
eIFU, Absolute Pro Vascular Self-Expanding Stent System

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Absolute Pro[®]
Vascular Self-Expanding Stent System
Instructions for Use

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1.0 DEVICE DESCRIPTION

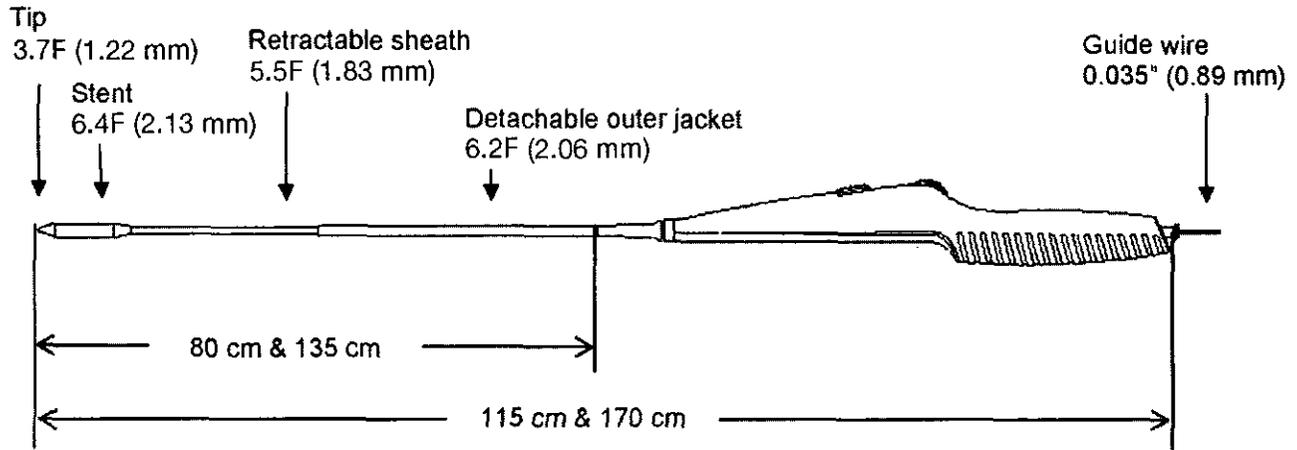
The **Absolute Pro Vascular Self-Expanding Stent System (Absolute Pro)** includes:

- A self-expanding nickel titanium stent that is pre-mounted on an over-the-wire delivery system;
- 12 (6 at each end of the stent) radiopaque markers made of a nickel titanium alloy

The **Absolute Pro** utilizes a 0.035" (0.89 mm) guide wire. The system includes radiopaque markers that identify the stent location.

The catheter comprises a retractable sheath that covers the stent during delivery, a tip, an I-Beam to support the stent during deployment with an internal guide wire lumen, a detachable outer jacket, and a handle assembly with a safety lock and retraction features. The entire system is shown in Figure 1 below. With the handle in the unlocked position, rolling back the thumbwheel deploys the stent.

Figure 1: Delivery System Schematic for 6.0 - 10.0 mm Stent Diameters



The **Absolute Pro** is available in several lengths and diameters, as listed in Table 1. Stents should always be sized to the reference vessel and should provide stent-to-lumen ratios between 1.1:1 and 1.4:1.

Table 1: Absolute Pro Vascular Self-Expanding Stent System – Product Specifications

Unconstrained Stent Diameter (mm)	Nominal Stent Length (mm)	Sheath Compatibility	Guiding Catheter Compatibility	Reference Vessel (mm)
6.0	20, 30, 40, 60, 80, 100	6F	8F	4.3 – 5.4
7.0	20, 30, 40, 60, 80, 100	6F	8F	5.0 – 6.3
8.0	20, 30, 40, 60, 80, 100	6F	8F	5.7 – 7.3
9.0	20, 30, 40, 60, 80, 100	6F	8F	6.4 – 8.2
10.0	20, 30, 40, 60, 80, 100	6F	8F	7.1 – 9.1

2.0 HOW SUPPLIED

Sterile. Sterilized with electronic beam radiation. Non-pyrogenic.

Contents. One (1) **Absolute Pro Vascular Self-Expanding Stent System**.

Storage. Store at room temperature only.

DO NOT USE IF THE TEMPERATURE INDICATOR ON THE INNER POUCH IS BLACK.

3.0 INDICATIONS

The **Absolute Pro Vascular Self-Expanding Stent System** is indicated for improving luminal diameter in patients with *de novo* or restenotic atherosclerotic lesions in the native common iliac artery and native external iliac artery with reference vessel diameters between 4.3 mm and 9.1 mm and lesion lengths up to 90 mm.

4.0 CONTRAINDICATIONS

There are no known contraindications.

5.0 WARNINGS

DO NOT USE IF THE TEMPERATURE INDICATOR IS BLACK.

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

Use prior to the "Use By" date specified on the package.

Persons with known hypersensitivities to nitinol and / or its components (e.g. nickel, titanium) may suffer an allergic reaction to this implant.

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.

Stenting across a major bifurcation may hinder or prevent future diagnostic or therapeutic procedures.

Use of an undersized guide wire, with insufficient support, may cause kinking in the Stent Delivery System.

Use of appropriate anticoagulant and/or antiplatelet therapy per standard of care is recommended for use with this stent system.

6.0 PRECAUTIONS

- Inspect the product prior to use. Do not use if the package is open or damaged, or if the product is damaged. Avoid unnecessary handling, which may kink or damage the Delivery System.
- Only physicians familiar with the complications, side effects and hazards commonly associated with iliac stent placement should use this device.
- The stent is not designed for resheathing or recapturing. The stent is not designed for repositioning once the stent has apposed the vessel wall.
- Once the stent is apposed to the vessel, it is not recommended to remove the stent with the delivery system.
- The **Absolute Pro** is intended to perform as a system. Do not remove the stent for use in conjunction with other dilatation catheters; do not use the Absolute Pro in conjunction with other stents.
- Refer to the instructions for use supplied with any interventional devices to be used in conjunction with the Absolute Pro for their intended uses, contraindications, and potential complications.
- Stent retrieval methods (use of additional wires, snares and / or forceps) may result in additional trauma to the vasculature.

