### DEVICE DESCRIPTION

The Express SD Renal Monorail Premounted Stent System consists of a single grade stainless steel balloon expandable stent. The stent is premounted on a Monorail Stent Delivery System (SDS) equipped with a semi-compliant balloon. The SDS has two radiopaque balloon markers embedded in the shaft to aid in the placement of the stent. The SDS is compatible with 0.014 in (0.36 mm) or 0.018 in (0.46 mm) guidewires. The SDS balloon has a maximum inflation pressure of 14 atm (1419 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 premounted stent system balloons that expand them from 4 mm to 7 mm in diameter. The premounted stent system balloon catheter is also offered in two shaft lengths. Table 1 summarizes individual product descriptions and nominal specifications.

**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 SD Renal Monorail Premounted Stent System is indicated for use as an adjunct to percutaneous transluminal renal angioplasty (PTRA) of a single de novo or restenotic atherosclerotic lesion (≤ 15 mm in length) of the renal artery, located within 5 mm of the opacified aortic lumen and with a reference vessel diameter of 4.0 mm to 7.0 mm to assist in maintenance of vessel patency.

**CONTRAINDICATIONS**

Generally, contraindications for Percutaneous Transluminal Renal Angioplasty (PTRA) of a single de novo or restenotic atherosclerotic lesion (≤ 15 mm in length) of the renal artery, located within 5 mm of the opacified aortic lumen and with a reference vessel diameter of 4.0 mm to 7.0 mm to assist in maintenance of vessel patency.

- Patients with uncorrected bleeding disorders or patients who cannot receive anticoagulation or antiplatelet aggregation therapy
- Patients 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 with a target lesion with a large amount of adjacent acute or subacute thrombus
- Patients with excessive vessel tortuosity
- Patients with perforated vessels evidenced by extravasation of contrast media
- Patients with a lesion that cannot be crossed with a wire and/or a balloon catheter

### WARNINGS

Do not exceed the maximum rated burst pressure. 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 embolism 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.

Do not exceed the maximum expanded stent diameter. 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. Overstretching 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).

Patients with lesions in arteries of transplanted or bypassed kidneys are not recommended for stent implantation.

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### Table 1. Express SD Renal Monorail Premounted Stent System Specifications

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Crimped Stent Length (mm)</th>
<th>Balloon Size</th>
<th>Catheter Usable Length (cm)</th>
<th>Stent Opening Pressure [atm (kPa)]</th>
<th>Nominal Pressure [atm (kPa)]</th>
<th>Max. Rated Burst Pressure [atm (kPa)]</th>
<th>Max. Expanded Stent Diameter (mm)</th>
<th>Minimum Guide Catheter size [F (in)]</th>
<th>Minimum Introducer Sheath size [F (in)]</th>
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<td>10 (1013)</td>
<td>14 (1419)</td>
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<td>6 (0.064)</td>
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<td>10 (1013)</td>
<td>14 (1419)</td>
<td>8.0</td>
<td>7 (0.078)</td>
</tr>
</tbody>
</table>
The long-term outcome (beyond nine months) for this permanent implant is unknown at present. Stent placement should only be performed at hospitals where emergency peripheral artery bypass graft surgery, including renal 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. Note: Patients with serum creatinine >3.0 mg/dl were excluded from the Renaissance clinical study.

Pre-packaging/FIT should be performed on per instructions given in Operational Instructions. Significant amounts of air in the balloon may decrease the pressure in the balloon.

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

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

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 pre-mounted stent system catheter through a smaller size sheath or guide catheter than indicated on the label.

When a pre-mounted 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 pre-mounted stent system without the guidance wire 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.

To assure full expansion, inflate the pre-mounted stent system to at least the opening pressure as shown on the labeling and in Table 1. To assure nominal sizing of the stent, inflate the pre-mounted stent system to nominal pressure as shown on the labeling and in 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. The second implanted stent should also be an Express™ SD Renal 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.

Recruiting a previously deployed stent with adjunct devices must be performed with extreme caution to ensure that the stent does not get caught within previously placed stent struts. 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. Use prior to the “Use By” date.

MAGNETIC RESONANCE IMAGING (MRI) INFORMATION

Magnetic Resonance Conditional

Non-clinical testing has demonstrated that the Express SD Stent is MR Conditional for single and overlapping lengths up to 32 mm. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla.
- Maximum spatial gradient magnetic field of 1600 Gauss/cm (19 T/m) or less.
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).

