



*Monorail® Coronary STENT DELIVERY SYSTEM
and
Over-The-Wire Coronary STENT DELIVERY SYSTEM*

*CAUTION: Federal law restricts this device to sale by or on
the order of a physician.*

INSTRUCTIONS FOR USE

**Boston
Scientific**

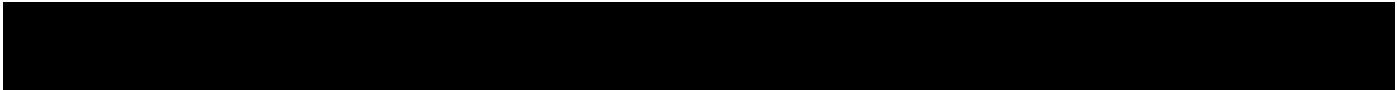


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1 DEVICE DESCRIPTION

The Express^{2™} Coronary Stent Systems include:

- A 316L surgical grade stainless steel Express[®] Stent premounted on an Over-The-Wire or Monorail[®] Balloon Catheter;
- Two radiopaque markers which aid in the accurate placement of the stent;
- A balloon enabling high pressure inflations that can be used for post-stent dilation.

Table 1. Balloon and Stent Specifications

System Balloon Diameter (mm)	Stent Length (mm)	Nominal Pressure During Stent Deployment (atm/kPa)	Rated Burst Pressure (atm/kPa)	Minimum I.D. of Guide Catheter For Monorail Catheter (in/mm)	Minimum I.D. Guide Catheter For OTW Catheter (in/mm)
2.25	8	9/912	18/1824	0.058/1.47	0.066/1.68
2.50	8	9/912	18/1824	0.058/1.47	0.066/1.68
2.75	8	9/912	18/1824	0.058/1.47	0.066/1.68
3.00	8	9/912	18/1824	0.058/1.47	0.066/1.68
3.50	8	9/912	18/1824	0.058/1.47	0.066/1.68
4.00	8	9/912	18/1824	0.058/1.47	0.066/1.68
2.25	12	9/912	18/1824	0.058/1.47	0.066/1.68
2.50	12	9/912	18/1824	0.058/1.47	0.066/1.68
2.75	12	9/912	18/1824	0.058/1.47	0.066/1.68
3.00	12	9/912	18/1824	0.058/1.47	0.066/1.68
3.50	12	9/912	18/1824	0.058/1.47	0.066/1.68
4.00	12	9/912	18/1824	0.058/1.47	0.066/1.68
4.50	12	9/912	16/1621	0.066/1.68	0.066/1.68
5.00	12	9/912	16/1621	0.066/1.68	0.066/1.68
2.25	16	9/912	18/1824	0.058/1.47	0.066/1.68
2.50	16	9/912	18/1824	0.058/1.47	0.066/1.68
2.75	16	9/912	18/1824	0.058/1.47	0.066/1.68
3.00	16	9/912	18/1824	0.058/1.47	0.066/1.68
3.50	16	9/912	18/1824	0.058/1.47	0.066/1.68
4.00	16	9/912	18/1824	0.058/1.47	0.066/1.68
4.50	16	9/912	16/1621	0.066/1.68	0.066/1.68
5.00	16	9/912	16/1621	0.066/1.68	0.066/1.68
2.25	20	9/912	18/1824	0.058/1.47	0.066/1.68
2.50	20	9/912	18/1824	0.058/1.47	0.066/1.68
2.75	20	9/912	18/1824	0.058/1.47	0.066/1.68
3.00	20	9/912	18/1824	0.058/1.47	0.066/1.68
3.50	20	9/912	18/1824	0.058/1.47	0.066/1.68
4.00	20	9/912	18/1824	0.058/1.47	0.066/1.68
4.50	20	9/912	16/1621	0.066/1.68	0.066/1.68
5.00	20	9/912	16/1621	0.066/1.68	0.066/1.68

Table 1. Balloon and Stent Specifications (continued from previous page)

