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 to 9.1 mm and lesion lengths up to 90 mm.

CONTRAINDICATIONS
There are no known contraindications.

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 device is intended to be used in conjunction with other dilatation catheters; do not use 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.

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.

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.

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 wall. Once the stent is apposed to the vessel, it is not recommended to remove the stent with the delivery system.
• 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.)

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.

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 ring. Under fluoroscopy the independent ring expansion may appear as a step in the contour of the ring. 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 with this implant may be scanned with this implant may be scanned 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.

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 systematic, 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

Prior to use, please reference the Instructions for Use at www.abbottvascular.com for more information on indications, contraindications, warnings, precautions, and adverse events.