Under the scan conditions defined above, the Express SD Stent is expected to produce a maximum temperature rise of less than 2.0°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 11.4 mm from the Express SD Stent when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artifact obscures the device lumen.

Recommendations

It is recommended that patients register the conditions under which the implant can be scanned safely with the MedicalAlert Foundation (www.medicalert.org) or an equivalent organization.

ADVERSE EVENTS

Potential complications associated with the use of vascular stents may include, but are not limited to:

- Abscess
- Acute myocardial infarction
- Acute or sub acute thrombosis
- Aneurysm
- Arhythmias, including VF and VT
- Artery injury, including perforation and dissection
- AV fistula
- Bowel infarct
- Death
- Drug reaction, allergic reaction to contrast medium
- Emboli or air
- Embolization of atherosclerotic thrombotic materials
- Emergency surgery to correct vascular complications
- Extremity ischemia/amputation
- GI symptoms from anticoagulation/antiplatelet medication
- Hemorrhage/Hematoma
- Hypotension or Hypertension
- Intimal tear
- Kidney infarct
- Nephrectomy
- Pseudoaneurysm formation
- Renal failure
- Restenosis of the stented artery
- Rupture of retro-peritoneal or of neighboring organ
- Rupture, overstretching of vessel
- Sepsis/Infection
- Stent embolization
- Stent migration
- Stent misplacement
- Stroke or other cerebrovascular accidents
- Thromboembolic event
- Tissue necrosis
- Total occlusion

CLINICAL STUDIES

BSC Renaissance Clinical Trial Safety Data

A total of 100 subjects were enrolled in this prospective, single-arm study at 15 centers (involving 14 sites). Table 2 presents the major clinical events for the Renaissance trial through 9 months post-index stenting procedure. There were no in-hospital Major Adverse Events. There were two (2.1%) Significant Embolic Events, eight (8.4%) Target Lesion Resascularizations and no reported stent thromboses. One subject died prior to the 9 month primary endpoint. The death was adjudicated to be neither device nor procedure related.

Table 2. Principal Safety Results through 9 Months

<table>
<thead>
<tr>
<th></th>
<th>Safety Measures</th>
<th>(N=117 Lesions)</th>
<th>(95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-Month TLR (per lesion)</td>
<td>8.1% (10/111)</td>
<td>[3.8%, 14.8%]</td>
<td></td>
</tr>
<tr>
<td>9-Month TVR (per lesion)</td>
<td>14.4% (16/111)</td>
<td>[8.5%, 22.4%]</td>
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</tr>
<tr>
<td>9-Month MACE (per subject)</td>
<td>10.5% (10/95)</td>
<td>[5.2%, 18.5%]</td>
<td></td>
</tr>
<tr>
<td>Device-Related Death</td>
<td>0.0% (0/95)</td>
<td>[0.0%, 3.8%]</td>
<td></td>
</tr>
<tr>
<td>Index Procedure-Related Death</td>
<td>0.0% (0/95)</td>
<td>[0.0%, 3.8%]</td>
<td></td>
</tr>
<tr>
<td>TLR (per subject)</td>
<td>8.4% (9/95)</td>
<td>[3.7%, 15.9%]</td>
<td></td>
</tr>
<tr>
<td>Major Embolic Events</td>
<td>2.1% (2/95)</td>
<td>[0.3%, 7.4%]</td>
<td></td>
</tr>
<tr>
<td>Safety Measures Death</td>
<td>(N=117 Subjects) (N=117 Lesions)</td>
<td>(95% CI)</td>
<td></td>
</tr>
<tr>
<td>Stent Thrombosis (per subject)</td>
<td>0.0% (0/100)</td>
<td>[0.0%, 3.6%]</td>
<td></td>
</tr>
<tr>
<td>Acute Stent Thrombosis (≥24 hours)</td>
<td>0.0% (0/100)</td>
<td>[0.0%, 3.6%]</td>
<td></td>
</tr>
<tr>
<td>Subacute Stent Thrombosis (&lt;24 hours to ≤30 days)</td>
<td>0.0% (0/100)</td>
<td>[0.0%, 3.6%]</td>
<td></td>
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<tr>
<td>Late Stent Thrombosis (≥30 days to &lt;30 days)</td>
<td>0.0% (0/100)</td>
<td>[0.0%, 3.6%]</td>
<td></td>
</tr>
<tr>
<td>Major Hemorrhagic/ Vascular Complication through 30 Days (per subject)</td>
<td>2.0% (2/100)</td>
<td>[0.2%, 7.0%]</td>
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<td>Intracranial Hemorrhage</td>
<td>0.0% (0/100)</td>
<td>[0.0%, 3.6%]</td>
<td></td>
</tr>
<tr>
<td>GI Bleeding</td>
<td>0.0% (0/100)</td>
<td>[0.0%, 3.6%]</td>
<td></td>
</tr>
<tr>
<td>Bleeding at the access site</td>
<td>0.0% (0/100)</td>
<td>[0.0%, 3.6%]</td>
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</tr>
<tr>
<td>Other Bleeding</td>
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<td>[0.2%, 7.0%]</td>
<td></td>
</tr>
<tr>
<td>Minor Hemorrhagic/ Vascular Complication (per subject)</td>
<td>4.0% (4/100)</td>
<td>[1.1%, 9.9%]</td>
<td></td>
</tr>
</tbody>
</table>

