (n/N)	1.4 (1/72)	0.0 (0/134)	ns*
Freedom from MACE @ 6 Months, %	93.1	92.8	ns*
Freedom from MACE @ 12 Months, %	85.6	85.9	ns*
Lesion Success, % (n/N)	95.8 (114/119)	83.6 (51/61)	0.0088
Hemodynamic Success, % (n/N)	73.0 (81/111)	56.0 (28/50)	0.045
Procedure Success, % (n/N)	85.8 (114/119)	63.6 (51/61)	0.0088
Clinical Success at 6 Months, % (n/N)	70.3 (83/118)	26.5 (18/66)	<0.0001
Primary Patency at 6 Months, %	94.2	49.0	<0.0001
Secondary Patency at 6 Months, %	100.0	98.4	ns*
Freedom from TVR/TLR at 6 Months, %	94.6	54.1	<0.0001
Clinical Success at 12Months, % (n/N)	70.5 (79/112)	33.8 (22/65)	<0.0001
Primary Patency at 12 Months, %	79.5	37.4	<0.0001
Secondary Patency at 12 Months, %	100.0	98.4	ns*
Freedom From TVR/TLR at 12 Months, %	83.2	46.2	<0.0001

ns\* - not significant

Definitions (secondary endpoints denoted with an asterisk (\*)):

**Major adverse clinical events\* (MACE):** Any event of death (through 30-days), stroke, myocardial infarction, significant distal embolization, emergent surgical revascularization of target limb, thrombosis, and/or

worsening Rutherford category post procedure at the indicated time point.

**Lesion Success\*:** Attainment of  $\leq 30\%$  residual stenosis of the target lesion using any percutaneous method and/or non-investigational device.

**Hemodynamic Success\*:** Angiographic evidence of improved flow across the treated area immediately post-procedure. ABI improved from baseline by  $\geq 0.10$  and not deteriorated by  $> 0.15$ .

**Procedure Success\*:** Attainment of  $\leq 30\%$  residual stenosis of the target lesion and no in-hospital serious adverse events defined as: death, stroke, myocardial infarction, emergent surgical revascularization, significant distal embolization in the target limb, and thrombosis of the target vessel.

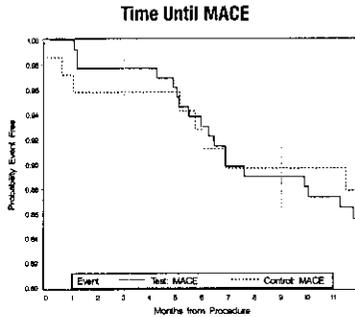
**Clinical Success\*:** Relief or improvement of baseline symptoms by Rutherford categories/grades for acute or chronic limb ischemia and the "definition of improvement". Improvement must be sustained by one clinical category above the pre-treatment clinical value.

**Primary Patency\*:** The continued flow through the target lesion as evidenced by DUS or angiogram without further/repeat intervention over time.

**Secondary Patency\*:** The patency history for the target lesion that is sustained or restored (with repeated intervention) over time.

**Target Vessel Revascularization (TVR) / Target Lesion Revascularization (TLR):** Any "clinically-driven" repeat percutaneous intervention of the target lesion or bypass surgery of the target vessel. If a control subject requires a stent peri-procedurally due to a bailout procedure, it will be considered a TLR/TVR for the control group.

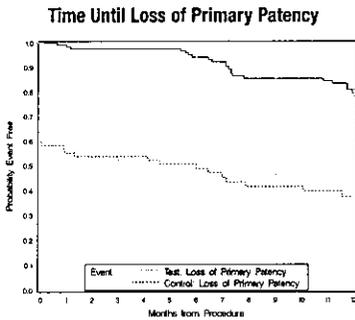
**Survival Analysis – Freedom from MACE (at 12-months)**



MACE	Event Free	Event Rate	P-Value*
Test (LifeStent)	85.6%	14.4%	0.62
Control (balloon angioplasty)	85.9%	14.1%	

\*p-value is from Log-rank test on all available data.

**Survival Analysis – Freedom from Loss of Primary Patency (at 12-months)**



Loss of Primary Patency	Event Free	Event Rate	P-Value*
Test (LifeStent)	79.5%	20.5%	<0.0001
Control (balloon angioplasty)	37.4%	62.6%	

\*p-value is from Log-rank test on all available data.

