

TAXUS[®] Express^{2™}

Clinical Programs

Boston
Scientific

Clinical Trial
and Registry
Summary



TAXUS II

International Efficacy Trial

Efficacy Demonstrated

Objective:	Demonstrate safety and efficacy of TAXUS® NIR® Paclitaxel-Eluting Stent for treatment of <i>de novo</i> lesions
Number of Patients:	536
Number of Sites:	38
Lesion Type:	<i>de novo</i> , ≤ 12 mm length, 3.0–3.5 mm vessel diameter
Stent Platform:	NIR® Conformer 15 mm
Release Kinetics:	Slow Release (SR) and Moderate Release (MR)
Primary Endpoint:	6-Month % net volume obstruction
Principal Investigator:	A. Colombo, MD
Status:	Enrollment complete

Baseline Demographics

	TAXUS® NIR® Paclitaxel-Eluting SR Stent (n=131)
Age	61.45 ± 10.46
Males	70.2% (92/131)
Diabetes Mellitus	10.7% (14/131)

Baseline Characteristics

	TAXUS® NIR® Paclitaxel-Eluting SR Stent (n=131)
Clinical Procedural Success	95.4% (125/131)
Lesion Length (mm)	10.55 ± 3.94 (131)
Reference Vessel Diameter (mm)	2.78 ± 0.44 (127)
Minimum Lumen Diameter (mm)	
Pre-Procedure	1.02 ± 0.30 (129)
Post Procedure	2.53 ± 0.29 (128)

6-Month Results

	TAXUS® NIR® Paclitaxel-Eluting SR Stent (n=131)
% Net Volume Obstruction, In-Stent	7.85 ± 9.87 (118)
MLD (mm)	2.23 ± 0.47 (128)
Binary Restenosis Rate	
In-Stent	2.3% (3/128)
Analysis Segment	5.5% (7/128)
% Diameter Stenosis, In-Stent	19.53 ± 12.71 (128)
Late Loss	0.31 ± 0.38 (127)
MACE, Overall	8.5% (11/130)
Death	0.0% (0/130)
Q-Wave MI	0.0% (0/130)
Non-Q-Wave MI	1.5% (2/130)
TVR, Overall	7.7% (10/130)
TVR, Non-TLR	3.1% (4/130)
TVR, TLR	4.6% (6/130)
TVR, CABG	0.8% (1/130)
Stent Thrombosis (≤ 1 day)	0.8% (1/131)
Stent Thrombosis (2–210 days)	0.0% (0/131)

Cumulative 3-Year Results

	TAXUS® NIR® Paclitaxel-Eluting SR Stent (n=131)
MACE, Overall	15.4%
Cardiac Death	1.6%
Q-Wave MI	0.8%
Non-Q-Wave MI	3.1%
TVR, Overall	12.3%
TVR, Non-TLR	3.9%
TVR, TLR	5.4%
TVR, CABG	3.9%

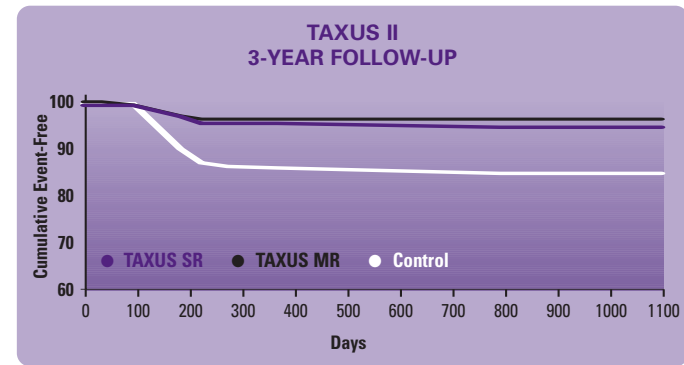
Cumulative 3-Year Results**

	TAXUS® NIR® Paclitaxel-Eluting SR Stent (n=131)
Stent Thrombosis to 3 Years	2.4% (3/124)
≤ 1 Day	0.8% (1/131)
2–210 Days	0.0% (0/131)
211–365 Days	0.8% (1/130)
366–790 Days	0.8% (1/130)
791–1095 Days	0.0% (0/126)

*Control is the NIR® Conformer Stent System.

**3-year data is kaplan meier; Due to long-term follow-up it is no longer statistically appropriate to use the simple proportion data that we used with all previous time points.

