Boston Scientific

Express™ SD Renal

MONORAIL™

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 Renal Monorail Premounted Stent System.

DEVICE DESCRIPTION:

The Express SD Renal Monorail Premounted Stent System consists of: 316L surgical 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 .014 in. (0.36 mm) or .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.

This product contains no detectable latex.

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 - 7.0 mm to assist in maintenance of vessel patency.

CONTRAINDICATIONS:

Generally, contraindications for Percutaneous Transluminal Renal Angioplasty (PTRA) are also contraindications for stent placement. Contraindications associated with the use of the Express SD Renal Monorail Premounted Stent System include:

- 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 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 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.

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 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.

Table 1. Express SD Renal Monorail Premounted Stent System Specifications

Product Code	Crimped Stent Length (mm)	Balloon Size		Catheter Usable Length (cm)	Stent Opening Pressure [atm (kPa)]	Stent Nominal Pressure [atm (kPa)]	Max. Rated Burst Pressure [atm (kPa)]	Max. Expanded Stent Diameter (mm)	Minimum Guide Catheter size [Fr (I.D. in.)]	Minimum Introducer Sheath size [Fr (I.D. in.)]
		Dia. (mm)	Length (mm)							
H74937911415900	15	4	16	90	8 (812)	10 (1013)	14 (1419)	6.0	6 (.064)	5 (.074)
H74937912419900	19	4	20	90	8 (812)	10 (1013)	14 (1419)	6.0	6 (.064)	5 (.074)
H74937911515900	15	5	16	90	8 (812)	10 (1013)	14 (1419)	6.0	6 (.067)	5 (.074)
H74937912519900	19	5	20	90	8 (812)	10 (1013)	14 (1419)	6.0	6 (.067)	5 (.074)
H74937911614900	14	6	15	90	8 (812)	10 (1013)	14 (1419)	7.0	6 (.067)	5 (.074)
H74937912618900	18	6	19	90	8 (812)	10 (1013)	14 (1419)	7.0	6 (.067)	5 (.074)
H74937911715900	15	7	16	90	8 (812)	10 (1013)	14 (1419)	8.0	7 (.078)	6 (.087)
H74937912719900	19	7	20	90	8 (812)	10 (1013)	14 (1419)	8.0	7 (.078)	6 (.087)
H74937911415150	15	4	16	150	8 (812)	10 (1013)	14 (1419)	6.0	6 (.064)	5 (.074)
H74937912419150	19	4	20	150	8 (812)	10 (1013)	14 (1419)	6.0	6 (.064)	5 (.074)
H74937911515150	15	5	16	150	8 (812)	10 (1013)	14 (1419)	6.0	6 (.067)	5 (.074)
H74937912519150	19	5	20	150	8 (812)	10 (1013)	14 (1419)	6.0	6 (.067)	5 (.074)
H74937911614150	14	6	15	150	8 (812)	10 (1013)	14 (1419)	7.0	6 (.067)	5 (.074)
H74937912618150	18	6	19	150	8 (812)	10 (1013)	14 (1419)	7.0	6 (.067)	5 (.074)
H74937911715150	15	7	16	150	8 (812)	10 (1013)	14 (1419)	8.0	7 (.078)	6 (.087)
H74937912719150	19	7	20	150	8 (812)	10 (1013)	14 (1419)	8.0	7 (.078)	6 (.087)

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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.

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.

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 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 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.

To assure full expansion, inflate the premounted 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 premounted 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.

Recrossing 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 PTRA 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.

The Express SD Renal Stent has been shown to be MR safe at field strength of 3 Tesla (T) or less, and a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MR imaging. The Express SD Renal Stent should not migrate in this MR environment. MR imaging at 3 T or less may be performed immediately following the implantation of the Express SD Renal Stent.

In this testing, the stent experienced a maximum temperature rise of 0.96 degrees C at a maximum whole body averaged SAR of 2 W/kg for 15 minutes of MR imaging. The temperature rise was observed to be similar for a stent with a fractured strut. The maximum temperature rise observed for two overlapping Express SD stents was 1.15 degrees C (5 mm overlap at the ends). MR imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent.

This stent has not been evaluated to determine if it is safe in MRI systems with field strengths greater than 3T.

The safety and effectiveness of using mechanical atherectomy devices (directional atherectomy catheters, rotational atherectomy catheters), or laser angioplasty catheters to treat in-stent stenosis have not been established.

