

TAXUS ATLAS

Objective:	To evaluate the safety and effectiveness of the TAXUS® Liberté™-SR Paclitaxel-Eluting Coronary Stent system for the treatment of <i>de novo</i> lesions
Number of Patients:	871 enrolled patients (991 patients in historical control)
Number of Sites:	61 sites globally
Control:	Lesion matched cohort of TAXUS® Express® Stent and TAXUS® Express ² ™ Stent patients from TAXUS IV and TAXUS V
Study Design:	Prospective, single arm
Lesion Type:	<i>de novo</i>
Lesion Size:	≥ 10 to ≤ 28 mm lesion length
Stent Platform:	TAXUS® Liberté™ 8–32 mm lengths, 2.5–4.0 mm diameters
Release Kinetics:	Slow Release (SR)
Primary Endpoint:	9-Month TVR
Principal Investigators:	Mark Turco, MD and John Ormiston, MD

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Caution - TAXUS® Liberté™ Stent is an investigational device for use in patients. Limited by U.S. federal law to investigational use only. The TAXUS Liberté Stent is not approved for sale in the U.S. and the safety and effectiveness of this device have not been established.

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Baseline Demographics	TAXUS® Liberté™ Stent (N=871)	Control* (N=991)	p-Value
Age (yrs)	61.9±10.7 (871)	62.7±11.2 (991)	0.1461
Male % (n)	69.5% (605/871)	72.6% (719/991)	0.1514
Medically Treated Diabetes % (n)	25.3% (220/871)	24.6% (244/991)	0.7884
Insulin Requiring % (n)	7.8% (68/871)	7.7% (76/991)	0.9309
Medically Treated Hyperlipidemia % (n)	76.3% (665/871)	67.1% (665/991)	<0.0001
Baseline Lesion Characteristics			
Lesion Length (mm)	14.76±6.61 (869)	13.60±6.11 (979)	<0.0001
Reference Vessel Diameter (RVD, mm)	2.75±0.50 (869)	2.79±0.49 (984)	0.1274
Lesion Type			
B2/C	75.5% (656/869)	61.2% (602/983)	<0.0001
Any Tortuosity	13.1% (114/869)	8.4% (82/982)	0.0011
Any Calcification	29.8% (259/869)	23.1% (227/983)	0.0012
Lesions on a Bend (degrees)	33.77±17.83	25.91±18.45	<0.0001
Branch Vessel Disease	10.9% (94/864)	5.0% (49/981)	<0.0001
Minimum Lumen Diameter (MLD, mm)	0.85±0.36	0.92±0.34	<0.0001
9-Month Results			
Clinical Procedural Success	96.9% (844/871)	96.7% (318/329)	0.8538
MACE, Overall	11.0% (95/862)	10.5% (102/974)	0.7064
Cardiac Death	0.8% (7/862)	0.9% (9/974)	1.0000
Myocardial Infarction	3.7% (32/862)	3.9% (38/974)	0.9030
Q-Wave MI	0.7% (6/862)	0.6% (6/974)	1.0000
Non-Q-Wave MI	3.0% (26/862)	3.3% (32/974)	0.7901
TVR, Overall	8.0% (69/862)	7.1% (69/974)	0.4787
TLR, Overall	5.7% (49/862)	4.5% (44/974)	0.2865
TVR Remote, Overall	3.2% (28/862)	2.7% (26/974)	0.4911
Stent Thrombosis	0.8% (7/858)	0.7% (7/966)	1.0000
Late Loss (mm)			
In-Stent	0.41±0.54 (446)	0.42±0.54 (484)	0.6872

*Control = lesion matched TAXUS® Express® Stent and TAXUS® Express²™ Stent Patients from TAXUS IV and TAXUS V Clinical Trials.

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