

**Patient Guide  
Absolute Pro Vascular Self-Expanding Stent System and  
Omnalink Elite Vascular Balloon-Expandable Stent System**

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**This version may not be purchased.**



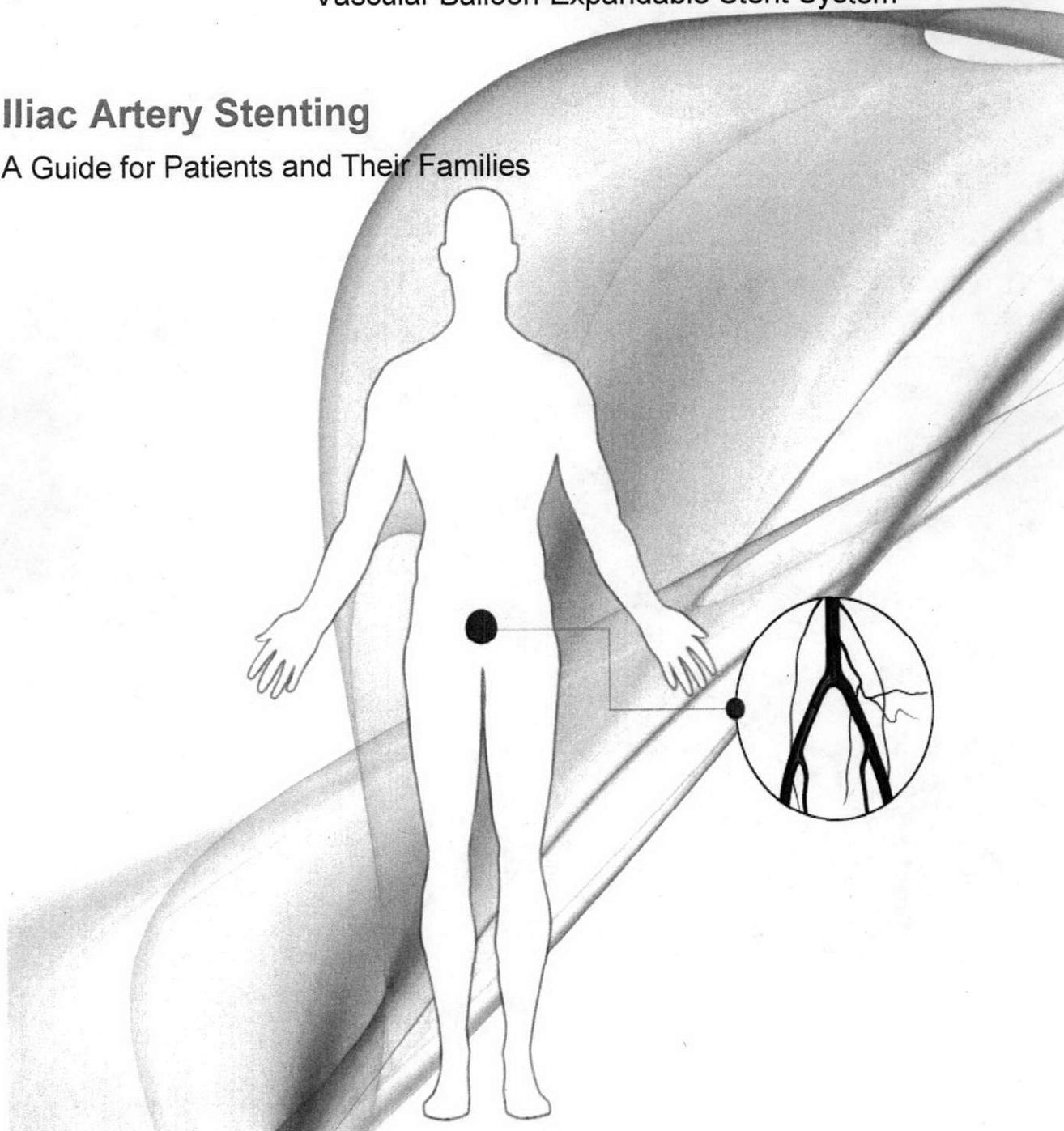
## Abbott Vascular

**Absolute Pro<sup>®</sup>**  
Vascular Self-Expanding Stent System and

**Omnilink Elite<sup>®</sup>**  
Vascular Balloon-Expandable Stent System

### Iliac Artery Stenting

A Guide for Patients and Their Families



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## **Abbott Vascular Iliac Artery Stenting**

This guide is provided to you by Abbott Vascular. Your doctor has given you this guide because he or she thinks you may need treatment for iliac artery disease (narrowing of one or both arteries that send blood to the legs). This guide will explain iliac artery disease and its treatment choices. One treatment choice is to place a stent in your iliac artery to keep it open. Your doctor can choose between self-expanding stents (such as the Absolute Pro Vascular Self-Expanding Stent System) or balloon-expandable stents (such as the Omnilink Elite Vascular Balloon-Expandable Stent System).

Abbott Vascular's Iliac Stent Systems are authorized by Federal (U.S.) law for use in the treatment of patients with atherosclerotic iliac artery disease (a narrowing caused by a build-up of fatty materials inside the artery).

In this guide, you will learn what will happen before, during, and after your stent procedure. As you read, you might think of more questions to talk about with your doctor or nurse. You will find a place in the back of this guide to write your questions and notes.

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## Iliac Artery Disease

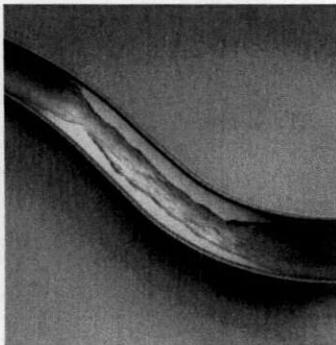
### Your Iliac Arteries

Figure 1 shows your iliac arteries, which are branches off your aorta. The aorta is the main blood vessel that comes off the heart. The iliac arteries begin at about the level of your navel (belly button). You have two iliac arteries – one on the right side and one on the left. The iliac arteries carry oxygen-rich blood down to your legs.

### What is Iliac Artery Stenosis?

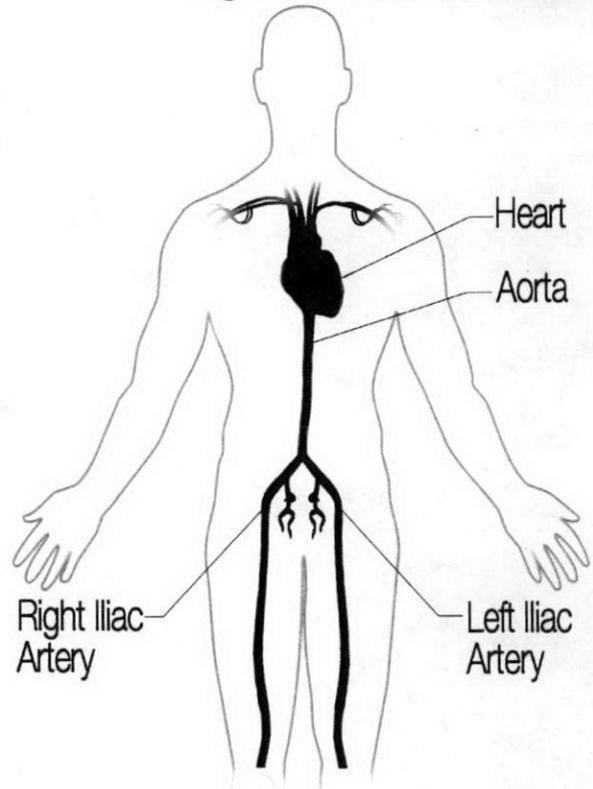
Iliac artery stenosis (pronounced “steh-NO-sis”) is a narrowing in one or both of the arteries that carry blood to the legs (Figure 2).

### Figure 2 – Iliac Artery Stenosis



This narrowing happens when fatty deposits, such as cholesterol, build up over time in the lining of the arteries. You may also hear this called a “plaque” or “lesion.” The narrowing in the arteries lowers blood flow to the legs. This lowered blood flow may cause pain in your legs or buttocks when you walk. This pain is called *claudication*.

Figure 1 – Your Iliac Arteries



**What are the Risk Factors for Iliac Artery Stenosis?**

Some people are more likely to get iliac artery stenosis if they have certain risk factors. A risk factor is something that might increase your chance of getting iliac artery disease. Some risk factors cannot be changed while others can.

***You cannot change:***

- your age, gender, or race
- if you or a close relative have had a heart attack or stroke

***You can change:***

- high blood pressure, high cholesterol, or diabetes
- if you are overweight
- if you smoke cigarettes or use tobacco

**How Will My Doctor Know if I Have Iliac Artery Stenosis?**

The most common symptom of iliac artery stenosis is leg pain that happens when walking (claudication). Often, the pain goes away after a person stops and rests for a few minutes.

To find out if you have iliac artery stenosis, your doctor will ask you questions about your medical history. Your doctor may recommend tests to determine whether you have iliac artery stenosis. One possible test is an ultrasound. An ultrasound uses sound waves to get images of the inside of your iliac artery. This test is done from outside the body.

