Express® LD Iliac
OVER-THE-WIRE
Premounted Stent System

RX ONLY
Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.
Please read instructions carefully prior to use!

WARNING
Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. Alter use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION:
The Express LD Iliac Premounted Stent System consists of 316L surgical grade stainless steel balloon expandable stent. The stent is premounted on a Stent Delivery System (SDS) equipped with a non compliant balloon. The SDS has two radioopaque balloon markers embedded in the shaft to aid in the placement of the stent. The SDS is compatible with 0.035 in. (0.89 mm) guidewires. The SDS balloon has a maximum inflation pressure of 12 atm (1216 kPa) that can be used for initial stent placement.(i.e. alcohol).
The premounted stent system balloon catheter is also offered in two shaft lengths. Table 1 summarizes individual product descriptions and nominal specifications.

Contents
• One (1) Express LD Iliac Premounted Stent System

Note: The diameter of the stent may be increased post-placement by expanding with a larger diameter balloon.

INTENDED USE/INDICATIONS FOR USE:
The Express LD Iliac Premounted Stent System is indicated for the treatment of atherosclerotic lesions found in iliac arteries up to 100 mm in length, with a reference diameter of 6 mm to 10 mm.

CONTRAINDICATIONS:
Generally, contraindications for Percutaneous Transluminal Angioplasty (PTA) and placement of intravascular stents. However, the following contraindications associated with the use of the Express LD Iliac Premounted Stent System include:

• Patients who exhibit persistent acute intraluminal thrombus at the treatment site, following thrombolytic therapy.

• Patients with uncorrected bleeding disorders or patients who cannot receive anticoagulation or antiplatelet aggregation therapy.

• Persons with known allergies to stainless steel or its components (for example nickel).

• A lesion that is within or adjacent to the proximal or distal segments of an aneurysm.

• Patients who experience the complication of arterial perforation or a fusiform or saccular aneurysm during the procedure, precluding possible stent implantation.

• Patients with excessive vessel tortuosity.

• Patients with perforated vessels evidenced by extravasation of contrast media.

WARNING:
• Do not exceed the maximum rated burst pressure. Exceeding this pressure increases the potential for balloon rupture and possible vessel damage.

• As with any type of intravascular implant, infection, secondary to contamination of the stent, may lead to thrombosis, pseudoaneurysm or rupture into a neighboring organ or into the retroperitoneum. The stent may cause thrombus or distal emboli to migrate from the site of the implant down the arterial lumen.

• Care should be taken during stent deployment to avoid stent placement beyond the iliac ostium into the aorta as this may result in thrombus formation.

• Do not exceed the maximum expanded stent diameter as per Table 1.

• The Express LD Iliac Stent may cause image artifacts with MRI scans due to distortion of the magnetic field.

• To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just distal to the stenosis. Oversizing of the artery may result in rupture and life threatening bleeding.

• Use only dilated contrast medium for balloon inflation (typically a 50/50 mixture by volume of contrast medium and normal saline). Never use air or any gaseous medium in the balloon.

• Persons with allergic reactions to stainless steel or its components (for example nickel) may suffer an allergic response.

• Do not expose the premounted stent system to organic solvents (i.e. alcohol).

• The long-term outcome (beyond twenty four months) for this permanent implant is unknown at present.

• Stent placement should only be performed at hospitals where emergency peripheral artery bypass graft surgery can be readily performed.

PRECAUTIONS:
• The device is intended for use by physicians who have been trained in interventional techniques such as percutaneous transluminal angioplasty (PTA) and placement of intravascular stents.

• The sterile packaging and device should be inspected prior to use. If sterility or performance of the device is suspect, it should not be used.

• Caution should be taken with patients with poor renal function who, in the physician’s opinion, may be at risk for a contrast medium reaction.

• Prep premounted stent system-per instructions given in Operational Instructions. Significant amounts of air in the balloon may cause difficulty in deploying the stent and deflation of the balloon.

• Do not attempt to pull a stent where deployment has been initiated back through a sheath or guide catheter, since dislodgement of the stent may result. If a stent that has not been fully deployed needs to be removed, use its sheath or guide catheter and the premounted stent system should be removed as a unit.

• The SDS is not designed for use with power injection systems. Inflation at a high rate can cause damage to the balloon. Use of a pressure monitoring device is recommended to prevent over pressurization.

• Do not attempt to manually remove or adjust the stent on the SDS balloon.

• The minimally acceptable sheath and guide catheter French size is printed on the package label. Do not attempt to pass the premounted stent system catheter through a smaller size sheath or guide catheter than indicated on the label.

• When a premounted stent system or SDS balloon is in the body, it should be manipulated only under fluoroscopy. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum.

• Never advance the premounted stent system without the guidewire extending from the tip.

• Prior to completion of the procedure, utilize fluoroscopy to ensure proper positioning of the stent. If the target lesion is not fully covered, use an additional stent as necessary to adequately treat the lesion.

• It is recommended that when stenting multiple lesions, the distal lesions should be initially stented, followed by stenting of the proximal lesion. Stenting in this order obviates the need to cross the proximal stent when placing the distal stent and reduces the chances for disrupting the proximal stent.

• Prior to stent expansion, utilize fluoroscopy to verify the stent has not been damaged or dislodged during positioning. Expansion of the stent should not be undertaken if the stent is not appropriately positioned in the vessel. If the position of the stent is not optimal, it should not be expanded.

• Expansion of the balloon dilatation catheter should be monitored during inflation. Do not exceed the maximum recommended inflation pressures as indicated on the product label. Exceeding this pressure increases the potential for balloon rupture and possible vessel damage.

