REF

H74938162520750	H74938162530750
H74938162540750	H74938162560750
H74938162520130	H74938162530130
H74938162540130	H74938162560130

Table 3. Symbol Definitions

	Contents
GW R	Recommended Guidewire
IS R	Recommended Introducer Sheath

AR REP

Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link bostonscientific.com/arg

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2026-02
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Express™ LD Vascular

OVER-THE-WIRE

Premounted Stent System

STERILE - DO NOT RESTERILIZE - SINGLE USE ONLY

℞ ONLY

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

REUSE 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.

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

DEVICE DESCRIPTION

The Express LD Vascular Premounted Stent System consists of a 316L surgical grade stainless steel balloon expandable stent. The stent is premounted on an over the wire Stent Delivery System (SDS) equipped with a non-compliant balloon. The SDS balloon catheter has two radiopaque 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 and post stent dilatation.

The Premounted Stent System is available in a variety of stent lengths with SDS balloons that expand them to 5 mm in diameter. The SDS balloon catheter is also offered in two lengths. Table 1 summarizes individual product descriptions and nominal specifications.

Contents

One (1) Express LD Vascular Premounted Stent System.

User Information

Only physicians experienced in interventional techniques such as percutaneous transluminal angioplasty (PTA) and placement of intravascular stents should use this device.

INTENDED USE/INDICATIONS FOR USE

The Express LD Vascular Premounted Stent System is indicated for use in the treatment of peripheral vascular lesions.

CONTRAINDICATIONS

Generally, contraindications for percutaneous transluminal angioplasty (PTA) are also contraindications for stent placement. Contraindications associated with the use of the Express LD Vascular Premounted Stent System include:

- Patients with highly calcified lesions resistant to PTA.
- Patients with a target lesion with a large amount of adjacent acute or subacute thrombus.
- Patients with uncorrected bleeding disorders or patients who cannot receive anticoagulation or antiplatelet aggregation therapy.
- Patients with perforated vessels evidenced by extravasation of contrast media.
- A lesion that is within or adjacent to the proximal or distal segments of an aneurysm.
- Patients with excessive vessel tortuousity.

WARNINGS

- Persons with allergic reactions to stainless steel or its components (for example nickel) may suffer an allergic response to the implant.
- Do not expose the Premounted Stent System to organic solvents (i.e. alcohol).
- Use only diluted 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.
- Prepare the Premounted Stent System per instructions given. Significant amounts of air in the balloon may cause difficulty in deploying the stent and deflation of the balloon.
- Do not exceed the rated burst pressure. Exceeding this pressure increases the potential for balloon rupture and possible vessel damage.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis. Overstretching of the artery may result in rupture and life threatening bleeding.
- 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.
- Do not exceed the Maximum Expanded Stent I.D. as per Table 1.
- The stent may cause thrombus or distal emboli to migrate from the site of the implant down the arterial lumen.
- When stenting the renal arteries, exercise great care to reduce the risk of plaque embolization.

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 in stenting patients with poor renal function, who, in the physician's opinion, may be at risk for a contrast medium reaction.
- The Premounted Stent System is not intended for precise arterial blood pressure monitoring.
- The Premounted Stent System 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.
- The minimally acceptable introducer sheath French size is printed on the package label. Do not attempt to pass the PTA catheter through a smaller size introducer sheath than indicated on the label.
- Never advance the Premounted Stent System without the guidewire extending from the tip.
- Do not attempt to manually remove or adjust the stent on the SDS balloon.
- When a catheter is in the body, they should be manipulated only under fluoroscopy. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum.
- Prior to stent expansion, utilize high-resolution 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.
- It is recommended that when treating multiple lesions, the lesion distal to the puncture site should be initially stented, followed by stenting of the proximal lesion. Stenting in this order eliminates the need to cross the proximal stent to achieve placement of the distal stent, and reduces the chance for dislodging the proximal stent from the SDS balloon.
- To assure full expansion, inflate the Premounted Stent System to at least the Nominal Pressure as shown on the labeling and in Table 1.
- 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.
- Do not attempt to pull a stent that has not been expanded back through an introducer sheath or guide catheter, since dislodgment of the stent may result. If a stent that has not been expanded needs to be removed, the introducer sheath or guide catheter and the Premounted Stent System should be removed as a unit.
- Prior to completion of the procedure, utilize fluoroscopy to ensure proper positioning of the stent. If the target lesion is not fully covered, use additional stents as necessary to adequately treat the lesion.
- Stenting across a bifurcation or side branch could compromise future diagnostic or therapeutic procedures, or could result in thrombosis of the side branch.
- In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted.
- In the event of complications such as infections, pseudoaneurysm, or fistulization, surgical removal of the stent may be required. Standard surgical procedure is appropriate.