**Stent Fracture Analysis**

X-Ray evaluation of the implanted stent was scheduled at 6-months, 12-months and 18-months post implant procedure. Of 287 implanted stents for which radiographic data were available, 11 stents in 10 patients demonstrated some form of stent fracture; five (5) stents in 5 subjects,

demonstrated single-strut (Type 1) fractures and 5 stents in 4 subjects, demonstrated multiple strut fractures with displacement (Type 4). A single stent was characterized with both a Type 1 and Type 4 fracture. 40% of the fractures occurred in patients where multiple ( $\geq 2$ ) stents were deployed in an overlapping fashion. 73% (8/11) of the fractures were identified within 7 months of implantation. All of the Type 4 fractures (occurring in 5 patients) were associated with stent elongation during implantation; thus 38% of patients with  $>10\%$  elongation went on to develop Type 4 fractures in less than 1 year. The following table summarizes the fractures according to Allie, Hebert, and Walker (Endovascular Today, 2004; 7:22-34).

RESILIENT Fracture Analysis	
Type	Count (stents/subjects)
Type 1	5/5
Type 4	5/4
Type 1 & 4	1/1
Total	11/10

#### Patency vs. Lesion Length

In order to assess the impact of lesion length on patency outcomes, a Cox regression analysis, with the total lesion length as a risk factor was performed which demonstrated that for the LifeStent group, lesion length is not a significant predictor of primary patency outcomes ( $p$ -value = 0.46). Additionally, the calculated hazard ratio of 1.003 indicates that there is only a remote relationship between lesion length and patency outcomes in the LifeStent group. It should be noted that based on the analysis, the lesion length is a significant predictor of patency outcomes for the control group ( $p$ -value = 0.0025).

#### b. E-TAGIUSS CONFIRMATORY STUDY

E-TAGIUSS Principal Safety and Effectiveness Table	
Variable	Test % (n/N)
Death at 30 Days	0% (0/37)
MACE at 30 Days	2.7% (1/37)
Deployment Success	100.0 (45/45)
Lesion Success	90.9 (30/33)
Procedure Success	90.9 (30/33)

Definitions (secondary endpoints denoted with an asterisk (\*)):

**Major adverse clinical events\* (MACE):** Any event of death, stroke, myocardial infarction, emergent surgical revascularization, significant distal embolization in the target limb, amputation of the target limb and thrombosis of the target vessel at the indicated time point.

**Deployment Success:** Ability to deliver the stent to the intended site with the post deployment stent length being within 10% of the pre-deployment length.

**Lesion Success\*:** Attainment of  $\leq 30\%$  residual stenosis of the target lesion using any percutaneous method and/or non-investigational device.

**Procedure Success\*:** Attainment of  $\leq 30\%$  residual stenosis of the target lesion and no in-hospital serious adverse events defined as: death, stroke, myocardial infarction, emergent surgical revascularization, significant distal embolization in the target limb, and thrombosis of the target vessel.

#### K. Patient Selection and Treatment

Patient selections should be based on the populations treated in the RESILIENT and E-TAGIUSS investigations. Demographics for the two investigations are provided in Section I – Clinical Investigations of this "Instructions for Use" document. Additionally, treatment of the patients should follow the treatment practices used by the RESILIENT and E-TAGIUSS investigators. These methods have been reiterated below in Section L – Patient Counseling Information and Section N – Instructions for Use.

#### L. Patient Counseling Information

Physicians should consider the following in counseling the patient about this product:

- Discuss the risks associated with stent placement.
- Discuss the risks associated with a LifeStent implant.

- Discuss the risks/benefits issues for this particular patient.
- Discuss alterations to current lifestyle immediately following the procedure and over the long term.
- Discuss the risks of early discontinuation antiplatelet therapy.

The following information is provided in the packaging for the physician to provide their patients:

- A Patient Guide which includes information on the LifeStent FlexStar™ Vascular Stent System, peripheral artery occlusive disease, the implantation procedure and patient care following the implant.
- A Patient Implant Card that is used to record and disseminate information about the patient and the stent.