6.1 Stent Delivery System Handling – Precautions

- **Do not remove the stent from its Delivery System**, as removal may damage the stent and / or lead to stent embolization. Stent system is intended to perform as a system.
- Special care must be taken not to handle or in any way disrupt the stent on the Delivery System. This is most important during Delivery System removal from packaging, mandrel removal, placement over guide wire, and advancement through rotating hemostatic valve (RHV) adapter and guiding catheter hub.
- Inspect to determine the outer jacket is attached to the handle. Reattach by pushing the outer jacket back into the handle.
- If the thumbwheel moves prior to unlocking, do not use unit; unintentional partial or full deployment may occur.
- Do not unlock the handle prior to positioning the stent at the intended location. Failure to follow this instruction could lead to deployment of the stent at an unintended location.
 - Once unlocked, the handle locking mechanism cannot be re-locked.
 - Once unlocked, the retraction sheath may unintentionally release the stent during device manipulation.

6.2 Stent Placement - Precautions

- Advance the Delivery System past the lesion and pull back to help remove slack from the system. Removing all slack from the delivery system prior to stent deployment will help ensure accurate stent delivery.

- If detachable outer jacket is not engaged in the introducer sheath, manually stabilize prior to deployment to help ensure accurate stent delivery. Do not restrict retracting sheath during stent deployment.
- If the thumbwheel moves freely in both directions after unlocking, remove the device together with the introducer sheath or guiding catheter as single unit; do not use the unit as unintentional partial or full deployment may occur.
- **Do not attempt to pull a partially expanded stent back through the sheath or guiding catheter; dislodgment of the stent from the Delivery System may occur.**
- Should **unusual resistance** be felt at any time, including resistance unlocking the handle or rotating the thumbwheel, during stent deployment, the entire system should be removed together with the introducer sheath or guiding catheter as a single unit. Failure to follow these instructions could result in failure to deploy, difficulties with deployment, partial stent deployment or deployment in an unintended location.
- Do not expand the stent if it is not properly positioned in the vessel. (See *Stent / System Removal – Precautions.*)

6.3 Stent / System Removal – Precautions

Do not attempt to pull a partially-expanded stent back through the introducer sheath or guiding catheter. The stent is not designed for recapturing. The stent is not designed for repositioning once the stent has apposed the vessel. Once the stent is apposed to the vessel, it is not recommended to remove the stent with the Delivery System.

Should **unusual resistance** be felt at any time during lesion access or removal of the Delivery System post stent implantation, the entire system should be **removed together with the introducer sheath or guiding catheter as a single unit.** Failure to follow these instructions could result in failure to deploy, difficulties with deployment, partial stent deployment or deployment in an unintended location.

When removing the Delivery System as a single unit:

- Do not retract the Delivery System into the guiding catheter or sheath.
- Tighten the RHV (if applicable) to secure the Delivery System to the guiding catheter, and then remove the guiding catheter or sheath and Delivery System as a single unit.
- If possible, retain the guide wire position for subsequent vessel access.

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.

6.4 Post Implant – Precautions

- Exercise great care when **crossing a newly deployed stent** with a guide wire, balloon or Delivery System to avoid disrupting the stent geometry.
- This stent is an open cell design. Open cell designs allow each ring to expand independently of the adjacent ring. Under fluoroscopy the independent ring expansion may appear as a step in the contour of the stent, and be erroneously interpreted as a

stent fracture. This should be considered when deciding whether additional diagnostics (x-ray and / or angiography with contrast material) is necessary.

Magnetic Resonance Imaging (MRI)

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 1W/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.

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.

Stent heating during MRI 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 calculated local specific absorption rates (SARs) in a digitized human model. For the SAR conditions above, the greatest *in-vivo* temperature rise was calculated to be 5.3°C at 128 MHz for a stent length of 60 mm. The calculations do not take into consideration the cooling effects of blood flow, and therefore, actual *in-vivo* rises are expected to be lower.

The effects of MRI on overlapped stents greater than 190 mm in length or stents with fractured struts are unknown.

Image artifact may be present when scanning the Absolute Pro 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 area, or relatively close to, the position of the Absolute Pro stent. Therefore, it may be necessary to optimize the MR imaging parameters in the presence of Absolute Pro stents.

Abbott Vascular recommends that patients register the MR conditions in this IFU with the MedicAlert Foundation or equivalent organization. The MedicAlert Foundation can be contacted by phone at: (888) 633-4298, (209) 668-3333 or on the internet at www.medicalert.org.

7.0 POTENTIAL ADVERSE EVENTS

Below is a list of the potential adverse effects (e.g., complications) that may be associated with the use of the device:

- 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 insertion 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 CLINICIAN USE INFORMATION

8.1 MOBILITY Clinical Study

The safety and effectiveness of the **Absolute Pro** were evaluated in one of two arms of the MOBILITY clinical study. (Note: The second arm of the study independently evaluated a different stent for use in the iliac artery.) The Absolute Pro arm of the MOBILITY study was a prospective, non-randomized, multicenter study to demonstrate the safety and effectiveness of the **Absolute Pro** when used to treat *de novo* and restenotic atherosclerotic lesions in the native common iliac artery and the native external iliac artery in subjects with peripheral artery disease (PAD). A total of 151 subjects were enrolled in the Absolute Pro arm at 33 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 ≥ 3.6 mm and ≤ 9.1 mm by visual estimate, and lesion lengths between 10 mm and 110 mm for stenotic lesions in the common iliac artery or external iliac artery or ≤ 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=151
Age (in years)	
Mean \pm SD (n)	62.8 \pm 9.3 (151)
Median	62.5
Range (min, max)	40.8, 89.2
Male	64.9% (98/151)
Female	35.1% (53/151)
Diabetes	31.1% (47/151)
Type I	6.4% (3/47)
Type II	93.6% (44/47)
Tobacco Use	
Former	35.8% (54/151)
Current	54.3% (82/151)
Dyslipidemia Requiring Medication	78.1% (118/151)
Hypertension Requiring Medication	76.8% (116/151)
Coronary Artery Disease	59.6% (90/151)
Previous Myocardial Infarction	22.3% (33/148)
Congestive Heart Failure	12.1% (18/149)
Cerebrovascular Disease	19.6% (29/148)
Stroke	9.4% (14/149)
Chronic Obstructive Pulmonary Disease	28.8% (42/146)
Bilateral Lower Extremity Artery Disease	71.5% (108/151)

Multi-level Peripheral Lower Extremity Artery Disease	98.7% (149/151)
Lower Extremity Artery Disease (excluding iliac artery disease)	52.3% (79/151)
Previous Endovascular or Surgical Intervention to the Target Limb	10.6% (16/151)

Note: Denominators are based on available data.