BSC Renaissance Clinical Trial Safety Data

- **Non-Observing pseudoaneurysm, AV fistula, hematoma of any size, and/or retroperitoneal bleeding** that requires transfusion ≥1 unit packed red blood cells and/or surgical repair (surgical repair ≥1 FU, US guided compression or other percutaneous intervention) through ≥30 days post procedure.
- **Early bleeding** which does not require surgical repair or ≥1 unit packed red blood cells (e.g. seeping from access site, drop in Hg/Kg).

Alternate Text: **BSC Renaissance Clinical Trial Safety Data**

- **Non-Observing pseudoaneurysm, AV fistula, hematoma of any size, and/or retroperitoneal bleeding** that requires transfusion ≥1 unit packed red blood cells and/or surgical repair (surgical repair ≥1 FU, US guided compression or other percutaneous intervention) through ≥30 days post procedure.
- **Early bleeding** which does not require surgical repair or ≥1 unit packed red blood cells (e.g. seeping from access site, drop in Hg/Kg).
Table 3. Freedom from MAE to 9 month Follow-up, Intent-to-Treat, Event-Free Survival ± 1.96 SE, All Subjects (N=100)

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<th>14</th>
<th>30</th>
<th>60</th>
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<tr>
<td>Event-Free</td>
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<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>99%</td>
<td>96%</td>
<td>93.9%</td>
<td>92.8%</td>
<td>89.6%</td>
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<td>Std Error - Greenwood</td>
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<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>1.0%</td>
<td>2.0%</td>
<td>2.4%</td>
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<tr>
<td>Std Error - Peto</td>
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<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>1.0%</td>
<td>2.0%</td>
<td>2.5%</td>
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<tr>
<td>Peto’s Lower Limit</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
<td>97.4%</td>
<td>92.7%</td>
<td>89.9%</td>
<td>88.4%</td>
<td>84.4%</td>
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Intervals are end inclusive, e.g. interval 121-180 days, inclusive. Event-free and standard error estimates are for interval end. Standard errors by Greenwood formula. Bars at selected time point show 95% confidence interval (event-free survival ± 1.96 SE (by Greenwood formula)). Peto’s standard error estimates and lower limit are also presented.

BSC Renaissance Clinical Trial

Objective: The primary objective of the study was to demonstrate superior 9-month binary restenosis rate for the Express® SD Renal Monorail® Premounted Stent System as compared to an Objective Performance Criterion (OPC) representative of PTRA, for atherosclerotic lesions in the aortorenal ostium.

Design: Renaissance was a prospective, single arm, multi-center study conducted at 15 centers, involving 14 distinct investigative sites enrolling a total of 100 subjects. Subjects were ≥18 years old who met at least one renal inclusion criteria that were eligible for percutaneous transluminal renal angioplasty (PTA) and stenting. Subjects were required to have a 9-month renal duplex ultrasound to assess for evidence of significant stenosis. Subjects with positive duplex ultrasound findings were required to have confirmatory angiography.

