**Table 2.1 REBEL Stent System Product Description**

<table>
<thead>
<tr>
<th>REBEL Monorail Stent Delivery System</th>
<th>REBEL Over-the-Wire Stent Delivery System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stent</td>
<td></td>
</tr>
<tr>
<td>Available Stent Lengths (mm)</td>
<td></td>
</tr>
<tr>
<td>8”, 12, 16, 20, 24, 28, 32”</td>
<td></td>
</tr>
<tr>
<td>Available Stent Diameters (mm)</td>
<td></td>
</tr>
<tr>
<td>2.25”, 2.50”, 2.75, 3.00, 3.50, 4.00, 4.50”</td>
<td></td>
</tr>
<tr>
<td>Stent Material</td>
<td></td>
</tr>
<tr>
<td>Platinum Chromium (PCCr) Alloy</td>
<td></td>
</tr>
<tr>
<td>Stent Strut Thickness</td>
<td></td>
</tr>
<tr>
<td>0.0022 inches (0.008 mm) for diameters 2.25 mm to 3.50 mm</td>
<td></td>
</tr>
<tr>
<td>0.0034 inches (0.008 mm) for diameters 4.00 mm and 4.50 mm</td>
<td></td>
</tr>
<tr>
<td>Effective Length</td>
<td></td>
</tr>
<tr>
<td>144 cm</td>
<td></td>
</tr>
<tr>
<td>Delivery System Ports</td>
<td></td>
</tr>
<tr>
<td>Single access port to inflation lumen</td>
<td></td>
</tr>
<tr>
<td>Guidewire exit port is located approximtely 25 cm from tip.</td>
<td></td>
</tr>
<tr>
<td>Designed for guidewire ≤ 0.014 inches (0.038 mm)</td>
<td></td>
</tr>
<tr>
<td>Y-Connector (Side arm for access to balloon inflation/deflation lumen. Straight arm is continuous with shaft inner lumen).</td>
<td></td>
</tr>
<tr>
<td>Designed for guidewire ≤ 0.014 inches (0.038 mm)</td>
<td></td>
</tr>
<tr>
<td>Stent Delivery</td>
<td></td>
</tr>
<tr>
<td>A balloon, with two radiopaque balloon markers, normally placed 0.4 mm (0.016 inches) beyond the stent at each end.</td>
<td></td>
</tr>
<tr>
<td>Balloon Inflation Pressure</td>
<td></td>
</tr>
<tr>
<td>Nominal Inflation Pressure: 11 atm (1117 kPa)</td>
<td></td>
</tr>
<tr>
<td>Rated Burst Inflation Pressure: 18 atm (1627 kPa)</td>
<td></td>
</tr>
<tr>
<td>Catheter Shaft Outer Diameter</td>
<td></td>
</tr>
<tr>
<td>2.1 F (0.70 mm) proximal and 2.7 F (0.95 mm) distal.</td>
<td></td>
</tr>
<tr>
<td>Guidewire Catheter Minimum Inner Diameter Requirement</td>
<td>\geq 0.016 inches (0.008 mm) for 2.25 – 4.00 mm sizes</td>
</tr>
<tr>
<td></td>
<td>\geq 0.066 inches (0.018 mm) for 4.50 mm sizes</td>
</tr>
<tr>
<td></td>
<td>\geq 0.066 inches (0.018 mm)</td>
</tr>
<tr>
<td>* 22 mm length is not available in 2.25 mm and 2.50 mm diameter sizes. 8 mm length is not available in 4.90 mm diameter size.</td>
<td></td>
</tr>
</tbody>
</table>
6.3 Longitudinal Stent Deformation
Longitudinal stent deformation is a recognized potential failure mode of thin strut coronary stents.1 Crossing a newly deployed stent with a second device, such as a balloon catheter, stent system, or IUS extending proximally or distally can lead to the second device transmitting force to the implanted stent. In this situation, if the second device is advanced or retracted, longitudinal stent deformation (i.e., longitudinal compression or elongation) of the implanted stent may occur. Although a rare event, longitudinal stent deformation may result in adverse clinical events and/or the need for additional treatment including repeat dilation of the implanted stent, placement of a second stent, or surgical intervention.

An analysis of complaint reports suggests that coronary artery calcification, vessel tortuosity, and stent malapposition in conjunction with crossing a newly deployed stent with an ancillary device may be associated with an increased risk of longitudinal stent deformation. Implantation techniques that may reduce the likelihood of procedure related complications, including stent deformation, are described in the appropriate sections of this OPU (see Sections 13.4 Delivery Procedure, 13.5 Deployment Procedure, 13.6 Removal Procedure, and 13.7 Post-Deployment Dilatation of Stented Segment). Please see section 7 Overview of Clinical Studies for an evaluation of the enhancements made to the REBEL Coronary Stent System.