System Balloon Diameter (mm)	Stent Length (mm)	Nominal Pressure During Stent Deployment (atm/kPa)	Rated Burst Pressure (atm/kPa)	Minimum I.D. of Guide Catheter For Monorail Catheter (in/mm)	Minimum I.D. of Guide Catheter For OTW Catheter (in/mm)
2.25	24	9/912	18/1824	0.058/1.47	0.066/1.68
2.50	24	9/912	18/1824	0.058/1.47	0.066/1.68
2.75	24	9/912	18/1824	0.058/1.47	0.066/1.68
3.00	24	9/912	18/1824	0.058/1.47	0.066/1.68
3.50	24	9/912	18/1824	0.058/1.47	0.066/1.68
4.00	24	9/912	18/1824	0.058/1.47	0.066/1.68
4.50	24	9/912	16/1621	0.066/1.68	0.066/1.68
5.00	24	9/912	16/1621	0.066/1.68	0.066/1.68
2.75	28	9/912	18/1824	0.058/1.47	0.066/1.68
3.00	28	9/912	18/1824	0.058/1.47	0.066/1.68
3.50	28	9/912	18/1824	0.058/1.47	0.066/1.68
4.00	28	9/912	18/1824	0.058/1.47	0.066/1.68
4.50	28	9/912	16/1621	0.066/1.68	0.066/1.68
5.00	28	9/912	16/1621	0.066/1.68	0.066/1.68
2.75	32	9/912	18/1824	0.058/1.47	0.066/1.68
3.00	32	9/912	18/1824	0.058/1.47	0.066/1.68
3.50	32	9/912	18/1824	0.058/1.47	0.066/1.68
4.00	32	9/912	18/1824	0.058/1.47	0.066/1.68
4.50	32	9/912	16/1621	0.066/1.68	0.066/1.68
5.00	32	9/912	16/1621	0.066/1.68	0.066/1.68

2 INDICATIONS and USAGE

The Express²™ Over-The-Wire and Monorail® Coronary Stent Systems are indicated for improving coronary luminal diameter in the following (see 7.1 Individualization of Treatment):

- Patients with symptomatic ischemic disease associated with stenotic lesions in native coronary arteries (length ≤ 18 mm) with a reference vessel diameter of 3.0 to 5.0 mm.
- Treatment of abrupt or threatened abrupt closure (AC/TAC) in patients with failed interventional therapy in lesions in native coronary arteries of 2.25 to 5.0 mm (inclusive) in diameter and ≤ 30 mm long.

Long-term outcome (beyond 6 months) for this permanent implant is unknown at present.

3 CONTRAINDICATIONS

The Express® Stent is contraindicated for use in:

- Patients in whom antiplatelet and/or anticoagulant therapy is contraindicated.
- Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon.
- Patients with known allergies to stainless steel. (See 4 WARNINGS and PRECAUTIONS) (see also 7.1 Individualization of Treatment).

4 WARNINGS and PRECAUTIONS

- The device carries an associated risk of subacute thrombosis, vascular complications, and/or bleeding events. Therefore, patients should be carefully selected.
- Persons allergic to stainless steel may suffer an allergic reaction to this implant.

- Implantation of the stent should be performed only by physicians who have received appropriate training.
- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.
- Subsequent restenosis may require repeat dilation of the arterial segment containing the stent. The long-term outcome following repeat dilation of coronary stents is unknown at present.
- When multiple stents are required, if placement results in metal to metal contact, stent materials should be of similar composition.
- 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 (SDS), visually confirm complete balloon deflation by fluoroscopy (See Table 2 for Deflation Time Specifications). Failure to do so may cause increased SDS withdrawal forces, and result in guide catheter movement into the vessel and subsequent arterial damage.

4.1 Stent Handling - Precautions

(see also 9 Operator's Instructions)

- 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.
- Use prior to the "Use By" date. Store in a dry, dark, cool place.
- The Express²™ Coronary Stent System is 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 device. This is most important during catheter removal from packaging, placement over guidewire, and advancement through hemostasis valve adapter and guiding catheter hub.
- Excessive manipulation, e.g., rolling the mounted stent, may cause dislodgment of the stent from the delivery balloon.
- Use only the appropriate balloon inflation media (see section 9 Operator's Instructions). Do not use air or any gas medium to inflate the balloon.

4.2 Stent Placement - Precautions

- Do not prepare or pre-inflate balloon prior to stent deployment other than as directed. Use balloon purging technique described in the Operator's Instructions.
- 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 be initially stented, followed by stenting of the more proximal lesion(s). Stenting in this order alleviates the need to cross the proximal stent in placement of the distal stent and reduces the chances for dislodging the proximal stent.
- Do not expand the stent if it is not properly positioned in the vessel. (see 4.3 Stent System Removal - Precautions)
- Placement of the stent has the potential to compromise side branch patency.
- 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.
- Balloon pressures should be monitored during inflation. Do not exceed rated burst pressure as indicated on product label (see Table 5). Use of pressures higher than specified on product label may result in a ruptured balloon and potential intimal damage and dissection. The stent I.D. should approximate 1.1 times the reference diameter of the vessel
- If unusual resistance is felt at any time during lesion access before stent implantation, the Stent System and the guiding catheter should be removed as a single unit. (See 4.3 Stent System Removal-Precautions).
- Do not attempt to pull an unexpanded stent back into the guiding catheter while engaged in the coronary arteries, as stent damage or stent dislodgment from the balloon may occur. (See 4.3 Stent System Removal-Precautions).
- 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 guiding 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.