8.3 Methods

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® 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. 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 = 181
Anatomic	
Unilateral artery treatment	66.9% (121/181)
Bilateral artery treatment	33.1% (60/181)
Target Artery	
Common iliac	76.0% (136/179)
Common & external iliac, or external iliac only	24.0% (43/179)

Preprocedure Morphology	
Eccentric	47.2% (85/180)
Ulceration	21.1% (38/180)
Calcification	
None/mild	3.3% (6/180)
Moderate	33.9% (61/180)
Severe	62.8% (113/180)
Thrombus	0.0% (0/180)
Postprocedure Morphology	
Dissection Grade	
0 (No dissection)	96.1% (172/179)
A	0.0% (0/179)
B	3.4% (6/179)
C	0.5% (1/179)
D	0.0% (0/179)
E	0.0% (0/179)
F	0.0% (0/179)

Note: Denominators are based on available data.

Table 4: Angiographic Quantitative Analysis

Lesions = 181			
	Mean \pm SD (n)	Median	Min, Max
Preprocedure Reference Vessel Diameter (mm)	7.6 \pm 1.8 (180)	7.4	4.0, 12.7
Preprocedure Lesion length (mm)	28.8 \pm 18.9 (180)	23.1	4.3, 107.7
Preprocedure Lesion Percent Diameter Stenosis (%)	70.3 \pm 15.3 (180)	67.0	23.0, 100.0
Preprocedure Minimum Lumen Diameter (mm)	2.3 \pm 1.4 (180)	2.3	0.0, 8.9
Postprocedure Lesion Percent Diameter Stenosis (%)	12.7 \pm 13.7 (178)	13.2	-42.8, 48.9
Postprocedure Minimum Lumen Diameter (mm)	6.5 \pm 1.6 (178)	6.3	3.6, 12.2

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 post-procedure and at 2 and 3 years. 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 the **Absolute Pro** in the treatment of iliac artery stenosis. The primary

endpoint of MAE rate at 9 months (270 days) is 6.1% (9/147), with the upper one-sided 95% confidence interval (CI) of 10.4%, which is significantly below the pre-specified OPC of 19.5% ($p < 0.0001$, one-sided exact binomial test).

Table 5 below details the individual subject counts for each of the MAE components.

Table 5. Non-hierarchical MAE - Per Subject Analysis

Events	0 – 30 Days	0 – 270 Days
Total Major Adverse Event (MAE) Rate	0.0% (0/148)	6,1% (9/147)
Death	0.0% (0/148)	2.7% (4/147)
Myocardial infarction	0.0% (0/148)	1.4% (2/147)
Major amputation of the treated limb(s)	0.0% (0/148)	0.7% (1/147)
Clinically-driven TLR	0.0% (0/148)	1.4% (2/147)

Note: Denominators are based on available data.

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 6** below). Study device success, on a per device basis, was 96.4% (186/193). There were 7 device malfunctions in 7 subjects. Technical success, on a per lesion basis, was 87.3% (158/181). There were no MAEs through 2 days post-procedure, therefore procedure success, on a per subject basis was 85.4% (129/151).

Table 6. Acute Success

Effectiveness	N = 151 Subjects M = 181 Lesions
Study Device Success ¹	96.4% (186/193)
Technical Success ²	87.3% (158/181)
Procedure Success ³	85.4% (129/151)

¹Device success: device success is defined as, on a per device basis, 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.

²Technical success is defined, on per target lesion basis, 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.

³Procedure success is defined as, on per patient basis, 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.

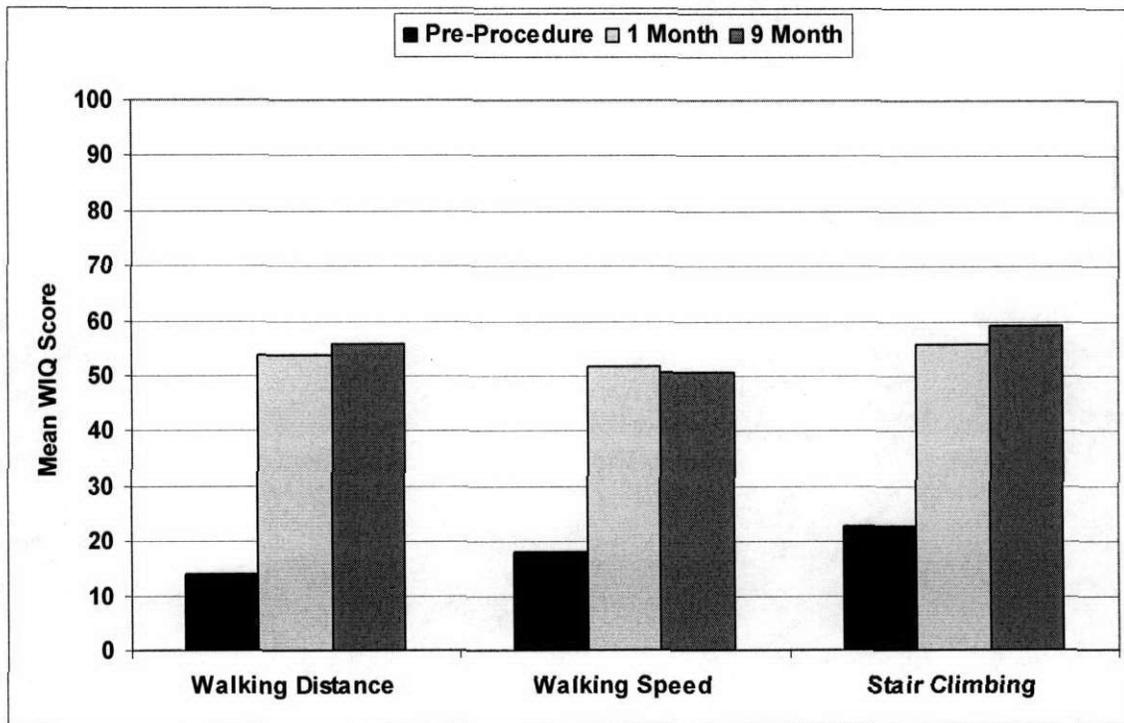
8.4.2.2 Thigh Brachial Index (TBI) and Ankle Brachial Index (ABI)

The majority of limbs, 95.9% (141/147), had 9-month hemodynamic success, defined as TBI or ABI improvement by ≥ 0.1 compared to baseline, or deterioration ≤ 0.15 compared to post-procedure values.