6.4 Use of Multiple Stents
In the OMEGA Clinical trial, the protocol specified that lesions were to be treated with no more than one stent, except in situations involving bailout stenting. When more than one stent is required, resulting in stent-to-stent contact, stent materials should be of similar composition to avoid the possibility of corrosion due to the presence of dissimilar metals in a conducting medium.

6.5 Brachytherapy
The safety and effectiveness of the REBEL stent in patients with prior brachytherapy of the target lesion have not been established. The safety and effectiveness of the use of brachytherapy to treat in-stent restenosis in a stent system have not been established. Both vascular brachytherapy and the REBEL stent alter arterial remodeling. The interaction between these two treatments has not been determined.

6.6 Use in Conjunction with Other Procedures
The safety and effectiveness of using mechanical atherectomy devices (directional atherectomy catheters or rotational atherectomy catheters) or laser angioplasty catheters in conjunction with REBEL stent implantation have not been established.

6.7 Use in Special Populations
The safety and effectiveness of the REBEL stent have not been established in the following patient populations:

- Patients with vessel thrombus at the lesion site.
- Patients with coronary artery reference vessel diameters < 2.25 or ≥ 4.50 mm.
- Patients with coronary artery lesions longer than 28 mm or requiring more than one REBEL stent.
- Patients with lesions located in the saphenous vein grafts, in the left main coronary artery, ostial lesions, or lesions located at a bifurcation.
- Patients with diffuse disease or poor flow distal to the identified lesions.
- Patients with tortuous vessels (> 90 degrees) in the region of the obstruction or proximal to the lesion.
- Patients with a recent acute myocardial infarction where there is evidence of thrombus or poor flow.
- Patients with in-stent restenosis.
- Patients with moderate or severe calcification in the lesion or a chronic total occlusion.
- Patients with 3 vessel disease.

6.8 Magnetic Resonance Imaging (MRI)
Non-clinical testing has demonstrated that the REBEL stent is MR Conditional for Single and overlapped conditions up to 74 mm. A patient with this device can be safely scanned in a Magnetic Resonance imaging system meeting the following conditions:

- Static magnetic field of 0 to 1.5 Tesla only
- Maximum spatial gradient magnetic field of 2200 gauss/cm (22 T/m)
- Maximum Magnetic Resonance system reported, whole body averaged specific absorption rate (SAR) of ≤ 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the REBEL stent is expected to produce a maximum temperature rise of 2.8°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 30 mm proximally and 15 mm distally. In clinical imaging, the artifact extends approximately 20 mm proximally and 20 mm distally when imaged with a spin echo pulse sequence and a 3.0 Tesla MRI system. The artifact does not obscure the device lumen.

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

Magnetic Resonance Conditional

6.8 Stent Handling (also see Section 13. Operational Instructions)

- For single use only. Do not resterilize or reuse this product. Note product “Use By” date. (see Section 1, Warning)
- The premounted REBEL stent and its delivery system are designed for use as a unit. The stent is not to be removed from its delivery balloon. The stent is not designed to be crimped onto another balloon. Removing the stent from its delivery balloon may damage the stent and/or lead to stent embolization.
- Special care must be taken not to handle or in any way disrupt the stent position on the delivery balloon. This is most important during catheter removal from packaging, placement over guidewire, and advancement through hemostasis valve adapter and guide catheter hub.
- Excessive manipulation or handling may cause stent damage, contamination, or dislodgment of the stent from the delivery balloon.
- Use only the appropriate balloon inflation media (see Section 13.3.3, Delivery System Preparation). DO NOT USE air or any gas medium to inflate the balloon.
- In the event the REBEL stent is not deployed, do not use the product and contact your local Boston Scientific Representative for return information.

6.10 Stent Placement Preparation

- DO NOT PREPARE OR PRE-INFLATE BALLOON PRIOR TO STENT DEPLOYMENT OTHER THAN AS DIRECTED. Use the balloon purging technique described in Section 13.3.3, Delivery System Preparation.
- An unexpanded stent should be introduced into the coronary arteries one time only. An unexpanded stent should not be subsequently moved in and out through the distal end of the guide catheter as stent damage or stent embolization from the balloon may occur.