Another common test is the ankle-brachial index (ABI). For this test, your blood pressure is measured in both arms as well as in the foot. The blood pressure numbers are then used to calculate your ABI. An ABI less than 0.90 is considered abnormal and may indicate that you have iliac artery disease.

Your doctor may also perform a special procedure called angiography to look inside your iliac arteries. Angiography is performed in a catheterization laboratory (cath lab). A cath lab is a room with special monitors that the doctor will watch during your procedure. Your doctor will insert a long, thin, hollow tube (catheter) into an artery in your groin area. The catheter will be passed through your blood vessels to your iliac artery. Your doctor will inject a special dye (contrast solution) through the catheter. This dye helps the doctor to see where your iliac arteries are narrowed or blocked.

Another possible test is called Magnetic Resonance Imaging (MRI), which uses a strong magnet to create images of your arteries.

Using the information from one or more of these tests, your doctor will be better able to recommend the best treatment for you.

## **Your Treatment Choices**

There are several ways to treat iliac artery stenosis. The goal of treatment is to improve blood flow to your legs. Your doctor will suggest what is best for you.

**Exercise:** Although this may sound strange to you, exercise is actually good for someone with iliac artery disease. Exercise, such as walking, helps keep blood flowing to the legs. Even if you have pain when you walk, you can stop and rest until the pain goes away. Exercise will not make your arteries less narrow but it may prevent them from becoming even narrower.

**Medicine:** Medicine can be used alone or with other treatments. Medicine does not make your arteries less narrow but can be used to improve blood flow to your legs. Your doctor may also tell you to take medicines to control other risk factors such as high cholesterol or high blood pressure.

**Surgery:** A surgeon can operate on your artery to clean out or bypass the narrowed part of your artery. Surgery is usually done under general anesthesia (you are completely asleep).

**Angioplasty:** A doctor threads a small deflated balloon through a catheter (tube) into the narrowed part of your iliac artery. The balloon is inflated to open the narrowed part of the artery. The doctor will take the balloon and catheter out of your body when the procedure is done. Patients are usually awake during the procedure. Your doctor may give you some medicine to help you relax.

**Iliac Artery Stenting:** A stent is a small, metal mesh tube that holds open the narrowed part of your iliac artery. The doctor will put the stent through a catheter (tube) into your iliac artery and open the stent by either pulling back a covering that is over the stent (self-expanding stent) or by inflating a balloon that is under the stent (balloon-expandable stent). The stent stays in the artery permanently. Patients are usually awake during the stenting procedure. Your doctor may give you some medicine to help you relax.

Your doctor may decide that iliac artery stenting is the best way to treat your iliac artery stenosis.

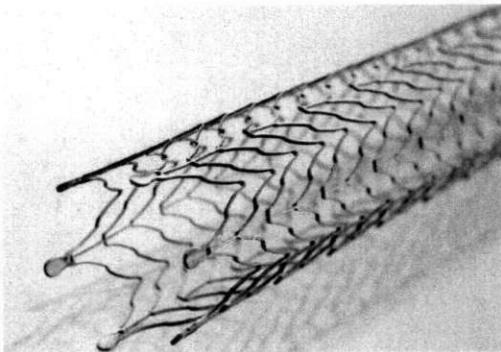
## **Iliac Artery Stent Procedure**

Your doctor can choose between two Abbott Vascular Iliac Stent Systems: the Absolute Pro Vascular Self-Expanding Stent System or the Omnilink Elite Vascular Balloon-Expandable Stent System. Each stent system is described below. Your doctor will explain to you why he or she chose the particular Abbott stent to treat your iliac artery disease.

### **Device Description**

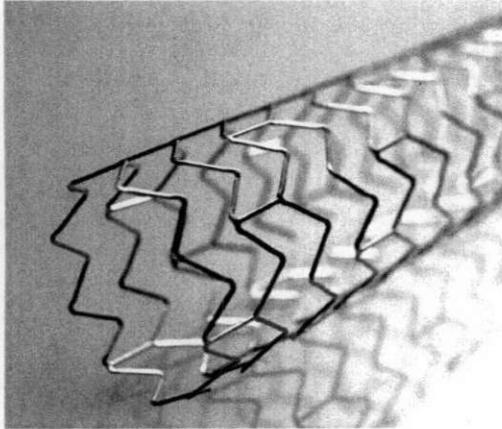
**The Absolute Pro Vascular Self-Expanding Stent** is a small mesh tube made from metals (nickel, titanium, and platinum) (Figure 3). When nickel and titanium are mixed together, they form something called nitinol. Nitinol stents can be gently collapsed into a smaller (unexpanded) shape. This is how the Absolute Pro stent is placed on the delivery system. To hold the stent in place, a sheath covers it. The delivery system is the sheath (covering) that is pulled back to uncover the Absolute Pro stent and allow it to expand on its own, back to its original shape and size.

### **Figure 3 – Absolute Pro Vascular Self-Expanding Stent**



**The Omnilink Elite Vascular Balloon-Expandable Stent** is a small mesh tube made from metal (cobalt chromium) (Figure 4). The stent is gently collapsed into a smaller (unexpanded) shape and placed over a deflated balloon at the end of the delivery catheter. To place the stent in the artery, the balloon is inflated to expand the stent and press it against the inner wall of the artery. Once the stent is in place in the artery, the balloon is deflated and the delivery catheter is removed from the body.

**Figure 4 – Omnilink Elite Vascular Balloon-Expandable Stent**



### **Discussions with Your Doctor**

#### **Before deciding to have a stent procedure, you should talk to your doctor:**

- About all medicines you take, including non-prescription medicine.
- About allergies to contrast dye or iodine, metals (nickel, titanium, platinum, cobalt, chromium), plastics, or anything else.
- If you cannot take aspirin. Aspirin and other medicines are started before the procedure and may be used for several months after the procedure.
- About how long you will have to be in the hospital for the procedure.
- About the possible risks and benefits of the stenting procedure. Your doctor can answer any questions you or your family may have.

#### **Once you and your doctor decide on a stent procedure:**

- Be sure you understand the risks and benefits before you agree to treatment.
- Your doctor may tell you not to eat or drink anything for several hours before your procedure. This time will depend on when your procedure is scheduled.
- Follow all instructions given to you by your doctor or your nurse.

### **Prior to Your Procedure**

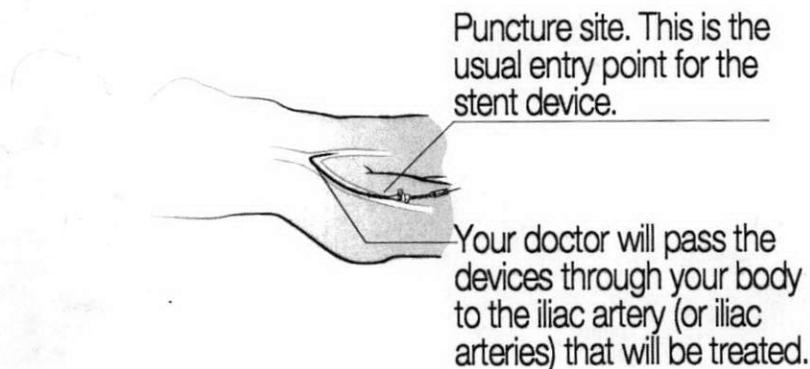
- In the procedure room, you will lie on a special table. The staff will make you as comfortable as possible.
- You will be attached to monitors that will keep track of your heart rate and oxygen levels. The doctor and staff will watch these monitors throughout your procedure.
- You may be given medicine to help you relax. This medicine may make you sleepy.

## During Your Procedure

Your iliac artery will be accessed through an artery in your leg (Figure 5). This place is called the access site.

- Your groin area (at the top of the leg) will be washed with an antiseptic solution and covered with a sterile sheet.
- You will receive medicine to numb the area around the access site. You may feel a sting from the needle and a brief warm feeling when the medicine is injected.

### Figure 5 – Access Site

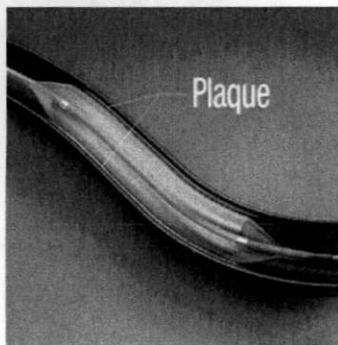


- Next, your doctor will put a needle into the artery in your groin. When the needle is first put into the artery, you may feel some pressure. A guide wire and sheath (tube) will be fed through your artery. Contrast dye will be injected so the doctor can view your iliac arteries.