Endpoints: The primary endpoint for the Renaissance clinical trial was the binary in-stent restenosis rate at 9 months, defined as the proportion of target lesions with >50% diameter stenosis based on Anaglogic Core Lab assessment. The primary analysis was a lesion-based analysis. Subjects were required to have a 9-month renal duplex ultrasound to assess for evidence of significant stenosis. Subjects with positive duplex ultrasound findings were required to have confirmatory angiography.

Secondary endpoints included:
- technical success of ≥30% residual stenosis immediately after stent deployment, including post-dilatation
- procedural success of ≥80% residual diameter stenosis without the occurrence of in-hospital major adverse events (MAE)
- target lesion revascularization (TLR)
- target vessel revascularization (TVR)
- change (improvement) in renal function defined as a change in serum creatinine and/or change in glomerular filtration rate (GFR) as estimated by Cockcroft-Gault formula
- change in renal to aortic ratio, resistive index, and peak systolic velocity, change (improvement) in hypertension control defined as a change in arterial systolic and diastolic blood pressure relative to hypertension medication
- major or minor hemorrhagic/vascular complications
- major adverse events (MAEs) defined as device or index procedure related death, target lesion revascularization (TLR)
- significant embolic event (causing end-organ damage, e.g., unanticipated kidney/bowel infarct, lower extremity ulceration or gangrene, or loss of kidney function)
- stent thrombosis

The primary endpoint will be met if the in-stent restenosis rate is statistically significantly lower than the OPC for failed PTRA, denoted as 40%. The primary endpoint for the Renaissance clinical trial indicated 48% were males. The average age was 71.4 (range 41 to 85 years), 26% of those enrolled had medically treated diabetes, 77% had a history of hyperlipidemia, 99% had hypertension requiring medication and 69% were current or previous smokers. Baseline lesion characteristics included average reference vessel diameter (RVD) of 5.1 mm, average minimum lumen diameter (MLD) of 1.6 mm, average percent diameter stenosis (%DS) of 68.4% and average lesion length of 8.8 mm.

Table 4. Baseline Demographics and Clinical Characteristics Intent-to-Treat, All Subjects (N=100)

<table>
<thead>
<tr>
<th>Variable</th>
<th>(N=100)</th>
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<tbody>
<tr>
<td>Age (Years)</td>
<td>71.4±9.0 (100)</td>
</tr>
<tr>
<td>Male</td>
<td>48.0% (48/100)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>97.0% (97/100)</td>
</tr>
<tr>
<td>Black, African Heritage</td>
<td>3.0% (3/100)</td>
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<tr>
<td>Asian</td>
<td>0.0% (0/100)</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
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<td>0.0% (0/100)</td>
</tr>
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<tr>
<td>Known Prior PCI</td>
<td>37.1% (36/97)</td>
</tr>
<tr>
<td>Known Prior CABG</td>
<td>27.0% (27/100)</td>
</tr>
<tr>
<td>Known Previous MI</td>
<td>20.6% (20/97)</td>
</tr>
<tr>
<td>Known CHF</td>
<td>17.3% (16/98)</td>
</tr>
<tr>
<td>Known Unstable Angina</td>
<td>3.1% (3/98)</td>
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<tr>
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<tr>
<td>Known Peripheral Vascular Surgery</td>
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</tr>
<tr>
<td>Prior Renal Percutaneous Intervention</td>
<td>4.0% (4/98)</td>
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<td>1.0% (1/98)</td>
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<tr>
<td>Stenting</td>
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<td>Other Peripheral Endovascular Interventions</td>
<td>5.1% (5/99)</td>
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<td>Known TIA</td>
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<tr>
<td>Non-Insulin Requiring</td>
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<tr>
<td>Known Hyperlipidemia</td>
<td>76.5% (75/98)</td>
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<tr>
<td>Previous Hypertension</td>
<td>1.0% (1/100)</td>
</tr>
</tbody>
</table>

*Responses of “Unknown” to the questions included in the Medical History and Risk Factors are not presented in this exhibit.

#References:
*^{4}$ Defined as Current Smoker (within past 6 months) or Previous Smoker (> 6 months ago).

*Defined as Current Smoker (within past 6 months) or Previous Smoker (> 6 months ago).