4.3 Stent System Removal - Precautions

- If unusual resistance is felt at any time during lesion access before stent implantation, the Stent System and the guiding catheter should be removed as a single unit.
- Do not attempt to pull an unexpanded stent back into the guiding

catheter while engaged in the coronary arteries, as stent damage or stent dislodgment from the balloon may occur.

When removing the entire Stent System and guiding catheter as a single unit:

NOTE: The following steps should be executed under direct visualization using fluoroscopy.

- Following stent placement, confirm complete balloon deflation (See Table 2 for Deflation Time Specifications). If unusual resistance is felt during SDS 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 movement) 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 System until the proximal balloon marker of the Stent System is aligned with the distal tip of the guiding catheter.
- The Stent System and the guiding catheter should be pulled back until the tip of the guiding catheter is just distal to the arterial sheath, allowing the guiding catheter to straighten. Carefully retract the Stent System into the guiding catheter and remove the Stent System and the guiding catheter from the patient **as a single unit** while leaving the guidewire across the lesion.

Failure to follow these steps, and/or applying excessive force to the Stent System can potentially result in stent damage, stent dislodgment from the balloon and/or damage to the Delivery System.

Table 2. System Deflation Time Specifications

Balloon Length/ Diameter	8mm	12mm	16mm	20mm	24mm	28mm	32mm	
2.25	≤ 16 seconds						Not Offered	
2.50								
2.75								
3.00								
3.50								
4.00	≤ 21 seconds							
4.50								Not Offered
5.00	Offered							

***All product tested during Design Verification met 95/95 confidence/conformance levels.**

4.4 Post Implant - Precautions

- Care must be exercised when crossing a newly deployed stent with an intravascular ultrasound (IVUS), a coronary guidewire, or a balloon catheter to avoid disrupting the stent placement, apposition and/or geometry.
- Through non-clinical testing, the Express® Stent has been shown to be MRI safe at field strengths 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 MRI. The Express Stent should not migrate in this MRI environment. MRI at 3T or less may be performed immediately following the implantation of the Express stent.
- In this testing, the stent produced a maximum temperature rise of 0.65 degrees C at a maximum whole body average SAR of 2 W/kg for 15 minutes of MRI. The effect of heating in the MRI environment was similar for overlapping bare metal stents (2 to 5 mm overlap at the ends), made of the same stainless steel material and having the same stent design. The effect of heating in the MRI environment for stents with fractured struts is not known.
- Non-clinical testing has not been performed to rule out the possibility of stent migration at field strengths higher than 3 Tesla.
- 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.

5 Adverse Events

5.1 Observed Adverse Events

A total of 450 patients were enrolled in the VICTORY Clinical Study, a prospective, multi-center, two arm registry. 303 patients were enrolled in the elective arm of the study and 147 were enrolled in the abrupt closure/threatened abrupt closure (AC/TAC) arm. The observed major adverse events were compared to the SCORES clinical study (Radius® or Palmatz-Schatz® stent) for the elective arm of the study. The AC/TAC registry early MACE rate was compared to an objective performance criterion.

5.1.1 VICTORY Clinical Trial Studies

Table 3. shows the major clinical events in the elective arm and the AC/TAC arm of the VICTORY Clinical Trial.

**Table 3. Major Clinical Events – In-Hospital vs. Out-of-Hospital
Intent-to-Treat, All Elective Patients (N=891 pts), AC/TAC Patients (N=147)**