Placement

- The vessel should be pre-dilated with an appropriate sized balloon. Failure to do so may increase the risk of placement difficulty and procedural complications.
- If unusual resistance is felt at any time during lesion access before stent implantation, the stent delivery system and the guide catheter should be removed as a single unit (see Section 6.1, Stent Delivery System Removal – Pre-deployment).
- Do not expand the stent if it is not properly positioned in the vessel (see Section 6.1, Stent Delivery System Removal – Pre-deployment).
- Balloon pressures should be monitored during inflation. Do not exceed rated burst pressure as indicated on product label (Table 13.1, Typical REBEL Stent System Compliance). Use of pressures higher than specified on product label may result in a ruptured balloon and internal and distal dissection.
- The stent inner diameter should approximate 1.1 times the distal reference diameter of the vessel.
- Placement of the stent has the potential to compromise side branch patency if stenting near a side branch (see Section 13.7, Post-Deployment Dilatation of Stented Segments).
- Implanting a stent may lead to dissection of the vessel distal and/or proximal to the stented portion, and may cause acute closure of the vessel requiring additional intervention (e.g., CABG, further dilation, placement of additional stents, or other).
• When treating multiple lesions, the distal lesion should generally be stented first, followed by stenting of the more proximal lesion(s). Stenting in this order alleviates the requirement to cross the proximal stent when placing the distal stent and reduces the chances of dislodging the proximal stent.

6.11 Stent Delivery System Removal – Pre-deployment
• If unusual resistance is felt at any time during lesion access before stent implantation, the stent delivery system and the guide catheter should be removed as a single unit under direct visualization using fluoroscopy.
• Do not attempt to pull an unexpanded stent back into the guide catheter, as stent damage or stent dislodgment from the balloon may occur.
• Stent retrieval methods (use of additional wires, snares, and/or forceps) may result in additional trauma to the vascular site. Complications can include bleeding, hematoma, or pseudoaneurysm.

6.12 Stent Delivery System Removal – Post-deployment
• Following stent placement, confirm complete balloon deflation (See Table 6.1, Delivery System Deflation Time Specifications). If greater than usual resistance is felt during delivery system withdrawal, pay particular attention to guide catheter position. In some cases it may be necessary to pull back slightly on the guide catheter in order to prevent deep seating (unplanned advancement) of the guide catheter and subsequent vessel damage. In cases where unplanned guide catheter movement has occurred, angiographic assessment of the coronary tree should be undertaken to ensure that there is no damage to the coronary vasculature.
• Maintain guidewire placement across the lesion during the entire removal process.
• Carefully pull back the stent delivery system until the proximal balloon marker of the stent delivery system is just distal to the guide catheter distal tip.
• The stent delivery system and the guide catheter should be pulled back until the tip of the guide catheter is just distal to the arterial sheath, allowing the guide catheter and subsequent vessel damage. In cases where unplanned guide catheter movement has occurred, angiographic assessment of the coronary tree should be undertaken to ensure that there is no damage to the coronary vasculature.
• Maintain guidewire placement across the lesion during the entire removal process.

7 OVERVIEW OF CLINICAL STUDIES:
The principal safety and effectiveness for the REBEL™ Stent System is derived from the global OMEGA Clinical Trial, a clinical trial conducted on the OMEGA™ Stent System. The OMEGA and REBEL stents utilize the same platinum chromium alloy. The REBEL Stent System has supplementary proximal stent connectors for increased axial strength, a short flexible stent delivery system tip, and a PTFE coated proximal hypotube for improved stent deliverability. Given the similarities between the OMEGA and REBEL Stent Systems and supportive bench and animal study information, the findings from the OMEGA Clinical Trial are applicable to the REBEL Stent System.

8 ADVERSE EVENTS:
8.1 Observed Adverse Events
Observed adverse event experience comes from the OMEGA Clinical Trial. Major clinical events for this study are shown in Table 8.1.