If your doctor has chosen to use the Absolute Pro Vascular stent, it will be placed as follows:

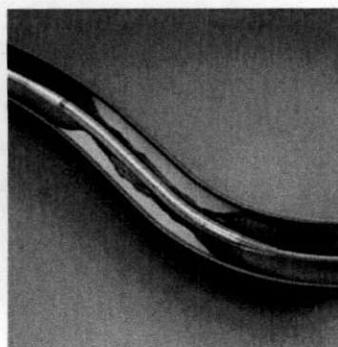
Your doctor may put a balloon catheter into the narrowed area and inflate the balloon to open up the artery more (Figure 6). Your doctor will remove the balloon catheter.

**Figure 6 – Balloon Inflation to Widen the Stenosis**



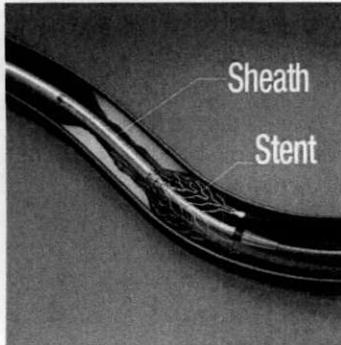
- The iliac stent system will be positioned in the artery where it is narrowed (Figure 7.)

**Figure 7 – Positioning of Iliac Stent in Narrowed Artery**



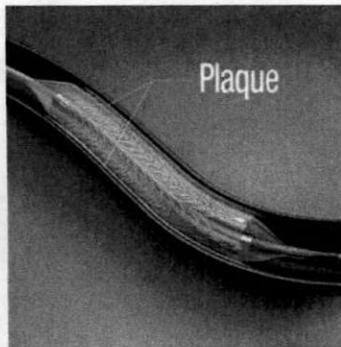
- The doctor will pull back the sheath that is covering the stent to allow the iliac stent to open up on its own (Figure 8).

**Figure 8 – Placement of the Iliac Stent (Sheath Partially Pulled Back)**



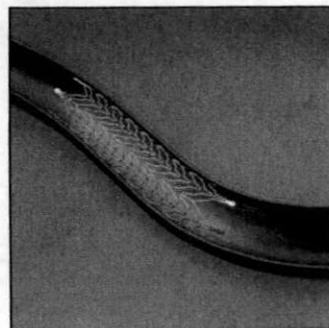
- Once the stent is placed, your doctor may use a balloon catheter to press the stent and plaque against the artery wall (Figure 9).

**Figure 9 – Balloon Catheter**



- The stent is permanent, but all catheters used in the procedure are removed (Figure 10).

**Figure 10 – Permanent Iliac Stent**

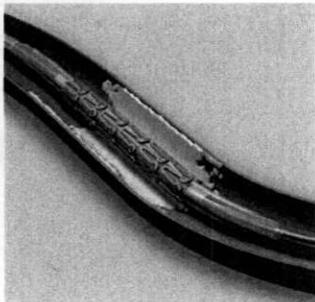


- Once all catheters are removed from the access site, pressure will be applied to the access site until bleeding stops. A special closure device may be used to close the small incision in the artery.

If your doctor has chosen to use the Omnilink Elite Vascular Stent, it will be placed as follows:

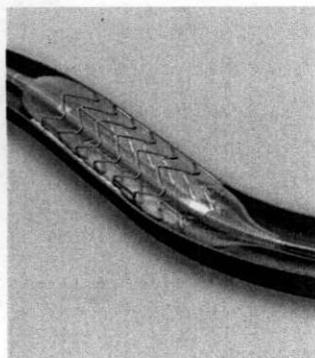
- The iliac stent system will be placed in the artery where it is narrowed (Figure 11).

**Figure 11 – Positioning of Iliac Stent in Narrowed Artery**



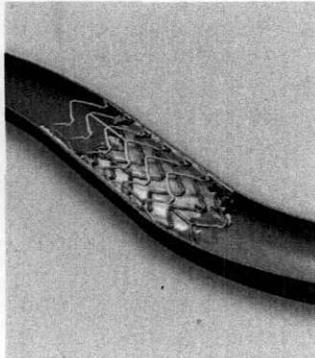
- The doctor will inflate the balloon inside the stent to allow it to expand (Figure 12). Once the stent is placed, your doctor may inflate the balloon again to press the stent and plaque against the artery wall.

**Figure 12 – Picture of Inflated Balloon Expanding the Stent**



- The stent is permanent, but all catheters used in the procedure are removed (Figure 13).

**Figure 13 – Permanent Iliac Stent**



- Once all catheters are removed from the access site, pressure will be applied to the access site until bleeding stops. A special closure device may be used to close the small incision in the artery.

#### **After Your Procedure**

- You may feel sleepy until the medicine you received wears off.
- You will be taken to a special area where nurses and doctors monitor your heart rate and blood pressure and the access site.
- You may need to stay in bed for several hours to allow the access site to heal.
- Do not try to sit up until your nurse or doctor tells you to do so. It is important to lie flat and keep still to prevent bleeding from the access site. If you see any bleeding, tell your doctor or nurse immediately.
- You should drink plenty of fluids to help your kidneys get rid of the dye that was injected into your arteries.
- Let the nurse or doctor know if you have any pain in your back, at the access site, or anywhere else.
- While you are in the hospital, let your doctor or nurse know if you have:
  - Dizziness
  - Severe headache
  - Sudden weakness or numbness on one or both sides of your body
  - Blurred vision or blindness in one or both eyes
  - Difficulty swallowing or speaking
  - Pain in your legs or feet

## Your Recovery

It is important to take all your medicines as your doctor told you. Ask your doctor about any side effects the medicines may cause and when you should call if you are having a side effect. Do not stop taking your medicines unless your doctor tells you to. Your doctor may be able to give you a different medicine.

Avoid lifting and tiring activity for as long as your doctor tells you. Your doctor may talk to you about making changes to your diet or lifestyle.

Make sure to keep all scheduled follow-up appointments. It is important for your doctor to check the condition of your iliac arteries after treatment. Most patients go home after the procedure and have no problems with the stent. In some patients, narrowing inside or around the iliac stent may occur (restenosis). Additional treatment may be needed. If you have any questions, ask your doctor.

Ask your doctor about when you should call if you are not feeling well. Call your doctor or hospital right away if you have any of the following:

- Severe dizziness, near fainting, fainting, or blackouts
- Severe headache that doesn't go away with your normal treatment
- Blood in your urine
- Pain, bleeding, or infection at the access site.
- Pain, blue color, or cold temperature in your legs or feet, especially on the same side as your access site

Your doctor may also tell you of other things to watch for as you get better.

Tell your doctor if your address or telephone number changes so you can be contacted if any information about your stent is available in the future.

## **Safety Information**

### **Benefits**

Iliac artery stenting can improve blood flow to your legs. The stenting procedure does not require a large cut and stitches. The healing process after stenting is usually faster and may be less painful than surgery. Both the Absolute Pro Vascular Self-Expanding Stent System and the Omnilink Elite Vascular Balloon-Expandable Stent System were studied in a clinical study in the United States. The results show that the use of the Absolute Pro Vascular Self-Expanding Stent System and the Omnilink Elite Vascular Balloon-Expandable Stent System for iliac artery stenting is safe and effective. Your doctor can help explain the risks and benefits that are specific to you.

### **When a Stent Might Not be Appropriate**

Your doctor may not choose stenting if:

- You cannot take medicines (anticoagulants) that make your blood take longer to form a clot
- You cannot take medicines (antiplatelets) that make it harder for cells in your blood to form a blood clot
- You are allergic to nickel, titanium, platinum, cobalt, or chromium the metals used to make the stents
- You have a bleeding disorder
- You are allergic to contrast (dye), unless your doctor is able to pre-treat you

If you have any more questions, now is the time to discuss them with your doctor.

### **Warnings**

**Warning:** People allergic to nickel, titanium, platinum, cobalt, or chromium may suffer an allergic reaction to these stents.

You can have a Magnetic Resonance Imaging (MRI) test, for any reason, at any time after your stent is implanted. **IMPORTANT: You must tell the people conducting the MRI test that you have a stent.** Show them your Stent Implant Card so that they will have the information needed about your stent to perform the testing correctly.

## **Potential Complications (Risks)**

Complications can occur during any procedure performed through the blood vessels. The following lists some of the possible risks of the iliac stent or the iliac stenting procedure. Ask your doctor to provide you more information on your risks for the procedure.

As with any stent procedure, there is a chance that complications may occur, including, but not limited to the following:

- Allergy or reaction to medicine, the stent material or contrast (dye)
- Bleeding
- Blood clots
- Bruising or bleeding at the access site
- Chest pain or heart attack
- Damage or injury to your blood vessels
- Damage to the stent, movement of the stent while it is being placed in your artery or after it has been placed in your artery
- Damage to your legs and/or feet due to lack of blood flow to them
- Death
- Difficulty breathing
- Emergency surgery to remove the stent or to improve blood flow to the leg
- High blood pressure
- Infection
- Kidney damage or failure
- Low blood pressure
- Nausea or vomiting
- Pain or discomfort
- Problems with the rhythm of your heart, such as slow heartbeat or uneven heartbeats
- Stenosis (narrowing) or restenosis (re-narrowing) of the stented iliac artery
- Stroke

Your doctor and nurses will watch you during and after the procedure for any complications. If any of these complications happen to you, your doctor will treat you as needed. Treatments will vary widely depending upon the type of complication and your medical history.