8.4.2.3 Walking Capacity

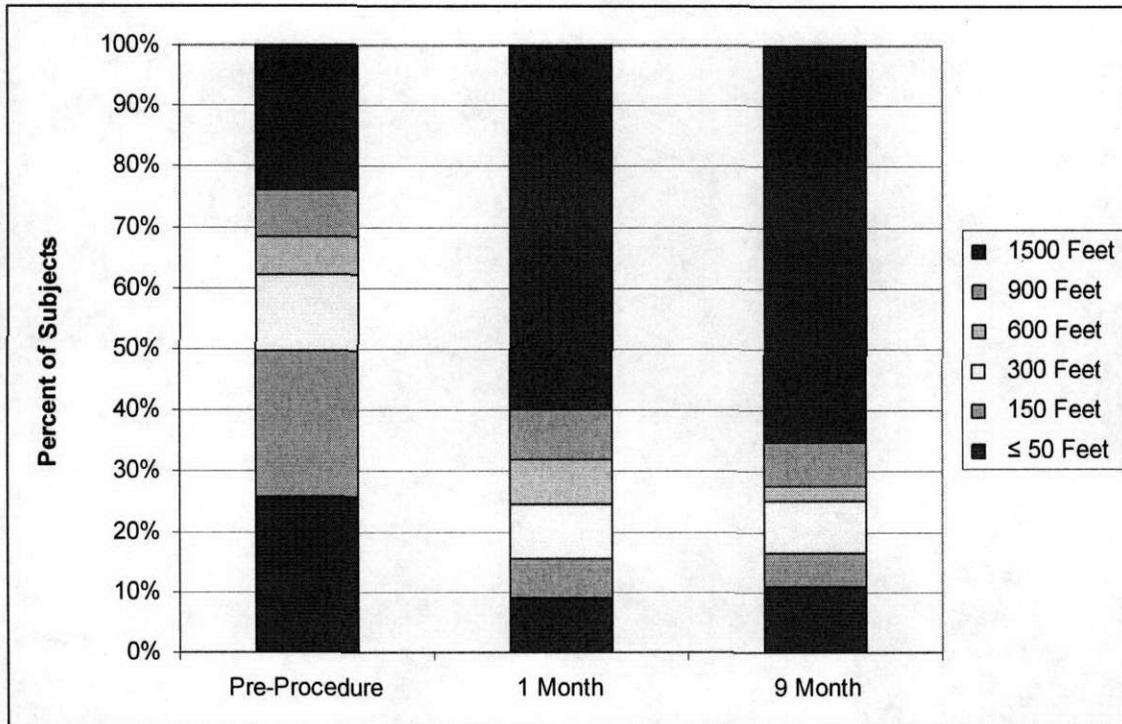
The WIQ was used to assess walking distance, walking speed and stair climbing for study subjects. The walking distance mean score increased from $14.0 \pm 19.9\%$ at baseline to $55.7 \pm 39.6\%$ at 9 months. The walking speed and stair climbing mean scores also increased from $17.9 \pm 20.8\%$ and $22.7 \pm 23.9\%$, respectively, at baseline to $50.6 \pm 33.9\%$ and $59.2 \pm 37.5\%$ at 9 months (Figure 2 below).

Figure 2. WIQ Score Changes – Per Subject Analysis (Absolute Pro: Intent-to-Treat Population)



Prior to intervention 25.8% (39/151) of the subjects could walk ≤ 50 feet, 49.7% (75/151) could walk ≤ 150 feet while 23.8% (36/151) could walk 1500 feet. There was an improvement in maximum walking distance; at 9 months, 11.0% (14/127) were limited to walking ≤ 50 feet, 16.5% (21/127) were limited to ≤ 150 feet, and 65.4% (83/127) of subjects could walk 1500 feet, (Figure 3).

Figure 3. Walking Distances



8.4.2.4 Rutherford Becker (RB) Clinical Category

At 9 months, 93.9% (139/148) of limbs had improved by ≥ 1 RB clinical category.

8.4.2.5 Restenosis

Restenosis, defined as $\geq 50\%$ stenosis by duplex ultrasound or arteriography, occurred in 8.4% (13/154) of lesions.

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 7: Serious Adverse Events through 30 Days

Adverse Event	N = 151
Access Site Complication	
Bleeding	0.7% (1/151)
Blood Dyscrasia	
Anemia	0.7% (1/151)
Thrombocytopenia	0.7% (1/151)
Cancer	
Cancer	0.7% (1/151)
Cardiac	
Arrhythmias (other than bradycardia)	1.3% (2/151)
Gastrointestinal	
Other: Gastritis	0.7% (1/151)
Other: Pancreatitis	0.7% (1/151)
Infection	
Wound complication or wound infection	0.7% (1/151)
Neurologic other than stroke	
Confusion	0.7% (1/151)
Procedure-related	
Dissection	2.6% (4/151)
Hypertension	0.7% (1/151)
Pulmonary	
Other: Pleural Effusion	0.7% (1/151)
Respiratory	
Pneumonia	0.7% (1/151)
Vascular	
Other: Peripheral Vascular Disease	0.7% (1/151)
Stenosis	1.3% (2/151)
Thrombosis	0.7% (1/151)

Table 8: Serious Adverse Events between 31 Days and 326 Days (Event Rate >1%)