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
- Aneursym
- Arrhythmias, 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-peritoneum 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 Revascularizations 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

Safety Measures	(N=100 Subjects) (N=117 Lesions)	[95% CI]
9-Month TLR (per lesion)	8.1% (9/111)	[3.8%, 14.8%]
9-Month TVR (per lesion)	14.4% (16/111)	[8.5%, 22.4%]
9-Month MAE (per subject)	10.5% (10/95)	[5.2%, 18.5%]
Device-Related Death	0.0% (0/95)	[0.0%, 3.8%]
Index Procedure-Related Death	0.0% (0/95)	[0.0%, 3.8%]
TLR (per subject)	8.4% (8/95)	[3.7%, 15.9%]
Significant Embolic Events	2.1% (2/95)	[0.3%, 7.4%]
Safety Measures	**(N=100 Subjects) (N=117 Lesions)**	**[95% CI]**
Stent Thrombosis (per subject)	0.0% (0/100)	[0.0%, 3.6%]
Acute Stent Thrombosis (≤24 hours)	0.0% (0/100)	[0.0%, 3.6%]
Subacute Stent Thrombosis (>24 hours to ≤30 days)	0.0% (0/100)	[0.0%, 3.6%]
Late Stent Thrombosis (>30 days to ≤90 days)	0.0% (0/100)	[0.0%, 3.6%]
Major Hemorrhagic/ Vascular Complication through 30 Days (per subject)	2.0% (2/100)	[0.2%, 7.0%]
Intracranial Hemorrhage	0.0% (0/100)	[0.0%, 3.6%]
GI Bleeding	0.0% (0/100)	[0.0%, 3.6%]
Bleeding at the access site	0.0% (0/100)	[0.0%, 3.6%]
Other Bleeding[1]	2.0% (2/100)	[0.2%, 7.0%]
Minor Hemorrhagic/ Vascular Complication[2] (per subject)	4.0% (4/100)	[1.1%, 9.9%]

[1]Other Bleeding: pseudoaneurysm, AV fistula, hematoma >6cm, and/or retroperitoneal bleeding) that requires transfusion >1 unit packed red blood cells) and/or vascular repair (surgical repair, PTA, US-guided compression or other percutaneous intervention) through 30 days post-index procedure.

[2]Any bleeding which does not require vascular repair or >1 unit packed red blood cells (e.g. oozing from access site, drop in Hgb/Hct).

Figure 1. Freedom from MAE to 9 month Follow-up, Intent-to-Treat, Event-Free Survival ± 1.96 SE, All Subjects(N=100)

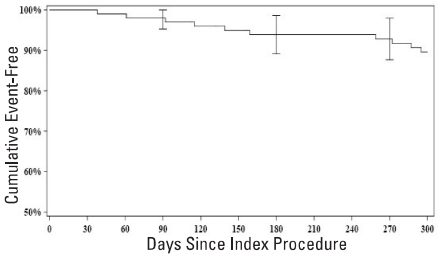

Table 3. Freedom from MAE to 9 month Follow-up, Intent-to-Treat, Event-Free Survival ± 1.96 SE, All Subjects (N=100)

100 Subjects	0	7	14	30	60	120	180	270	300
Entered	100	100	100	100	100	99	94	89	87
Censored	0	0	0	0	0	2	3	1	1
At Risk	100	100	100	100	100	98	92.5	88.5	86.5
Events	0	0	0	0	1	3	2	1	3
Events/Month	0.0	0.0	0.0	0.0	1.0	1.5	1.0	0.3	3.0
Event Free	100%	100%	100%	100%	99.0%	96.0%	93.9%	92.8%	89.6%
Std Error - Greenwood	0.0%	0.0%	0.0%	0.0%	1.0%	2.0%	2.4%	2.6%	3.1%
Std Error - Peto	0.0%	0.0%	0.0%	0.0%	1.0%	2.0%	2.5%	2.7%	3.2%
Peto's Lower Limit	100.0%	100.0%	100.0%	100.0%	97.4%	92.7%	89.9%	88.4%	84.4%

Intervals are end inclusive, e.g. interval 180 is defined as 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 (PTRA) and stenting.

- Target lesions were to involve the aortorenal ostium or the leading edge of the stenosis was located within 5 mm of the opacified aortic lumen.
- Subject's renal artery stenosis was either bilateral (one stent for one lesion in each renal artery) or unilateral, including a solitary functioning kidney.
- Eligible subjects had lesion lengths ≤15 mm, diameter stenosis ≥70% by angiographic visual estimate and vessel diameter ≥4.0 mm ≤7.0 mm.

The exclusion criteria for this study include the following: patients with unresolved vessel thrombus at the lesion site; patients with renal artery reference diameters < 4.0 mm or > 7.0 mm; patients with advanced renal disease: serum creatinine ≥ 3.0 mg/dL; patients with restenotic lesions; patients with more than one lesion in a renal artery; patients that have had renal bypass surgery or are on renal dialysis; patients that have had an organ transplant (i.e heart, lung, kidney) and are currently taking immuno-suppressant medications; patients with childbearing potential; patients with a history of bleeding disorders.