## **Summary of Clinical Information**

The Absolute Pro Vascular Self-Expanding Stent System and the Omnilink Elite Vascular Balloon-Expandable Stent System were independently evaluated in the MOBILITY Clinical Study. The MOBILITY Clinical Study enrolled a total of 304 patients: 151 patients were treated with the Absolute Pro stent and 153 patients were treated with the Omnilink Elite stent.

The procedure was successful in most patients. Many patients had improved blood flow to their legs. Thirty days after the procedure, there were no major adverse events (death, heart attack, amputation of the treated leg or foot, or re-treatment of the iliac artery) with the Absolute Pro stent, while there was one major adverse event with the Omnilink Elite stent.

At 9 months after the procedure, 2 out of 147 (1.4%) patients treated with the Absolute Pro stent and 6 out of 149 (4.0%) patients treated with the Omnilink Elite stent needed to have their iliac arteries treated again because of re-narrowing.

The results of this study showed that both the Absolute Pro Vascular Self-Expanding Stent System and the Omnilink Elite Vascular Balloon-Expandable Stent System were safe and effective for treating iliac artery stenoses. Your doctor can explain the risks and benefits that are specific to you.

## **Lifestyle Changes**

Iliac artery disease can be treated, but it has no cure. Keep all follow-up appointments and take all of the medicine your doctor has given to you. Your doctor may also recommend some of the following lifestyle changes:

### **Stop smoking**

If you smoke, quitting is the single most important thing you can do to lower your risk of further iliac artery disease. Chemicals in cigarette smoke may make it easier for plaque to build up on your artery walls. Smoking increases your heart rate and blood pressure, which also raises your risk of heart attack and stroke. If you are ready to quit, ask your doctor for advice – he or she can recommend ways to help you quit.

### **Increase your activity**

Regular exercise can help lower your blood pressure and blood cholesterol. It can help you reach a healthy weight. Exercise can also help you more easily deal with the daily stresses of modern life. Your doctor can recommend an activity program that meets your needs.

### **Eat a healthy diet**

Choose a healthy diet that is low in saturated fats and cholesterol. This can help you reach a healthy weight, as well as help you control your blood pressure and cholesterol levels.

### **Manage your stress**

You can help lessen the health effects of stress by practicing the “relaxation response.” Research has shown that reducing stress can decrease your heart rate, blood pressure, and stress hormone levels.

## Your Stent Implant Card

Tell any medical person who treats you that you have a stent in your iliac artery. Keep your Stent Implant Card with you at all times. It has the name of the doctor who implanted your stent and how to reach him/her, the hospital where you received your stent, the date it was implanted, and where it was placed in your iliac artery. It also identifies the size of your stent, and the date the stent was made. The card has valuable information that is necessary if you need an MRI. There are also phone numbers on the card that your doctor can call if he/she has any questions.

Below are samples of the stent card you may receive:

### Stent Card for Absolute Pro Stent

**Please carry this card at all times.  
Show it to any medical personnel  
who may be treating you.**



Non-clinical testing has demonstrated that the Absolute Pro stent in single and in overlapped configurations up to 190 mm in length is MR Conditional as defined in ASTM F2503. For placement in the iliac artery, patients with this implant may be scanned safely anytime after implantation under the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla.
- Spatial gradient field of 2500 Gauss/cm or less.
- Maximum whole body average specific absorption rate (WB-SAR) of 2 W/kg for 15 minutes of scanning per sequence for patient landmarks above umbilicus. (Total duration of all scans may exceed 15 minutes.)
- Maximum WB-SAR of 1 W/kg for 15 minutes of scanning for patient landmarks below umbilicus.
- Transmit HF body coil should be used in normal operating mode, as defined in IEC 60601-2-33.

The Absolute Pro stent should not migrate in this MRI environment. Magnetic force on the Absolute Pro stent was tested according to ASTM F2052-06e. Non-clinical testing at field strengths greater than 3 Tesla has not been performed to evaluate stent migration or heating.

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**Absolute Pro<sup>®</sup>**  
**Vascular Self-Expanding Stent System**

**Abbott Vascular**  
Santa Clara, CA 95054-2807 USA

TEL: (800) 227-9902  
FAX: (800) 601-8874  
Outside U.S. TEL: (951) 914-4669  
Outside U.S. FAX: (951) 914-2531



PPT:2081866 (8/16/11)

**Stent Patient Implant Card**

Patient Name \_\_\_\_\_ Date of Birth \_\_\_\_\_

Implanting Physician's Name \_\_\_\_\_ Phone Number \_\_\_\_\_

Hospital Name \_\_\_\_\_

City/State \_\_\_\_\_ Date of Implant \_\_\_\_\_

Abbott Vascular recommends registering the MR conditions on this card with the MedicAlert Foundation or equivalent organization. The MedicAlert Foundation can be contacted by phone at: (888) 635-4238; (209) 688-3533 or on the internet at [www.medicalert.org](http://www.medicalert.org).

**Stent Identification Information**

Affix Product Label Here or complete:	Affix Product Label Here or complete:	Affix Product Label Here or complete:
Product Part # (REF) _____	Product Part # (REF) _____	Product Part # (REF) _____
Product Lot # _____	Product Lot # _____	Product Lot # _____
Location of First Stent _____	Location of Second Stent _____	Location of Third Stent _____

**Stent Card for Omnilink Elite Stent**

**Please carry this card at all times.  
Show it to any medical personnel  
who may be treating you.**

**MRI Conditional**

Non-clinical testing has demonstrated that the Omnilink Elite stent, in single and in overlapped configurations up to 100 mm in length, is MRI Conditional as defined in ASTM F2503. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla
- Spatial gradient field of 2500 Gauss/cm or less
- Maximum whole body average specific absorption rate (WB-SAR) of 2 W/kg for 15 minutes of scanning per sequence for patient landmarks above umbilicus
- (Total duration of all scans may exceed 15 minutes)
- Maximum WB-SAR of 1 W/kg for 15 minutes of scanning for patient landmarks below umbilicus
- Transaxial RF body coil should be used in normal operating mode, as defined in IEC 60601-2-43

The Omnilink Elite stent should not migrate in this MRI environment. Magnetic force on the Omnilink Elite stent was tested according to ASTM F2052-06a. Non-clinical testing at field strengths greater than 3 Tesla has not been performed to evaluate stent migration or heating.

**Stent Patient Implant Card**

Patient Name \_\_\_\_\_ Date of Birth \_\_\_\_\_

Implanting Physician's Name \_\_\_\_\_ Phone Number \_\_\_\_\_

Hospital Name \_\_\_\_\_

City/State \_\_\_\_\_ Date of Implant \_\_\_\_\_

Abbott Vascular recommends registering the MRI conditions on this card with the MedAlert Foundation or equivalent organization. The MedAlert Foundation can be contacted by phone at (866) 833-4298, (209) 868-3333 or on the internet at [www.medalert.org](http://www.medalert.org).

Omnilink Elite is a trademark of the Abbott Group of Companies.

Location of First Stent	Location of Second Stent	Location of Third Stent
Product Lot # _____	Product Lot # _____	Product Lot # _____
Product Part # (PEP) _____	Product Part # (PEP) _____	Product Part # (PEP) _____
Label Here or complete: _____	Label Here or complete: _____	Label Here or complete: _____

**Stent Identification Information**

**Omnilink Elite**  
Vascular Balloon-Expandable Stent System

Abbott Vascular  
Santa Clara, CA 95054-2807, USA

TEL: (800) 227-9902  
FAX: (800) 601-8874  
Outside U.S. TEL: (651) 1614-4699  
Outside U.S. FAX: (651) 1614-2531



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**Notes**

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**Abbott Vascular**  
3200 Lakeside Dr., Santa Clara, CA 95054  
USA  
Tel: 1.800.227.9902

**CAUTION: This product is intended for use by or under the direction of a physician.** Prior to use, it is important to read the package insert thoroughly for Instructions for Use, Warnings and Potential Complications associated with the use of this device.

Tests performed by and data on file at Abbott Vascular.  
All illustrations included are artist's renditions.  
All photos taken by and on file at Abbott Vascular.

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[www.AbbottVascular.com](http://www.AbbottVascular.com)

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# Omnilink Elite® Vascular Balloon-Expandable Stent System

## Instructions for Use

**R<sub>x</sub>**  
ONLY

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## 1.0 DEVICE DESCRIPTION

The Omnilink Elite Vascular Balloon-Expandable Stent System (Omnilink Elite Stent System) is a flexible, balloon-expandable L605 cobalt-chromium stent pre-mounted on the balloon of an over-the-wire (OTW) stent delivery system. The OTW stent delivery system is compatible with a 0.035" guide wire and comes in lengths of 80 cm and 135 cm. The stent is mounted on the balloon between the two radiopaque markers. The delivery system can be utilized to optimize the stent wall apposition post stent deployment. See Table 1 for stent dimensions.