Table 1. Express™ LD Vascular Premounted Stent System Specifications

Product Code	Balloon Size		Nominal Pressure	Rated Burst Pressure	Catheter Useable Length	Minimum Introducer Sheath Size I.D.	Stent Size			
	Diameter	Length					Diameter	Crimped Length	Expanded Length	Maximum Expanded I.D.
	mm	mm	atm (kPa)	atm (kPa)	cm	F (mm)	mm	mm	mm	mm
H74938162520750	5	20	8 (811)	12 (1216)	75	6 (2.00)	5	17	16.9	9
H74938162530750	5	30	8 (811)	12 (1216)	75	6 (2.00)	5	27	26.9	9
H74938162540750	5	40	8 (811)	12 (1216)	75	6 (2.00)	5	37	37.0	9
H74938162560750	5	60	8 (811)	12 (1216)	75	6 (2.00)	5	57	57.0	9
H74938162520130	5	20	8 (811)	12 (1216)	135	6 (2.00)	5	17	16.9	9
H74938162530130	5	30	8 (811)	12 (1216)	135	6 (2.00)	5	27	26.9	9
H74938162540130	5	40	8 (811)	12 (1216)	135	6 (2.00)	5	37	37.0	9
H74938162560130	5	60	8 (811)	12 (1216)	135	6 (2.00)	5	57	57.0	9

Note: The diameter of the stent may be increased post-placement by expanding with a larger diameter balloon. Do not exceed the maximum recommended expanded stent diameter.

MAGNETIC RESONANCE IMAGING (MRI) INFORMATION

MR

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 above the umbilicus (patient navel).
- Maximum WB-SAR of 1 W/kg for 15 minutes of scanning for patient landmarks below the umbilicus.

The Express LD Stent should not migrate in this MRI environment. Non-clinical testing at field strengths other than 1.5 Tesla or 3 Tesla has not been performed to evaluate stent migration or heating.

BSC (MB IFU Template 16.5354 x 11.6929 A3; 92310061IN), IFU, MB, Express LD Vasc 5, en, 52131671-01B

3.0 Tesla Temperature Information

Non-clinical testing of RF-induced heating was performed at 128 MHz in a 3.0 Tesla Magnetom Trio, Siemens Medical Solutions MR system, software version Numaris/4, syngo MR A30. The testing was according to ASTM F2182 and the stents were in a location and orientation in the phantom that produced the worst case Radio Frequency (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 1.8 W/kg. The maximal in-vitro temperature rise was 4.0 °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 the following maximal in vivo rises:

- For landmarks above the umbilicus the calculated temperature rise was 5.2 °C with an uncertainty upper bound 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.
- For landmarks below the umbilicus the calculated temperature rise was 4.1 °C with an uncertainty upper bound temperature of 5.2 °C for a whole body average SAR value of 1.0 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.

1.5 Tesla Temperature Information

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 above the umbilicus, the calculated temperature rise was 3.2 °C with an uncertainty upper bound 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.
- For landmarks below the umbilicus the calculated temperature rise was 3.2 °C with an uncertainty upper bound temperature of 4.1 °C for a whole body average SAR value of 1.0 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 beyond 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 this device include, but are not limited to, the following:

- Abscess
- Aneurysm
- Arrhythmias
- AV fistula
- Bleeding/Hemorrhage
- Death
- Drug reaction or allergic reaction (including to antiplatelet agent, contrast medium, stent materials, or other)
- Embolization of device, air, plaque, thrombus, tissue, or other
- Emergency surgery to correct vascular complications
- Extremity ischemia/amputation
- Hematoma
- Hypotension or Hypertension
- Myocardial infarction
- Pseudoaneurysm formation
- Renal Insufficiency or Renal Failure
- Restenosis of the stented artery
- Sepsis/Infection
- Stent migration
- Stent thrombosis
- Stroke, TIA, or other cerebrovascular accident
- Vessel injury, including perforation, trauma, rupture, and dissection
- Vessel occlusion

HOW SUPPLIED

- Do not use if package is opened or damaged.
- Do not use if labeling is incomplete or illegible.

Handling & Storage

Store in a cool, dry, dark place. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that products are used prior to the "Use By" date on package label.

OPERATIONAL INSTRUCTIONS

Recommended Materials

- Micropuncture™ kit
- 0.035 in (0.89 mm) Guidewire of appropriate length
- Introducer sheaths or guide catheters of appropriate size and length, and equipped with a hemostatic valve.
- Syringe (10 ml (10 cc) or greater for preparing the Premounted Stent System)
- 3 Way Stopcock
- Inflation device (20 ml (20 cc) or greater)

Application of Therapy

1. Patient Preparation

A. The percutaneous placement of the stent in a stenotic or obstructed artery should be done in an angiography/fluoroscopy procedure room. Patient preparation and sterile precautions should be the same as for any PTA procedure. Angiography/fluoroscopy should be performed to map out the extent of the lesion(s) and the collateral flow. If thrombus is present or suspected, thrombolysis should precede stent deployment using standard acceptable practice. Access vessels must be sufficiently patent, or sufficiently recanalized, to proceed with further intervention. Multiple views are necessary for appropriate vessel sizing, and angiographic magnification is suggested.

2. Device Selection

A. Estimate the distance between the lesion and the entry site to select the proper Premounted Stent System length (refer to Table 1).

B. Measure the length of the target lesion to determine the length of the stent required. Size the stent length to extend slightly proximal and distal to the lesion. The appropriate stent length should be selected based on covering the entire lesion with a single stent (Refer to Table 1).

C. Measure the diameter of the reference vessel to determine the appropriate diameter stent and delivery balloon (Refer to Table 1).

Note: To reduce the potential for vessel damage the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.

3. Device Preparation

A. Open the box and remove the sterile package. Carefully inspect the sterile package before opening it. Do not use if the integrity of the sterile package has been compromised.

B. Open the package and remove hoop with the Premounted Stent System.

C. Remove the Premounted Stent System from the hoop.

D. Verify the stent is positioned between the proximal and distal balloon markers.

Caution: Do not attempt to manually reposition the Premounted Stent in any way. Check for bends, kinks and other damage. Do not use if any defects are noted.

E. Flush the Premounted Stent System guidewire lumen with heparinized normal saline. Rinse the stent in sterile saline.

F. Prepare inflation device/syringe with diluted contrast medium. The standard inflation medium is a 1:1 mixture of contrast medium and normal saline. Do not use air or any gaseous substance as a balloon inflation medium.

G. Attach inflation device/syringe to stopcock; attach to the Premounted Stent System inflation port as indicated by "Balloon" printed on the hub.

Note: A 10 ml (10 cc) syringe is recommended for use for aspirating this device.

H. Open stopcock to the Premounted Stent System. With the distal balloon tip pointing down and placed below the level of the inflation device/syringe, pull negative pressure for 20 - 30 seconds. Carefully release to neutral for contrast fill.

I. Close stopcock to the Premounted Stent System. Purge inflation device/syringe of all air.

J. Repeat steps H and I until all air is expelled. If bubbles persist, do not use the Premounted Stent System.

K. If a syringe was used for preparation, attach a prepared inflation device to stopcock.

Note: A 20 ml (20 cc) Inflation device is recommended for use with this device.

L. Open stopcock between the Premounted Stent System and the inflation device.

4. Delivery Procedure

A. Insert the appropriate sheath or guide catheter for the selected Premounted Stent System and procedure. Reference Table 1 for the Minimum Introducer Sheath Size I.D. for this device.

