

TAXUS[®] Express^{2™}

Clinical Programs

Boston
Scientific

Clinical Trial
and Registry
Summary



TAXUS IV

US Pivotal Trial

Consistently Safe and Effective

Objective:	Demonstrate safety and superior performance of TAXUS® Express® Paclitaxel-Eluting Stent for treatment of <i>de novo</i> lesions over control
Number of Patients:	1,326 enrolled
Number of Sites:	76
Lesion Type:	<i>de novo</i>
Stent Platform:	Express 16, 24 and 32 mm lengths, 2.5, 3.0 and 3.5 mm diameters
Release Kinetics:	Slow Release (SR)
Primary Endpoint:	9-Month TVR, superiority to control arm
Principal Investigators:	G.W. Stone, MD and S. Ellis, MD
Status:	Enrollment complete

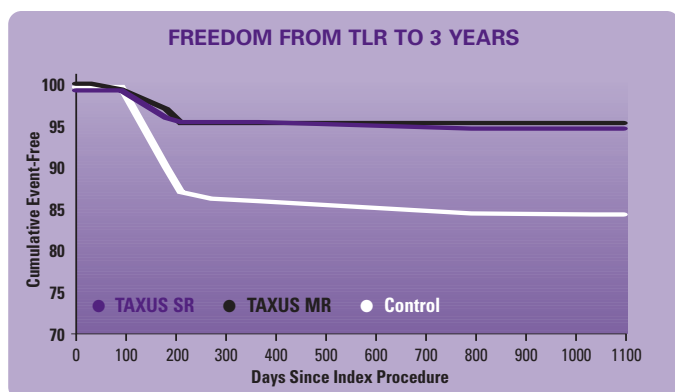
	TAXUS® Express® Paclitaxel-Eluting Stent (n=662)	Control* (n=652)	p-Value
Baseline Demographics			
Age (years)	62.8 ± 11.2	62.1 ± 10.9	0.2106
Males (n)	71.8% (475/662)	72.4% (472/652)	0.8060
Medically Treated Diabetes (n)	23.4% (155/662)	25.0% (136/652)	0.5198
Requiring Insulin (n)	7.7% (51/662)	8.3% (54/652)	0.7604
No Insulin Required (n)	15.7% (104/662)	16.7% (109/652)	0.6535
Medically Treated Hyperlipidemia (n)	65.0% (430/662)	65.6% (428/652)	0.8168
Medically Treated Hypertension (n)	70.5% (467/662)	69.0% (450/652)	0.5487
Baseline Lesion Characteristics			
Lesion Length (mm)	13.38 ± 6.31	13.37 ± 6.19	0.9778
Reference Vessel Diameter (RVD) (mm)	2.75 ± 0.47	2.75 ± 0.49	0.9317
Minimum Lumen Diameter (MLD) (mm)	0.92 ± 0.33	0.95 ± 0.34	0.1618
Diameter Stenosis (%)	66.54 ± 10.66	65.60 ± 10.68	0.1096
9-Month QCA and IVUS Endpoints			
Clinical Procedural Success	97.3%	97.4%	1.0000
Binary Restenosis Rate			
In-Stent	5.5%	24.4%	<0.0001
Analysis Segment	7.9%	26.6%	<0.0001
Late Loss (mm)			
In-Stent	0.39 ± 0.50	0.92 ± 0.58	<0.0001
Analysis Segment	0.23 ± 0.44	0.61 ± 0.57	<0.0001
Post Procedure MLD (mm)			
In-Stent	2.65 ± 0.42	2.67 ± 0.41	0.6577
Analysis Segment	2.26 ± 0.48	2.29 ± 0.50	0.4562
9-Month Follow-Up MLD (mm)			
In-Stent	2.26 ± 0.58	1.75 ± 0.65	0.0001
Analysis Segment	2.03 ± 0.55	1.68 ± 0.61	0.0001
Post Procedure % Diameter Stenosis			
In-Stent	4.21 ± 10.84	5.16 ± 11.41	0.2497
Analysis Segment	19.16 ± 9.67	19.33 ± 10.45	0.8219
9-Month Follow-Up % Diameter Stenosis			
In-Stent	17.43 ± 17.71	37.24 ± 19.76	0.0001
Analysis Segment	26.29 ± 15.45	39.79 ± 18.45	0.0001
% In-Stent Net Volume Obstruction	12.20 ± 12.44	29.40 ± 14.05	0.0001
9-Month Results			
MACE, Overall	8.5% (56/662)	15.0% (98/652)	0.0002
Cardiac Death	1.4% (9/662)	1.1% (7/652)	0.8025
Q-Wave MI	0.8% (5/662)	0.3% (2/652)	0.4520
Non-Q-Wave MI	2.7% (18/662)	3.4% (22/652)	0.5237
TVR, Overall	4.7% (31/662)	12.0% (78/652)	<0.0001
TLR, Overall	3.0% (20/662)	11.3% (74/652)	<0.0001
TLR, PCI	2.4% (16/662)	8.7% (57/652)	<0.0001
TLR, CABG	0.6% (4/662)	3.1% (20/652)	0.0008
Non-TLR, Overall	1.7% (11/662)	1.1% (7/652)	0.4778
Non-TLR, PCI	1.2% (8/662)	0.8% (5/652)	0.5793
Non-TLR, CABG	0.5% (3/662)	0.3% (2/652)	1.0000
TVF	7.6% (50/662)	14.4% (94/652)	0.0001
Stent Thrombosis (In-Hospital)	0.0% (0/662)	0.3% (2/652)	0.2460
Stent Thrombosis (Out-of-Hospital to 30 days)	0.3% (2/662)	0.3% (2/652)	1.0000
Stent Thrombosis (Overall, to 9 months)	0.6% (4/662)	0.8% (5/652)	0.7513

