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REBEL®

MONORAIL®

OVER-THE-WIRE

Platinum Chromium Coronary Stent System

TABLE OF CONTENTS

℞ ONLY

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

This device is supplied in sterile condition. All materials inside the sterile barrier pouch (the delivery system and stent, as well as the carrier tube and pouch liner) are sterile. The external surface of the sterile barrier pouch, as well as the product carton, should not be considered sterile.

1 WARNING:

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

For single use only. **DO NOT REUSE, REPROCESS OR RESTERILIZE.** Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

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

2 DEVICE DESCRIPTION:

REBEL Platinum Chromium Coronary Stent System:

The REBEL Platinum Chromium Coronary Stent System is a device product consisting of a balloon expandable stent, pre-mounted on a Monorail (MR) or Over-The-Wire (OTW) delivery catheter. The stent is made from a platinum chromium alloy (PtCr). The characteristics of the REBEL Stent System are described in Table 2.1.

Table 2.1 REBEL Stent System Product Description

	REBEL Monorail Stent Delivery System	REBEL Over-the-Wire Stent Delivery System
Stent		
Available Stent Lengths (mm)	8*, 12, 16, 20, 24, 28, 32*	
Available Stent Diameters (mm)	2.25*, 2.50*, 2.75, 3.00, 3.50, 4.00, 4.50*	
Stent Material	Platinum Chromium (PtCr) Alloy	
Stent Strut Thickness	0.0032 inches (0.081 mm) for diameters 2.25 mm to 3.50 mm 0.0034 inches (0.086 mm) for diameters 4.00 mm and 4.50 mm	
Delivery System		
Effective Length	144 cm	
Delivery System Ports	Single access port to inflation lumen. Guidewire exit port is located approximately 25 cm from tip. Designed for guidewire ≤ 0.014 inches (0.36 mm)	Y-Connector (Side arm for access to balloon inflation/deflation lumen. Straight arm is continuous with shaft inner lumen). Designed for guidewire ≤ 0.014 inches (0.36 mm)
Stent Delivery	A balloon, with two radiopaque balloon markers, nominally placed 0.4 mm (0.016 inches) beyond the stent at each end.	
Balloon Inflation Pressure	Nominal Inflation Pressure: 11 atm (1117 kPa) Rated Burst Inflation Pressure: 18 atm (1827 kPa)	
Catheter Shaft Outer Diameter	2.0F (≤ 0.68 mm) proximal and 2.7 F (≤ 0.95 mm) distal.	3.4F (≤ 1.20 mm) proximal for 2.25 mm to 4.50 mm sizes 2.4F (≤ 0.85 mm) distal for 2.25 mm to 2.75 mm sizes 2.7F (≤ 0.95 mm) distal for 3.00 mm to 4.50 mm sizes
Guide Catheter Minimum Inner Diameter Requirement	≥ 0.056 inches (1.42 mm) for 2.25 mm – 4.00 mm sizes ≥ 0.066 inches (1.68 mm) for 4.50 mm size	≥ 0.066 inches (1.68 mm)

* 32 mm length is not available in 2.25 mm and 2.50 mm diameter sizes. 8 mm length is not available in 4.50 mm diameter size.

2.1 Device Component Description

The REBEL® Stent component is made from a platinum chromium alloy mounted onto a Monorail® or Over-the-Wire Delivery System.

The REBEL Stent System is available in four stent models, each engineered for specific diameters to provide consistent stent-to-artery ratios across the range of reference vessel diameters indicated:

- Small Vessel (SV): 2.25 mm
- Small Workhorse (SWH): 2.50 mm, 2.75 mm
- Workhorse (WH): 3.00 mm, 3.50 mm
- Large Vessel (LV): 4.00 mm, 4.50 mm

Contents for (1) REBEL Monorail Stent System

- One (1) REBEL Monorail Stent System

Contents for (1) REBEL Over-the-Wire Stent System

- One (1) REBEL Over-the-Wire Stent System

3 INTENDED USE/INDICATIONS FOR USE:

The REBEL Coronary Stent System is indicated for improving coronary luminal diameter in patients with *de novo* lesions ≤ 28 mm in length in native coronary arteries with a reference vessel diameter (RVD) of ≥ 2.25 mm to ≤ 4.50 mm.

