

TAXUS Stent Meta-analysis 5-Year

OBJECTIVE:	A patient level meta-analysis evaluating the long-term safety and clinical efficacy of the TAXUS® Express ^{2™} Paclitaxel-Eluting Coronary Stent System compared to bare metal stent control up to 5-Years of follow up
STENT:	TAXUS NIRx® Paclitaxel-Eluting Stent and the TAXUS Express Stent (slow release (SR) formulation)
PURPOSE:	Safety and Efficacy
DESIGN:	Prospective, randomized, double-blind patient level data from TAXUS I (5yr), II-SR (5yr), IV (5yr), and V (3yr)
LESION:	<i>De novo</i> lesions, RVD>2.25mm - <4.0mm, lesion length 10 – 46mm
CONTROL:	Bare metal Express® Stent
PRIMARY ENDPOINT:	TAXUS I = MACE 30 d TAXUS II = % net vol obstruction 6 mo TAXUS IV and V TVR 9 mo
PATIENTS:	2,797
PRESENTER:	Stephen G. Ellis, MD, USA

Patient/Lesion Characteristics	TAXUS NIRx Stent TAXUS Express Stent (N=1,400)	Control* (N=1,397)	p-Value
Diabetes (%)	25.4	25.7	0.90
Insulin-Requiring Diabetes (%)	7.6	8.2	0.62

Lesion Characteristics (Determined by QCA)	TAXUS NIRx Stent TAXUS Express Stent (N=1,400)	Control* (N=1,397)	p-Value
Lesion Length (mm)	14.6 ± 7.9	14.6 ± 7.7	0.87
RVD (mm)	2.7 ± 0.5	2.7 ± 0.5	0.98
Modified ACC/AHA			
B2 Lesions	36.0	36.4	0.83
C Lesions	28.0	29.2	0.53
Multiple Stents (%)	18.2	17.3	0.55
Visual Length >26mm (%)	13.2	12.9	0.82

TAXUS Meta-analysis(5-Year)**	TAXUS NIRx Stent TAXUS Express Stent (N=1,400)	Control* (N=1,397)	p-Value
MACE			
Death	9.4%	9.7%	0.92
Cardiac Death	4.2%	3.6%	0.44
MI	7.3%	6.8%	0.76
QMI	1.4%	1.1%	0.46
NQMI	5.9%	6.1%	1.0
All Death or MI	15.4%	14.9%	0.86
TVR	19.9%	27.5%	<0.001
TLR	12.1%	21.0%	<0.001
TLR in Diabetics	15.1%	25.8%	<0.001
TLR in Multiple Stents	19.3%	34.6%	<0.001
TLR Small Vessels RVD <2.5mm	19.5%	29.9%	<0.001
TLR Lesion Length >26mm	14.2%	31.3%	<0.001
Stent Thrombosis Protocol	1.5%	0.9%	0.14
Stent Thrombosis ARC (def+prob)	2.1%	1.7%	0.46

*Control is the NIRx® Conformer Stent System and the Express^{2™} Stent System.

**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.

Caution - Investigational device for use in patients with reference vessel diameters < 2.5mm and >3.75mm, with multiple overlapping stents, or with lesions longer than 28mm. Limited by U.S. Federal law to investigational use. Not approved for sale in the U.S.

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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