Adverse Event	N=151
Blood Dyscrasia	
Anemia	1.3% (2/151)
Cardiac	
Angina	3.3% (5/151)
Arrhythmias (other than bradycardia)	2.0% (3/151)
Other: Coronary Artery Disease	2.6% (4/151)
Gastrointestinal	
GI Bleed	2.0% (3/151)
Infection	
Wound complication or wound infection	2.0% (3/151)
Myocardial Infarction	
Myocardial Infarction	1.3% (2/151)
Pulmonary	
Chronic Obstructive Pulmonary Disease	1.3% (2/151)
Respiratory	
Pneumonia	2.6% (4/151)
Respiratory Failure	2.0% (3/151)
Stroke	
Other: CVA	1.3% (2/151)
Vascular	
Occlusion	2.0% (3/151)
Other: Peripheral Vascular Disease	4.0% (6/151)
Stenosis	5.3% (8/151)

The adverse events reported within the Absolute Pro 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 Absolute Pro Vascular Self-Expanding Stent System in subjects with atherosclerotic *de novo* or restenotic iliac artery stenoses. The MOBILITY study demonstrated a MAE rate of 6.1%. Iliac stenting with the Absolute Pro is safe as shown by the low MAE rate at 270 days and absence of any MAE through 30 days. Both TBI and ABI clinical values improved at 9 months. Additionally, walking scores and distance, as measured by WIQ, were improved. The restenosis rate of 8.4% is acceptable and consistent with other stents that are used for iliac intervention even with 62.8% of the lesions having severe

calcification.

8.7 Lesion Evaluation

8.7.1 Vessel Lesion Evaluation

Standard transfemoral angiography should be performed followed by the passage of a guide wire through the lesion.

8.8 Lesion Treatment

8.8.1 Lesion Pre-dilatation

1. Standard percutaneous technique should be used to place the sheath / guiding catheter in the vessel. An appropriately sized (0.035") guide wire should be advanced across the lesion.
2. Lesion / vessels should be pre-dilated using standard PTA technique. Pre-dilatation balloon diameter should closely match the lumen diameter proximal and distal to the lesion to be treated. Withdraw the balloon dilatation catheter while leaving the guide wire in place.

8.8.2 Inspection Prior to Use

1. Inspect the temperature indicator on the inner pouch. **Do not use if the indicator is BLACK.** Remove the Delivery System from its protective packaging. Remove the handle from the package and the shaft from the hoop. Lay the device flat and minimize excessive handling. **THE SHAFT MAY KINK IF NOT HANDLED CAREFULLY.** Do not use if shaft is kinked.
2. Inspect the stent through the transparent, amber colored Delivery System sheath to verify that it has not been damaged during shipment and that the stent does not overlap the proximal marker.
3. Ensure that the stent is fully covered by the sheath. Examine the label on the housing assembly and verify that the stent is the correct diameter and length. Do not use if any defects are noted.
4. Inspect to determine the outer jacket is attached to the handle. Reattach by pushing the outer jacket back into the handle.
5. Ensure that the safety lock on the handle is in the locked position. Do not use if found in the unlock position.

8.8.3 Materials Required

- One (1) 0.035" (0.89 mm) diameter guide wire
- Guiding catheter / introducer sheath in the appropriate size and configuration for the selected Stent Delivery System (refer to Table 1)
- 10 cc syringes
- 1,000 u / 500 cc of Heparinized Normal Saline (HepNS)
- Rotating hemostatic valve (RHV) of appropriate size, (if applicable)
- PTA balloon dilatation catheter
- Torque device
- Guide wire introducer

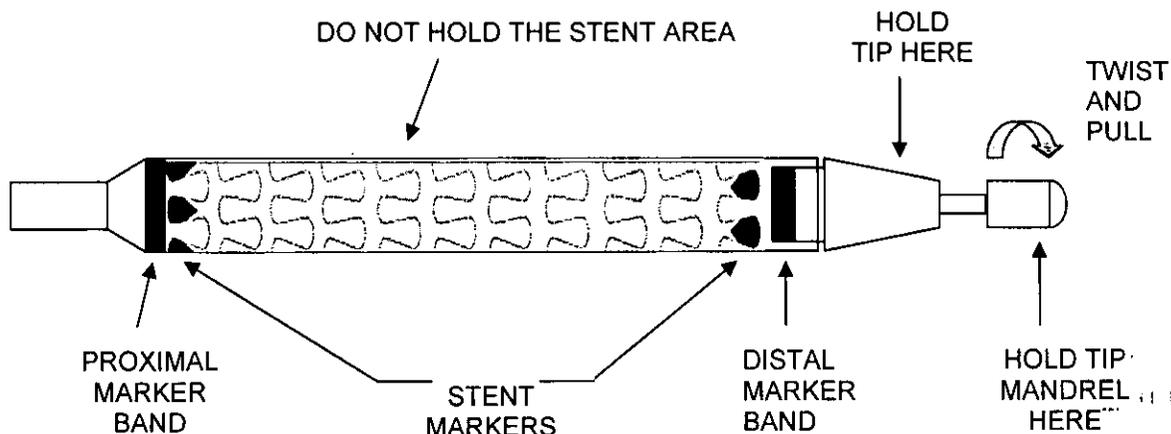
8.9 Delivery System Preparation

LEAVE THE SAFETY LOCK CLOSED UNTIL THE STENT IS READY TO DEPLOY.

Inspect to determine the outer jacket is attached to the handle. Reattach by pushing the outer jacket back into the handle.

1. Holding the tip mandrel in place, inject heparinized saline into the lumen through the proximal luer fitting at the end of the housing assembly. Flush until fluid is observed exiting distally near the stent and at the distal end of the outer jacket. Hold the distal tip of the Delivery System as in Figure 5. **DO NOT HOLD THE STENT AREA.**
2. Gently **twist and pull** to remove the tip mandrel. If the tip mandrel is not easily removed, do not use the device.
3. Continue flushing until fluid is observed exiting at the distal portion of the tip.
4. Keep the device lying flat to avoid kinking in the shaft.