4 CONTRAINDICATIONS:

Use of the REBEL Stent System is contraindicated in patients with the following:

- Known hypersensitivity to platinum, the platinum chromium alloy, or similar alloy types such as stainless steel.
- Known severe reaction to contrast agents that cannot be adequately premedicated prior to the REBEL Stent placement procedure.

Coronary artery stenting is contraindicated for use in the following:

- Patients who cannot receive recommended anti-platelet and/or anticoagulant therapy.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or delivery device.

5 WARNINGS:

- This product should not be used in patients who are not likely to comply with recommended anti-platelet therapy.
- The use of this product carries the risks associated with coronary artery stenting, including: stent thrombosis, vascular complications, and/or bleeding events.

6 PRECAUTIONS:

6.1 General Precautions

- Only physicians who have received adequate training should perform implantation of the stent.
- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft (CABG) surgery is readily available.
- Subsequent stent blockage may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of previously implanted stents is not well characterized.
- Do not expose the delivery system to organic solvents such as alcohol or detergents.
- Care should be taken to control the position of the guide catheter tip during stent delivery, deployment, and balloon withdrawal.
- Before withdrawing the stent delivery system, visually confirm complete balloon deflation by fluoroscopy (see Table 6.1 System Deflation Time Specifications). Failure to do so may cause increased stent delivery system withdrawal forces and result in guide catheter movement into the vessel and subsequent arterial damage.

6.2 Pre- and Post-Procedure Anti-platelet Regimen

Administer appropriate anticoagulant/anti-platelet therapy according to current medical guidelines. The 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention (PCI) are provided at the following website: http://content.onlinejacc.org/cgi/content/full/j.jacc.2011.08.007v1.

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 IVUS catheter 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 and/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 DFU (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 a description of the enhancements made to the REBEL Coronary Stent System.

[1] Hanratty CG, Walsh SJ. Longitudinal Compression: A "new" Complication with Modern Coronary Stent Platforms – Time to Think Beyond Deliverability? Eurointervention 2011;7:872-877

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 REBEL stent 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 mm 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 (> 60 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 system meeting the following conditions:

- Static magnetic field of 3.0 Tesla and 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 2.6 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 8 mm from the REBEL stent 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 safely with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.

Magnetic Resonance Conditional

6.9 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 dislodgment 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 6.11, Stent Delivery System Removal – Pre-deployment).
- Do not expand the stent if it is not properly positioned in the vessel (see Section 6.11, 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 intimal damage and 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 to straighten. Carefully retract the stent delivery system into the guide catheter and remove the stent delivery system and the guide catheter from the patient as a single unit while leaving the guidewire across the lesion.

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 6.1 Delivery System Deflation Time Specifications

		Stent Length (mm)						
		8	12	16	20	24	28	32
Balloon Diameter (mm)	2.25	≤ 16 Sec	≤ 16 Sec	≤ 16 Sec	≤ 16 Sec	≤ 16 Sec	≤ 16 Sec	N/A
	2.50							
	2.75						≤ 21 Sec	≤ 21 Sec
	3.00							
	3.50				≤ 21 Sec	≤ 21 Sec		
	4.00							
	4.50	N/A	≤ 30 Sec	≤ 30 Sec	≤ 30 Sec	≤ 30 Sec	≤ 30 Sec	≤ 30 Sec

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).

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 and a short flexible stent delivery system tip 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