Caution: Always use an appropriately sized introducer sheath for the implant procedure to protect the puncture site. It is advisable to use an introducer sheath or guide catheter that is of sufficient length so as to minimize the risk of dislodging the stent from the balloon during tracking.

B. Advance a 0.035 in (0.89 mm) guidewire of appropriate length across the target lesion.

Note: It is strongly recommended that the guidewire remain across the lesion until the procedure is complete to avoid having to regain access.

C. Pre-dilate the lesion as necessary with a balloon dilatation catheter using conventional techniques.

D. After the lesion has been properly pre-dilated, remove the dilatation catheter.

E. Backload the Premounted Stent System onto the proximal portion of 0.035 in (0.89 mm) guidewire while maintaining guidewire position across target lesion.

F. Carefully advance the Premounted Stent System into the introducer sheath or guide catheter. Ensure introducer sheath or guide catheter stability before advancing the Premounted Stent System into the vessel.

Caution: If resistance is encountered to the Premounted Stent System prior to exiting the introducer sheath or guide catheter, do not force passage. Resistance may indicate a problem and may result in damage or dislodgement to the stent if forced. Maintain guidewire placement across the lesion and remove the Premounted Stent System with introducer sheath or guide catheter as a single unit.

G. Advance Premounted Stent System over the guidewire to target lesion under direct fluoroscopic visualization.

Caution: If strong resistance is met during advancement of the Premounted Stent System, discontinue movement and determine the cause of the resistance before proceeding. If the cause of resistance cannot be determined, withdraw both the Premounted Stent System and introducer sheath or guide catheter as a single unit.

H. Utilize the proximal and distal radiopaque markers as well as the radiopaque stent as reference points to position the stent in the lesion. During positioning, verify that the stent is still centered within the marker bands and has not been dislodged. Do not deploy the stent unless it is properly centered on the balloon and properly positioned within the target lesion. If the position of the stent within the lesion is not optimal, it should be carefully repositioned or removed.

Removal of a stent that has not been expanded: Do not attempt to pull a Premounted Stent System that has not been expanded back into the introducer sheath or guide catheter, as dislodgement of the stent from the balloon may occur. The Premounted Stent System should be withdrawn until the proximal end of the stent is aligned with the distal tip of the introducer sheath or guide catheter. The introducer sheath or guide catheter and the Premounted Stent System should be removed as one unit.

I. The stent is now ready to be deployed.

5. Deployment Procedure

A. To deploy the stent, use an inflation device to slowly inflate the Premounted Stent System to at least the Nominal Pressure shown on Product Label or in Table 1. Higher pressure may be necessary to expand the stent and optimize apposition against the lesion. Balloon pressures must not exceed Rated Burst Pressure as show on Product Label or in Table 1.

Note: It is strongly recommended that the guidewire remain across the lesion until the procedure is complete to avoid having to regain access.

B. After deploying the stent, deflate the balloon by pulling negative pressure on inflation device until balloon is fully deflated.

Caution: Allow adequate time for the balloon to fully deflate prior to removal. Observe fluoroscopically that the balloon is fully deflated prior to removal.

C. Maintaining proper introducer sheath or guide catheter support, very slowly withdraw the balloon. Observe under fluoroscopy to ensure that the balloon disengages from the stent.

Caution: If resistance is encountered upon attempted removal, do not force removal, use fluoroscopy and conventional techniques to determine and remedy the cause of resistance before proceeding.

D. Confirm stent position and deployment using angiographic/fluoroscopic techniques. For optimal results when stenting renal arteries, the entire lesion should be covered by the stent with 1-2 mm of the stent extending into the aorta. Fluoroscopic visualization should be used in order to properly judge the optimum expanded stent diameter as compared to the proximal and distal reference vessel diameter.

E. If re-sizing is necessary, re-advance the SDS catheter, or another balloon catheter of appropriate size, to the stented area using standard angioplasty techniques.

F. While observing under fluoroscopy, inflate the balloon to the desired pressure, do not exceed the rated burst pressure. Do not expand the stent beyond Maximum Expanded I.D. as shown in Table 1. Deflate the balloon and follow the instructions as outlined in "Deployment Procedure" step C.