Figure 1. Freedom from MAE to 9 month Follow-up, Intent-to-Treat, Event-Free Survival ± 1.96 SE, All Subjects (N=100)
Methods: Clinical or telephone follow-up is to be conducted in-hospital, 30-days, 4 months, 9 months and annually through 5 years post procedure. Follow-up duplex ultrasonography was conducted in 93% (83/100) of the Renal artery subjects enrolled. Baseline, post-procedure and 9 month follow-up data were collected and assessed by an independent core laboratory. Baseline, post-procedure and follow-up angiographic data were collected and assessed by quantitative analysis by a core laboratory. An independent Clinical Events Committee adjudicated major adverse events and stent thrombosis.

Results: All subjects enrolled in the Renaissance trial received an Express® SD Renal Stent. Procedural success was achieved in 99.0% of subjects with technical success being achieved in 99.5% of 117 lesions. The 1 failure for technical and procedural success was due to a >30% residual stenosis post-procedure noted by visual assessment.

As shown in Table 5 the in-stent binary restenosis rate at 9 months (270 days) was statistically significantly lower than the ODC (21.3% vs. 40.6%, p<0.0001) thus demonstrating a superior restenosis rate compared to PTRA for treatment of atherosclerotic lesions in the aortorenal system.

Conclusion: Overall the Renaissance trial demonstrated the Express SD Renal Stent to be safe and effective for the treatment of renal artery stenosis.

**Table 5. Principal Effectiveness**

<table>
<thead>
<tr>
<th>Effectiveness Measures</th>
<th>[N=100 Subjects] (N=117 Lesions) CI (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical Success (per lesion)</td>
<td>99.1% (116/117) CI: 95.3%, 100.0%</td>
</tr>
<tr>
<td>Procedural Success (per subject)</td>
<td>99.0% (99/100) CI: 94.6%, 100.0%</td>
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<tr>
<td>9-Month Binary In-Stent Restenosis (per lesion)</td>
<td>21.3% (23/108) CI: 14.0%, 30.2%</td>
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</tbody>
</table>

Do not store catheters where they are directly exposed to organic solvents or ionizing radiation. Excessive aging may cause the polymers used in these products to deteriorate. Rotate inventory so that the catheters and other dated products are used prior to the “Use By” date shown on the label.

**Non-lyeronic**

- One [1] Express SD Renal Monorail® Premounted Stent System
- One [1] Electronic DU Reference Card

**OPERATIONAL INSTRUCTIONS**

Recommended Materials:

- Micropuncture™ kit
- 0.014 in (0.36 mm) or 0.018 in (0.46 mm) Guide wire of appropriate length
- Introducer/Guide sheaths of appropriate size and length, and equipped with a hemostatic valve
- Luer-lock Syringe (10 cm(10 cc) or greater for preparing the premounted stent system)
- 3 Way Stopcock
- Inflation device (20 cm(20 cc) or greater)
- Guide Catheter of appropriate size and length
- Y-Adapter

**STENT PLACEMENT PROCEDURE**

**Patient Preparation**

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 PTRA procedure. Angiography/fluoroscopy should be performed to map out the extent of the lesion(s) and the collateral flow. Access vessels must be sufficiently patent, to proceed with further intervention. Multiple views are necessary for appropriate vessel sizing, and angiographic magnification is suggested.

**Select Proper Premounted Stent System**

1. Estimate the distance between the lesion and the entry site
2. Follow the implant procedure. It is advisable to use a sheath or guide catheter that is long enough to cover the lesion. Use of a guide sheath or guide catheter minimizes the risk of dislodging the stent from the balloon during tracking.

**Delivery Procedure**

1. Insert the appropriate sheath or guide catheter for the selected premounted stent system and procedure. Reference Table 1 for the minimum acceptable size for this device.

**Note:** Always use an appropriately sized sheath for the implant procedure. It is advisable to use a sheath or guide catheter that is long enough to cross the lesion. Use of a guide sheath or guide catheter minimizes the risk of dislodging the stent from the balloon during tracking.

2. Advance e 0.014 in (0.36 mm) or 0.018 in (0.46 mm) guidewire of appropriate length across 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.

3. Pre-dilate the lesion as necessary with a balloon dilatation catheter of appropriate size using conventional techniques.

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

2. 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 distal to the stenosis.

3. 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).

