

# TAXUS IV Final 5-Year Outcomes

US PIVOTAL TRIAL

OBJECTIVE:	To evaluate the safety and effectiveness of the TAXUS® Express <sup>2™</sup> Paclitaxel-Eluting Coronary Stent System with 1µg/mm <sup>2</sup> of paclitaxel incorporated into a slow-release formulation of a triblock copolymer carrier system for the treatment of de novo coronary artery lesions (US Pivotal Trial) through 5-Years of follow-up
STENT:	TAXUS® Express® Stent
PURPOSE:	Safety and efficacy
DESIGN:	Prospective, randomized, double-blind
LESION:	Single <i>de novo</i> lesion covered by one stent, RVD>2.5mm - <3.75mm, lesion length 10 – 28mm
CONTROL:	Uncoated Express® Stent
RELEASE KINETICS:	Slow-release (SR)
PRIMARY ENDPOINT:	9-month ischemia-driven target vessel revascularization (TVR)
LOCATION & SITES:	73 United States sites
PATIENTS:	1,314 Intent-to-treat
PRINCIPLE INVESTIGATORS:	G.W. Stone, MD, USA and S.G. Ellis, MD, USA

Patient Characteristics	TAXUS Express Stent (N=662)	Control* (N=652)	p-Value
Age (years)	62.9 ± 11.2	62.1 ± 10.9	0.21
Male (%)	71.8	72.4	0.80
Diabetes (%)	23.4	25.0	0.50
Hyperlipidemia (%)	65.0	65.6	0.79
Hypertension (%)	70.5	69.0	0.55
Smoker, Current (%)	23.4	20.1	0.14
Unstable Angina (%)	35.8	32.7	0.23

Lesion Characteristics (Determined by QCA)	TAXUS Express Stent (N=662)	Control* (N=652)	p-Value
Lesion Length (mm)	13.4 ± 6.3	13.4 ± 6.2	0.98
RVD (mm)	2.75 ± 0.47	2.75 ± 0.49	0.93
Diameter Stenosis (%)	66.5% ± 10.7	65.6% ± 10.7	0.11
MLD (mm)	0.92 ± 0.33	0.95 ± 0.34	0.16

TAXUS IV 5-year Clinical Follow-up**	TAXUS Express Stent (N=651***)	Control* (N=643***)	p-Value
MACE	24.0%	32.8%	0.0001
Death	10.0%	11.2%	0.49
Cardiac Death	4.4%	4.5%	0.85
MI	7.2%	7.4%	0.87
TVR	16.9%	27.4%	<0.0001
TLR	9.1%	20.5%	<0.0001
TLR in Medically Treated DM	13.4%	26.9%	0.0018
TLR Large Vessels RVD ≥3.0 mm	7.3%	14.4%	0.0232
TLR Small Vessels RVD <3.0mm	9.9%	23.0%	<0.0001
TLR Lesion Length <18mm	9.1%	20.2%	<0.0001
TLR Lesion Length ≥18mm	9.2%	21.6%	0.0056
Stent Thrombosis Protocol	1.6%	1.1%	0.46
Stent Thrombosis Protocol 4-5 yr	0%	0%	NA
Stent Thrombosis ARC (def+prob)	2.5%	2.5%	0.94
Stent Thrombosis ARC (def+prob) 4-5 yr	0%	0.2%	0.50

\*Control is the Express Stent.

\*\*5-year data is from the Kaplan Meier analysis with log-rank p-Value; due to long-term follow-up it is no longer statistically appropriate to use the simple proportion data that we used with all previous time points.

\*\*\*Study Stent Population

MACE: The composite endpoint comprised of Cardiac Death, MI, Ischemia-driven TLR by CABG or PCI

Stent thrombosis was defined as acute coronary syndrome with angiographic documentation of either vessel occlusion or thrombus within or adjacent to a previously successfully treated vessel or, in the absence of angiographic confirmation, either acute myocardial infarction in the distribution of the treated vessel or death from cardiac causes within 30 days.

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