

*Addressing In-Stent Restenosis\****INDICATIONS**

The TAXUS<sup>®</sup> Express<sup>2™</sup> Paclitaxel-Eluting Coronary Stent System is indicated for improving luminal diameter for the treatment of *de novo* lesions  $\leq 28$ mm in length in native coronary arteries  $\geq 2.5$ mm to  $\leq 3.75$ mm in diameter.

**CONTRAINDICATIONS**

Use of the TAXUS Express<sup>2</sup> Paclitaxel-Eluting Coronary Stent System is contraindicated in patients with:

- Known hypersensitivity to paclitaxel or structurally related compounds.
- Known hypersensitivity to the polymer or its individual components.

Coronary Artery Stenting is contraindicated for use in:

- Patients in whom antiplatelet and/or anticoagulant therapy is contraindicated.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or delivery device.

**WARNINGS**

- To maintain sterility, the inner package should not be opened or damaged prior to use.
- The use of this product carries the risks associated with coronary artery stenting, including subacute thrombosis, vascular complications and/or bleeding events. Patients with known hypersensitivity to 316L stainless steel may suffer an allergic reaction to this implant.

**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:**

Aneurysm, Arrhythmias, Bleeding complications, Death, Distal emboli, Emergent CABG, Myocardial infarction, Myocardial ischemia, Occlusion, Stent delivery failures, Target lesion revascularization, Thrombosis, Vascular complications, Vessel dissection.

**Potential adverse events not captured above that may be unique to the paclitaxel drug coating:**

Alopecia, allergic reaction to the drug or the polymer, anemia, blood product transfusion, gastrointestinal symptoms, hematologic dyscrasia, hepatic enzyme changes, histologic changes in vessel wall, including inflammation, cellular damage or necrosis, myalgia/arthralgia, peripheral neuropathy.

**The safety and effectiveness of the TAXUS Express<sup>2</sup> Paclitaxel-Eluting Coronary Stent System have not been established in the following patient populations:**

- Women who are pregnant or lactating.
- Men intending to father children.
- Pediatric patients.
- Patients with unresolved vessel thrombus at the lesion site.
- Patients with coronary artery reference vessel diameters  $< 2.5$ mm or  $> 3.75$ mm.
- Patients with lesions located in the saphenous vein grafts, in the unprotected 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 multiple overlapping stents.
- Patients with longer than 12 month follow-up.

Prior to use, please see the complete "Directions for Use" at [www.taxus-stent.com](http://www.taxus-stent.com) for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events and Operator's Instructions.

**CAUTION**

Federal law restricts this product to sale by or on the order of a physician.

<b>Objective:</b>	To demonstrate superior or non-inferior 9-month target vessel revascularization (TVR) rate for TAXUS <sup>®</sup> Express <sup>2™</sup> Paclitaxel-Eluting SR Stent compared to intracoronary brachytherapy (beta source)
<b>Number of Patients:</b>	488
<b>Number of Sites:</b>	Up to 40
<b>Lesion Type:</b>	In-stent restenosis (ISR) of previously implanted stent; length $< 46$ mm
<b>Stent Platform:</b>	Express <sup>2</sup> ; 8, 16, 20, 24 and 32mm lengths; 2.25, 2.5, 3.0, 3.5 and 4.0mm diameters
<b>Release Kinetics:</b>	Slow (SR)
<b>Primary Endpoint:</b>	9-month TVR
<b>P.I. and Co P.I.:</b>	G.W. Stone, MD and S. Ellis, MD

# Boston Scientific

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\*Caution: The TAXUS Express<sup>2</sup> Stent is an investigational device for coronary artery reference diameters of 2.25mm and 4.0mm. This product is currently under US IDE for investigational use in in-stent restenosis.

The safety and effectiveness of the TAXUS Express<sup>2</sup> Stent has not been proven in patients with coronary artery lesions longer than 28mm, in overlapping stents or in patients with diabetes.