Event	VICTORY(N=303 pts)	SCORES(N=588 pts)	AC/TAC(N=147 pts)
MACE (Death, MI, TVR) Early (In-hospital) Out-of-hospital	9.1% (26/287) [6.0%, 13.0%] 2.0% (6/303) [0.7%, 4.3%] 7.3% (21/287) [4.6%, 11.0%]	12.4% (71/571) [9.8%, 15.4%] 2.0% (12/588) [1.1%, 3.5%] 10.5% (60/569) [8.1%, 13.4%]	2.7% (4/146) [0.8%, 6.9%] 2.7% (4/147) [0.7%, 6.8%] 0.0% (0/146) [0.0%, 2.5%]
Death - Total Early (In-hospital) Out-of-hospital	0.0% (0/287) [0.0%, 1.3%] 0.0% (0/303) [0.0%, 1.2%] 0.0% (0/287) [0.0%, 1.3%]	0.4% (2/571) [0.0%, 1.3%] 0.3% (2/588) [0.0%, 1.2%] 0.0% (0/569) [0.0%, 0.6%]	0.0% (0/146) [0.0%, 2.5%] 0.0% (0/147) [0.0%, 2.5%] 0.0% (0/146) [0.0%, 2.5%]
Q-wave MI - Total Early (In-hospital) Out-of-hospital	0.7% (2/287) [0.1%, 2.5%] 0.0% (0/303) [0.0%, 1.2%] 0.7% (2/287) [0.1%, 2.5%]	0.5% (3/571) [0.1%, 1.5%] 0.0% (0/588) [0.0%, 0.6%] 0.5% (3/569) [0.1%, 1.5%]	0.0% (0/146) [0.0%, 2.5%] 0.0% (0/147) [0.0%, 2.5%] 0.0% (0/146) [0.0%, 2.5%]
Non Q-wave MI - Total Early (In-hospital) Out-of-hospital	2.8% (8/287) [1.2%, 5.4%] 1.7% (5/303) [0.5%, 3.8%] 1.0% (3/287) [0.2%, 3.0%]	1.9% (11/571) [1.0%, 3.4%] 1.2% (7/588) [0.5%, 2.4%] 0.7% (4/569) [0.2%, 1.8%]	2.7% (4/146) [0.8%, 6.9%] 2.7% (4/147) [0.8%, 6.8%] 0.0% (0/146) [0.0%, 2.5%]
TVR - Total Early (In-hospital) Out-of-hospital	7.7% (22/287) [4.9%, 11.4%] 0.3% (1/303) [0.0%, 1.8%] 7.3% (21/287) [4.6%, 11.0%]	10.7% (61/571) [8.3%, 13.5%] 0.7% (4/588) [0.2%, 1.7%] 10.0% (57/569) [7.7%, 12.8%]	0.0% (0/146) [0.0%, 2.5%] 0.0% (0/147) [0.0%, 2.5%] 0.0% (0/146) [0.0%, 2.5%]
Stent Thrombosis - Total Early (In-hospital) Out-of-hospital	1.0%(3/287) [0.2%,3.0%] 0.0%(0/303) [0.0%,1.2%] 1.0%(3/287) [0.2%,3.0%]	0.4% (2/571) [0.0%, 1.3%] 0.3%(2/588) [0.0%,1.2%] 0.0%(0/569) [0.0%,0.6%]	0.0% (0/146) [0.0%, 2.5%] 0.0% (0/147) [0.0%, 2.5%] 0.0% (0/146) [0.0%, 2.5%]
Bleeding Complication Early (In-hospital) Out-of-hospital	8.7% (25/288) [5.7%, 12.5%] 4.6% (14/303) [2.5%, 7.6%] 4.2% (12/287) [2.2%, 7.2%]	9.1% (52/571) 6.9%, 11.8%] 7.7% (45/588) [5.6%, 10.1%] 2.1% (12/569) [1.1%, 3.7%]	4.8% (7/146) [1.9%, 9.6%] 3.4% (5/147) [1.1%, 7.8%] 1.4% (2/146) [0.2%, 4.9%]
Vascular Complication Early (In-hospital) Out-of-hospital	1.0% (3/287) [0.2%, 3.0%] 0.0% (0/303) [0.0%, 1.2%] 1.0% (3/287) 0.2%, 3.0%]	0.5% (3/571) [0.1%, 1.5%] 0.2% (1/588) 0.0%, 0.9%] 0.4% (2/569) [0.0%, 1.3%]	1.4% (2/146) [0.2%, 4.9%] 1.4% (2/147) [0.2%, 4.8%] 0.0% (0/146) [0.0%, 2.5%]

5.2 Potential Adverse Events

Adverse events (alphabetically) which may be associated with the use of a coronary stent in native coronary arteries:

- Acute myocardial infarction
- Arrhythmias
- Death
- Dissection
- Drug reactions to antiplatelet agents/contrast media
- Emboli, distal (air, tissue or thrombotic)
- Emergent Coronary Artery Bypass Surgery
- Hemorrhage, requiring transfusion
- Hypotension/Hypertension
- Infection and/or pain at the access site
- Ischemia, myocardial
- Perforation
- Pseudoaneurysm, femoral
- Restenosis of stented segment
- Spasm
- Stent embolization
- Stent thrombosis/occlusion
- Stroke/cerebrovascular accident
- Total occlusion of coronary artery

6 Clinical Studies

6.1 VICTORY Trial

The Express® Coronary Stent System was evaluated in a prospective two-arm, multi-center study (VICTORY Clinical Trial). A total of 450 patients (303-Elective, 147-AC/TAC) were treated at 26 US investigational sites in the study. The elective arm of the study compared the Express™ to a historical control comprised of randomized patients in the SCORES study who received a Radius® or Palmatz-Schatz® stent. The AC/TAC registry arm of the VICTORY Clinical Trial was an evaluation of the Express® Stent compared to an Objective Performance Criterion.