Table 8.1. OMEGA Major Clinical Events From Post-Procedure to 9-Month Follow-Up

<table>
<thead>
<tr>
<th>Event</th>
<th>OMEGA (N=328)</th>
<th>In-Hospital</th>
<th>30 Days</th>
<th>9 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Death, MI, TVR</td>
<td>3.0% (10/328)</td>
<td>3.4% (11/327)</td>
<td>12.9% (42/325)</td>
<td></td>
</tr>
<tr>
<td>All Death or MI</td>
<td>3.0% (10/328)</td>
<td>3.4% (11/327)</td>
<td>5.5% (18/325)</td>
<td></td>
</tr>
<tr>
<td>All Death</td>
<td>0.0% (0/328)</td>
<td>0.3% (1/327)</td>
<td>1.8% (6/325)</td>
<td></td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>0.0% (0/328)</td>
<td>0.3% (1/327)</td>
<td>1.2% (4/325)</td>
<td></td>
</tr>
<tr>
<td>Non-Cardiac Death</td>
<td>0.0% (0/328)</td>
<td>0.0% (0/327)</td>
<td>0.6% (2/325)</td>
<td></td>
</tr>
<tr>
<td>MI</td>
<td>3.0% (10/328)</td>
<td>3.1% (10/327)</td>
<td>3.7% (12/325)</td>
<td></td>
</tr>
<tr>
<td>Q-wave MI</td>
<td>0.0% (0/328)</td>
<td>0.6% (6/327)</td>
<td>0.0% (0/325)</td>
<td></td>
</tr>
<tr>
<td>Non-Q-wave MI</td>
<td>3.0% (10/328)</td>
<td>3.1% (10/327)</td>
<td>3.7% (12/325)</td>
<td></td>
</tr>
<tr>
<td>TVR</td>
<td>0.0% (0/328)</td>
<td>0.3% (1/327)</td>
<td>8.6% (28/325)</td>
<td></td>
</tr>
<tr>
<td>TLR</td>
<td>0.0% (0/328)</td>
<td>0.3% (1/327)</td>
<td>7.4% (24/325)</td>
<td></td>
</tr>
<tr>
<td>Non-TLR</td>
<td>0.0% (0/328)</td>
<td>0.6% (6/327)</td>
<td>1.8% (6/325)</td>
<td></td>
</tr>
<tr>
<td>Cardiac Death or MI</td>
<td>3.0% (10/328)</td>
<td>3.4% (11/327)</td>
<td>4.9% (16/325)</td>
<td></td>
</tr>
<tr>
<td>TLF</td>
<td>3.0% (10/328)</td>
<td>3.4% (11/327)</td>
<td>11.5% (37/322)</td>
<td></td>
</tr>
<tr>
<td>TVF</td>
<td>3.0% (10/328)</td>
<td>3.4% (11/327)</td>
<td>12.4% (40/322)</td>
<td></td>
</tr>
<tr>
<td>ARC Stent Thrombosis</td>
<td>0.0% (0/328)</td>
<td>0.3% (1/326)</td>
<td>0.6% (2/318)</td>
<td></td>
</tr>
<tr>
<td>Definite or Probable</td>
<td>0.0% (0/328)</td>
<td>0.3% (1/326)</td>
<td>0.6% (2/318)</td>
<td></td>
</tr>
<tr>
<td>Definite</td>
<td>0.0% (0/328)</td>
<td>0.3% (1/326)</td>
<td>0.6% (2/318)</td>
<td></td>
</tr>
<tr>
<td>Probable</td>
<td>0.0% (0/328)</td>
<td>0.0% (0/326)</td>
<td>0.0% (0/326)</td>
<td></td>
</tr>
</tbody>
</table>

Note: Failure to follow these steps, and/or applying excessive force to the stent delivery system, can potentially result in stent damage, stent dislodgment from the balloon, and/or damage to the delivery system.

Table 8.1 Delivery System Deflation Time Specifications

<table>
<thead>
<tr>
<th>Stent Length (mm)</th>
<th>8</th>
<th>12</th>
<th>20</th>
<th>28</th>
<th>32</th>
<th>≤ 16 Sec</th>
<th>≤ 16 Sec</th>
<th>≤ 16 Sec</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.25</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.50</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.75</td>
<td>50</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.00</td>
<td></td>
<td>50</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.50</td>
<td></td>
<td></td>
<td>50</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.00</td>
<td></td>
<td></td>
<td></td>
<td>50</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.50</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>50</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6.13 Post-Procedure
• Care must be exercised when crossing a newly deployed stent with any wire, catheter or ancillary device to avoid disrupting the stent placement, apposition, and/or geometry.
• If the patient requires imaging, see Section 6.8, Magnetic Resonance Imaging (MRI).
8.2 Potential Adverse Events
Potential adverse events (in alphabetical order) which may be associated with the use of a coronary stent in native coronary arteries include but are not limited to:

- Abrupt closure
- Allergic reaction (including to medications, contrast, stent materials)
- Aneurysm (coronary)
- Angina
- Arrhythmias, including ventricular fibrillation and ventricular tachycardia
- Arteriovenous fistula
- Bleeding
- Cardiac tamponade
- Cardiogenic shock
- Cardiomyopathy
- Death
- Embol (including air, tissue, thrombus, plaque, or device materials)
- Heart failure
- Hematoma
- Hemorrhage
- Hypotension/hypertension
- Infection, local and/or systemic
- Ischemia, myocardial
- Myocardial infarction
- Pain
- Pericardial effusion
- Pseudoaneurysm, femoral
- Pulmonary edema
- Renal insufficiency or failure
- Respiratory failure
- Restenosis of stented segment
- Shock
- Stent embolization
- Stent fracture
- Stent migration
- Stent thrombosis and/or vessel occlusion
- Stroke/cerebrovascular accident/transient ischemic attack
- Total occlusion of coronary artery
- Vessel spasm
- Vessel injury (including dissection, perforation, rupture or trauma)

There may be other potential adverse events that are unforeseen at this time.