All subjects were to receive the hospital's standard anti-coagulation regimen for renal artery stent implantation. After the index-procedure, subjects were to receive aspirin indefinitely and clopidogrel or ticlopidine for 30 days. Follow-up includes a 30-day office visit, 4-month telephone follow-up, 9 month office visit (primary endpoint, time point for presented data), with additional follow-ups at 12 months, then annually for a total follow-up period of 5 years post-index procedure. All subjects were required to have ultrasound follow-up at 9-months.

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 Angiographic 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 <30% 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%.

Demographics: Baseline characteristics of 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 8.6 mm.

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

Variable	(N=100)	[95% CI]
Age (Years)	71.4±9.0 (100) (41.0, 85.0)	[69.6, 73.1]
Male	48.0% (48/100)	[37.9%, 58.2%]
Race		
White	97.0% (97/100)	[91.5%, 99.4%]
Black, of African Heritage	3.0% (3/100)	[0.6%, 8.5%]
Asian	0.0% (0/100)	[0.0%, 3.6%]
Native Hawaiian or Other Pacific Islander	0.0% (0/100)	[0.0%, 3.6%]
American Indian or Alaska Native	0.0% (0/100)	[0.0%, 3.6%]
Medical History[1]		
Known Prior PCI	37.1% (36/97)	[27.5%, 47.5%]
Known Prior CABG	37.0% (37/100)	[27.6%, 47.2%]
Known Previous MI	20.6% (20/97)	[13.1%, 30.0%]
Known CHF	17.8% (16/90)	[10.5%, 27.3%]
Known Unstable Angina	3.1% (3/98)	[0.6%, 8.7%]
Known Coronary Artery Disease	73.1% (68/93)	[62.9%, 81.8%]
Known Peripheral Vascular Surgery	9.2% (9/98)	[4.3%, 16.7%]
Prior Renal Percutaneous Intervention	4.0% (4/99)	[1.1%, 10.0%]
PTRA	1.0% (1/96)	[0.0%, 5.7%]
Stenting	4.0% (4/99)	[1.1%, 10.0%]
Other Peripheral Endovascular Interventions	5.1% (5/99)	[1.7%, 11.4%]
Known Cerebrovascular Accident (CVA)	4.0% (4/99)	[1.1%, 10.0%]
Known TIA	4.2% (4/95)	[1.2%, 10.4%]
Risk Factors[1]		
Current or Previous Smoker[2]	68.7% (68/99)	[58.6%, 77.6%]
Known Medically Treated Diabetes	26.0% (26/100)	[17.7%, 35.7%]
Insulin Requiring	7.0% (7/100)	[2.9%, 13.9%]
Non-Insulin Requiring	19.0% (19/100)	[11.8%, 28.1%]
Known Hyperlipidemia	76.5% (75/98)	[66.9%, 84.5%]
Known Hypertension Requiring Treatment	99.0% (99/100)	[94.6%, 100.0%]
Current Hypertension	98.0% (98/100)	[93.0%, 99.8%]
Previous Hypertension	1.0% (1/100)	[0.0%, 5.4%]

[1] Responses of "Unknown" to the questions included in the Medical History and Risk Factors are not presented in this exhibit.

[2] Defined as Current Smoker (within past 6 months) or Previous Smoker (> 6 months ago).

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 ultrasound was conducted in 93% (93/100) of the Renaissance subjects enrolled. Baseline, post-procedure and 9 month follow-up ultrasound data were collected and assessed by a designated 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 99.1% 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 OPC (21.3% vs. 40.0%, p<0.0001) thus demonstrating a superior restenosis rate compared to PTRA for treatment of atherosclerotic lesions in the aortorenal ostium.

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

Effectiveness Measures	(N=100 Subjects) (N=117 Lesions)	[95% CI]
Technical Success (per lesion)	99.1% (116/117)	[95.3%, 100.0%]
Procedural Success (per subject)	99.0% (99/100)	[94.6%, 100.0%]
9-Month Binary In-Stent Restenosis (per lesion)	21.3% (23/108)	[14.0%, 30.2%]

Table 6 summarizes the secondary efficacy endpoints comparing baseline to 9 months.