#### M. How Supplied

**STERILE: FOR SINGLE USE ONLY.** The LifeStent FlexStar™ Vascular Stent System is supplied sterile (by ethylene oxide gas) and is nonpyrogenic. Do not resterilize and/or reuse the device. Do not use if the temperature exposure indicator (i.e., square label found on the pouch) is black as the unconstrained stent diameter may have been compromised. The temperature exposure indicator label should be grey and must be clearly visible on the pouch. Do not use if pouch is opened or damaged. Do not use the stent after the end of the month indicated by the "Use By" date specified on the package. For returned product or product issues, please contact Bard Peripheral Vascular at the address below:

**Bard Peripheral Vascular, Inc.**  
 Subsidiary of C. R. Bard, Inc.  
 1625 West 3<sup>rd</sup> Street  
 Tempe, AZ 85281 USA

**CONTENTS** for one (1) LifeStent FlexStar™ Vascular Stent System:

- One (1) LifeStent FlexStar™ Vascular Stent System
- One (1) Patient Implant Card

- One (1) Instructions for Use
- One (1) Patient Guide

**STORAGE:** Store in a cool, dark, dry place. Storage temperature should not exceed 60°C. Use by the end of the month indicated by the "Use By" date specified on the package.

**DISPOSAL INSTRUCTIONS:** After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

#### N. Instructions for Use

##### Pre-Deployment Procedure

###### 1. Inject Contrast Media

Perform an angiogram using standard technique.

###### 2. Evaluate and Mark Target Site

Fluoroscopically evaluate and mark the target site, observing the most distal diseased or obstructed segment.

###### 3. Select Stent Size

Measure the length of the target lesion to identify the appropriate length of stent(s) required. Ensure that the stent is long enough to permit the area proximal and distal of the lesion to be covered by the stent.

Identify the diameter of the reference vessel (proximal and distal to the lesion). To ensure secure placement, refer to the stent size selection table for proper sizing scheme.

Stent Size Selection Table: LifeStent FlexStar™ Vascular Stent System	
Reference Vessel Diameter	Unconstrained Stent Inner Diameter
4.0 – 5.5 mm	6.0 mm
5.5 – 6.5 mm	7.0 mm

Refer to product labeling for stent length

###### 4. Materials Required

In addition to the LifeStent FlexStar™ Vascular Stent System, the following standard materials

may also be required to facilitate delivery and deployment of the LifeStent FlexStar™ Vascular Stent System: heparinized normal saline, 6F (2.0 mm) (or larger) introducer sheath, 0.035" diameter guidewire, standard balloon angioplasty (PTA) catheter, contrast medium diluted 1:1 with heparinized normal saline, inflation device and appropriate anticoagulation and antiplatelet drugs.

**5. Prepare Stent System**

- a) Open the box and remove the pouch containing the stent system.
- b) Check the temperature exposure indicator label on the pouch to confirm that the grey background is clearly visible. See "Warnings" section.
- c) Carefully inspect the pouch for damage to the sterile barrier. Do not use after the expiration date. Peel open the pouch and remove the tray containing the stent system. Extract the stent system from the tray and check the following:
  - i) Verify that the shipping lock is still secure in the stent system handle.
  - ii) Examine the stent system for any damage. If it is suspected that the sterility or performance of the stent system has been compromised, the device should not be used.
- d) Visually inspect the distal end of the stent system to ensure that the stent is contained within the sheath. Do not use if the stent is partially deployed.
- e) Visually inspect the distal end of the delivery system catheter to ensure there is no gap between the delivery system catheter tip (grey colored) and the primary sheath (braided catheter with light blue colored end) such that the guidewire lumen (orange colored) is visible. Do not use the device if the orange colored guidewire lumen is visible.
- f) Flush the inner lumen of the stent system with heparinized normal saline prior to use.

- g) Wipe the usable length portion of the stent system with gauze soaked with heparinized normal saline.

**Stent Deployment Procedure**

**1. Insert Introducer Sheath and Guidewire**

- a) Gain access at the appropriate site utilizing a 6F (2.0 mm) (or larger) introducer sheath.
- b) Insert a guidewire of appropriate length (see table) and diameter across the lesion to be stented via the introducer sheath.