9 CLINICAL STUDIES:

OMEGA Clinical Trial

Primary Objective: To evaluate the safety and effectiveness of the OMEGA™ Coronary Stent System for the treatment of de novo atherosclerotic coronary artery lesions ≤ 28 mm in length (by visual estimate) in a native coronary artery ≥ 2.25 mm to ≤ 4.50 mm in diameter (by visual estimate).

Design: The OMEGA Clinical Trial is a prospective, single-arm, multicenter study. Eligible patients were to be ≥ 18 years of age and with left ventricular ejection fraction (LVEF) > 30% and symptomatic coronary artery disease or documented silent ischemia. Lesions were to be coverable by a single stent and to have visually estimated stenosis ≥ 50% and < 100% with Thrombolysis in Myocardial Infarction (TIMI) flow > 1. Patients could have 1 target lesion treated. Patients with a single target lesion could also have 1 de novo native coronary artery lesion within a different epicardial vessel (non-target lesion) treated with a commercially-available treatment (e.g., stent, balloon angioplasty, excluding brachytherapy) during the index procedure. The non-target lesion had to be treated before the target lesion and the treatment had to be a clinical angiographic success (defined as visually assessed stenosis ≤ 50% [< 30% for stents] with TIMI 3 flow without prolonged chest pain or electrocardiogram [ECG] changes consistent with MI) before the patient could be enrolled. The protocol mandated antplatelet therapy compliance in accordance with the 2007 ACC/AHA/SCAI Guidelines for PCI.

Baseline and post-procedure angiographic data were collected and assessed by quantitative visual estimate) in a native coronary arteries ≥ 2.25 mm to ≤ 4.50 mm in diameter (by visual estimate).

There may be other potential adverse events that are unforeseen at this time.

Primary Endpoint (9-Month TLF): The primary endpoint was met. The 9 month TLF rate was 11.5% and the upper 1-sided 95% confidence bound of 14.79% was less than the prespecified PG of 21.2% (p<0.001).

Secondary endpoints were found whether the per protocol or the ITT subject populations were analyzed.

Table 9.1 OMEGA 9-Month Clinical Results, Intent-to-Treat Patients

<table>
<thead>
<tr>
<th>OMEGA (N=328)</th>
<th>95% Confidence Interval</th>
<th>Performance Goal*</th>
<th>1-sided P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>OMEGA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TLR, Overall</td>
<td>8.6% (28/325)</td>
<td>8.2% (14/174)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>TLR, PCI</td>
<td>7.4% (24/325)</td>
<td>7.4% (12/164)</td>
<td></td>
</tr>
<tr>
<td>TLR, CABG</td>
<td>0.0% (0/325)</td>
<td>0.0% (0/42)</td>
<td></td>
</tr>
<tr>
<td>Non-TLR TLR, Overall</td>
<td>1.8% (6/325)</td>
<td>1.8% (1/2)</td>
<td></td>
</tr>
<tr>
<td>Non-TLR TLR, PCI</td>
<td>1.8% (6/325)</td>
<td>1.8% (1/2)</td>
<td></td>
</tr>
<tr>
<td>Non-TLR TLR, CABG</td>
<td>0.0% (0/325)</td>
<td>0.0% (0/42)</td>
<td></td>
</tr>
</tbody>
</table>

**Table 9.2 OMEGA Primary Endpoint**

Baseline lesion characteristics: Baseline lesion characteristics included average reference vessel diameter (RVD) of 2.73±0.63 mm, average minimum lumen diameter (MLD) of 0.86±0.38 mm, average percent diameter stenosis (%DS) of 67.41±11.34, and average lesion length of 12.49±5.15 mm.

9-Month Clinical Outcomes
Table 9.3 OMEGA 9-Month TLF Results by Gender, Intent-to-Treat, All Patients (N=328)

<table>
<thead>
<tr>
<th>Event</th>
<th>OMEGA Females (N=106)</th>
<th>[95% CI]</th>
<th>OMEGA Males (N=222)</th>
<th>[95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>9 Month TLF</td>
<td>9.9% (10/104)</td>
<td>[4.7%, 17.0%]</td>
<td>13.3% (27/219)</td>
<td>[8.3%, 17.4%]</td>
</tr>
</tbody>
</table>

1.4% (3/220)

6.7% (7/105)

[4.7%, 17.0%]

1.0% (1/104)

2.9% (3/105)

0.0% (0/220)

Rotating hemostatic valve

5.5% (12/220)

≤ 0.014 in (0.36 mm) guidewire

0.0% (0/105)

0.0% (0/220)

0.5% (1/214)

3.8% (4/105)