Table 1: *In vitro*\* Device Specifications

Expanded Stent Diameter** (mm)	Stent Lengths (mm)	<i>In vitro</i> * Stent Deployment Pressure (atm)	Rated Burst Pressure RBP (atm)	Recommended Minimum Sheath / Introducer*** (F)
6.0	12, 16, 19, 29, 39, 59	11	14	6
7.0	12, 16, 19, 29, 39, 59	11	14	6
8.0	19, 29, 39, 59	11	14	6
9.0	19, 29	11	14	6
9.0	39, 59	11	14	7
10.0	19, 29, 39, 59	11	14	7

\* All data provided are based on *in vitro* testing. Assure full deployment of the stent. (Refer to *Clinician Use Information*) in Section 8.0 of the IFU) Deployment pressures should be based on lesion characteristics.

\*\* The inflated balloon diameter of the system used to deploy the stent should approximate the diameter of the vessel.

\*\*\* See individual manufacturer specifications for (F) equivalent on box label and pouch label.

## 2.0 HOW SUPPLIED

**Sterile** – This device is sterilized with electron beam radiation. Non-pyrogenic. Do not use if the package is open or damaged.

**Storage** – Keep dry, keep away from sunlight, temperature limitation 15°C – 30°C (59°F – 86°F).

**Contents** – One each: Omnilink Elite Stent System

## 3.0 INDICATIONS

The Omnilink Elite Stent System is indicated for the treatment of atherosclerotic iliac artery lesions with reference vessel diameters of  $\geq 5.0$  mm and  $\leq 11.0$  mm, and lesion lengths up to 50 mm.

## 4.0 CONTRAINDICATIONS

There are no known contraindications.

## 5.0 WARNINGS

- This device is intended for single-use only; do not reuse. Do not resterilize. Do not use if package is open or damaged.

- 
- Since the use of this device carries the associated risk of subacute thrombosis, vascular complications, and / or bleeding events, judicious selection of patients is necessary.
  - Persons allergic to L605 cobalt chromium alloy may suffer an allergic reaction to this implant.
  - This device should be used only by physicians trained in angiography and percutaneous transluminal angioplasty and stent placement.
  - The safety and effectiveness of multiple overlapping stents have not been established. However, when multiple stents are required, stent materials should be of similar composition to avoid the potential for dissimilar metal corrosion.
  - Use of appropriate anticoagulant and / or antiplatelet therapy per standard of care is recommended for use with this stent system.

## **6.0 PRECAUTIONS**

The device should be used only by physicians trained in angiography and percutaneous transluminal angioplasty and stent placement.

### **6.1 Stent Delivery System Handling – Precautions**

- For single use only. Do not resterilize or reuse.
- Use the stent system prior to the "Use by" date specified on the package.
- Do not remove stent from its delivery balloon, as removal may damage the stent and / or lead to stent embolization.
- Carefully inspect the Omnilink Elite Stent System prior to use to verify that the stent has not been damaged in shipment and that the device dimensions are suitable for the specific procedure. Take care to avoid unnecessary handling.
- The Omnilink Elite Stent System is intended to perform as a system. The stent should not be removed for use in conjunction with other dilatation catheters, nor should the delivery system be used in conjunction with other stents.
- Refer to the instructions for use supplied with any interventional devices to be used in conjunction with the Omnilink Elite Stent System, for their intended uses, contraindications, and potential complications.
- Special care must be taken not to handle or in any way disrupt the stent on the balloon. This is most important during stent system removal from the packaging, placement over a guide wire and advancement through a guiding catheter or introducer sheath.
- Do not "roll" the mounted stent with your fingers, as this action may loosen the stent from the delivery balloon.
- Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon, as this may cause uneven expansion and difficulty in deployment of the stent.
- Do not advance the stent delivery system without the guide wire extending from the tip.

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## 6.2 Stent Placement – Precautions

- Do not prepare or pre-inflate balloon prior to stent deployment other than as directed. Use balloon purging technique described in the *Clinician Use Information* section.
- The inflated balloon diameter of the system used to deploy the stent should approximate the diameter of the vessel. Oversizing of the stent can result in a ruptured vessel. To ensure full expansion of the stent, the balloon should be inflated to a minimum of nominal pressure.
- Implanting a stent may lead to dissection of the vessel distal and / or proximal to the stent and may cause acute closure of the vessel, requiring additional intervention (surgical intervention, further dilatation, placement of additional stents, or other).
- When treating multiple lesions, the distal lesion should be initially stented, followed by stenting of the proximal lesion. Stenting in this order obviates the need to cross the proximal stent in placement of the distal stent and reduces the chances for dislodging the proximal stent.
- Do not expand the stent if it is not properly positioned in the vessel. (See *Stent / System Removal – Precautions*.)
- Stenting across a major bifurcation may hinder or prevent future side branch access.
- Balloon pressures should be monitored during inflation. Do not exceed Rated Burst Pressure (RBP) as indicated on product label. Use of pressures higher than specified on product label may result in a ruptured balloon with possible vessel damage or perforation.
- Stent retrieval methods (use of additional wires, snares, and / or forceps) may result in additional trauma to the vasculature and / or the vascular access site. Complications may include bleeding, hematoma, or pseudoaneurysm.
- The Omnalink Elite Stent System is intended for deployment and post-deployment dilatation of the stent only and should not be used to dilate other locations.
- Do not attempt to pull an unexpanded stent back through the introducer sheath / guiding catheter; dislodgment of the stent from the balloon may occur.
- Once fully deployed, the stent cannot be repositioned.

## 6.3 Stent / System Removal – Precautions

Should unusual resistance be felt at any time during either lesion access or removal of the delivery system post-stent implantation, the entire system should be removed as a single unit.

When removing the delivery system as a single unit:

- DO NOT retract the delivery system into the introducer sheath / guiding catheter.
- Position the proximal balloon marker just distal to the tip of the introducer sheath / guiding catheter.
- Advance the guide wire in the anatomy as far distally as safely possible.

- 
- Secure the delivery system to the introducer sheath / guiding catheter; then remove the introducer sheath / guiding catheter, guide wire and delivery system as a single unit.

Failure to follow these steps and / or applying excessive force to the delivery system can potentially result in loss or damage to the stent and / or delivery system components.

If it is necessary to retain guide wire position for subsequent vessel access, leave the guide wire in place and remove all other system components.

#### **6.4 Post Implant – Precautions**

Exercise great care when crossing a newly deployed stent with a guide wire or balloon catheter to avoid disrupting the stent geometry.

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

Non-clinical testing has demonstrated that the Omnilink Elite stent, in single and in overlapped configurations up to 100 mm in length, is MR Conditional as defined in ASTM F2503. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla
- Spatial gradient field of 2500 Gauss/cm or less
- Maximum whole body average specific absorption rate (WB-SAR) of 2 W/kg for 15 minutes of scanning per sequence for patient landmarks above umbilicus (Total duration of all scans may exceed 15 minutes)
- Maximum WB-SAR of 1 W/kg for 15 minutes of scanning for patient landmarks below umbilicus
- Transmit RF body coil should be used in normal operating mode, as defined in IEC 60601-2-33

MRI at 1.5 or 3 Tesla may be performed immediately following the implantation of the Omnilink Elite stent.

The Omnilink Elite stent should not migrate in this MRI environment. Magnetic force on the Omnilink Elite stent was tested according to ASTM F2052-06e. The deflection angle was measured to be 6° in a GE Signa 3T HDx MR system. Stent heating was derived by using the measured non-clinical, *in vitro* temperature rise according to ASTM F2182-09 in a GE Signa HDx 3 Tesla scanner and in a GE 1.5 Tesla coil in combination with the local specific absorption rates (SARs) in a digitized human model. For the SAR conditions above, the maximum *in vivo* temperature rise was calculated to be 6°C at 64 MHz (1.5 T) and 128 MHz (3T) for stent lengths 100 mm and less. These calculations do not take into consideration the cooling effects of blood flow.

The effects of MRI on overlapped stents greater than 100 mm in length or stents with fractured struts are unknown.

Image artifact may be present when scanning the Omnilink Elite stent as demonstrated in non-clinical testing performed according to ASTM F2119-07 in a GE Signa HDx 3 Tesla scanner. The image artifact (both inside and outside the device lumen) extends approximately 5 mm from the device, using the spin echo sequence, and 10 mm from the device, using the gradient echo sequence. MR image quality may be compromised if the area of interest is in the exact same

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area, or relatively close to, the position of the Omnilink Elite stent. Therefore, it may be necessary to optimize the MR imaging parameters in the presence of Omnilink Elite stents.