**Prepare the Premounted Stent System**

1. Do not use product after the “Use By” date indicated on the package.

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

3. Open package and remove hoop with premounted stent system.

4. Remove the premounted stent system from the hoop.

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

**Stent: A 10 cm(10 cc) luer-lock syringe is recommended for use for aspirating this device.**

9. Open stent to 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 seconds to 30 seconds. Carefully release to neutral for contrast fill.

10. Close stent to the premounted stent system; purge inflation device/syringe of all air.

11. Repeat steps 9 and 10 until all air is expelled. If bubbles persist, do not use the premounted stent system.

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

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

13. Open stopcock between the premounted stent system and the inflation device.

HOW SUPPLIED

Store in a cool, dry, dark place.

Do not store if package is opened or damaged.

Do not use if labeling is incomplete or illegible.
5. Backload the premounted stent system onto proximal portion of guidewire while maintaining guidewire position across target lesion.

6. Carefully advance the premounted stent system into the hemostasis valve of the sheath or Y-adapter attached to the guide catheter. Ensure sheath/guide stability before advancing the premounted stent system into the vessel.

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

7. 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 sheath or guide catheter as a single unit.

8. 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. Position stent so 1 mm to 2 mm of the proximal end is extending into aorta. 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 been partially expanded back into the 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 sheath or guide catheter. The sheath or guide catheter and premounted stent system should be removed as one unit.

   Deployment Procedure

1. To deploy the stent, use an inflation device to slowly inflate the premounted stent system to at least the opening pressure shown in Table 1. Higher pressure may be necessary to optimize apposition against the lesion. Balloon pressures must not exceed rated burst pressure (14 atm/1419 kPa).

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

2. After deploying the stent, slowly deflate the balloon manually using the inflation device to ensure proper balloon rewrap.

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

3. Position the sheath or guide to a coaxial position with the balloon catheter.

4. Maintaining proper 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.

5. Confirm stent position and deployment using angiographic techniques. For optimal results, the entire lesion should be covered by the stent with 1 mm to 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.

6. 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.

7. 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 stent diameter as shown in Table 1. Deflate the balloon and follow the instructions as outlined in “Deployment Procedure” steps 3 and 4.

8. Reconfirm stent position and angiographic result. Repeat inflations until the desired result is achieved.

9. While maintaining negative pressure in the balloon, remove the SDS from the body through the sheath or guide catheter.

Table 7. Typical Express® SD Renal Monorail® Premounted Stent System Compliance

<table>
<thead>
<tr>
<th>Pressure (atm-kPa)</th>
<th>Stent I.D. (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4.0 mm</td>
</tr>
<tr>
<td>8.0 - 811</td>
<td>3.70</td>
</tr>
<tr>
<td>9.0 - 912</td>
<td>3.82</td>
</tr>
<tr>
<td>10.0 - 1013</td>
<td>Nominal</td>
</tr>
<tr>
<td>11.0 - 1115</td>
<td>4.02</td>
</tr>
<tr>
<td>12.0 - 1216</td>
<td>4.11</td>
</tr>
<tr>
<td>13.0 - 1317</td>
<td>4.20</td>
</tr>
<tr>
<td>14.0 - 1419*</td>
<td>4.27*</td>
</tr>
</tbody>
</table>

*Rated Burst Pressure. DO NOT EXCEED.

User should confirm stent diameter angiographically during balloon inflation.

**WARRANTY**

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.

Micropuncture is a registered trademark of Cook, Inc.
Express® SD Biliary

Premounted Stent System

**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 patient 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 NAME**

Express SD Biliary Monorail Premounted Stent System.

**DEVICE DESCRIPTION**

The Express SD Biliary Monorail Premounted Stent System consists of:

- A 316L surgical grade stainless steel balloon expandable stent. The stent is pre-mounted on a Monorail Stent Delivery System (SDS) equipped with a semi- compliant balloon.

- The SDS balloon catheter has two radiopaque markers embedded in the shaft to aid in the placement of the stent.

- The pre-mounted stent system is compatible with 0.014 inch (0.36 mm) or 0.018 inch (0.46 mm) guidewires. The Premounted Stent System balloon has a maximum inflation pressure of 14 atm (1419 kPa) that can be used for initial stent placement and post stent dilation.

