

TAXUS[®] Express^{2™}

Clinical Programs

Boston
Scientific

Clinical Trial
and Registry
Summary



TAXUS V - De Novo

US Randomized *de novo* Lesion Pivotal Expansion Trial (continued)

TAXUS V Trial Data (9-Month)		<i>TAXUS Express²</i> <i>Paclitaxel-Eluting</i> <i>Stent (n=108)</i>	<i>Control*</i> <i>(n=95)</i>	<i>p-Value</i>
9-Month Subgroup Analysis (2.25 mm Stents)**				
MACE	18.9% (20/106)	26.9% (25/93)	0.2343	
TVR, Overall	16.0% (17/106)	24.7% (23/93)	0.1565	
TLR, Overall	10.4% (11/106)	21.5% (20/93)	0.0332	
Stent Thrombosis	1.0% (1/104)	1.1% (1/92)	1.0000	
Late Loss (mm)				
Analysis Segment	0.36 ± 0.53 (93)	0.61 ± 0.59 (85)	0.0036	
In-Stent	0.49 ± 0.61 (93)	0.90 ± 0.63 (85)	<.0001	
Restenosis				
Analysis Segment	31.2% (29/93)	49.4% (42/85)	0.0147	
In-Stent	24.7% (23/93)	44.7% (38/85)	0.0070	
Diabetic Patients	47.2% (51/108)	31.6% (30/95)	0.0310	
Lesion Length (mm)	16.44 ± 9.55 (104)	16.44 ± 9.21 (95)	0.9973	
Baseline RVD (mm)	2.07 ± 0.31 (106)	2.10 ± 0.33 (95)	0.3989	
Total Study Stent Length Implanted (mm)	26.44 ± 12.07 (108)	26.82 ± 12.40 (95)	0.8269	
9-Month Subgroup Analysis**				
Large Vessel		<i>TAXUS[®] ExpressTM</i> <i>Paclitaxel-Eluting</i> <i>Stent (n=99)</i>	<i>Control*</i> <i>(n=103)</i>	<i>p-Value</i>
MACE	6.5% (6/93)	14.9% (15/101)	0.0676	
TVR, Overall	4.3% (4/93)	7.9% (8/101)	0.3775	
TLR, Overall	0.0% (0/93)	5.0% (5/101)	0.0603	
Stent Thrombosis	0.0% (0/93)	0.0% (0/100)	Undef	
Late Loss (mm)				
Analysis Segment	0.22 ± 0.40 (86)	0.54 ± 0.57 (90)	<.0001	
In-Stent	0.42 ± 0.47 (86)	0.87 ± 0.60 (90)	<.0001	
Restenosis				
Analysis Segment	3.5% (3/86)	14.4% (13/90)	0.0163	
In-Stent	2.3% (2/86)	14.4% (13/90)	0.0054	
Diabetic Patients	29.3% (29/99)	22.3% (23/103)	0.2655	
Lesion Length (mm)	16.45 ± 8.45 (99)	15.97 ± 8.00 (102)	0.6765	
Baseline RVD (mm)	3.41 ± 0.45 (99)	3.33 ± 0.44 (102)	0.1915	
Total Study Stent Length Implanted (mm)	25.78 ± 11.55 (99)	26.76 ± 11.91 (103)	0.5537	
9-Month Subgroup Analysis**				
Patients Receiving Overlapping Stents, planned		<i>TAXUS Express²</i> <i>Paclitaxel-Eluting</i> <i>Stent (n=195)</i>	<i>Control</i> <i>(n=184)</i>	<i>p-Value</i>
MACE	20.4% (39/191)	32.0% (58/181)	0.0130	
TVR, Overall	16.2% (31/191)	29.8% (54/181)	0.0020	
TLR, Overall	12.6% (24/191)	28.2% (51/181)	0.0003	
Stent Thrombosis	1.1% (2/190)	0.6% (1/180)	1.0000	
Late Loss (mm)				
Analysis Segment	0.45 ± 0.61 (173)	0.85 ± 0.62 (161)	<.0001	
In-Stent	0.60 ± 0.67 (173)	1.17 ± 0.61 (161)	<.0001	
Restenosis				
Analysis Segment	27.2% (47/173)	57.8% (93/161)	<.0001	
In-Stent	17.9% (31/173)	57.1% (92/161)	<.0001	
Lesion Length (mm)	25.03 ± 9.57 (192)	25.69 ± 10.40 (183)	0.5260	
Baseline RVD (mm)	2.65 ± 0.55 (194)	2.68 ± 0.56 (183)	0.6252	
Total Study Stent Length Implanted (mm)	43.61 ± 10.51 (195)	43.83 ± 10.41 (183)	0.8420	
9-Month Subgroup Analysis**				
Medically Treated Diabetic Patients***		<i>TAXUS Express²</i> <i>Paclitaxel-Eluting</i> <i>Stent (n=183)</i>	<i>Control*</i> <i>(n=173)</i>	<i>p-Value</i>
MACE	16.9% (30/178)	24.6% (42/171)	0.0858	
TVR, Overall	14.6% (26/178)	19.9% (34/171)	0.2041	
TLR, Overall	9.6% (17/178)	17.5% (30/171)	0.0406	
Stent Thrombosis	0.6% (1/177)	1.8% (3/170)	0.3630	
Restenosis				
Analysis Segment	18.2% (29/159)	38.4% (58/151)	<.0001	
In-Stent	14.5% (23/159)	34.4% (52/151)	<.0001	
Late Loss (mm)				
Analysis Segment	0.31 ± 0.56 (158)	0.62 ± 0.61 (151)	<.0001	
In-Stent	0.49 ± 0.64 (158)	0.93 ± 0.63 (151)	<.0001	
Diabetic Patients	100.0% (183/183)	100.0% (173/173)	Undef	
Lesion Length (mm)	17.97 ± 10.21 (180)	16.81 ± 9.07 (172)	0.2616	
Baseline RVD (mm)	2.55 ± 0.59 (182)	2.60 ± 0.53 (172)	0.3606	
Total Study Stent Length Implanted (mm)	29.08 ± 14.16 (182)	28.31 ± 13.24 (169)	0.6003	

*Control for TAXUS V *de novo* is the Express Stent.