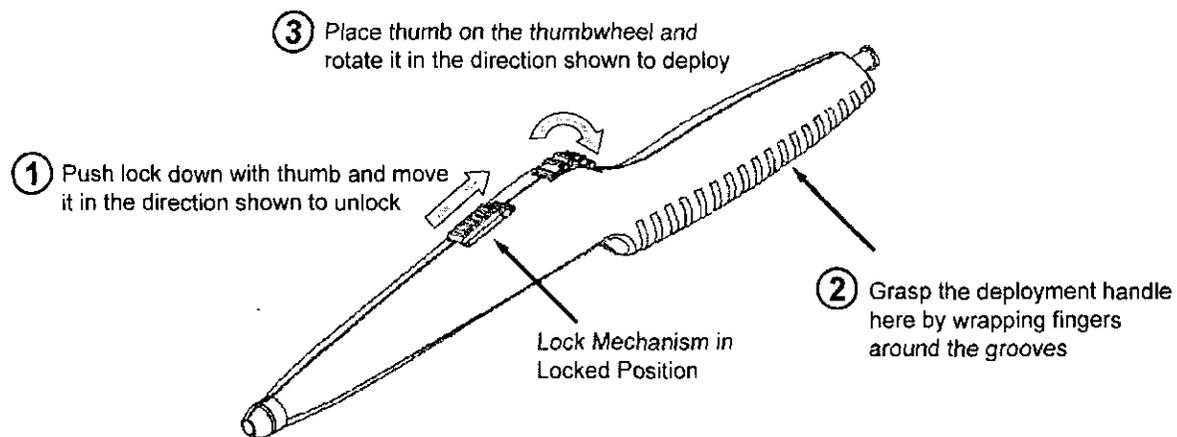
Figure 4: Tip Mandrel Removal



8.10 Delivery Procedure

1. After the pre-dilatation catheter has been removed, **BACKLOAD** the Delivery System onto the appropriately sized (0.035" [0.89 mm]) guide wire.
2. Advance the Delivery System over the guide wire up to the lesion site. Use the radiopaque markers to locate the stent.
3. If an RHV is utilized, ensure that the RHV remains **OPEN**.

Figure 5: Deployment Demonstration



8.11 Stent Deployment

1. Advance the Delivery System past the lesion and pull back to remove any slack in the Delivery System. Position the stent so that the radiopaque stent markers are proximal and distal to the target lesion. Confirm the stent position angiographically. Adjust the stent position if necessary.
Note: The Absolute Pro Vascular Stent is designed not to shorten upon deployment. Bench testing has shown the post-deployment length may vary up to 1.1 mm for all stent lengths.
2. If detachable outer jacket is not engaged in the introducer sheath, manually stabilize prior to deployment to help ensure accurate stent delivery. Do not restrict retracting sheath during stent deployment.
3. If an RHV is used, **ENSURE THAT THE RHV IS OPEN**.
4. Slide the safety lock proximally to the unlocked position, symbolized by an open padlock icon . If unit does not unlock, remove **together with the introducer sheath or guiding catheter as single unit**; do not use the unit. If an RHV is used, **ENSURE THAT THE RHV IS OPEN**.
5. Once unlocked, the lock cannot be relocked.
6. Place one hand on the proximal end of the handle with the thumbwheel positioned superiorly and the thumb on the thumbwheel.

7. **ENSURE THAT THE SHEATH or GUIDING CATHETER DOES NOT MOVE DURING DEPLOYMENT.**

8. Roll the thumbwheel back in the direction of the arrow.

Note: If inaccuracy is observed during initial deployment (**PRIOR TO STENT APPOSING WALL OF LUMEN**), then the Delivery System position can be adjusted to achieve desired accuracy; if necessary prior to apposing the vessel, the system (including the stent) can then be removed together with the introducer sheath or guiding catheter as a single unit. **ENSURE THAT THE DELIVERY SYSTEM MARKERS DO NOT MOVE DURING DEPLOYMENT.** If delivery system markers are observed moving distally, pull back using the catheter shaft to maintain delivery system marker position.

ENSURE THAT THE DELIVERY SYSTEM MARKERS DO NOT MOVE DURING DEPLOYMENT. If delivery system markers are observed moving distally, pull back using the catheter shaft to maintain delivery system marker position.

9. Should **unusual resistance** be felt at any time, including resistance **unlocking the handle or thumbwheel rotation**, during either lesion access or stent deployment, the entire system should be **removed together with the introducer sheath or guiding catheter as a single unit**. Failure to follow these instructions could result in failure to deploy, difficulties with deployment, partial stent deployment or deployment in an unintended location.
10. Remove the Delivery System from the lesion through the sheath or guiding catheter.

8.12 Removal Procedure

1. While maintaining guide wire position, withdraw the Delivery System.

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

2. Repeat angiography to confirm optimal stent apposition.

ENSURE STENT IS NOT UNDERDILATED. DO NOT EXPAND THE STENT PAST ITS LABELED MAXIMUM UNCONSTRAINED DIAMETER. If necessary, post-dilate within the stent. Post-dilatation balloon diameters should closely match vessel reference diameter.

9.0 PATENTS AND TRADEMARKS

This product and / or its use are covered by one or more of the following United States Patents: 5,421,955; 5,457,605; 5,458,615; 5,507,768; 5,514,154; 5,569,295; 5,603,721; 5,649,952; 5,725,572; 5,728,158; 5,759,192; 5,766,238; 5,780,807; 5,782,855; 5,916,234; 6,056,776; 6,066,167; 6,066,168; 6,131,266; 6,143,016; 6,241,758;

6,352,824; 6,369,355; 6,375,676; 6,375,826; 6,432,133; 6,468,302; 6,511,504;
6,521,865; 6,537,311; 6,568,235; 6,576,006; 6,582,460; 6,596,022; 6,602,284;
6,626,937; 6,635,083; 6,641,608; 6,651,478; 6,676,693; 6,679,980; 6,689,159;
6,695,862; 6,709,454; 6,755,854; 6,764,506; 6,814,749; 6,840,081; 6,846,323;
6,855,161; 6,893,458; 6,896,697; 6,908,479; 6,927,359; 6,929,657; 6,929,660;
6,939,373; 6,964,750; 6,997,944; 7,018,403; 7,112,055; 7,128,757; 7,128,758;
7,152,452; 7,163,553; 7,175,650; 7,175,655; 7,258,697; 7,303,798; and 7,308,748.
Other U.S. patents pending. Foreign patents issued and pending.

Absolute Pro is a registered trademark of the Abbott Group of Companies.
SF-12[®] is a registered trademark of Medical Outcomes Trust, Inc.

