

TAXUS[®] Express^{2™}

Clinical Programs

Boston
Scientific

Clinical Trial
and Registry
Summary



MILESTONE II

International Registry*

Objective:	Established physician's usage patterns by lesion type and patient subsets for the TAXUS® Express ² ™ Paclitaxel-Eluting Coronary Stent System
Number of Patients:	3,688
Number of Sites:	164 sites in 31 countries
Lesion Type:	<i>de novo</i>
Stent Platform:	TAXUS® Express ² ™ Paclitaxel-Eluting Stent
Release Kinetics:	Slow Release (SR)
Primary Endpoint:	Real world physician usage by lesion type and patient subset
Principal Investigator:	K. Niemela, MD
Status:	Enrollment complete

	TAXUS Express ²	Paclitaxel-Eluting Stent
Baseline Demographics		
Age (years)	60.7 +/-	11.3
Males	77.4%	
Diabetes	34%	
Insulin Treated	8.4%	
Medically Treated Hypertension	59.2%	
Medically Treated Hypercholesterolemia	61.0%	

	TAXUS Express ²	Paclitaxel-Eluting Stent
Adjudicated 1-Year TAXUS Related Cardiac Adverse Event Rates 1-Year Data		
MACE, Overall	7.5% (248/3303)	
Cardiac Death	1.5% (51/3303)	
Q-Wave MI	0.3% (11/3303)	
Non-Q-Wave MI	1.4% (46/3303)	
TVR, Overall	5.5% (183/3303)	
Angiographically Confirmed Stent Thrombosis	1.3% (42/3303)	
Angiographically Confirmed		1.3%
Presumed		
Sudden Death	0.3% (10/3303)	
MI In Region or TAXUS Treated Vessel	0.09% (3/3303)	

	TAXUS Express ²	Paclitaxel-Eluting Stent
Adjudicated 1-Year TAXUS Related Cardiac Adverse Event Rates 1-Year Subgroup Analysis		
Cardiac Adverse Events		
Diabetes	9.4% (103/1098)	
Acute MI < 24 hours	8.3% (11/132)	
RVD, ≤ 2.5 mm	10.3% (76/740)	
Lesion Length > 20 mm	7.3% (56/767)	
Total Occlusion	5.5% (12/219)	
Multiple Stents	8.8% (80/908)	
Cardiac Death		
Diabetes	2.8% (31/1098)	
Acute MI < 24 hours	3.0% (4/132)	
RVD, ≤ 2.5 mm	2.0% (15/740)	
Lesion Length > 20 mm	1.7% (13/767)	
Total Occlusion	1.4% (3/219)	
Multiple Stents	1.1% (10/908)	
MI		
Diabetes	1.6% (18/1098)	
Acute MI < 24 hours	2.3% (3/132)	
RVD, ≤ 2.5 mm	2.4% (18/740)	
Lesion Length > 20 mm	2.2% (17/767)	
Total Occlusion	1.4% (3/219)	
Multiple Stents	2.4% (22/908)	
TVR		
Diabetes	6.7% (74/1098)	
Acute MI < 24 hours	4.5% (6/132)	
RVD, ≤ 2.5 mm	7.8% (58/740)	
Lesion Length > 20 mm	5.0% (38/767)	
Total Occlusion	3.2% (7/219)	
Multiple Stents	7.0% (64/908)	

*The Directions For Use require proper preparation of the vessel prior to Stent placement. This includes predilatation of the lesion/ vessel with an appropriate diameter balloon. The safety and effectiveness of direct stenting of the TAXUS Express² Stent have not been proven with direct stenting, SVG, AMI, bifurcations or ISR.

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.™

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
www.bostonscientific.com
www.taxus-stent.com

*To order product or for
more information, contact
customer service at
1.888.272.1001*

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