7.7% (17/220)

0.0% (0/220)

3.6% (8/220)

7.6% (8/105)

1.0% (1/104)

0.5% (1/214)

98.3% (226/230)

[95% CI]

13.3% (27/219) | [8.3%, 17.4%] |

1.0% (1/104) | 1.4% (2/220) |

2.9% (3/105) | 1.4% (2/220) |

0.0% (0/105) | 0.0% (0/220) |

0.5% (1/214) | 0.0% (0/105) |

3.8% (4/105) | 3.6% (8/220) |

1.0% (1/104) | 0.5% (1/214) |

1.0% (1/104) | 0.5% (1/214) |

0.0% (0/105) | 0.0% (0/220) |

Procedural Success

95.3% (101/106)

95.5% (212/222)

Technical Success * 8

99.1% (108/108) | 98.3% (226/230) |

• An Angioplasty and Stent Education Guide (available on-line or by request) which includes information on coronary artery disease, the implant procedure, and frequently asked questions

12 HOW SUPPLIED:

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling and Storage

Store in cool, dry, dark place.

13 OPERATIONAL INSTRUCTIONS:

13.1 Inspection Prior to Use

Do not use the product after the “Use By” date. Carefully inspect the sterile package before opening. If the integrity of sterile package has been compromised prior to the product “Use By” date (e.g., damage of the package), contact your local Boston Scientific representative for return information. Do not use if any defects are noted.

13.2 Materials Required (not included in Stent Delivery System package)

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Appropriate guide catheter (see Table 3.1, REBEL Stent System Product Description)</td>
</tr>
<tr>
<td>2-3</td>
<td>20 mL (cc) syringe</td>
</tr>
<tr>
<td>1000 u/500 cc</td>
<td>Normal heparinized sterile saline</td>
</tr>
<tr>
<td>1</td>
<td>l ≤ 0.14 in (0.36 mm) guidewire</td>
</tr>
<tr>
<td>1</td>
<td>Rotating hemostatic valve</td>
</tr>
<tr>
<td>1</td>
<td>Diluted contrast medium 1:1 with normal heparinized sterile saline</td>
</tr>
<tr>
<td>1</td>
<td>Inflation Device</td>
</tr>
<tr>
<td>1</td>
<td>Torque Device</td>
</tr>
<tr>
<td>1</td>
<td>Pre-deployment dilation catheter</td>
</tr>
<tr>
<td>1</td>
<td>Three-way stopcock</td>
</tr>
<tr>
<td>1</td>
<td>Appropriate arterial sheath</td>
</tr>
</tbody>
</table>

13.3 Preparation

13.3.1 Packaging Removal

Step Action

1. Open the outer box to reveal the pouch and carefully inspect the pouch for damage.

2. Carefully peel open the sterile barrier using aseptic techniques and extract the stent delivery system.

3. Carefully remove the stent delivery system from its protective tubing for preparation of the delivery system. When using a Monorail® system, do not bend or kink proximal shaft during removal.

4. Remove the product mandrel and stent protector by grasping the catheter just proximal to the stent (at the proximal balloon bond site), and, with the other hand, grasp the stent protector and gently remove distally.

Note: If unusual resistance is felt during product mandrel and stent protector removal, do not use the product and replace with another.

5. Examine the device for any damage. If it is suspected that the sterility or performance of the device has been compromised, the device should not be used.

6. A Monorail® Catheter may be called once and secured using the CLIPIT® Coll Clips provided in the catheter package. Only the proximal shaft should be inserted into the CLIPIT device; the clip is not intended for the distal end of the catheter.

Note: Care should be taken not to kink or bend the shaft upon application or removal of the CLIPIT Coll Clip.

13.3.2 Guidewire Lumen Flush

Step Action

1. (Over-The-Wire only) Flush the stent delivery system guidewire lumen with normal heparinized saline through the straight arm of the Y-connector manifold.

2. (Monorail® only) Flush the stent delivery system guidewire lumen with normal heparinized saline using the flushing needle supplied for the Monorail delivery system at the distal end.

3. Verify that the stent is positioned between the proximal and distal balloon markers. Check for bends, kinks, and other damage. Do not position if any defects are noted.

Note: Avoid manipulation of the stent during flushing of the guidewire lumen, as this may disrupt the placement of the stent on the balloon.

13.3.3 Delivery System Preparation

Step Action

1. Prepare inflation device/syringe with diluted contrast medium.

2. Attach inflation device/syringe to stopcock; attach to inflation port. Do not bend the proximal shaft/hypotube when connecting to inflation device/syringe.

