

TAXUS[®] Express^{2™}

Clinical Programs

Boston
Scientific

Clinical Trial
and Registry
Summary



TAXUS III

In-Stent Restenosis Feasibility Trial

Expanding Understanding

Objective:	Evaluate feasibility of slow rate release TAXUS® NIRx® Paclitaxel-Eluting Stent to treat and reduce recurrent restenosis of previously implanted stents
Number of Patients:	28
Number of Sites:	2
Lesion Type:	In-Stent restenosis, < 30 mm length, 3.0 and 3.5 mm diameters
Stent Platform:	NIR® Conformer 15 mm
Release Kinetics:	Slow Release (SR)
Primary Endpoint:	30-Day MACE
Principal Investigators:	E. Grube, MD and P. Serruys, MD
Status:	Enrollment complete

Baseline Demographics	TAXUS NIR® Paclitaxel-Eluting Stent (n=28)
Male	67.9% (19/28)
Age (year)	63.2 ± 10.5
Unstable Angina	7.1% (2/28)
Stable Angina	78.6% (22/28)
Silent Ischemia	0.0% (0/28)
Smoking, Current	7.4% (2/27)*
Smoking, Previous	37.0% (10/27)*
Medically Treated Diabetes	14.8% (4/27)*
Insulin Requiring	3.7% (1/27)*
Non-Insulin Requiring	11.1% (3/27)*
Hypercholesterolemia	71.4% (20/28)
Hypertension	64.3% (18/28)
Family History of CAD	17.9% (5/28)

TAXUS III Trial Results 30-Day	TAXUS NIR® Paclitaxel-Eluting Stent (n=28)
MACE	3.6%
MI, Q-Wave & Non-Q-Wave	3.6%
TVR, Non-Target Lesion	0%
TLR	0%
CABG	0%
Cardiac Death	0%
Stent Thrombosis	0%

TAXUS III Trial Results 3-Year	TAXUS NIR® Paclitaxel-Eluting Stent (n=28)
MACE (Hierarchical)	35.7% (10/28)
MI, Q-Wave & Non-Q-Wave	3.6% (1/28)
TVR, Non-Target Lesion	3.6% (1/28)
TLR	25% (7/28)
CABG	3.6% (1/28)
Cardiac Death	3.6% (1/28)
Stent Thrombosis	0% (0/28)

*Information on one patient not available.
The TAXUS NIR® Stent is currently under investigation pursuant to an approved U.S. IDE for use in this indication.
Caution: The safety and efficacy of the TAXUS Express² Stent have not been established for the treatment of in-stent restenosis.

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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