

TAXUS[®] Express^{2™}

Clinical Programs

Boston
Scientific

Clinical Trial
and Registry
Summary



ARRIVE 1

US Safety Registry*

Objective: US peri-approval safety surveillance study
 Number of Patients: 2,585
 Number of Sites: 50
 Lesion Type: All inclusive and open registry of consecutive patients
 Stent Platform: TAXUS® Express™ Paclitaxel-Eluting Stent
 Release Kinetics: Slow Release (SR)
 Primary Endpoint: 1-Year site reported cardiac events
 Principal Investigators: D. Cox, MD and J. Lasala, MD, PhD
 Status: Enrollment complete

ARRIVE 1 (1-Year) Baseline Demographics

	TAXUS Express [®] Paclitaxel-Eluting Stent (n=2585)
Age (years)	63.9 ± 11.5
Males (%)	68%
Diabetes (%)	31%
Medication Requiring (%)	25%
Insulin Treated (%)	10%
Multi-Vessel Disease (%)	38%

Baseline Lesion Characteristics

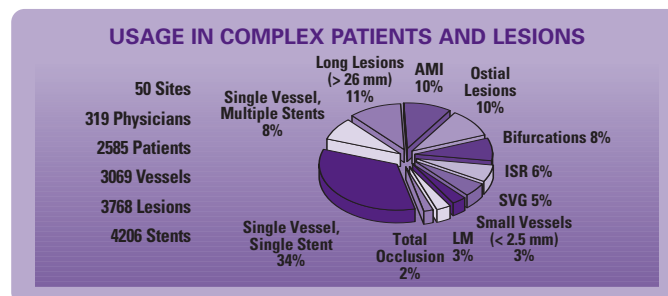
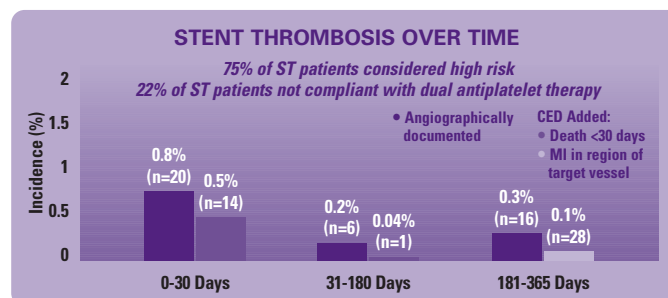
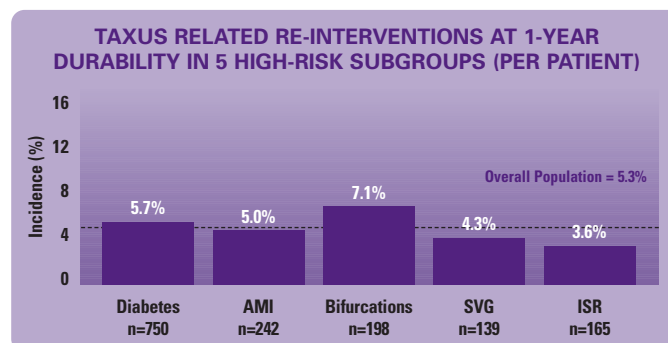
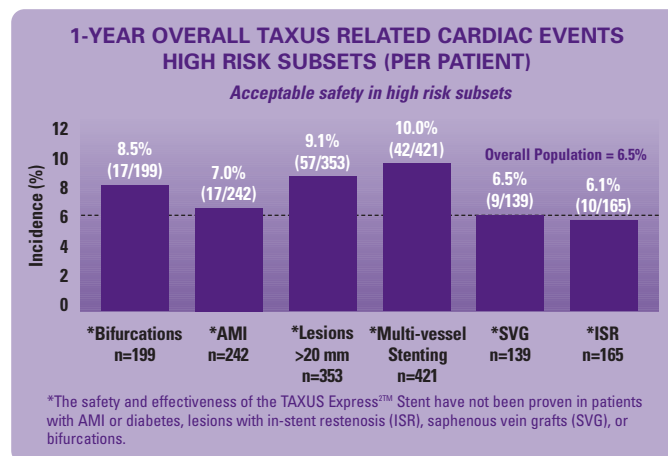
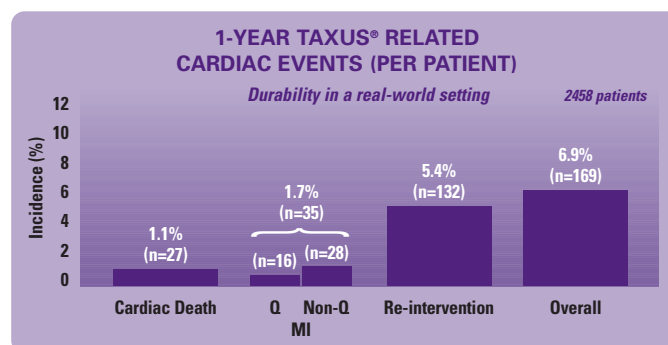
	TAXUS Express [®] Paclitaxel-Eluting Stent (n=3768)
Reference Vessel Diameter (mm)	3.0 ± 0.4
Average Lesion Length (mm)	16.0 ± 9.2
Lesion Type	
A	13.1% (492/3764)
B1	33.9% (1276/3764)
B2	32.6% (1228/3764)
C	20.4% (768/3764)

1-Year Data

	TAXUS Express [®] Paclitaxel-Eluting Stent (n=2585)
TAXUS-Related Cardiac Event (Death, MI, TLR)	6.9% (169/2458)
Cardiac Death	1.1% (27/2458)
MI	1.7% (43/2458)
Q-Wave MI	0.7% (16/2458)
Non-Q-Wave MI	1.1% (28/2458)
TAXUS-Related Re-Intervention	5.4% (132/2458)
Stent Thrombosis (per patient)	2.1% (51/2458)
0-30 Days	0.8% (34/2522)
31-180 Days	0.2% (7/2511)
181-365 Days	0.3% (10/2461)

*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 the TAXUS Express[®] Stent have not been proven with direct stenting, SVG, AMI, bifurcations or ISR.

1-Year Results



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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