	OMEGA (N=328)		
	In-Hospital	30 Days	9 Months
All Death, MI, TVR	3.0% (10/328)	3.4% (11/327)	12.9% (42/325)
All Death or MI	3.0% (10/328)	3.4% (11/327)	5.5% (18/325)
All Death	0.0% (0/328)	0.3% (1/327)	1.8% (6/325)
Cardiac Death	0.0% (0/328)	0.3% (1/327)	1.2% (4/325)
Non-Cardiac Death	0.0% (0/328)	0.0% (0/327)	0.6% (2/325)
MI	3.0% (10/328)	3.1% (10/327)	3.7% (12/325)
Q-wave MI	0.0% (0/328)	0.0% (0/327)	0.0% (0/325)
Non-Q-wave MI	3.0% (10/328)	3.1% (10/327)	3.7% (12/325)
TVR	0.0% (0/328)	0.3% (1/327)	8.6% (28/325)
TLR	0.0% (0/328)	0.3% (1/327)	7.4% (24/325)
Non-TLR	0.0% (0/328)	0.0% (0/327)	1.8% (6/325)
Cardiac Death or MI	3.0% (10/328)	3.4% (11/327)	4.9% (16/325)
TLF	3.0% (10/328)	3.4% (11/327)	11.5% (37/323)
TVF	3.0% (10/328)	3.4% (11/327)	12.4% (40/323)
ARC Stent Thrombosis	0.0% (0/328)	0.3% (1/326)	0.6% (2/318)
Definite or Probable	0.0% (0/328)	0.3% (1/326)	0.6% (2/318)
Definite	0.0% (0/328)	0.3% (1/326)	0.6% (2/318)
Probable	0.0% (0/328)	0.0% (0/326)	0.0% (0/318)

Numbers are % (count/sample size).
Abbreviations: ARC=Academic Research Consortium; MI=myocardial infarction; PCI=percutaneous coronary intervention; TLR=target lesion revascularization; TVR=target vessel revascularization.

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
- Emboli (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 arteries ≥ 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 study 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 antiplatelet therapy compliance in accordance with the 2007 ACC/AHA/SCAI Guidelines for PCI.[2]

Baseline and post-procedure angiographic data were collected and assessed by quantitative analysis at a designated core laboratory. An independent Clinical Events Committee adjudicated major adverse clinical events and stent thrombosis.

The primary endpoint was the rate of target lesion failure (TLF), defined as any ischemia-driven revascularization of the target lesion (TLR), myocardial infarction (MI; Q-wave and non–Q-wave) related to the target vessel, or cardiac death, at 9 months post-index procedure. The rate of the primary endpoint was compared to a predefined performance goal (PG) of 21.2%, which was calculated based on historical bare metal stent (BMS) results.

A total of 328 patients were enrolled at 37 sites in the United States and Europe. Of the 328 patients included in the intent-to-treat (ITT) analysis set, a total of 323 patients were evaluable for the 9-month primary endpoint.

Follow-up included clinical assessments at 30 days, 9 months, and 12 months post-index procedure. The study is now considered complete with regard to the 9-month primary endpoint.

Demographics: Baseline characteristics for the OMEGA Clinical Trial indicated 67.7% were male with an average age of 65.46 years±11.23 years, 17.4% had diabetes requiring medication, 70.8% had known hyperlipidemia requiring medication, 28.2% were known current smokers, and 75.0% had known hypertension requiring medication.

Baseline lesion characteristics: Baseline lesion characteristics included average reference vessel diameter (RVD) of 2.77 mm±0.53 mm, average minimum lumen diameter (MLD) of 0.90 mm±0.38 mm, average percent diameter stenosis (%DS) of 67.41%±11.34%, and average lesion length of 12.49 mm±5.15 mm.

9-Month Clinical Outcomes

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

	OMEGA (N=328)
EFFICACY	
TVR, Overall	8.6% (28/325)
TLR, Overall	7.4% (24/325)
TLR, PCI	7.4% (24/325)
TLR, CABG	0.0% (0/325)
Non-TLR TVR, Overall	1.8% (6/325)
Non-TLR TVR, PCI	1.8% (6/325)
Non-TLR TVR, CABG	0.0% (0/325)
SAFETY	
All Death	1.8% (6/325)
Cardiac Death or MI	4.9% (16/325)
Cardiac Death	1.2% (4/325)
MI	3.7% (12/325)
Q-wave MI	0.0% (0/325)
Non-Q-wave MI	3.7% (12/325)
ARC Stent Thrombosis	0.6% (2/318)
Definite or Probable	0.6% (2/318)
Definite	0.6% (2/318)
Probable	0.0% (0/318)
Peri-Procedural Endpoints	
Procedural Success	95.4% (313/328)
Technical Success [a]	98.5% (332/337)

[a] denominator is number of study stents attempted
Numbers are % (count/sample size).
This trial was not sized to determine the rate of low frequency events with a pre-specified precision.
Abbreviations: ARC=Academic Research Consortium; CABG=coronary artery bypass graft; MI=myocardial infarction; PCI=percutaneous coronary intervention; TLR=target lesion revascularization; TVR=target vessel revascularization.