Primary endpoints: The primary endpoint for the elective arm of the VICTORY clinical trial is major adverse cardiac events (MACE) at 6 months. MACE is comprised of death, myocardial infarction (Q-wave and non-Q-wave), and target vessel revascularization. The primary endpoint for the AC/TAC arm of the VICTORY clinical trial is MACE at 14 days. An independent clinical events committee adjudicated all of the major clinical endpoints for the VICTORY clinical trial.

Patients Studied: Patients with ischemic coronary artery disease with de novo and restenotic lesions in native coronary arteries 3.0 to 4.0 mm (inclusive) in diameter and ≤ 18 mm long were enrolled in the elective arm of the VICTORY clinical trial. Patients who experienced abrupt or threatened abrupt closure (AC/TAC) with failed interventional therapy in lesions in native coronary arteries 2.25 to 4.0 mm (inclusive) in diameter and ≤ 30 mm long. Additionally AC/TAC patients needed 2 or more of the following criteria at the time of enrollment : diameter stenosis $\geq 50\%$, National Heart, Lung, and Blood Institute (NHLBI) Type B or C dissection, NHLBI Type D, E or F dissection, thrombolysis in MI (TIMI) 0-2 flow due primarily to mechanical obstruction of the treated site, angina or anginal equivalent symptoms, ischemic electrocardiographic changes.

Methods: Lesions in patients were pre-dilated with an appropriate balloon diameter in relation to the target vessel diameter (balloon to vessel ratio of 1:1). The appropriate stent size (approximately 2-4 mm longer than the shoulder-to-shoulder measured lesion length with a stent to distal target vessel ratio of 1:1 or 1.1:1.0) was selected and prepared. Post-stent deployment dilations could be performed with the delivery system or a non-compliant balloon to assure that the stent is in full contact with the arterial wall. To achieve this, a high-pressure balloon, with a balloon to artery ratio of 1:1 to 1.1:1.0 was used, and optimal stent expansion was determined by visual angiographic assessment

Clinical follow-up occurred at 14 ± 4 days, 30 ± 7 days, and 180 months ± 60 days for VICTORY patients in the elective arm. AC/TAC patients were followed at 14 ± 4 days and 30 ± 7 days. A subset of patients in the elective arm underwent angiographic follow-up at six-months. Baseline characteristics were similar to the control group for the elective arm. All treated patients were included in the intent to treat analysis. Anticoagulation included aspirin (325 mg/day for 12 months and clopidigrel 75 mg/day for one month).

Results: Table 4. shows the principal effectiveness and safety results for both arms of the VICTORY clinical trial. Figure 1 shows freedom from MACE.

Table 4. Principal Effectiveness and Safety Results

Efficacy Measures	VICTORY (N=303 pts)	SCORES (N=588 pts)	Difference [95% CI]	AC/TAC Registry (N=147)
Clinical Procedural Success	97%(293/303) [94.0%, 98.4%]	96%(566/588) [94.4%, 97.6%]	0.4% [-2.1%, 3.0%]	96% (141/147) [91.3%, 98.5%]
Technical Success	97%(294/303) [94.4%,98.6%]	95%(560/588) [93.2%,96.8%]	1.8% [-0.8%, 4.4%]	95% (140/147) [90.4%, 98.1%]
30-Day MACE	2%(7/297) [1.0%,4.8%]	2%(14/574) [1.3%,4.1%]	-0.1% [-2.2%, 2.1%]	3% (4/136) [0.8%, 7.4%]
6-Month MACE	9%(26/287) [6.0%,13.0%]	12%(71/571) [9.8%,15.4%]	-3.4% [-7.7%, 0.9%]	
6-Month TVF	9%(26/287) [6.0%,13.0%]	12%(71/571) [9.8%,15.4%]	-3.4% [-7.7%, 0.9%]	
6-Month Restenosis	19%(22/113) [12.6%,28.0%]	24%(35/148) [17.1%,31.3%]	-4.2% [-14.2%, 5.8%]	
Safety Measures				
In-Hospital MACE	2%(6/303) [0.7%,4.3%]	2%(12/588) [1.1%,3.5%]	-0.1% [-2.0%, 1.9%]	3% (4/147) [0.7%, 6.8%]
Out-of-Hospital MACE	7%(21/287) [4.6%,11.0%]	11%(60/569) [8.1%,13.4%]	-3.2% [-7.2%, 0.7%]	0% (0/146) [0.0%, 2.5%]

Numbers are % (count/sample size). CI = Confidence Interval.