Table 6. Secondary Effectiveness Results with Matched Data - Change from Baseline to 9-month

Secondary Effectiveness Measures (Change from Baseline to 9-month)	Mean Change from Baseline	95% CI for Change	Improved	No Change	Worsened
Renal Function					
Serum Creatinine mg/dL (per subject) [1]	0.07±0.48 (81) (-1.10, 2.50)	[-0.03, 0.18]	33.3% (27)	29.6% (24)	37.0% (30)
GFR mL/min (per subject) [2]	-0.81±13.76 (79) (-54.99, 24.89)	[-3.89, 2.27]	31.7% (25)	31.7% (25)	36.7% (29)
Renal-to-Aortic Ratio (per lesion) [3]	-1.96±1.80 (71) (-7.50, 3.70)	[-2.39, -1.53]	70.4% (50)	15.5% (11)	14.1% (10)
Resistive Index (per lesion) [4]	0.01±0.09 (62) (-0.17, 0.18)	[-0.01, 0.03]	35.5% (22)	24.2% (15)	40.3% (25)
Renal PSV cm/sec (per lesion) [5]	-156.75±158.37 (81) (-615.00, 379.00)	[-191.8, -121.7]	65.4% (53)	25.9% (21)	8.6% (7)
Hypertension Control					
Systolic BP mmHg (per subject) [6]	-8.60±25.65 (88) (-101.67, 46.50)	[-14.03, -3.17]	61.4% (54)	11.4% (10)	27.3% (24)
Diastolic BP mmHg (per subject) [7]	-0.82±12.54 (88) (-26.80, 35.75)	[-3.47, 1.84]	42.1% (37)	29.6% (26)	28.4% (25)
Number of Anti-Hypertensive Medications (per subject)	0.03±1.15 (97) (-3.00, 5.00)	[-0.20, 0.26]			

1. Serum creatinine; improvement = decrease greater than 0.1 mg/dL,

worsened = increase greater than 0.1 mg/dL

2. GFR; improvement = increase greater than 5 mL/min, worsened = decrease greater than 5 mL/min

3. Renal-to-Aortic Ratio; improvement = decrease greater than 1, worsened = increase greater than 0

4. Resistive Index; improvement = decrease greater than 0.03, worsened = increase greater than 0.03

5. Renal PSV; improvement = decrease greater than 100 cm/sec, worsened = increase greater than 0 cm/sec

6. Systolic BP; improvement = decrease greater than 5 mmHg, worsened = increase greater than 5 mmHg

7. Diastolic BP; improvement = decrease greater than 5 mmHg, worsened = increase greater than 5 mmHg

HOW SUPPLIED:

Store in a cool, dry dark place.

Do not use if package is opened or damaged.

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-pyrogenic.

Contents:

- One (1) Express SD Renal Monorail™ Premounted Stent System
- One (1) Electronic DFU Reference Card
- One (1) Flushing needle with luer fitting

OPERATIONAL INSTRUCTIONS:

Recommended Materials:

- Micropuncture™ kit
- .014 in. (0.36 mm) or .018 in. (0.46 mm) Guidewire of appropriate length
- Introducer/Guide sheaths of appropriate size and length, and equipped with a hemostatic valve
- Luer-lock Syringe [10 cc or greater for prepping the premounted stent system]
- 3 Way Stopcock
- Inflation device [20 cc or greater]
- Guide Catheter of appropriate size and length
- Y-Adaptor

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 to select the proper premounted stent system length (refer to Table 1).
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. Remove the stent protector and product mandrel.
5. 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.

6. Using the supplied flushing needle, insert flushing needle in to distal guide wire lumen. Flush the premounted stent system guidewire lumen with heparinized normal saline. Carefully remove the flushing needle from the distal guidewire lumen.
7. Prepare inflation device/syringe with diluted contrast medium. The standard inflation medium is a 50/50 mixture of contrast medium and normal saline. Do not use air or any gaseous substance as a balloon inflation medium.
8. Attach inflation device/syringe to stopcock. Attach to premounted stent system inflation port.

Note: A 10 cc luer-lock syringe is recommended for use for aspirating this device.

9. Open stopcock 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 20-30 seconds. Carefully release to neutral for contrast fill.
10. Close stopcock 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 cc Inflation device is recommended for use with this device.

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

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.

Caution: 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 a .014 in. / 0.36 mm or .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.
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 1-2 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 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

Pressure (atm-kPa)	Stent I.D. (mm)			
	4.0 mm	5.0 mm	6.0 mm	7.0 mm
8.0 - 811	3.70	4.67	5.75	6.50
9.0 - 912	3.82	4.81	5.94	6.72
10.0 - 1013*	3.93*	4.94*	6.10*	6.91*
11.0 - 1115	4.02	5.06	6.25	7.09
12.0 - 1216	4.11	5.16	6.39	7.25
13.0 - 1317	4.20	5.26	6.52	7.40
14.0 - 1419**	4.27**	5.35**	6.63**	7.54**
* Nominal Pressure = 10.0 atm				
**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.**