## 7.0 POTENTIAL ADVERSE EVENTS

Potential complications associated with percutaneous iliac artery treatment, including the use of an iliac stent, may include, but are not limited to, the following:

- Acute myocardial infarction
- Allergic reaction (contrast medium, drug, or stent material)
- Aneurysm, pseudoaneurysm, or arteriovenous fistula
- Angina or coronary ischemia
- Arrhythmias, with or without the need for a temporary pacemaker
- Bleeding complications from anticoagulant or antiplatelet medication requiring transfusion or surgical intervention
- Death
- Detachment and / or implantation of a component of the system
- Embolization, arterial or other (air, tissue, plaque, thrombotic material, stent)
- Emergent or urgent surgery to perfuse limb or remove stent
- Fever
- Hematoma or hemorrhagic event
- Hypotension or hypertension
- Infection, local or systemic, including bacteremia or septicemia
- Ischemia or infarction of tissue or organ
- Pain (limb or catheter site)
- Pulmonary embolism
- Renal failure or insufficiency secondary to contrast medium
- Restenosis of vessel in stented segment
- Stent malapposition or migration
- Stent strut fracture
- Stent thrombosis or occlusion
- Stroke, cerebrovascular accident (CVA), or transient ischemic attack (TIA)
- Target limb loss (amputation of toe, foot, and / or leg)
- Vascular thrombosis or occlusion at puncture site, treatment site, or remote site
- Vessel dissection, perforation, or rupture
- Vessel spasm or recoil
- Worsening claudication or rest pain

## 8.0 CLINICAL USE INFORMATION

### 8.1 MOBILITY Clinical Study

The safety and effectiveness of Omnilink Elite was evaluated in one of two arms of the MOBILITY clinical study. (**Note:** The second arm of the study is independently evaluating a different stent for use in the iliac artery.) The Omnilink Elite arm of the MOBILITY study is a prospective, non-randomized, multicenter study to demonstrate the safety and effectiveness of Omnilink Elite, when used to treat *de novo* and restenotic atherosclerotic lesions in the native common iliac artery and the native external iliac artery. A total of 153 subjects were enrolled in the Omnilink Elite arm at 44 clinical sites in the United States.

## 8.2 Subject Demographics

Subjects between the ages of 18 and 89 with symptomatic ischemic PAD (Rutherford Becker clinical category 2 – 4), with stenotic lesions  $\geq 50\%$  and  $\leq 100\%$  in the common iliac artery or  $\geq 50\%$  and  $\leq 99\%$  in the external iliac artery, with target vessel reference vessel diameters  $\geq 5.0$  mm and  $\leq 11.0$  mm by visual estimate, and lesion lengths between 10 mm and 50 mm for stenotic lesions in the common iliac artery or external iliac artery or  $\leq 40$  mm for total occlusions of the common iliac artery, were eligible for the MOBILITY study.

Both primary endpoint and secondary endpoints were analyzed for the intent-to-treat (ITT) and per-protocol (PP) populations. The primary analysis is based on the ITT population and is reported here. The ITT population includes all subjects enrolled into the study (Table 2).

**Table 2: Baseline Demographics, Risk Factors, and Medical History**

Subject Characteristics	N = 153
Age (in years)	
Mean $\pm$ SD (n)	63.9 $\pm$ 9.0 (153)
Median (Q1, Q3)	63.8 (57.5, 70.8)
Range (min, max)	(44.6, 86.0)
Male	57.5% (88/153)
Female	42.5% (65/153)
Diabetes	30.7% (47/153)
Type I	4.3% (2/47)
Type II	95.7% (45/47)
Tobacco Use	91.5% (140/153)
Former	43.8% (67/153)
Current	47.7% (73/153)
Dyslipidemia Requiring Medication	79.1% (121/153)
Hypertension Requiring Medication	83.0% (127/153)
Coronary Artery Disease	58.9% (89/151)
Previous Myocardial Infarction	20.7% (31/150)
Congestive Heart Failure	7.9% (12/152)
Cerebrovascular Disease	24.0% (36/150)
Stroke	6.0% (9/151)
Chronic Obstructive Pulmonary Disease	29.4% (45/153)
Bilateral Lower Extremity Artery Disease	81.0% (124/153)
Multi-level Peripheral Lower Extremity Artery Disease	100% (153/153)
Lower Extremity Artery Disease (excluding iliac artery disease)	62.1% (95/153)

Previous Endovascular or Surgical Intervention to the Target Limb	12.4% (19/153)
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**Note:** Denominators are based on available data.

### 8.3 Methodology

Pre-procedure assessments consisted of the following for each subject:

- Medical history, review of current medications
- Serum creatinine
- Thigh-brachial index (TBI) and ankle-brachial index (ABI) for both limbs
- Walking Impairment Questionnaire (WIQ) to determine subject's self-perception of walking distance, walking speed, and stair climbing
- SF-12<sup>®</sup> Health Survey (quality of life)
- Rutherford-Becker (RB) clinical category for both limbs

Subjects received pre-procedure antiplatelet therapy in the form of either aspirin or clopidogrel, or a combination of both drugs. Subjects unable to take clopidogrel could take ticlopidine instead. Subjects underwent iliac stent placement following standard procedures and according to the Instructions for Use. During the stent procedure, use of supplemental anticoagulation was per the investigator's standard of care. The protocol allowed planned use of one stent to treat the target lesion. Additional stents were allowed for bailout purposes only. Treatment of bilateral iliac lesions was allowed, provided both lesions met all eligibility criteria. Fifty (50) subjects had bilateral iliac artery treatment and 103 subjects had unilateral iliac artery treatment, resulting in a total of 153 subjects with 203 target lesions. Baseline target lesion characteristics (per angiographic core lab analysis) are detailed in **Tables 3 and 4** below.

**Table 3: Anatomic and Lesion Morphology**

Characteristics	Lesions = 203
Anatomic	
Unilateral artery treatment	50.7% (103/203)
Bilateral artery treatment	49.3% (100/203)
Target Artery	
Common iliac	84.2% (170/202)
Common & external iliac, or external iliac only	15.8% (32/202)
Preprocedure Morphology	
Eccentric	62.4% (126/202)

Ulceration	17.8% (36/202)
Calcification	
None / mild	9.9% (20/202)
Moderate	27.2% (55/202)
Severe	62.9% (127/202)
Thrombus	0.5% (1/202)
Postprocedure Morphology	
Dissection Grade	
0 (No dissection)	
A	0.0% (0/201)
B	2.0% (4/201)
C	0.0% (0/201)
D	0.0% (0/201)
E	0.0% (0/201)
F	0.0% (0/201)

† Only 202 procedural angiographic images were available for analysis.

**Table 4: Angiographic Quantitative Analysis**

<b>Lesions = 203</b>			
	Mean ±SD (n)	Median	Min, Max
Preprocedure Reference Vessel Diameter (mm)	8.1 ± 1.7 (202)	7.8	4.5, 12.7
Preprocedure Lesion length (mm)	21.8 ± 12.2 (202)	19.2	5.5, 82.6
Preprocedure Lesion Percent Diameter Stenosis (%)	68.3 ± 15.4 (202)	66.8	16.2, 100.0
Preprocedure Minimum Lumen Diameter (mm)	2.6 ± 1.4 (202)	2.6	0.0, 8.1
Postprocedure Lesion Percent	10.6 ± 11.7 (202)	10.3	-27.3, 50.5

Diameter Stenosis (%)			
Postprocedure Minimum Lumen Diameter (mm)	7.1 ± 1.4 (202)	6.9	4.2, 11.2

After discharge, subjects were followed at 1 month (23 – 44 days) and 9 months (249 – 326 days). At each of these visits, the following data were collected:

- Adverse events
- Current medications
- TBI and ABI for the treated limb(s)
- RB clinical category for the treated limb(s)
- WIQ and SF-12
- Duplex ultrasound (DUS) of the stented artery(ies)
- Arteriogram at 9-month visit (only if DUS was unreadable)

Follow-up visits will continue at 18 months and at 2 and 3 years post-procedure. At the 18-month telephone contact, data will be gathered for adverse events and current medications only; at the 2- and 3-year follow-up visits, the same data as above will be collected, with the exception of the arteriogram.

## 8.4 Results

### 8.4.1 Primary Endpoint

The primary endpoint for the MOBILITY clinical study was the major adverse event (MAE) rate at 9 months defined as: death due to any causes, myocardial infarction (MI), clinically-driven target lesion revascularization (TLR) (worsening Rutherford Becker clinical category that is clearly referable to the target lesion, and target lesion diameter stenosis  $\geq 50\%$ ), and limb loss (major amputation only) on the treated side(s). The Performance Goal (PG) for this endpoint was developed from published literature from previous iliac artery stenting studies and was set at 19.5%.

MOBILITY met the primary objective of the study demonstrating the safety and effectiveness of Omnilink Elite in the treatment of iliac artery stenosis. The primary endpoint of MAE rate at 9 months (270 days) is 5.4% (8/149), with the upper one-sided 95% confidence interval (CI) of 9.5%, which is significantly below the pre-specified PG of 19.5% ( $p < 0.0001$ , one-sided exact binomial test).

Table 4 details the individual subject counts for each of the MAE components.