- The Premounted Stent System is available in a variety of stent lengths with pre-mounted stent system balloons that expand from 4 mm to 7 mm in diameter. The Premounted Stent System balloon catheter is also offered in two shaft lengths. Table 1 summarizes individual product descriptions and nominal specifications.

**INTENDED USE/INDICATIONS FOR USE**

The Express SD Biliary Monorail Premounted Stent System is indicated for palliation of malignant neoplasms in the biliary tree.

**CONTRAINDICATIONS**

Contraindications associated with the use of the Express SD Biliary Monorail Premounted Stent System as a transhepatic endoprosthesis include:

- Stenting of a perforated duct where leakage from the duct could be exacerbated by the prosthesis.

- Patients with bleeding disorders.

- Severe ascites.

**WARNINGS**

- 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 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 maximum rated burst pressure.

- Persons with allergic reactions to stainless steel may suffer an allergic response to the implant.

- Do not expose the Premounted Stent System to organic solvents (i.e., alcohol).

- To reduce the potential for patient injury, the inflated diameter of the balloon should approximate the diameter of the duct just proximal and distal to the stricture. Overstretching of the duct may result in patient injury.

- Stenting across a bifurcation could compromise future diagnostic or therapeutic procedures.

**PRECAUTIONS**

- The device is intended for use by physicians who have received appropriate training.

- 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.

- Do not attempt to pull a stent that has not been expanded back through an introducer sheath, since dislodgment of the stent may result. If a stent that has not been expanded needs to be removed, the introducer sheath and the Premounted Stent System should be removed as a unit.

- When treating multiple strictures, the stricture distal to the puncture site should be initially stented, followed by stenting of the proximal stricture. 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 with the SDS balloon or the Premounted Stent System or dislodging the stent from the SDS balloon.

- 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.

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

- The minimally acceptable introducer sheath French size is printed on the package label. Do not attempt to pass the pre-mounted stent system through a smaller introducer sheath than indicated on the label.

- When catheters are 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.

- 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 stricture is not fully covered, use additional stents as necessary to adequately treat the structure.

- To ensure expansion of the premounted stent, inflate the Premounted Stent System to at least the opening pressure as shown on the label. To assure nominal sizing of the stent, inflate the Premounted Stent System to nominal pressure as shown on the label.

- 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 duct. If the position of the stent is not optimal, it should not be expanded.

**Table 1. Express SD Biliary Monorail Premounted Stent System Specifications**

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Crimped Stent Length (mm)</th>
<th>Balloon Size</th>
<th>Catheter Usable Length (cm)</th>
<th>Max Rated Burst Pressure atm (kPa)</th>
<th>Max Expanded Stent Diameter (mm)</th>
<th>Minimum Guide Introducer Sheath Size [F (in)]</th>
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<tr>
<td>H74018711415900</td>
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<td>20</td>
<td>150</td>
<td>14</td>
<td>8</td>
</tr>
</tbody>
</table>

Express SD stent may exhibit foreshortening of <17% at nominal diameter.
1. To deploy the stent, slowly inflate the Premounted Stent System with an inflation device. Higher pressure may be necessary to optimize apposition against the stricture.

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

3. 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 that is long enough to cross the stricture. Use of an introducer sheath minimizes the risk of dislodging the stent from the balloon during tracking.

4. Advance a 0.014 in (0.36 mm) or 0.018 in (0.46 mm) guidewire of appropriate length across target stricture.

5. Carefully advance the Premounted Stent System into the introducer sheath. Ensure introducer sheath stability before advancing the Premounted Stent System into the duct.

6. Utilize the proximal and distal radiopaque balloon markers as well as the radiopaque stent as reference points to position the stent in the stricture. 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 stricture. If the position of the stent within the stricture is not optimal, it should be carefully repositioned or removed.

7. Note: 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.

8. Do not try to manually reposition the premounted stent. Do not use if any defects are noted. Do not attempt to reposition or remove 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, 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. The introducer sheath and Premounted Stent System should be removed as one unit.

9. Deployment Procedure

1. The stent system, inflated balloon catheter, is intended to close the stricture. Proper inflation is necessary to optimize apposition against the stricture. Balloon pressures must not exceed the rated burst pressure (14 atm/1419 kPa) of the device if the cause of resistance cannot be determined. Do not reposition or remove the Premounted Stent System prior to exiting the introducer sheath, 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. The introducer sheath and Premounted Stent System should be removed as one unit.