Relative Risk = VICTORY/SCORES

SE = $\sqrt{\{(1-p_1)/n_1 + (1-p_2)/n_2\}}$

CI = RR exp(± 1.96 SE)

Difference = VICTORY-SCORES

SE = $\sqrt{\{p_1q_1/n_1 + p_2q_2/n_2\}}$

CI = Diff ± 1.96 SE

Clinical Procedural Success: using the stent to achieve a residual diameter stenosis of <30% as visually assessed by the Investigator at the end of the stent procedure, without the occurrence of MACE as of the time of hospital discharge. In SCORES, the residual %DS is assessed by QCA.

Technical Success: successful delivery and deployment of the stent to the target lesion, without balloon rupture, embolization, guidewire fracture, or use of a device outside the treatment strategy. In SCORES, this is successful delivery and deployment of the stent to the target lesion without bailout.

6-Month MACE (primary endpoint): the proportion of patients who experience a MACE up to the 6-month follow-up. MACE includes death, myocardial infarction (MI) including Q- and non-Q-wave MI, and target vessel revascularization (TVR).

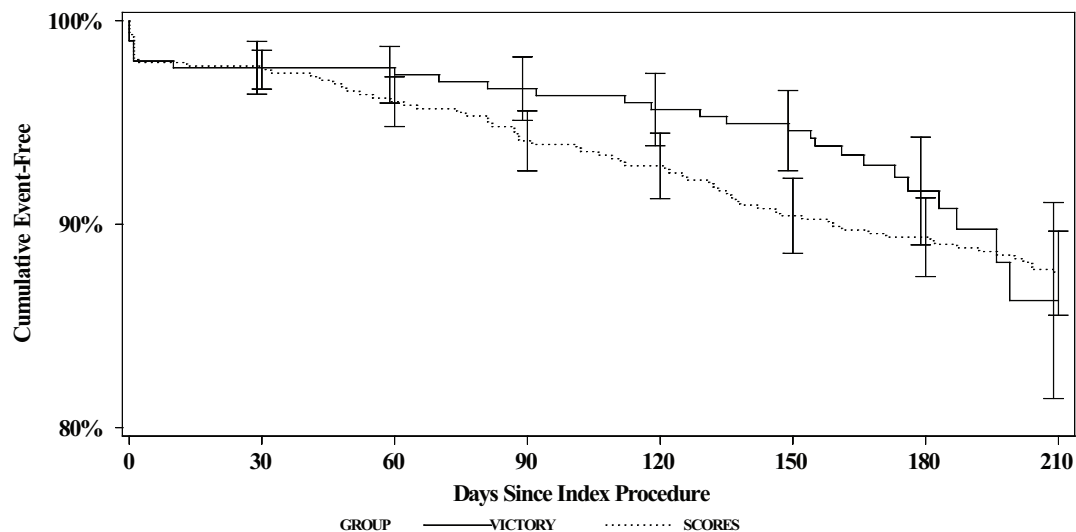
30-Day MACE: binary MACE rate at 30 days post-procedure.

Target Vessel Failure (TVF): any revascularization of the target vessel, or MI (Q- and non-Q-wave), or death that cannot be clearly attributed to a vessel other than the target vessel.

6-Month Restenosis: proportion of patients who demonstrate restenosis of the target lesion with percent diameter stenosis $\geq 50\%$ as assessed by QCA 6 months after the study procedure.

6-Month Follow-up: 150 - 210 days.

Figure 1. Figure of Survival Free of MACE
Intent-to-Treat, Event-Free Survival \pm 1.5 SE, All Elective Patients (N=891 pts)



VICTORY	0	7	14	30	60	90	120	150	180	210
Entered	303	300	295	293	289	285	282	279	267	120
Censored 0	2	1	4	3	1	0	9	141	96	
Events	3	3	1	0	1	2	3	3	6	4
At Risk	303	299	294.5	291	287.5	284.5	282	274.5	196.5	72
Events/Month	90.0	12.9	4.3	0.0	1.0	2.0	3.0	3.0	6.0	4.0
Event Free	99.0%	98.0%	97.7%	97.7%	97.3%	96.7%	95.6%	94.6%	91.6%	86.2%
Std Error 0.6%	0.8%	0.9%	0.9%	0.9%	1.0%	1.2%	1.3%	1.8%	3.2%	