***p-Value compares three survival curves for SR, MR, and Combined Control. Data was not reported separately for 3-year results.



	TAXUS NIR® Paclitaxel-Eluting MR Stent (n=135)	Combined Control* (n=270)	p-Value SR vs Control	p-Value MR vs Control
Age	59.30 ± 10.12	59.83 ± 9.67	0.1268	0.6148
Males	76.3% (103/135)	77.8% (210/270)	0.1092	0.8015
Diabetes Mellitus	17.0% (23/135)	15.2% (41/270)	0.2786	0.6655
Clinical Procedural Success	96.3% (130/135)	93.7% (253/270)	0.6480	0.3557
Lesion Length (mm)	10.16 ± 4.78 (135)	10.61 ± 4.10 (270)	0.8968	0.3125
Reference Vessel Diameter (mm)	2.72 ± 0.46 (132)	2.75 ± 0.47 (262)	0.5996	0.4442
Minimum Lumen Diameter (mm)				
Pre-Procedure	0.95 ± 0.32 (135)	0.97 ± 0.36 (270)	0.2385	0.4895
Post Procedure	2.53 ± 0.36 (134)	2.55 ± 0.35 (269)	0.5370	0.5508
% Net Volume Obstruction, In-Stent	7.84 ± 9.66 (118)	21.89 ± 17.48 (244)	<0.0001	<0.0001
MLD (mm)	2.24 ± 0.47 (128)	1.77 ± 0.55 (264)	<0.0001	<0.0001
Binary Restenosis Rate				
In-Stent	4.7% (6/128)	19.0% (50/263)	<0.0001	<0.0001
Analysis Segment	8.6% (11/128)	22.0% (58/264)	<0.0001	0.0010
% Diameter Stenosis, In-Stent	18.23 ± 12.33 (128)	32.83 ± 17.56 (263)	<0.0001	<0.0001
Late Loss	0.30 ± 0.39 (127)	0.78 ± 0.47 (264)	<0.0001	<0.0001
MACE, Overall	7.8% (10/129)	19.8% (52/263)	0.0035	0.0019
Death	0.0% (0/129)	0.4% (1/263)	1.0000	1.0000
Q-Wave MI	0.0% (0/129)	0.8% (2/263)	1.0000	1.0000
Non-Q-Wave MI	2.3% (3/129)	4.6% (12/263)	0.1567	0.4029
TVR, Overall	6.2% (8/129)	16.0% (42/263)	0.0262	0.0059
TVR, Non-TLR	2.3% (3/129)	2.7% (7/263)	0.7572	1.0000
TVR, TLR	3.1% (4/129)	13.3% (35/263)	0.0080	0.0010
TVR, CABG	0.8% (1/129)	0.8% (2/263)	1.0000	1.0000
Stent Thrombosis (≤ 1 day)	0.0% (0/135)	0.0% (0/270)	0.3267	Undef
Stent Thrombosis (2–210 days)	0.0% (0/135)	0.0% (0/269)	Undef	Undef

	TAXUS® NIR® Paclitaxel-Eluting MR Stent (n=135)	Combined Control* (n=270)	p-Value Overall***
MACE, Overall	15.1%	26.1%	0.0058
Cardiac Death	1.6%	1.1%	0.9205
Q-Wave MI	3.1%	1.9%	0.4081
Non-Q-Wave MI	2.2%	4.5%	0.4953
TVR, Overall	9.0%	21.4%	0.0028
TVR, Non-TLR	3.1%	6.1%	0.3718
TVR, TLR	3.7%	15.7%	0.0001
TVR, CABG	2.3%	3.0%	0.7559

	TAXUS® NIR® Paclitaxel-Eluting MR Stent (n=135)	Combined Control* (n=270)	p-Value SR vs Control	p-Value MR vs Control
Stent Thrombosis to 3 Years	1.7% (2/117)	0.4% (1/251)	0.1076	0.2383
≤ 1 Day	0.0% (0/135)	0.0% (0/270)	0.3267	Undef
2–210 Days	0.0% (0/135)	0.0% (1/269)	Undef	Undef
211–365 Days	0.7% (1/134)	0.0% (1/268)	0.3266	0.3333
366–790 Days	1.5% (2/132)	0.0% (1/265)	0.3291	0.1100
791–1095 Days	0.0% (0/135)	0.4% (1/258)	1.0000	1.0000

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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USCV3111.114.7 03/06