**Table 4: Non-hierarchical MAE at 270 Days – Per Subject Analysis**

Events	0 – 30 Days	0 – 270 Days
Total Major Adverse Event (MAE) Rate	0.7% (1/151)	5.4% (8/149)
Death	0.0% (0/151)	0.7% (1/149)

Myocardial infarction	0.0% (0/151)	0.7% (1/149)
Major amputation of the treated limb(s)	0.0% (0/151)	0.0% (0/149)
Clinically-driven TLR	0.7% (1/151)	4.0% (6/149)

**Note:** Data available for 149 subjects

## 8.4.2 Key Secondary Endpoints

### 8.4.2.1 Device, Technical, and Procedure Success

Acute success is comprised of device, technical, and procedural success (Table 5). Study device success, on a per device basis, was 98.6% (208/211). Technical success, on a per lesion basis, was 93.1% (189/203). Procedure success, on a per subject basis was 91.5% (140/153).

**Table 5. Acute Success**

<b>Effectiveness</b>	<b>N = 153 Patients M = 203 Lesions</b>
Study Device Success <sup>1</sup>	98.6% (208/211)
Technical Success <sup>2</sup>	93.1% (189/203)
Procedure Success <sup>3</sup>	91.5% (140/153)

<sup>1</sup> Device success is defined, on a per-device basis, as the achievement of successful delivery and deployment of the assigned device(s), and successful removal of the delivery system as intended to the designated location.

<sup>2</sup> Technical success is defined, on a per-target lesion basis, as device success and attainment of a final in-stent residual stenosis < 30% by quantitative angiogram (QA), or as reported by the investigator if the assessment by QA is not available.

<sup>3</sup> Procedure success is defined, on a per-patient basis, as technical success without any of the following complications: death due to all causes, myocardial infarction, major amputation of the treated limb(s), stent thrombosis, and target lesion revascularization of the treated limb(s), within two days after the index procedure or at hospital discharge, whichever is sooner.

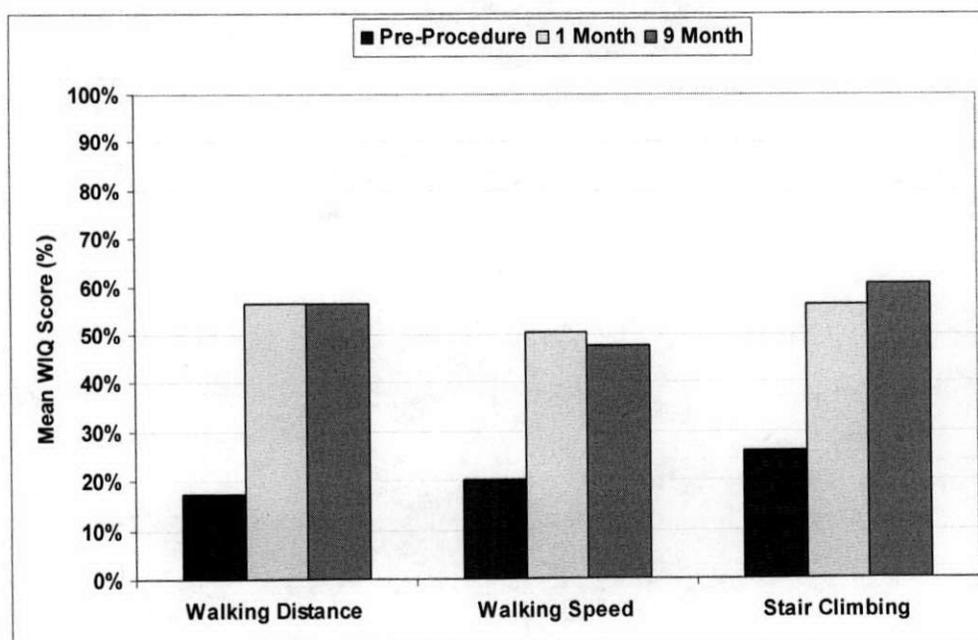
**8.4.2.2 Thigh Brachial Index (TBI) and Ankle Brachial Index (ABI)**

The majority of limbs, 93.4% (170 / 182), had 9-month hemodynamic success, defined as TBI or ABI improvement by > 0.1 compared to baseline, or had no deterioration by ≤ 0.15 compared to post-procedure values.

**8.4.2.3 Walking Capacity**

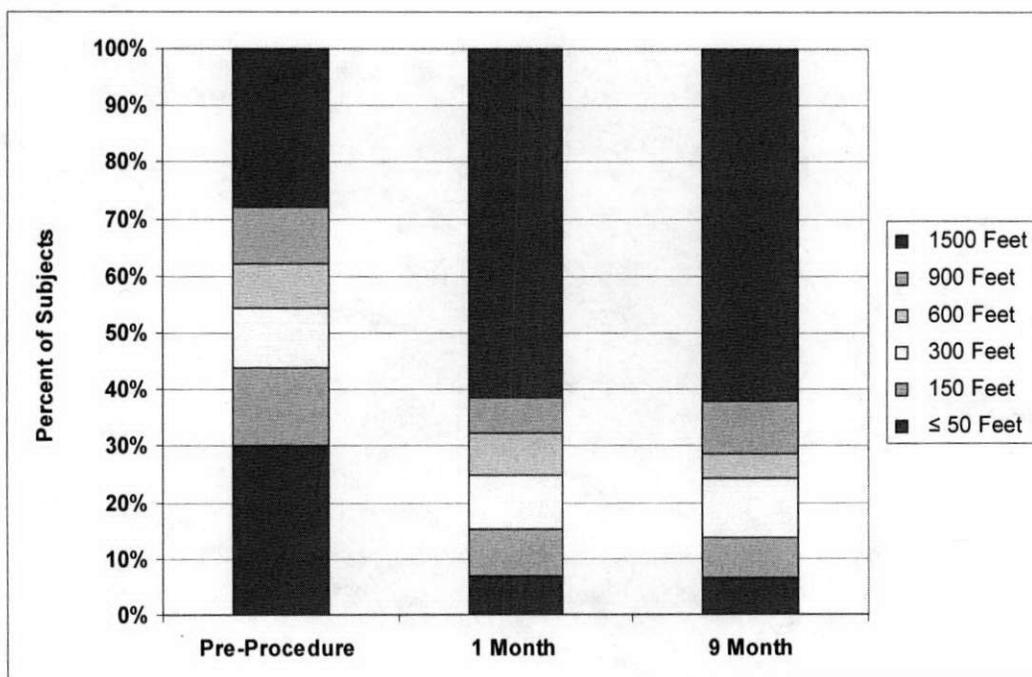
The WIQ was used to assess walking distance, walking speed and stair climbing for study subjects. The walking distance mean score increased from 17.5 ± 22.7% at baseline to 56.6 ± 38.6% at 9 months. The walking speed and stair climbing mean scores also increased from 20.1 ± 24.0% and 26.0 ± 25.8%, respectively, at baseline, to 47.6 ± 33.2% and 60.4 ± 35.9%, respectively, at 9 months (Figure 1 below).

**Figure 1: WIQ Score Changes – Per Subject Analysis (Omnalink Elite: Intent-to-Treat Population)**



Prior to intervention, 30.1% (46/153) of the subjects could walk  $\leq 50$  feet, 13.7% (21/153) could walk 150 feet, while 28.1% (43/153) could walk 1500 feet. There was an improvement in maximum walking distance; at 9 months, 6.4% (9/140) were limited to walking  $\leq 50$  feet, 7.1% (10/140) were limited to walking 150 feet, and 62.1% (87/140) of subjects could walk 1500 feet (Figure 2).

**Figure 2: Walking Distances**



#### 8.4.2.4 Rutherford Becker (RB) Clinical Category

At 9 months, 89.0% (162/182) of limbs had improved  $\geq 1$  RB clinical category.

#### 8.4.2.5 Restenosis

Restenosis, defined as  $\geq 50\%$  stenosis by duplex ultrasound or arteriography, occurred in 9.0% (16/178) of lesions at 9 months.

### 8.5 Adverse Events

An independent Clinical Events Committee (CEC) adjudicated all cases of death, amputation, MI, TLR, target vessel revascularization (TVR), and stent thrombosis that occurred within 9 months of the index procedure, as well as all instances of TLR that occurred within 3 years. Clinical sites also reported all adverse events that occurred. Serious adverse events that occurred within the first 30 days and between 31 to 326 days post procedure are listed in Tables 7 and 8.

