

TAXUS[®] Liberté[™]

Clinical Trials

**Boston
Scientific**

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Caution: Investigational device.
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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 [®] 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

Baseline Demographics	<i>TAXUS Liberté Stent (N=871)</i>	<i>Control* (N=991)</i>	<i>p-Value</i>
Age (yrs)	61.9 ± 10.7	62.7 ± 11.2	0.15
Males (%)	69.5	72.6	0.15
Diabetes (%)	25.3	24.6	0.79
Insulin Req. (%)	7.8	7.7	0.93
Hyperlipidemia Req. Med. (%)	76.3	67.1	<0.0001

Baseline Lesion Characteristics

Reference Vessel Diameter (RVD, mm) – Site Reported	3.1 ± 0.48	3.14 ± 0.43	0.0177
Lesion Length (mm)			
Site Reported	15.8 ± 5.5	15.5 ± 5.6	0.13
Total Length Implanted (mm)	22.3 ± 8.2	22.2 ± 7.9	0.78

MACE Composite	<i>Group X</i>	<i>Group Y</i>	<i>p-Value</i>
30-Day MACE	3.3%	2.8%	0.5036
Cardiac Death	0.2%	0.2%	1.0000
Q-Wave MI	0.3%	0.1%	0.6280
Non Q-Wave MI	2.7%	2.4%	0.7700
TVR, Overall	0.4%	0.2%	0.6913
TLR, Overall	0.3%	0.2%	1.0000
TLR, CABG	0.1%	0.1%	1.0000
Non-TLR, Overall	0.1%	0.1%	1.0000
Stent Thrombosis	0.5%	0.2%	0.4599
In-Hospital	0.2%	0.0%	0.5018
Out of Hospital to 30 Days	0.3%	0.2%	1.0000

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*Control = lesion matched TAXUS Express^{2™} Stent Patients from TAXUS IV and TAXUS V Clinical Trials.

ATLAS-DS

Direct Stent

Objective:	To compare outcomes of direct stenting vs. balloon catheter pre-dilatation
Stent Platform:	TAXUS® Liberté™
Purpose:	Safety and efficacy
Design:	Multi-center, single-arm
Lesion:	<i>de novo</i>
Control:	Lesion matched patients from QCA subset of TAXUS ATLAS trial
Release Kinetics:	Slow Release (SR)
Primary Endpoint:	9-Month % diameter stenosis (analysis segment)
Location and Sites:	25 global sites in North America and Asia Pacific
Enrollment:	Enrollment complete
Number of Patients:	248
Principal Investigators:	Mark Turco, MD and John Ormiston, MD

ATLAS-LL

Long Lesion

Objective:	To evaluate clinical outcomes of TAXUS Liberté-SR 38 mm Stent in long, <i>de novo</i> lesions
Stent Platform:	TAXUS Liberté
Purpose:	Safety and efficacy
Design:	Multi-center, single-arm
Lesion:	<i>de novo</i>
Control:	Historical lesion matched cohort of TAXUS Express® patients TAXUS Express-SR Stent (from TAXUS IV and V)
Release Kinetics:	Slow Release (SR)
Primary Endpoint:	9-Month % diameter stenosis (analysis segment)
Location and Sites:	25 global sites in North America and Asia Pacific
Enrollment:	Enrolling
Number of Patients:	150 planned
Principal Investigators:	Mark Turco, MD and John Ormiston, MD

ATLAS-SV

Small Vessel

Objective:	To evaluate clinical and angiographic outcomes of TAXUS Liberté-SR 2.25 mm stent in <i>de novo</i> lesions
Stent Platform:	TAXUS Liberté
Purpose:	Safety and efficacy
Design:	Multi-center, single-arm
Lesion:	<i>de novo</i> lesion in small coronary vessel
Control:	Control 1: TAXUS Express ² ™ Stent (TAXUS V <i>de novo</i> lesion and stent-size matched cohort randomized to receive single, planned 2.25 mm DES) Control 2: Express ² Stent (TAXUS V <i>de novo</i> lesion and stent-sized matched cohort randomized to receive 2.25 mm or 2.5 mm BMS)
Release Kinetics:	Slow Release (SR)
Primary Endpoint:	9-Month % diameter stenosis (analysis segment)
Location and Sites:	25 global sites in North America and Asia Pacific
Enrollment:	Enrolling
Number of Patients:	260 planned
Principal Investigators:	Mark Turco, MD and John Ormiston, MD

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OLYMPIA Phase I

Transitional

Objective:	To compile real world and early safety and clinical outcomes data for the TAXUS® Liberté™ Paclitaxel-Eluting Coronary Stent system in routine clinical practice
Stent Platform:	TAXUS Liberté
Purpose:	Early safety and clinical outcomes data
Design:	1st phase of a 5-phase, single-arm, multi-center, web-based registry (Transitional, IC Launch, CE Mark Launch, US Peri-Approval, US Launch)
Lesion:	<i>de novo</i>
Control:	N/A (registry)
Release Kinetics:	Slow Release (SR)
Primary Endpoint:	30-Day TAXUS Liberté Stent related cardiac events as classified by a Clinical Events Committee (CEC)
Location and Sites:	Inter-Continental; 16 sites in 7 countries
Enrollment:	Complete
Number of Patients:	529
Principal Investigator:	Waqar H. Ahmed, MD

OLYMPIA Phase II

Inter-Continental Launch

Objective:	To compile safety surveillance and clinical outcomes data for the TAXUS Liberté Paclitaxel-Eluting Coronary Stent system in routine clinical practice
Stent Platform:	TAXUS Liberté
Purpose:	Safety surveillance
Design:	2nd phase of a 5-phase, single-arm, multi-center, web-based registry (Transitional, IC Launch, CE Mark Launch, US Peri-Approval, US Launch)
Lesion:	<i>de novo</i>
Control:	N/A (registry)
Release Kinetics:	Slow Release (SR)
Primary Endpoint:	12-Month TAXUS Liberté stent related cardiac events as classified by an Independent Medical Reviewer (IMR)
Location and Sites:	Inter-Continental; Up to 250 sites
Enrollment Start:	Enrolling
Number of Patients:	TBD
Principal Investigators:	Waqar H. Ahmed, MD and Oscar A. Mendiz, MD

OLYMPIA Phase III

European Launch

Objective:	To compile safety surveillance and clinical outcomes data for the TAXUS Liberté Paclitaxel-Eluting Coronary Stent system in routine clinical practice
Stent Platform:	TAXUS Liberté
Purpose:	Safety surveillance
Design:	3rd phase of a 5-phase, single-arm, multi-center, web-based registry (Transitional, IC Launch, CE Mark Launch, US Peri-Approval, US Launch)
Lesion:	<i>de novo</i>
Control:	N/A (registry)
Release Kinetics:	Slow Release (SR)
Primary Endpoint:	12-Month TAXUS Liberté Stent related cardiac events as classified by an Independent Medical Reviewer (IMR)
Location and Sites:	European Union; Up to 250 sites
Enrollment Start:	Enrolling
Number of Patients:	Up to 15,000 patients
Principal Investigator:	Martyn Thomas, MD