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 that the prespecified PG of 21.2% (p<0.0001). Similar results were found whether the per protocol or the ITT subject populations were analyzed.

Table 9.2 OMEGA Primary Endpoint

	OMEGA	95% Confidence Interval	95% UCB[a]	Performance Goal[b]	1-sided *P* value
ITT[c] (N=328)	11.5% (37/323)	[8.2%, 15.4%]	14.79%	21.2%	< 0.0001
Per protocol (N=325)	11.6% (37/320)	[8.3%, 15.6%]	14.93%	21.2%	< 0.0001

P value is based on the exact binomial test.
a: One-sided 95% Clopper-Pearson upper confidence bound
b: Based on historical BMS results
c: Primary analysis

Results in Males and Females: OMEGA data were evaluated retrospectively for possible gender-based differences in clinical outcomes. OMEGA was not designed or powered to study safety or effectiveness of the OMEGA Stent in gender-specific subgroups, so these analyses were performed post hoc and are considered hypothesis-generating.

In the OMEGA ITT population, of the 328 enrolled patients, 222 patients were male (67.7%) and 106 patients were female (32.3%). In the United States, an estimated 15.4 million adults of 20 years and older (7.9% of men and 5.1% of women) suffer from coronary artery disease (CAD).[3] However, it is estimated that only about 33% of the annual PCIs are performed in women. In PCI clinical trials, women represent only 25%-35% of the enrolled populations, and there are relatively little gender specific data. The disproportionate enrollment distribution in this trial may be partly attributable to gender differences in pathophysiology, risk factors, and symptoms which may lead to under-diagnosis and under-referral of female patients with CAD.[4,5] Once diagnosed and treated, poorer revascularization outcomes have been reported in women due to smaller coronary arteries and increased prevalence of baseline comorbidities including advanced age, diabetes, hypertension, and peripheral vascular disease compared with men.

In patients treated with the OMEGA stent, the 9-month rate of TLF was 12.3% in males and 9.6% in females.

This post hoc analysis shows similar treatment effect between genders for the primary endpoint of 9-month TLF and its components. This suggests that the overall conclusions of the trial regarding both safety and effectiveness of the OMEGA stent can be generalized to males and females.

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

Event	OMEGA Females (N=106)	[95% CI]	OMEGA Males (N=222)	[95% CI]
9 Month TLF	9.6% (10/104)	[4.7%, 17.0%]	12.3% (27/219)	[8.3%, 17.4%]

This trial was not sized to determine the rate of low frequency events with a pre-specified precision. Numbers are % (count/sample size). 9-Month TLF is the proportion of patients who experience a target lesion failure (defined as any ischemia-driven revascularization of the target lesion [TLR], MI [Q-wave and non -Q wave] related to the target vessel, or cardiac death) up to 270 days post-procedure out of the population that have been followed for at least 240 days or who have experienced a TLF up to 270 days post-procedure.

Table 9.4 shows OMEGA 9-Month clinical results for male and female patients. Given the small number of patients enrolled, no conclusions can be drawn from these data.