# TAXUS V-ISR

## US Randomized Pivotal ISR Trial

Baseline Demographics and Clinical Characteristics Intent-to-Treat, All Patients (N=396)	Brachytherapy (N=201)	TAXUS® Express <sup>2</sup> ™ Paclitaxel-Eluting Stent (N=195)	p-Value
Age (yrs)	62.72±12.07 (201)	62.10±11.11 (195)	0.5961
Male (%)	70.1% (141/201)	62.1% (121/195)	0.0886
Diabetes Requiring Medication	30.3% (61/201)	40.0% (78/195)	0.0442
Insulin Requiring	10.4% (21/201)	19.5% (38/195)	0.0116
Non-insulin requiring	19.9% (40/201)	20.5% (40/195)	0.8794
<b>Baseline Lesion Characteristics Determined by QCA</b>			
Reference Vessel Diameter (RVD, mm)	2.63±0.46 (201)	2.68±0.47 (193)	0.2498
Lesion Length (mm)	17.40±9.21 (200)	18.54±9.52 (191)	0.2302
<b>QCA Measurements: Paired Lesion Analysis, 9-Month Follow-Up</b>			
Clinical Procedural Success	90.5 (182/201)	98.5 (192/195)	0.0006
<b>9-Month Binary Restenosis (%)</b>			
In-Stent*	NA	7.0% (12/172)	NA
Injury Segment**	20.1% (34/169)	7.0% (12/171)	0.0004
Analysis Segment†	31.2% (53/170)	14.5% (25/172)	0.0002
<b>9-Month Late Loss (mm)</b>			
In-Stent*	NA	0.38±0.49 (172)	NA
Injury Segment**	0.28±0.67 (169)	0.38±0.45 (171)	0.1270
Analysis Segment†	0.40±0.58 (170)	0.29±0.54 (172)	0.0694
<b>9-Month Min. Lumen Diameter (mm)</b>			
In-Stent*	NA	2.16±0.60 (172)	NA
Injury Segment**	1.76±0.73 (169)	2.15±0.59 (171)	<0.0001
Analysis Segment†	1.46±0.66 (170)	1.90±0.63 (172)	<0.0001
<b>9-Month Diameter Stenosis (%)</b>			
In-Stent*	NA	21.04±20.55 (172)	NA
Injury Segment**	32.27±27.12 (169)	21.52±19.79 (171)	<0.0001
Analysis Segment†	44.61±22.89 (170)	30.83±20.23 (172)	<0.0001
Percent In-Stent Net Volume Obstruction	32.35±11.74 (41)	12.21±10.26 (42)	<0.0001
<b>9-Month Results</b>			
9-Month MACE	20.1% (39/194)	11.5% (22/191)	0.0211
Cardiac Death	0.5% (1/194)	0.0% (0/191)	1.0000
MI	4.6% (9/194)	3.7% (7/191)	0.6320
Q-Wave MI	0.0% (0/194)	0.5% (1/191)	0.4961
Non-Q-Wave MI	4.6% (9/194)	3.1% (6/191)	0.4476
TVR, Overall	17.5% (34/194)	10.5% (20/191)	0.0463
TLR, Overall	13.9% (27/194)	6.3% (12/191)	0.0130
TLR, PCI	12.4% (24/194)	4.2% (8/191)	0.0036
TLR, CABG	2.6% (5/194)	2.6% (5/191)	1.0000
9-Month TVF	19.6% (38/194)	11.5% (22/191)	0.0291
<b>Target Vessel or Stent Thrombosis</b>			
	<b>Target Vessel Thrombosis<sup>1</sup> (Brachytherapy)</b>	<b>Stent Thrombosis<sup>2</sup> (TAXUS Express<sup>2</sup>)</b>	
Any	2.6% (5/193)	1.6% (3/191)	0.7237
In-Hospital	0.0% (0/201)	0.0% (0/195)	Undef
Discharge to 30 Days	0.5% (1/199)	0.5% (1/194)	1.0000

\*In-Stent Definition: TAXUS Express<sup>2</sup>: Area covered by the newly placed stent; Brachytherapy: Not Applicable.

\*\*Injury Segment Definition: Area in which the index procedure balloon is inflated against the vessel wall (for both TAXUS Express<sup>2</sup> and brachytherapy).

†Analysis Segment Definition: TAXUS Express<sup>2</sup>: Stented segment plus 5mm on each edge; Brachytherapy: Radiation Segment (area exposed to brachytherapy, by definition).

1. Target Vessel Thrombosis (independent adjudication by CEC subcommittee) – Brachytherapy group only: (1) Clinical presentation of acute coronary syndrome with angiographic documentation of occlusion or thrombus; or (2) Acute MI in the target vessel territory; or (3) Cardiac death within 30 days.

2. Stent Thrombosis (CEC adjudication) – TAXUS Express<sup>2</sup> group only: (1) Clinical presentation of acute coronary syndrome with angiographic evidence of stent thrombosis; or (2) MI in distribution of treated vessel; or (3) Death in first 30 days without obvious cause.

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