3. With tip closed, orient stent system vertically.

1000 u/500 cc | Normal heparinized sterile saline

≤ 0.014 in (0.36 mm) guidewire
4. Open stopcock to stent delivery system; pull negative for 15 seconds; release to neutral for contrast fill.
5. Close stopcock to stent delivery system; purge inflation device/syringe of all air.
6. Repeat steps 4 through 6 until all air is expelled. If bubbles persist, do not use product.
7. If a syringe was used, attach a prepared inflation device to stopcock.
8. Open stopcock to stent delivery system.
9. Leave inflation device on neutral pressure.

13.4 Delivery Procedure

Step Action

1. Prepare the vascular access site according to standard PTA CA practice.
2. Predilate the lesion/vessel with appropriate diameter balloon.
3. Maintain neutral pressure on inflation device attached to stent delivery system.
4. Backload stent delivery system onto proximal end of guidewire while maintaining guidewire position across target lesion.
5. Fully open rotating hemostatic valve to allow for easy passage of the stent and prevent damage to the stent.
6. Carefully advance the stent delivery system into the hub of the guide catheter. When using a Monorail® stent delivery system be sure to keep the proximal shaft/hypotube straight.

Note: If unusual resistance is felt before the stent exits the guide catheter, do not force passage. Resistance may indicate a problem, and use of excessive force may result in stent damage or stent dislodgment from the balloon. Maintain guidewire placement across the lesion, and remove the stent delivery system and guide catheter as a single unit.

7. Advance the stent delivery system over the guidewire to target lesion under direct fluoroscopic visualization. Utilize the proximal and distal radiopaque balloon markers as a reference point.
8. If the position of the stent is not optimal, it should be carefully repositioned or removed (See also Precautions – Section 6.1, Stent Delivery System Removal Pre-deployment).
9. Once the stent delivery system has been removed do not re-use.

8. Sufficiently tighten the rotating hemostatic valve. The stent is now ready to be deployed.

13.5 Deployment Procedure

Step Action

1. Under fluoroscopic visualization, inflate the delivery system expanding the stent to a minimum pressure of 11 atm (1117 kPa). Higher pressure may be necessary to optimize stent apposition to the arterial wall. Accepted practice generally targets an initial deployment pressure that would achieve a stent inner diameter of about 1.1 times the reference vessel diameter (see Table 13.1). Balloon pressure must not exceed rated burst pressure of 18 atm (1827 kPa).
2. Maintain inflation pressure for 15-30 seconds for full expansion of the stent.
3. Deflate balloon by pulling negative pressure on inflation device until balloon is fully deflated (see Table 6.1, Delivery System Deflation Time Specifications).
4. Confirm stent position and deployment using standard angiographic techniques. For optimal results, the entire stented arterial segment should be covered by the stent. Fluoroscopic visualization during stent expansion should be used in order to properly judge the optimum expanded stent diameter as compared to the proximal and distal coronary artery diameter(s). Optimal expansion requires that the stent be in full contact with the arterial wall. Stent wall contact should be verified through routine angiography or intravascular ultrasound (IVUS).
5. If stent sizing/apposition requires optimization, readvance the stent delivery system balloon, or another high-pressure, balloon catheter of the appropriate size, to the stented area using standard angioplasty techniques.
6. Inflate the balloon to the desired pressure while observing under fluoroscopy (refer to product labeling and/or Table 13.1 for compliance chart). Deflate the balloon (see Table 6.1, Delivery System Deflation Time Specifications).
7. If more than one REBEL™ stent is needed to cover the lesion and balloon treated area, it is suggested that, to avoid the potential for gap restenosis, the stents be adequately overlapped. To ensure that there are no gaps between stents, the balloon marker bands of the second stent should be positioned inside of the deployed stent prior to expansion.
8. Confirm stent position(s) and angiographic result. Repeat inflations until optimal deployment is achieved.

13.6 Removal Procedure

Step Action

1. Ensure balloon is fully deflated before delivery system withdrawal.
2. Fully open rotating hemostatic valve.
3. While maintaining guidewire position and negative pressure on inflation device, withdraw delivery system.
4. Monorail Catheters may be coiled once and secured using the CLIPIT® Coil Clip (see Section 13.3.1, Packaging Removal).

Note: If unusual resistance is felt at any time during lesion access before stent implantation, the stent delivery system and the guide catheter should be removed as a single unit. (See also Precautions – Section 6.1, Stent Delivery System Removal Pre-deployment). Once the stent delivery system has been removed do not re-use.

5. Repeat angiography to assess the stented area. If an adequate expansion has not been obtained, exchange back to the original stent delivery catheter or exchange to another balloon catheter of appropriate balloon diameter to achieve proper stent apposition to the vessel wall.

13.7 Post-Deployment Dilatation of Stented Segments

Precaution: Do not dilate the stent beyond the limits tabulated below.