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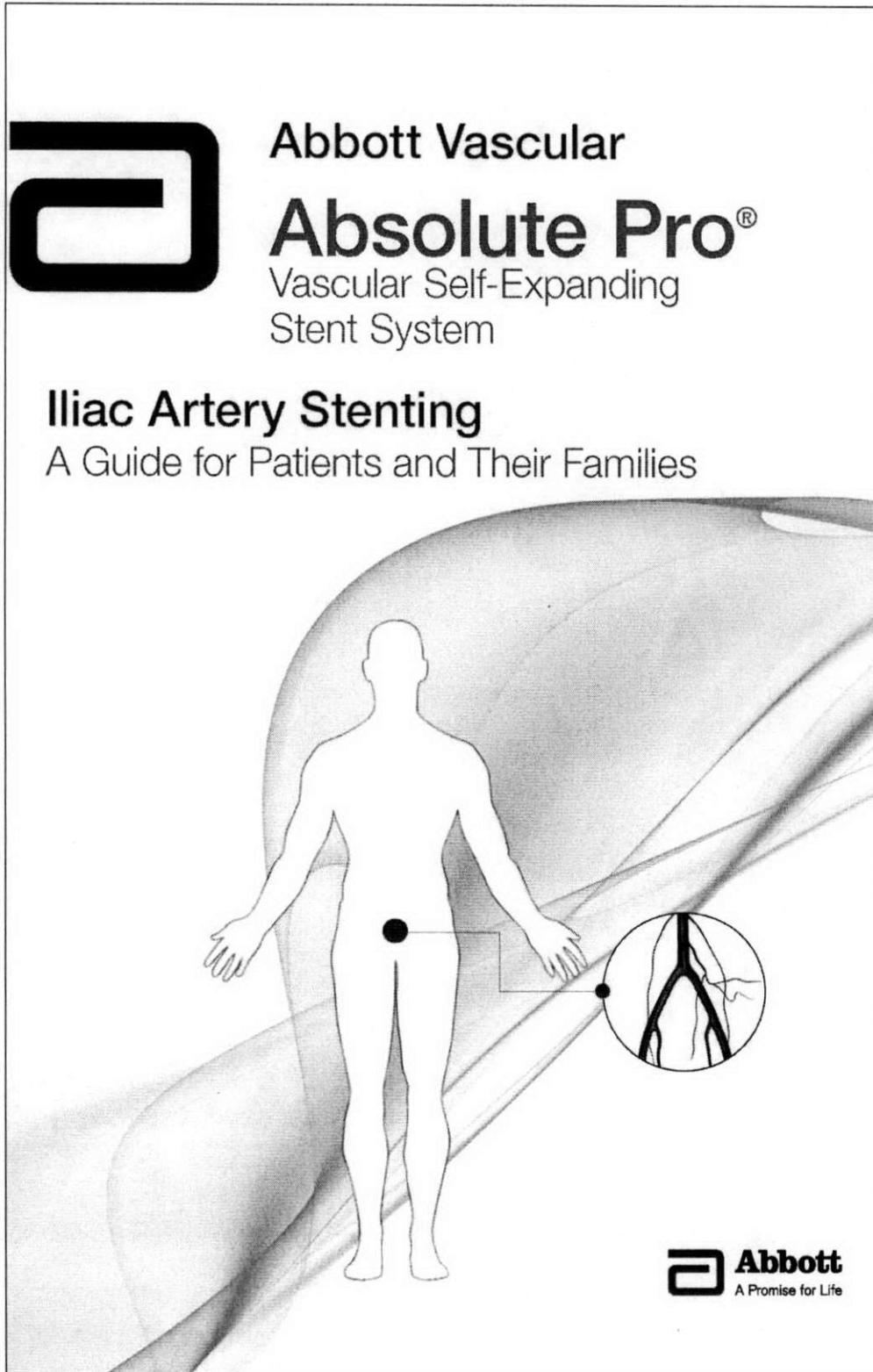
Graphical Symbols for Medical Device Labeling

 Manufacturer	 Sterilized using irradiation
 Catalogue number	 Outer diameter
 French size	 Stent length
 Consult instructions for use	 Date of manufacture
 Contents (numeral represents quantity of units inside)	 Use by
 Do not reuse	 Batch code
 Guiding catheter	 MR conditional

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Label Type	Domestic
Languages Appearing on Label	English
Note: English text in this document is for content reference only and should not be used for artwork use or placement verification.	
Generic Specification	See PK2011944 for requirements not listed below.
Material Requirements	Cover: 80# Jefferson Gloss cover Inside 70# Jefferson Gloss book
Ink Color	CMYK + Aqueous
Dimensional Requirements	5-1/2" ±1/8 W x " 8-1/2"±1/8" H
Binding	Saddle Stitch
Artwork Date	2/21/12
Label Control Level	A
Receiving Inspection Requirements	
Dimensional and Color	Inspect per Zero Acceptance Sampling Plan Latest Edition, Index Value: 6.5.
Text	Inspect legibility and content by randomly selecting 2 samples. Use an overlay of the original artwork for a word-for-word comparison.
Barcode Scans	2083061

FRONT COVER



 **Abbott Vascular**
Absolute Pro[®]
Vascular Self-Expanding
Stent System

Iliac Artery Stenting
A Guide for Patients and Their Families

 **Abbott**
A Promise for Life

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 the Absolute Pro Vascular Self-Expanding Stent System.

Abbott Vascular's Absolute Pro Vascular Self-Expanding Stent System is 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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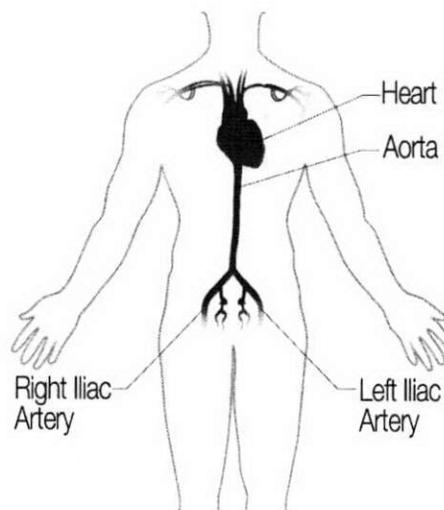
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Iliac Artery Disease

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.