• To assure full expansion, inflate the balloon to at least the nominal pressure as shown on the label and Table 1.

• Stenting across a bifurcation or side branch could compromise future diagnostic or therapeutic procedures, or could result in thrombosis of the side branch.

• More than one stent per lesion should only be used when clinically indicated for suboptimal results that compromise vessel integrity and threaten vessel closure, such as edge dissection type B (i.e. bailout). The second implanted stent should also be an Express LD Iliac Stent, or a stent of similar material composition, for component compatibility.

• Do not attempt to reposition a partially deployed stent. Attempted repositioning may result in severe vessel damage. Incomplete deployment of the stent (i.e. stent not fully opened) may cause complications resulting in patient injury.

• Recrossing a partially or fully deployed stent with adjunct devices must be performed with extreme caution to ensure that the adjunct device does not get caught within previously placed stent struts.

• In the event of thrombosis of the expanded stent, thrombolysis should be attempted.

• In the event of complications such as infections, pseudoaneurysm, or fistulization, surgical removal of the stent may be required.

• Use prior to the “Use By” date.

• When multiple stents are required, if placement results in metal to metal contact, stent materials should be of similar composition.
MAGNETIC RESONANCE IMAGING (MRI) INFORMATION:

Non-clinical testing has demonstrated the Express LD Stent in single and overlapped conditions is MR Conditional. It can be scanned safely, immediately after placement of this implant, under the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla.
- Spatial gradient field of 700 Gauss/cm or less.
- Normal operating mode of the MR system and use of whole body transmit coils only.
- Maximum whole-body-averaged specific absorption rate (WBA-SAR) of 2 Watts/kilogram (W/kg), for 15 minutes of scanning for patient landmarks below the umbilicus.
- Maximum WB-SAR of 1 W/kg for 15 minutes of scanning.

The actual in vivo rise is expected to be less than these values as the calculations did not include the cooling effects due to blood flow in the lumen of the stent and blood perfusion in the tissue outside the stent.

3.0 TESLA TEMPERATURE INFORMATION:

Non-clinical testing of RF-induced heating was performed at 128 MHz in a 3.0 Tesla Intera Philips Medical Systems, software version Release 10.6.2.0, 2006-03-10 whole body coil MR scanner. The testing was performed according to ASTM F2182 and the stents were in a location and orientation in the phantom that produced the worst case RF heating. RF power was applied for 15 minutes and the conductivity of the phantom material was about 0.3 S/m. The phantom average SAR calculated using calorimetry was 2.1 W/kg. The maximal in-vitro temperature rise was 2.2 °C when the local SAR was scaled to 2 W/kg for a stent length of 101 mm. Other stent lengths exhibited a lower temperature rise. Fractured stents exhibited similar heating. Predicted in-vivo heating based on these non-clinical tests and computer simulation of the patient exposure to the electromagnetic fields in MRI yielded to the following maximal in vivo rises:

- For landmarks above the umbilicus, the calculated temperature rise was 3.2 °C with an uncertainty upper boundary temperature of 4.1 °C for a whole body average SAR value of 2.0 W/kg and a continuous scan time of 15 minutes. Non-clinical testing of RF-induced heating was performed at 64 MHz in a 1.5 Tesla Intera Philips Medical Systems, software version Release 10.6.2.0, 2006-03-10 whole body coil MR scanner. The testing was performed according to ASTM F2182 and the stents were in a location and orientation in the phantom that produced the worst case RF heating. RF power was applied for 15 minutes and the conductivity of the phantom material was about 0.3 S/m. The phantom average SAR calculated using calorimetry was 2.1 W/kg. The maximal in-vitro temperature rise was 2.2 °C when the local SAR was scaled to 2 W/kg for a stent length of 101 mm. Other stent lengths exhibited a lower temperature rise. Fractured stents exhibited similar heating. Predicted in-vivo heating based on these non-clinical tests and computer simulation of the patient exposure to the electromagnetic fields in MRI yielded to the following maximal in vivo rises:

- For landmarks below the umbilicus, the calculated temperature rise was 5.2 °C with an uncertainty upper boundary temperature of 6.6 °C for a whole body average SAR value of 2.0 W/kg and a continuous scan time of 15 minutes.

The actual in vivo rise is expected to be less than these values as the calculations did not include the cooling effects due to blood flow in the lumen of the stent and blood perfusion in the tissue outside the stent.

IMAGE ARTIFACT INFORMATION:

The image artifact extends approximately 7 mm from the perimeter of the device diameter and 6 mm between each end of the length of the stent when scanned in nonclinical testing using a Spin Echo sequence. With a Gradient Echo sequence the image artifact extends 13 mm beyond the perimeter of the diameter and 12 mm beyond each end of the length with both sequences partially shielding the lumen in a 3.0 Tesla Intera (Achieva Upgrade), Philips Medical Solutions, software version Release 2.5.3.0 2007-09-28 MR system with a transmit/receive head coil. It is recommended that patients register the conditions under which the implant can be scanned safely with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

ADVERSE EVENTS:

Potential adverse events (in alphabetical order) that may be associated with the use of intravascular stents include, but are not limited to, the following:

- Abscess
- Aneurysm
- Arrhythmias
- AV fistula
- Bleeding / Hemorrhage
- Death
- Drug reaction or allergic reaction (including to antibiotic/agent, contrast medium, stent materials, or other)
- Embolization of device, air, plaque, thrombus, tissue, or other
- Extremity ischemia/amputation
- Hematoma
- Hypertension or Hypertension
- Myocardial infarction
- Need for urgent intervention or surgery