SCORES	0	7	14	30	60	90	120	150	180	210
Entered	588	577	569	564	560	548	537	530	516	508
Censored 7	0	4	3	3	0	0	0	2	5	
Events	4	8	1	1	9	11	7	14	6	10
At Risk	584.5	577	567	562.5	558.5	548	537	530	515	505.5
Events/Month	120.0	34.3	4.3	1.9	9.0	11.0	7.0	14.0	6.0	10.0
Event Free	99.3%	97.9%	97.8%	97.6%	96.0%	94.1%	92.9%	90.4%	89.4%	87.6%
Std Error 0.3%	0.6%	0.6%	0.6%	0.8%	1.0%	1.1%	1.2%	1.3%	1.4%	

Tests Between Groups, To 210 Days

Test	Chi-Square	Degrees of Freedom	p-Value
<i>Log-Rank</i>	0.559	1	0.454
<i>Wilcoxon</i>	1.037	1	0.309

Patients event-free at 210 days or later are censored at 211 days. Intervals are end inclusive, e.g. interval 180 is defined as 151-180 days, inclusive. Event-free and standard error estimates are for interval end. Standard errors by Greenwood formula.

7 PATIENT SELECTION AND TREATMENT

7.1 Individualization of Treatment

The risks and benefits should be carefully considered for each patient before use of the Express²™ Coronary Stent System. Patient selection factors to be assessed should include a judgment regarding risk of prolonged anticoagulation. Stenting is generally avoided in those patients at heightened risk of bleeding (e.g., those patients with recently active gastritis or peptic ulcer disease, see 3 CONTRAINDICATIONS).

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.

Thrombosis following stent implantation is affected by several baseline angiographic and procedural factors. These include vessel diameter less than 3.0 mm, vessel thrombosis, poor distal flow, and/or dissection following stent implantation. In patients undergone coronary stenting, the persistence of a thrombus or dissection is considered a marker for subsequent thrombotic occlusion. These patients should be monitored very carefully during the first month after stent implantation, because stent thrombosis may occur during this period.

7.2 Specific Patient Populations

The safety and effectiveness of the Express² Stent System has not been established for patients with any of the following characteristics:

- Patients with unresolved vessel thrombus at the lesion site.
- Patients with coronary artery reference vessel diameters < 2.25 mm.
- Patients with lesions located in the unprotected left main coronary artery, ostial lesions, or lesions located at a bifurcation.
- Patients with diffuse disease or poor outflow distal to the identified lesions.
- Patients with a recent acute myocardial infarction where there is evidence of thrombus or poor flow.
- Patients with more than two overlapping stents due to risk of thrombus.
- Patients for longer than 6 months follow-up.
- Patients with moderate or severe calcification in the lesion.

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

8 HOW SUPPLIED

STERILE: This device is sterilized with ethylene oxide gas. It is intended for single use only. Non-pyrogenic. Do not use if package is opened or damaged.

CONTENTS: Express²™ Over-The-Wire Stent System
One (1) Express² Over-The-Wire Stent System
One (1) Instructions for Use Manual
One (1) Patient Guide with Patient Implant Card

CONTENTS: Express²™ Monorail® Stent System
One (1) Express² Monorail Stent System
One (1) Instructions for Use Manual
Two (2) CLIPIT® Hypotube Clips
One (1) Flushing needle with luer fitting
One (1) Patient Guide with Patient Implant Card

STORAGE: Store in a cool, dry dark place.

9 OPERATOR'S INSTRUCTIONS

9.1 Inspection Prior to Use

Carefully inspect the sterile package before opening. Do not use after the "Use By" date. If the integrity of the 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.

NOTE: At any time during use of the Premounted Stent System, if the stainless steel proximal shaft has been bent or kinked, do not continue to use the catheter.

9.2 Materials Required (not included in Stent System package)

Quantity	Material
1	Appropriate guiding catheter (see Table 1 - Balloon and Stent Specifications)
1	20 ml (cc) syringe
1	Normal heparinized saline
1	≤0.014 in. / 0.36 mm guidewire
1	Rotating hemostatic valve
1	Diluted contrast medium 1:1 with normal heparinized saline
1	Inflation Device with pressure gauge
1	Torque Device
1	Pre-deployment dilation catheter
1	Three-way stopcock
1	Appropriate arterial sheath

9.3 Preparation

Packaging Removal

Step	Action
1.	Carefully remove the delivery system from its protective tubing for preparation of the delivery system. When using the Monorail System, do not bend or kink hypotube during removal.
2.	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. If unusual resistance is felt during product mandrel and stent protector removal, do not use this product and replace with another. Follow product returns procedure for the unused device.

3. A Monorail® Catheter may be coiled once and secured using the Clipit® Coil Clip provided in the catheter package. Only the proximal shaft should be inserted into the Clipit Coil Clip; 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 coil clip.