Table 9.4 9-Month Clinical Endpoints by Gender, Intent-to-Treat, All Patients

	OMEGA Female Patients (N=106)	OMEGA Male Patients (N=222)
EFFICACY		
TVR, Overall	7.6% (8/105)	9.1% (20/220)
TLR, Overall	6.7% (7/105)	7.7% (17/220)
TLR, PCI	6.7% (7/105)	7.7% (17/220)
TLR, CABG	0.0% (0/105)	0.0% (0/220)
Non-TLR TVR, Overall	2.9% (3/105)	1.4% (3/220)
Non-TLR TVR, PCI	2.9% (3/105)	1.4% (3/220)
Non-TLR TVR, CABG	0.0% (0/105)	0.0% (0/220)
SAFETY		
All Death	1.0% (1/105)	2.3% (5/220)
Cardiac Death or MI	3.8% (4/105)	5.5% (12/220)
Cardiac Death	0.0% (0/105)	1.8% (4/220)
MI	3.8% (4/105)	3.6% (8/220)
Q-wave MI	0.0% (0/105)	0.0% (0/220)
Non-Q-wave MI	3.8% (4/105)	3.6% (8/220)
ARC Stent Thrombosis	1.0% (1/104)	0.5% (1/214)
Definite or Probable	1.0% (1/104)	0.5% (1/214)
Definite	1.0% (1/104)	0.5% (1/214)
Probable	0.0% (0/104)	0.0% (0/214)
Peri-Procedural Endpoints		
Procedural Success	95.3% (101/106)	95.5% (212/222)
Technical Success [a]	99.1% (106/107)	98.3% (226/230)

[a] denominator is number of study stents attempted
Numbers are % (count/sample size).
This trial was not sized to determine the rate of low frequency events with a pre-specified precision.
Abbreviations: ARC=Academic Research Consortium; CABG=coronary artery bypass graft; MI=myocardial infarction; PCI=percutaneous coronary intervention; TLR=target lesion revascularization; TVR=target vessel revascularization.

[2]King SB, 3rd, Smith SC, Jr., Hirshfeld JW, Jr., et al. 2007 Focused Update of the ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines: 2007 Writing Group to Review New Evidence and Update the ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention, Writing on Behalf of the 2005 Writing Committee. Circulation 2008;117:261-95.

[3]Alan S. Go, Dariush Mozaffarian, Veronique L. Roger et al. Heart Disease and Stroke Statistics--2014 Update: A Report From the American Heart Association Circulation 2014, 29:e28-d292

[4]Shaw LJ, Bairey Merz CN, Pepine CJ, et al. Insights from the NHLBI-Sponsored Women's Ischemia Syndrome Evaluation (WISE) Study: Part 1: gender differences in traditional and novel risk factors, symptom evaluation, and gender-optimized diagnostic strategies. J Am Coll Cardiol. 2006; 47(3):S4-S20.

[5]Lori Mosca, Emilia J. Benjamin, Kathy Berra et al. Effectiveness Based Guidelines for the Prevention of Cardiovascular Disease in Women--2011 Update: A Guideline From the American Heart Association Circulation 2011, 123:1243-1262

10 INDIVIDUALIZATION OF TREATMENT:

The risks and benefits should be carefully considered for each patient before use of the REBEL® Stent System. Patient selection factors to be assessed should include a judgment regarding risk of prolonged antiplatelet therapy. Aspirin should be administered indefinitely. Stenting is generally avoided in those patients at heightened risk of bleeding (e.g., those patients with recently active gastritis or peptic ulcer disease) in whom antiplatelet therapy would be contraindicated.

Premorbid conditions that increase the risk of poor initial results or the risks of emergency referral for bypass surgery (diabetes mellitus, renal failure, and severe obesity) should be reviewed.

11 PATIENT COUNSELING INFORMATION:

Physicians should consider the following in counseling patients about this product:

- Discuss the risks associated with stent placement.
- Discuss the risks/benefits issues for this particular patient.
- Discuss alteration to current lifestyle immediately following the procedure and over the long term.

The following patient materials are available for this product:

- A Patient Information Guide (included in the package and available on-line) which includes both product information and a stent implant card.
- 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)

Quantity	Material
1	Appropriate guide catheter (see Table 2.1, REBEL Stent System Product Description)
2-3	20 mL (cc) syringe
1000 u /500 cc	Normal heparinized sterile saline
1	≤ 0.014 in (0.36 mm) guidewire
1	Rotating hemostatic valve
1	Diluted contrast medium 1:1 with normal heparinized sterile saline
1	Inflation Device
1	Torque Device
1	Pre-deployment dilation catheter
1	Three-way stopcock
1	Appropriate arterial sheath

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.

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 through the distal tip of the catheter.
3. Verify that the stent is positioned between the proximal and distal balloon markers. Check for bends, kinks, and other damage. Do not use 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 down, orient stent delivery system vertically.
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 PTCA 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. Ensure guide catheter stability before advancing the stent delivery system into the coronary artery.