**Table 6: Serious Adverse Events through 30 Days**

<b>Adverse Event</b>	<b>N = 153</b>
<b>Blood Dyscrasia</b>	
Anemia	0.7% (1/153)
<b>Gastrointestinal</b>	
GI Bleed	0.7% (1/153)
Nausea	0.7% (1/153)
<b>Infection</b>	
Other: Cellulitis	0.7% (1/153)
Pneumonia	1.3% (2/153)
<b>Metabolic</b>	
Other: Hyponatremia	0.7% (1/153)
<b>Miscellaneous</b>	
Edema (non pulmonary)	0.7% (1/153)
<b>Neurologic other than stroke</b>	
Mental Status Change	0.7% (1/153)
Transient Ischemic Attack	0.7% (1/153)
<b>Procedure-related</b>	
Dissection	1.3% (2/153)
Distal Emboli	0.7% (1/153)
<b>Renal</b>	
Renal Failure	0.7% (1/153)
<b>Respiratory</b>	
Other: COPD Exacerbation	0.7% (1/153)
<b>Stroke</b>	
Other: Cerebral Vascular Accident	0.7% (1/153)
<b>Vascular</b>	
Occlusion	0.7% (1/153)
Other: Deep Vein Thrombosis	0.7% (1/153)

**Table 7: Serious Adverse Events between 31 Days and 326 Days  
(Event Rate > 1%)**

Adverse Event	N = 153
<b>Blood Dyscrasia</b>	
Anemia	2.0% (3/153)
<b>Cancer</b>	
Cancer	3.3% (5/153)
<b>Cardiac</b>	
Congestive Heart Failure	1.3% (2/153)
Other: Coronary Artery Disease	3.9% (6/153)
<b>Cardiac / Hemodynamic</b>	
Bradycardia	1.3% (2/153)
<b>Gastrointestinal</b>	
GI Bleed	1.3% (2/153)
Other: Cholecystitis	1.3% (2/153)
<b>Infection</b>	
Pneumonia	2.0% (3/153)
<b>Miscellaneous</b>	
Musculoskeletal	3.9% (6/153)
<b>Neurologic other than stroke</b>	
Transient Ischemic Attack	1.3% (2/153)
<b>Respiratory</b>	
Respiratory Failure	1.3% (2/153)
<b>Vascular<sup>1</sup></b>	
Restenosis	3.9% (6/153)
Stenosis	6.5% (10/153)
Surgery / Interventional Procedure	1.3% (2/153)

<sup>1</sup>Includes any lesion within the vasculature

The adverse events reported within the Omnilink Elite arm of the MOBILITY study were as anticipated for the study population and are considered acceptable.

## 8.6 Conclusion

In conclusion, the MOBILITY study results support the safety and effectiveness of the Omnilink Elite Vascular Balloon-Expandable Stent System in subjects with atherosclerotic *de novo* or restenotic iliac artery stenoses. The MOBILITY study demonstrated a MAE rate of 5.4%. Iliac stenting with Omnilink Elite is safe as shown by the low MAE rate at 270 days and absence of any death and MAE through 30 days. TBI, ABI, and RB clinical category all improved at 9

months. Additionally, walking scores and distance, as measured by WIQ, were improved. The restenosis rate of 9.0% is acceptable and consistent with other stents that are used for iliac intervention even with 62.9% of the lesions having severe calcification.

## **9.0 OPERATOR'S INSTRUCTIONS**

### **9.1 Stent Inspection Prior to Use**

Prior to using the Omnilink Elite Stent System, carefully remove the system from the package and inspect for bends, kinks, and other damage. Verify that the stent is located between the radiopaque balloon markers. Do not use if any defects are noted.

### **9.2 Materials Required**

- Introducer sheath / guiding catheter in the appropriate size and configuration for the selected stent delivery system (refer to **Table 1**).
- 2 – 3 syringes (10 – 20 cc)
- 1,000 u/500 cc normal saline
- 0.035" guide wire of appropriate length
- 60% contrast diluted 1:1 with normal saline
- Inflation device
- Three-way stopcock
- Torque device (if applicable)
- Guide wire introducer

### **9.3 Lesion Preparation**

1. Standard percutaneous technique should be used to place the introducer sheath / guiding catheter in the vessel. An appropriate size (0.035") guide wire should be advanced across the lesion and into the common vessel.
2. Pre-dilate the lesion with an appropriate size balloon dilatation catheter to closely match the lumen diameter proximal and distal to the lesion.
3. Withdraw the balloon dilatation catheter leaving the guide wire in place.

### **9.4 Guide Wire Lumen Flush**

1. Remove the protective cover from the tip.
2. Attach the syringe with HepNS to the guide wire port.
3. Flush until fluid exits the distal tip.

### **9.5 Stent Delivery System Preparation**

1. Prepare an inflation device / syringe with diluted contrast medium.
2. Attach the inflation device / syringe to the stopcock; attach to the inflation port.

3. With the tip down, orient the delivery system vertically.
4. Open the stopcock to the delivery system; pull negative for 30 seconds; release to neutral for contrast fill.
5. Close the stopcock to the delivery system; purge the inflation device / syringe of all air.
6. Repeat steps 3 through 5 until all air is expelled. **Note:** If air is seen in the shaft, repeat *Delivery System Preparation* steps 3 through 5 to prevent uneven stent expansion.
7. If a syringe was used, attach a prepared inflation device to stopcock.
8. Open the stopcock to the delivery system, leave on neutral.

### 9.6 Stent Delivery Procedure

1. Wipe the exposed guide wire with heparinized saline to remove residual blood or contrast medium.
2. Fully open the hemostatic valve. Maintain neutral pressure on the inflation device.
3. Backload the delivery system onto the proximal portion of the guide wire while maintaining guide wire position across the target lesion.
4. Advance the delivery system over the guide wire to target lesion. Utilize radiopaque balloon markers to position the stent across the lesion; perform angiography to confirm stent position. If applicable tighten the hemostatic valve.

**Note:** If during the process of moving the delivery system into position you notice the stent has moved on the balloon, do not deploy the stent. The entire system should be **removed as a single unit**. See *Stent / System Removal – Precautions* section for specific removal instructions.

5. The stent is now ready to be deployed.

### 9.7 Stent Deployment Procedure

**CAUTION: Refer to product label for expanded stent outer diameter, deployment pressure, and RBP.**

1. Slowly inflate the delivery balloon to low pressure; hold until balloon inflation is observed both proximally and distally to the stent. Continue balloon expansion to the specified stent deployment pressure. Confirm complete expansion of the stent / balloon fluoroscopically. If necessary, the delivery balloon can be used to post dilate the stent to optimize stent apposition.

**Do not exceed RBP:** A larger PTA catheter may be used to dilate the stent. Do not expand the 6 – 7 mm stent beyond 8 mm. Do not expand the 8 – 10 mm stent beyond 11 mm.

2. Deflate the balloon by pulling negative pressure on the inflation device. Ensure that the balloon is fully deflated.
3. With the inflation device on **negative pressure**, carefully withdraw the delivery catheter with the guide wire remaining across the lesion.

**Note:** Should **unusual resistance** be felt at **any time** during either lesion access, or removal of an undeployed stent, the Stent System, wire, and guiding catheter should be **removed as a single unit**. See *Stent / System Removal – Precautions* section for specific removal instructions.

4. Confirm optimal stent apposition using standard angiographic techniques. If necessary, post-dilate within stent. Post dilatation balloon diameters should closely match vessel reference diameter.

## 9.8 Removal Procedure

1. Maintain **negative pressure** to allow the balloon to remain fully deflated during removal through the sheath.
2. With the inflation device on **negative pressure**, carefully withdraw the delivery catheter with the guide wire remaining across the lesion.

**Note:** Should unusual resistance be felt at any time during lesion access or removal of delivery system post-stent implantation, the entire system should be removed as a single unit See *Stent / System Removal – Precautions* section for specific removal instructions.

3. Confirm optimal stent apposition using standard angiographic techniques. If necessary, post-dilate within stent. Post dilatation balloon diameters should closely match vessel reference diameter.

## 10.0 REFERENCES

The physician should consult current literature on current medical practice on balloon dilatation and placement of balloon expandable stents.

## 11.0 PATENTS AND TRADEMARKS

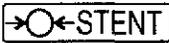
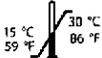
This product and / or its use may be covered by one or more of the following United States Patents: 5,514,154; 5,569,295; 5,649,952; 5,759,192; 5,780,807; 6,131,266; 6,139,525; 6,221,425; 6,217,547; 6,224,803; 6,368,301; 6,369,355; 6,572,813; 6,568,235; 6,620,193; 6,835,059; 6,908,479; 7,828,766. Other U.S. patents pending. Foreign patents issued and pending.

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## Graphical Symbols for Medical Device Labeling

	Date of manufacture		Do not resterilize
	Manufacturer		Keep dry
	Do not use if package is damaged	<b>LOT</b>	Batch code / LOT number
	Do not reuse	<b>REF</b>	Catalogue number
<b>STERILE R</b>	Sterilized using irradiation	<b>NPR</b>	Nominal pressure
	Use by	<b>NON PYROGENIC</b>	Only sterile and non pyrogenic in unopened packages
<b>RBP</b>	Rated burst pressure		Caution, consult accompanying documents
<b>REC GW</b>	Recommended guide wire		Expanded stent outer diameter
	Keep away from sunlight		Expanded stent length
	Nominal stent length		Number of units
	Temperature limitation	<b>DO NOT EXCEED!</b>	Do not exceed
<b>REC MIN INTRO</b>	Recommended minimum sheath introducer		Usable catheter length
<b>OTW</b>	Over-the-wire	<b>F</b>	French size
	Consult instructions for use		MR Conditional

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