Guidewire Lumen Flush

- | Step | Action |
|------|--|
| 1. | Flush Stent System guidewire lumen with normal heparinized saline. Use flushing needle supplied for the Monorail® System. |
| 2. | 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. |

Balloon Preparation

- | Step | Action |
|------|---|
| 1. | Rinse the stent in sterile saline. |
| 2. | Prepare inflation device/syringe with diluted contrast medium. |
| 3. | Attach inflation device/syringe to stopcock; attach to inflation port. With Monorail Systems, do not bend the hypotube when connecting to inflation device/syringe. |
| 4. | With tip down, orient Stent System vertically. |
| 5. | Open stopcock to Stent System; pull negative for 15 seconds; release to neutral for contrast fill. |
| 6. | Close stopcock to Stent System; purge inflation device/syringe of all air. |
| 7. | Repeat steps 4 through 6 until all air is expelled. If bubbles persist, do not use device. |
| 8. | Remove the syringe or inflation device from the stopcock affixed to the delivery catheter. |
| 9. | Fill the stopcock port with a meniscus of contrast medium. |
| 10. | Prepare the inflation device to remove all entrapped air and fill the inflation device connector with a meniscus of contrast medium. |
| 11. | Securely couple the inflation device to the stopcock. |
| 12. | Open stopcock to stent system and leave on neutral. |

9.4 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 system.
4. Backload Stent System onto proximal portion 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 System into the hub of the guiding catheters. When using a Monorail System be sure to keep the hypotube straight. Ensure guiding catheter stability before advancing the Stent System into the coronary artery.

NOTE: If unusual resistance is felt before the stent exits the guiding 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 System and guiding catheter as a single unit.

7. Advance the Stent 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 4.3 Stent System Removal - Precautions). 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 System and the guiding catheter should be removed as a single unit. (See 4.3 Stent System Removal - Precautions).

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

9.5 Deployment Procedure

- | Step | Action |
|------|--|
| 1. | Inflate the delivery system expanding the stent to a minimum pressure of 9 atm/912 kPa (stent nominal pressure). 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 ID of about 1.1 times the reference vessel diameter (see Table 5). Balloon pressure must not exceed rated burst pressure. (see Table 5) |

2. Maintain inflation pressure for 15-30 seconds for full expansion of the stent.
3. Deflate balloon by pulling negative on inflation device until balloon is fully deflated.
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. All efforts should be taken to assure that the stent is not underdilated.
5. If stent sizing/apposition requires optimization, readvance the Stent System balloon, or another 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. Deflate the balloon. (refer to product labeling and/or Table 5 for proper stent inflation pressure.)
7. Reconfirm stent position and angiographic result. Repeat inflations until the desired result is achieved.

9.6 Removal Procedure

- | Step | Action |
|------|---|
| 1. | Ensure balloon is fully deflated. |
| 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 9.3 Preparation). |

9.7

In Vitro Information

Table 5. Typical Express® Stent and Balloon Compliance

Pressure (Atm-kPa)	2.25 mm Stent I.D. (mm)	2.50 mm Stent I.D. (mm)	2.75 mm Stent I.D. (mm)	3.00 mm Stent I.D. (mm)	3.50 mm Stent I.D. (mm)	4.0 mm Stent I.D. (mm)	4.50 mm Stent I.D. (mm)	5.00 mm Stent I.D. (mm)	
9.0-912	Stent Nominal	2.25	2.50	2.75	3.00	3.50	4.00	4.50	5.00
10.0-1013		2.30	2.55	2.81	3.06	3.57	4.07	4.58	5.09
11.0-1115		2.34	2.60	2.86	3.12	3.64	4.14	4.65	5.17
12.0-1216		2.37	2.65	2.91	3.17	3.69	4.20	4.72	5.24
13.0-1317		2.41	2.69	2.95	3.21	3.75	4.26	4.78	5.31
14.0-1419		2.44	2.72	2.99	3.26	3.80	4.31	4.83	5.37
15.0-1520		2.47	2.76	3.03	3.30	3.85	4.36	4.88	5.43
16.0-1621		2.50	2.79	3.06	3.33	3.89	4.41	4.93*	5.48*
17.0-1723		2.52	2.82	3.10	3.37	3.93	4.45		
18.0-1824		2.55*	2.85*	3.13*	3.40*	3.97*	4.49*		

*Rated Burst Pressure. DO NOT EXCEED.

10 PATIENT INFORMATION

The following information is included in the package for physicians to provide to their patients.

- A Patient Guide which includes information on coronary artery disease, the implant procedure and the Express²™ Coronary Stent System.
- A Patient Implant Card that includes both patient information and stent implant information.

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