G. Reconfirm stent position and angiographic/fluoroscopic result. Repeat inflations until the desired result is achieved.

H. While maintaining negative pressure in the balloon, remove the SDS from the body through the introducer sheath or guide catheter using clockwise rotation.

Table 2. Typical Express™ LD Vascular Premounted Stent System Compliance

Pressure		Stent Inner Diameters (mm)
atm	**kPa**	**5.0**
6	608	N/A
7	709	4.66
8	811	4.72
9	912	4.77
10	1013	4.83
11	1115	4.88
12	1216	4.92
		Stent Outer Diameters (mm)
atm	**kPa**	**5.0**
6	608	N/A
7	709	5.02
8	811	5.08
9	912	5.13
10	1013	5.19
11	1115	5.24
12	1216	5.28

Nominal Pressure

Rated Burst Pressure. DO NOT EXCEED.

User should monitor stent expansion angiographically during balloon inflation.

Disposal

To minimize the risk of infection or microbial hazards after use, dispose device and packaging as follows:

After use, device may contain biohazardous substances. The device and packaging should be treated and disposed of as biohazardous waste or have them treated and disposed of in accordance with any applicable hospital, administrative, and/or local government regulations. Use of a biohazardous container with biological hazard symbol is recommended. Untreated biohazardous waste should not be disposed of in the municipal waste system.

Post-Procedure

Assess patient for hematoma and/or other signs of bleeding at the puncture site.

Determine appropriate antiplatelet therapy based on the Inter-Society Consensus (TASC II) Guidelines recommendations (or other applicable country guidelines) for antiplatelet therapy post-procedure to reduce the risk of thrombosis.

Patients who require premature discontinuation of antiplatelet therapy due to significant active bleeding or the expectation of significant active bleeding should be monitored carefully for cardiovascular and thromboembolic events and once stabilized have their antiplatelet therapy restarted without unnecessary delay.

Any serious incident that occurs in relation to this device should be reported to the manufacturer and relevant local regulatory authority.

Implantable Device Patient Information

Advise the patient that additional information may be available to them on the Boston Scientific website (www.bostonscientific.com/patientlabeling).

Implant Card Instructions

Apply the peel-off label from the product onto the supplied patient implant card.

Fill in the implant date, patient name, healthcare institution and/or physician information.

Give the completed card to the patient.

PATIENT COUNSELING INFORMATION

The physician should consider the following points while counseling patients on the use of Express LD Vascular stent in association with the interventional procedure:

- Discuss the risks and benefits including review of potential adverse events listed in this document, both for Express LD Vascular stent and for other interventional treatments likely to be employed.
- Discuss patient allergies in particular the risk for patients who may be allergic to stainless steel or its components (for example nickel) or contrast.
- Discuss the risks and benefits of antiplatelet therapy including risk of thromboembolism should the patient be allergic or discontinue use.
- Discuss post procedure instructions, including any follow-up appointments, lifestyle changes, medications, and home-care or rehabilitation guidelines.
- Provide the patient with the completed implant card to carry and advise the patient that additional information, including MRI conditions, may be available to them on the Boston Scientific website (www.bostonscientific.com/patientlabeling).
- Instruct the patient to present the implant card to their Healthcare professionals (doctors, dentist, technicians) so they can take the necessary precautions.

Expected Lifetime:

- The Express LD Vascular stent is a permanent implantable and has been tested for structural integrity (fracture resistance) for a minimum of 10 years; however, the materials of the device are nonbiodegradable and are intended to last for the lifetime of the patient.

WARRANTY

For device warranty information, visit (www.bostonscientific.com/warranty).

SYMBOL DEFINITIONS

Commonly used medical device symbols that appear on the labeling are defined at www.bostonscientific.com/SymbolsGlossary.

Additional symbols are defined at the end of this document.

MB Drawing 51308373

Black (K) ΔE ≤5.0

BSC (MB IFU Template 16.5354 x 11.6929 A3,92310061IN), IFU, MB, Express LD Vasc 5, en, 52131671-01B