*Control is the Express Stent System.

TAXUS IV

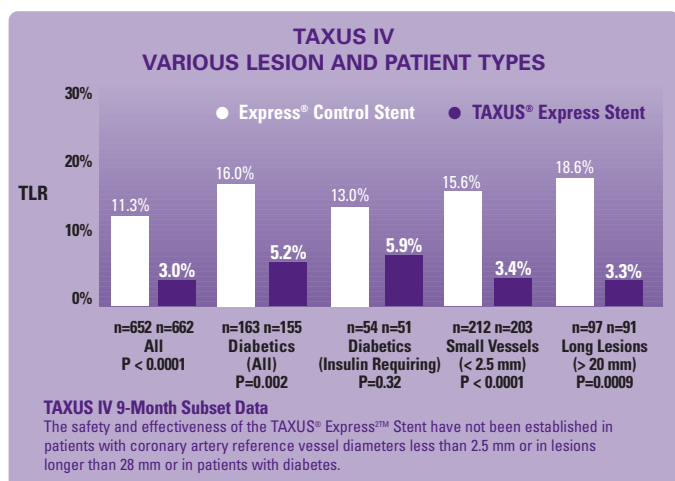
US Pivotal Trial (continued)

Cumulative 3-Year Results	TAXUS [®] Express [®] Paclitaxel-Eluting Stent (n=651)	Control* (n=643)	p-Value
MACE, Overall	18.2	28.3	<0.0001
Cardiac Death	2.5	2.5	0.9836
Q-Wave MI	1.3	0.8	0.4096
Non-Q-Wave MI	4.6	5.9	0.3007
TVR, Overall	13.4	23.8	<0.0001
TVR, PCI	10.7	19.4	<0.0001
TVR, CABG	2.9	6.1	0.0056
TLR, Overall	6.9	18.6	<0.0001
TLR, PCI	6.1	14.9	<0.0001
TLR, CABG	0.8	4.6	<0.0001
TVF	17.4	26.7	<0.0001
Stent Thrombosis Through 3-Years	1.2% (7/651)	0.8% (5/643)	NA



The TAXUS Express Stent has not been proven safe and effective for longer than 12-months.

9-Month TLR Data



INDICATIONS

The TAXUS[®] Express[™] Paclitaxel-Eluting Coronary Stent System is indicated for improving luminal diameter for the treatment of *de novo* lesions ≤ 28 mm in length in native coronary arteries ≥ 2.5 to ≤ 3.75 mm in diameter.

CONTRAINDICATIONS

Use of the TAXUS Express² 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 Express² 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 1-Year follow-up.

Prior to use, please see the complete "Directions for Use" at 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.

TRADEMARKS

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Delivering what's next.™

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