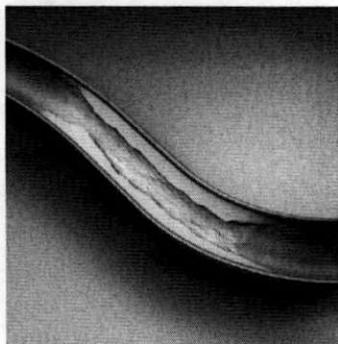
Figure 1. Your Iliac Arteries



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*.

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 narrow 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 more narrow.

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 pulling back a covering that is over the 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

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



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), 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

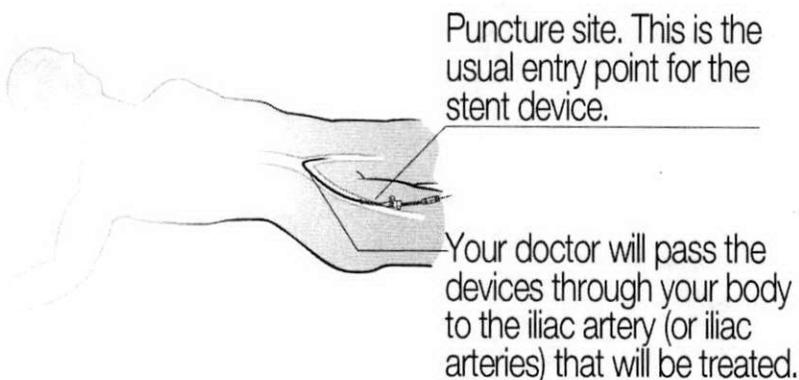
- In the procedure room, you will lie on a special table. The staff will make you as comfortable as possible.
- You will be attached to monitors that will keep track of your heart rate and oxygen levels. The doctor and staff will watch these monitors throughout your procedure.
- You may be given medicine 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 4). 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.

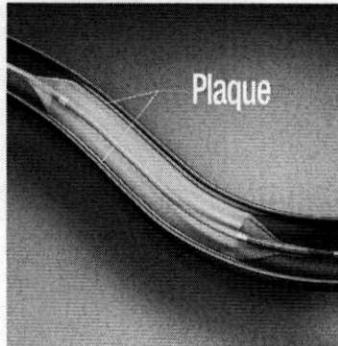
Figure 4. Access Site



- 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.

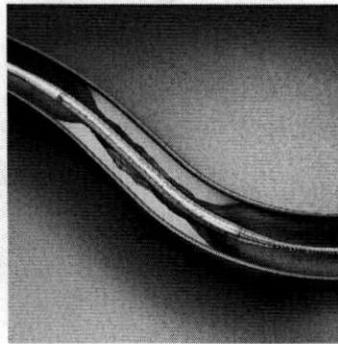
- Your doctor may put a balloon catheter into the narrowed area and inflate the balloon to open up the artery more (Figure 5). Your doctor will remove the balloon catheter.

Figure 5 – Balloon Inflation to Widen the Stenosis



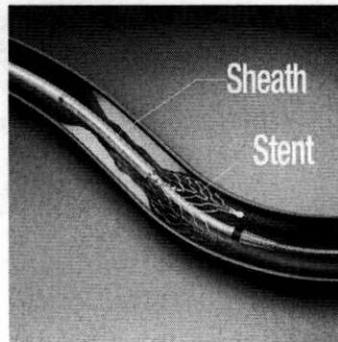
- The iliac stent system will be positioned in the artery where it is narrowed (Figure 6.)

Figure 6 – Positioning of Iliac Stent in Narrowed Artery



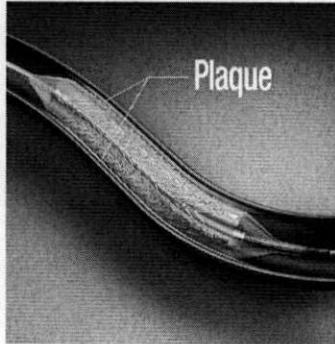
- The doctor will pull back the sheath that is covering the stent to allow the iliac stent to open up on its own (Figure 7).

Figure 7 – Placement of the Iliac Stent (Sheath Partially Pulled Back)



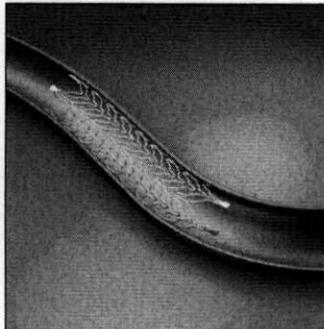
- Once the stent is placed, your doctor may use a balloon catheter to press the stent and plaque against the artery wall (Figure 8).

Figure 8 – Balloon Catheter



- The stent is permanent, but all catheters used in the procedure are removed (Figure 9).

Figure 9 – 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. The Absolute Pro Vascular Self-Expanding Stent System was studied in a clinical study in the United States. The results show that the use of the Absolute Pro Vascular Self-Expanding 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, or platinum, the metals used to make the stent
- 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, or platinum may suffer an allergic reaction to this stent.

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
- 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
- Pain or discomfort
- Nausea or vomiting
- Problems with the rhythm of your heart such as slow heartbeat or uneven heartbeats
- Stenosis (narrowing) or restenosis (renarrowing) of the stented iliac artery
- Stroke
- Damage to your legs and / or feet due to lack of blood flow to them

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 was evaluated in the MOBILITY Clinical Study. In this study, 151 patients with narrowing in one or both iliac arteries were treated.

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). At 9 months after the procedure, 2 out of 147 (1.4%) patients needed to have their iliac arteries treated again because of re-narrowing.

The results of this study showed that the Absolute Pro Vascular Self-Expanding Stent System was 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 a MRI. There are also phone numbers on the card that your doctor can call if he / she has any questions.

Below is a sample of a stent card you may receive:

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



MR Conditional

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 RF 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 F2052-06a. No clinical testing at field strengths greater than 3 Tesla has not been performed to evaluate stent migration or heating.

Absolute Pro[®]
Vascular Self-Expanding Stent System

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Outside U.S. FAX: (951) 914-2531



PPI 2081966 (E/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 MH conditions on this card with the MedicAlert Foundation or equivalent organization. The MedicAlert Foundation can be contacted by phone at: (888) 633-4288, (209) 659-3333 or on the internet at 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

Notes

BACK COVER

Abbott Vascular

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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.

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