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. If the position of the stent is not optimal, it should be carefully repositioned or removed (See also Precautions – Section 6.11, Stent Delivery System Removal Pre-deployment). The inside edges of the marker bands indicate both the stent edges and balloon shoulders. Expansion of the stent should not be undertaken if the stent is not properly positioned in the target lesion segment of the vessel.

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 6.11, 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).
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 stenosed 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 artery 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 REBEL stent should be positioned inside of the deployed stent prior to expansion.
8.	Reconfirm stent position(s) and angiographic result. Repeat inflations until optimal stent 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.	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.

Nominal Stent Diameter (ID)	Dilatation Limits (ID)*
2.25 mm	2.75 mm
2.50 mm – 2.75 mm	3.50 mm
3.00 mm – 3.50 mm	4.25 mm
4.00 mm – 4.50 mm	5.75 mm

*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-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.

13.8 In Vitro Information

Table 13.1 Typical REBEL Stent System Compliance

Pressure		Stent I.D. (mm)						
atm - kPa		2.25	2.50	2.75	3.00	3.50	4.00	4.50
8.0 - 814		N/A	2.31	2.53	2.78	3.23	3.73	4.18
9.0 - 910		2.13	2.38	2.60	2.85	3.32	3.83	4.29
10.0 - 1014		2.19	2.45	2.67	2.93	3.41	3.92	4.39
11.0 - 1117	Nominal	2.25	2.51	2.74	3.00	3.49	4.00	4.48
12.0 - 1213		2.29	2.57	2.80	3.05	3.55	4.07	4.55
13.0 - 1317		2.35	2.62	2.86	3.11	3.60	4.14	4.62
14.0 - 1420		2.38	2.66	2.90	3.15	3.65	4.19	4.68
15.0 - 1517		2.42	2.70	2.94	3.18	3.70	4.24	4.73
16.0 - 1620		2.45	2.73	2.98	3.22	3.74	4.28	4.77
17.0 - 1724		2.48	2.76	3.01	3.24	3.78	4.32	4.82
18.0 - 1827	Rated*	2.50	2.79	3.04	3.28	3.81	4.36	4.87
19.0 - 1924		2.53	2.82	3.07	3.31	3.85	4.40	4.91
20.0 - 2027		2.55	2.84	3.09	3.34	3.89	4.46	4.97
21.0 - 2130		2.58	2.87	3.12	3.38	3.94	4.53	5.03
* Rated Burst Pressure. DO NOT EXCEED.								

Pressure		Stent O.D. (mm)						
atm - kPa		2.25	2.50	2.75	3.00	3.50	4.00	4.50
8.0 - 814		N/A	2.47	2.69	2.94	3.39	3.90	4.35
9.0 - 910		2.29	2.54	2.76	3.02	3.48	4.00	4.46
10.0 - 1014		2.35	2.61	2.83	3.09	3.57	4.09	4.57
11.0 - 1117	Nominal	2.41	2.67	2.90	3.17	3.66	4.18	4.65
12.0 - 1213		2.46	2.73	2.96	3.22	3.71	4.24	4.72
13.0 - 1317		2.51	2.78	3.02	3.27	3.77	4.31	4.80
14.0 - 1420		2.55	2.82	3.06	3.31	3.81	4.37	4.85
15.0 - 1517		2.58	2.86	3.11	3.35	3.86	4.41	4.90
16.0 - 1620		2.62	2.89	3.14	3.38	3.90	4.45	4.95
17.0 - 1724		2.65	2.92	3.17	3.41	3.94	4.49	4.99
18.0 - 1827	Rated*	2.67	2.95	3.20	3.44	3.97	4.53	5.04
19.0 - 1924		2.69	2.98	3.23	3.47	4.01	4.58	5.09
20.0 - 2027		2.72	3.01	3.25	3.51	4.05	4.63	5.15
21.0 - 2130		2.74	3.04	3.28	3.54	4.10	4.70	5.21
* Rated Burst Pressure. DO NOT EXCEED.								

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