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

3. 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 that is long enough to cross the stricture. Use of an introducer sheath minimizes the risk of dislodging the stent from the balloon during tracking.

4. Advance a 0.014 in (0.36 mm) or 0.018 in (0.46 mm) guidewire of appropriate length across target stricture.

5. Carefully advance the Premounted Stent System into the introducer sheath. Ensure introducer sheath stability before advancing the Premounted Stent System into the duct.

6. Utilize the proximal and distal radiopaque balloon markers as well as the radiopaque stent as reference points to position the stent in the stricture. 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 stricture. If the position of the stent within the stricture is not optimal, it should be carefully repositioned or removed.

7. Note: 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.

8. Do not try to manually reposition the premounted stent. Do not use if any defects are noted. Do not attempt to reposition or remove 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, 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. The introducer sheath and Premounted Stent System should be removed as one unit. Implementation of an intraluminal stent system is intended to close the stricture. Proper inflation is necessary to optimize apposition against the stricture. Balloon pressures must not exceed the rated burst pressure (14 atm/1419 kPa) of the device if the cause of resistance cannot be determined. Do not reposition or remove the Premounted Stent System prior to exiting the introducer sheath, 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. The introducer sheath and Premounted Stent System should be removed as one unit.

9. Deployment Procedure

1. The stent system, inflated balloon catheter, is intended to close the stricture. Proper inflation is necessary to optimize apposition against the stricture. Balloon pressures must not exceed the rated burst pressure (14 atm/1419 kPa) of the device if the cause of resistance cannot be determined. Do not reposition or remove the Premounted Stent System prior to exiting the introducer sheath, 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. The introducer sheath and Premounted Stent System should be removed as one unit.

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

3. 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 that is long enough to cross the stricture. Use of an introducer sheath minimizes the risk of dislodging the stent from the balloon during tracking.

4. Advance a 0.014 in (0.36 mm) or 0.018 in (0.46 mm) guidewire of appropriate length across target stricture.

5. Carefully advance the Premounted Stent System into the introducer sheath. Ensure introducer sheath stability before advancing the Premounted Stent System into the duct.

6. Utilize the proximal and distal radiopaque balloon markers as well as the radiopaque stent as reference points to position the stent in the stricture. 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 stricture. If the position of the stent within the stricture is not optimal, it should be carefully repositioned or removed.

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3. Maintaining proper introducer sheath 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.

4. Confirm stent position and deployment using fluoroscopic techniques. For optimal results, the entire stricture should be covered by the stent. Fluoroscopic visualization should be used in order to properly judge the optimum expanded stent diameter as compared to the proximal and distal reference duct diameter.

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

6. 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 stent diameter as shown in Table 1. Deflate the balloon and follow the instructions as outlined in step 3 above.

7. Reconfirm stent position and fluoroscopic result. Repeat inflations until the desired result is achieved.

8. While maintaining negative pressure in the balloon, remove the SDS from the body and through the introducer sheath.

Table 2. Typical Express® SD Biliary Monorail® Premounted Stent System Compliance

<table>
<thead>
<tr>
<th>Pressure (atm-kPa)</th>
<th>Stent I.D. (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.0</td>
<td>5.0 mm</td>
</tr>
<tr>
<td>5.0</td>
<td>6.0 mm</td>
</tr>
<tr>
<td>6.0</td>
<td>7.0 mm</td>
</tr>
<tr>
<td>8.0 - 8.11</td>
<td>3.70</td>
</tr>
<tr>
<td>9.0 - 9.12</td>
<td>3.82</td>
</tr>
<tr>
<td>10.0 - 10.13 Nominal</td>
<td>3.93</td>
</tr>
<tr>
<td>11.0 - 11.15</td>
<td>4.02</td>
</tr>
<tr>
<td>12.0 - 12.16</td>
<td>4.11</td>
</tr>
<tr>
<td>13.0 - 13.17</td>
<td>4.20</td>
</tr>
<tr>
<td>14.0 - 14.19*</td>
<td>4.27*</td>
</tr>
</tbody>
</table>

*Rated Burst Pressure. DO NOT EXCEED.

User should confirm stent diameter fluoroscopically during balloon inflation.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.

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