<table>
<thead>
<tr>
<th>Nominal Stent Diameter (ID)</th>
<th>Dilatation Limits (ID)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.25 mm</td>
<td>2.75 mm</td>
</tr>
<tr>
<td>2.50 mm – 2.75 mm</td>
<td>3.50 mm</td>
</tr>
<tr>
<td>3.00 mm – 3.50 mm</td>
<td>4.25 mm</td>
</tr>
<tr>
<td>4.00 mm – 4.50 mm</td>
<td>5.75 mm</td>
</tr>
</tbody>
</table>

*Rated Burst Pressure. DO NOT EXCEED.

Maximum Stent Inner Diameter

All efforts should be taken to assure that the stent is not under-dilated. If the deployed stent size is still inadequate with respect to vessel diameter, or if full contact with the vessel wall is not achieved, a larger balloon may be used to expand the stent. The stent may be expanded using a low profile and high pressure balloon catheter. If this is required, the stented segment should be recrossed carefully with a prolapsed guidewire to avoid dislodging the stent. The balloon should be centered within the stent and should not extend outside of the stented region.

Note: In line with Section 6.13, Post-Procedural Care: Must be exercised when crossing a newly deployed stent with any wire, catheter or ancillary device to avoid disrupting the stent placement, apposition, and/or geometry.

13.8 In Vitro Information

Table 13.1 Typical REBEL Stent System Compliance

<table>
<thead>
<tr>
<th>Pressure atm - kPa</th>
<th>Stent I.D. (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>atm</td>
<td>2.25</td>
</tr>
<tr>
<td>8.0 - 814</td>
<td>2.50</td>
</tr>
<tr>
<td>9.0 - 910</td>
<td>2.75</td>
</tr>
<tr>
<td>10.0 - 1014</td>
<td>3.00</td>
</tr>
<tr>
<td>11.0 - 1117</td>
<td>3.50</td>
</tr>
<tr>
<td>12.0 - 1213</td>
<td>4.00</td>
</tr>
<tr>
<td>13.0 - 1317</td>
<td>4.50</td>
</tr>
<tr>
<td>14.0 - 1420</td>
<td>8.00</td>
</tr>
<tr>
<td>15.0 - 1524</td>
<td>12.00</td>
</tr>
<tr>
<td>16.0 - 1620</td>
<td>20.00</td>
</tr>
<tr>
<td>17.0 - 1724</td>
<td>30.00</td>
</tr>
<tr>
<td>18.0 - 1827 Rated*</td>
<td>40.00</td>
</tr>
<tr>
<td>19.0 - 1924</td>
<td>60.00</td>
</tr>
<tr>
<td>20.0 - 2027 Rated*</td>
<td>80.00</td>
</tr>
<tr>
<td>21.0 - 2130 Rated*</td>
<td>100.00</td>
</tr>
</tbody>
</table>

* Rated Burst Pressure. DO NOT EXCEED.

Note: If unusual resistance is felt before the stent exits the guide catheter, do not force passage. Resistance may indicate a problem, and use of excessive force may result in stent damage or stent dislodgment from the balloon. Maintain guidewire placement across the lesion, and remove the stent delivery system and guide catheter as a single unit. (See also Precautions – Section 6.1, Stent Delivery System Removal Pre-deployment). Once the stent delivery system has been removed do not re-use.

8. Sufficiently tighten the rotating hemostatic valve. The stent is now ready to be deployed.

13.5 Deployment Procedure

Step Action

1. Under fluoroscopic visualization, inflate the delivery system expanding the stent to a minimum pressure of 11 atm (1117 kPa). Higher pressure may be necessary to optimize stent apposition to the arterial wall. Accepted practice generally targets an initial deployment pressure that would achieve a stent inner diameter of about 1.1 times the reference vessel diameter (see Table 13.1). Balloon pressure must not exceed rated burst pressure of 18 atm (1827 kPa).
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8. Confirm stent position(s) and angiographic result. Repeat inflations until optimal deployment is achieved.

13.6 Removal Procedure

Step Action

1. Ensure balloon is fully deflated before delivery system withdrawal.
2. Fully open rotating hemostatic valve.
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4. Monorail Catheters may be coiled once and secured using the CLIPIT® Coil Clip (see Section 13.3.1, Packaging Removal).

Note: If unusual resistance is felt before the stent exits the guide catheter, do not force passage. Resistance may indicate a problem, and use of excessive force may result in stent damage or stent dislodgment from the balloon. Maintain guidewire placement across the lesion, and remove the stent delivery system and guide catheter as a single unit. (See also Precautions – Section 6.1, Stent Delivery System Removal Pre-deployment). Once the stent delivery system has been removed do not re-use.
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