Recommended Guidewire Length Table	
Catheter Working Length	Recommended Guidewire Length
130 cm	300 cm
80 cm	260 cm

**2. Dilate Lesion**

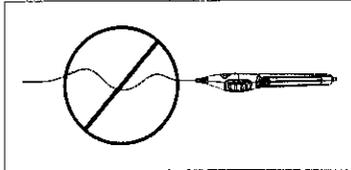
Predilation of the lesion should be performed using standard techniques. While maintaining site access with a guidewire, remove the balloon catheter from the patient.

**Caution:** During dilation, do not expand the balloon such that dissection complication or perforation could occur.

**3. Introduce stent system**

- a) Advance the stent system over the guidewire through the sheath introducer.
  - Note:** If resistance is met during stent system introduction, the stent system should be withdrawn and another stent system should be used.
  - Caution:** Always use an introducer sheath for the implant procedure to protect the vasculature and the puncture site. A 6F (2.0 mm) (or larger) introducer sheath is recommended.
- b) Position the tip of the stent system past the target site.
- c) Pull back the stent system until the distal and proximal stent radiopaque markers are in position so that they are distal and proximal to the target site.

- d) Remove slack from the stent system held outside the patient



**Caution:** Any slack in the stent system (outside the patient) could result in deploying the stent beyond the target site.

#### 4. Deploy stent

- a) Verify that the distal and proximal stent radiopaque markers are distal and proximal to the target lesion.

- b) Confirm that the introducer sheath is secure and will not move during deployment.

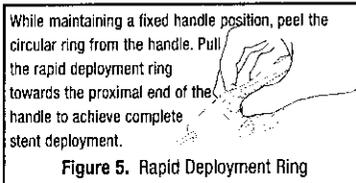
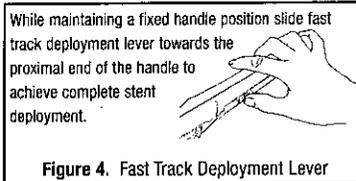
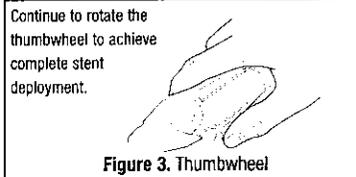
- c) Remove the shipping lock.

- d) Initiate stent deployment by rotating the thumbwheel in the direction of the arrows while holding the handle in a fixed position.

**Note:** If second hand is used to hold the stent system, gently support the catheter at the stability sheath. DO NOT constrict the stent delivery sheath during stent deployment. If excessive force is felt during stent deployment, do not force the stent system. Remove the stent system as possible, and replace with a new unit.

- e) While using fluoroscopy, maintain position of the distal and proximal stent radiopaque markers relative to the targeted site. Watch for the distal stent radiopaque markers to begin separating; separation of the distal stent radiopaque markers signals that the stent is deploying. Continue turning the thumbwheel until the distal end of the stent obtains complete wall apposition.

- f) With distal end of the stent apposing the vessel wall, final deployment can be continued with the following methods (Fig. 3, 4, 5).



- g) Deployment of the stent is complete when the proximal stent radiopaque markers appose the vessel wall and the sheath radiopaque zone is proximal to the proximal stent radiopaque markers.

- h) **DO NOT** attempt to re-sheath stent system prior to removal.

#### 5. Post stent placement

- a) Remove the stent system from the body.

**Note:** If resistance is met while retracting the delivery system over a guidewire, remove the delivery system and guidewire together.

- b) Post stent expansion with a PTA catheter is recommended. If performed, select a balloon catheter that matches the size of the reference

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vessel, but that is not larger than the stent diameter itself.

- c) Remove the guidewire and introducer sheath from the body.
- d) Close entry wound as appropriate.
- e) Discard the stent system, guidewire, and introducer sheath.

**Note:** Physician experience and discretion will determine the appropriate drug regimen for each patient.

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### **Symbols used on labeling**



**Keep away from sunlight**



**Keep dry**



**The Green Dot**



**Recyclable**

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## LifeStent® Vascular Stent Systems

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This product is manufactured and sold under one or more of the following patents: U.S. Patent No. 6,878,162. Other international and U.S. patents pending.

**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.

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