**Caution: Investigational device limited by United States law to investigational use.

***The safety and efficacy of the TAXUS Express² Stent have not been established in patients with coronary artery reference vessel diameters less than 2.5 mm or greater than 3.75 mm, in patients with diabetes, or with multiple overlapping stents.

TAXUS V - De Novo

US Randomized *de novo* Lesion Pivotal Expansion Trial (continued)

TAXUS V Trial Data (9-Month) 9-Month Subgroup Analysis**

	TAXUS [®] Express [™] Paclitaxel-Eluting Stent (n=134)	Control* (n=120)	p-Value
MACE	15.4% (20/130)	26.1% (31/119)	0.0418
TVR, Overall	13.1% (17/130)	20.2% (24/119)	0.1709
TLR, Overall	10.0% (13/130)	17.6% (21/119)	0.0967
Stent Thrombosis			
Analysis Segment	17.2% (21/116)	34.9% (37/106)	0.0034
In-Stent	12.1% (14/116)	33.0% (35/106)	0.0002
Late Loss (mm)			
Analysis Segment	0.33 ± 0.55 (115)	0.63 ± 0.63 (106)	0.0002
In-Stent	0.49 ± 0.60 (115)	0.94 ± 0.64 (106)	<.0001
Diabetic Patients	100.0% (134/134)	100.0% (120/120)	Undef
Lesion Length (mm)	18.62 ± 10.80 (132)	16.26 ± 8.85 (120)	0.0604
Baseline RVD (mm)	2.58 ± 0.62 (133)	2.64 ± 0.52 (120)	0.3808
Total Study Stent Length Implanted (mm)	29.59 ± 14.90 (133)	28.24 ± 13.48 (116)	0.4559

9-Month Subgroup Analysis** Insulin Requiring Diabetic Patients***

	TAXUS Express ² Paclitaxel-Eluting Stent (n=49)	Control (n=53)	p-Value
MACE	20.8% (10/48)	21.2% (11/52)	1.0000
TVR, Overall	18.8% (9/48)	19.2% (10/52)	1.0000
TLR, Overall	8.3% (4/48)	17.3% (9/52)	0.2392
Stent Thrombosis			
Analysis Segment	20.9% (9/43)	46.7% (21/45)	0.0138
In-Stent	20.9% (9/43)	38.8% (17/45)	0.1042
Late Loss (mm)			
Analysis Segment	0.26 ± 0.58 (43)	0.59 ± 0.57 (45)	0.0085
In-Stent	0.50 ± 0.74 (43)	0.90 ± 0.60 (45)	0.0058
Diabetic Patients	100.0% (49/49)	100.0% (53/53)	Undef
Lesion Length (mm)	16.16 ± 8.21 (48)	18.06 ± 9.55 (52)	0.2902
Baseline RVD (mm)	2.47 ± 0.53 (49)	2.51 ± 0.54 (52)	0.6570
Total Study Stent Length Implanted (mm)	27.67 ± 11.97 (49)	28.45 ± 12.83 (53)	0.7523

TAXUS V Trial Data (1-Year)

	TAXUS Express ² Paclitaxel-Eluting Stent (n=577)	Control* (n=579)	p-Value
MACE, Overall	18.9% (105/556)	25.9% (146/563)	0.0052
Cardiac Death	1.1% (6/556)	1.1% (6/563)	1.0000
Q-Wave MI	0.5% (3/556)	0.2% (1/563)	0.3712
Non-Q-Wave MI	4.9% (27/556)	4.4% (25/563)	0.7777
TVR, Overall	15.8% (88/556)	21.8% (123/563)	0.0116
TLR, Overall	11.2% (62/556)	19.0% (107/563)	0.0003
TVR Remote, Overall	6.3% (35/556)	6.2% (35/563)	1.0000
TVR Remote, PCI	5.6% (31/556)	4.8% (27/563)	0.5913
TVR Remote, CABG	0.7% (4/556)	1.4% (8/563)	0.3852
TVR, PCI	14.4% (80/556)	19.4% (109/563)	0.0310
TVR, CABG	1.4% (8/556)	2.7% (15/563)	0.2055
TVF	18.7% (104/556)	25.0% (141/563)	0.0114
Stent Thrombosis	0.7% (4/553)	0.7% (4/553)	1.0000
In-Hospital	0.2% (1/579)	0.2% (1/579)	0.3735
Out-of-Hospital to 30 Days	0.5% (3/576)	0.5% (3/576)	0.6244
31-180 Days	0.2% (1/575)	0.2% (1/575)	1.0000
181-284 Days	0.0% (0/563)	0.0% (0/563)	Undef
285-365 Days	0.0% (0/556)	0.0% (0/556)	Undef
In-Hospital MACE	3.1% (18/579)	3.1% (18/579)	0.4319

*Control for TAXUS V *de novo* is the Express Stent.

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***The safety and efficacy of the TAXUS Express² Stent have not been established in patients with coronary artery reference vessel diameters less than 2.5 mm or greater than 3.75 mm, in patients with diabetes, or with multiple overlapping stents.

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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