

PERSEUS Clinical Program – Small Vessel Trial

OBJECTIVE:	Evaluation of TAXUS® Element™ Paclitaxel Eluting Coronary Stent System compared to bare metal Express® Coronary Stent System for the treatment of <i>de novo</i> lesions in small vessels
STENT:	TAXUS Element Stent
PURPOSE:	Safety and Efficacy (Pivotal Study)
DESIGN:	Prospective, single-arm, superiority trial (lesion length ≤20 and vessel diameter ≥2.25 to <2.75mm)
LESION:	Single <i>de novo</i> lesions
CONTROL:	Matched bare metal (Express Stent) historic control
RELEASE KINETICS:	Slow Release
PRIMARY ENDPOINT:	In-stent late loss by QCA on 9-month angiographic assessment
LOCATION & SITES:	US: 28 sites
ENROLLMENT:	July 13, 2007- August 27, 2008 (complete)
PATIENTS:	224
INVESTIGATOR:	Dean J. Kereiakes, MD. Louis A Cannon, MD, USA

	TAXUS® Element™ Stent (N=224)	Bare Metal Express Control (N=125)	p-Value
Patient Characteristics			
Age (years)	64.7 ± 10.3	64.2 ± 10.9	0.64
Male	63.8%	60.8%	0.57
Diabetes	36.6%	32.0%	0.39
Current Smoker	13.6%	22.2%	0.04
Unstable Angina	20.1%	29.6%	0.04

Lesion Characteristics			
Lesion Length (mm)	11.7 ± 5.1	12.9 ± 5.1	0.04
RVD (mm)	2.1 ± 0.3	2.2 ± 0.4	0.001
B2/C Lesions	58.0	77.6	0.001
%DS (mm)	73.5 ± 10.2	71.5 ± 10.4	0.08

PERSEUS SV Post-Procedure QCA			
MLD			
In-Stent (mm)	2.11 ± 0.21	2.09 ± 0.30	0.50
In-Segment	1.70 ± 0.29	1.76 ± 0.38	0.18
Acute Gain			
In-Stent	1.57 ± 0.27	1.47 ± 0.33	0.007
In-Segment	1.16 ± 0.30	1.14 ± 0.39	0.55
PERSEUS SV 9-Month QCA			
Late Loss (Propensity Adjusted)			
In-Stent	0.37	0.81	0.001
Diameter Stenosis			
In-Stent	0.38 ± 0.51	0.80 ± 0.53	0.001
In-Segment	0.21 ± 0.41	0.53 ± 0.52	0.001

PERSEUS WH 12 -Month Clinical Outcomes, Propensity-Adjusted			
TLF	6.6%	20.5%	0.01
MACE	10.5%	30.4%	0.002
TLR	4.7%	19.7%	0.006
Cardiac Death	1.8%	0.4%	0.26
All-Cause death	1.8%	1.0%	0.56
MI	0.6%	2.5%	0.26
Q-Wave MI			
Non-Q -Wave MI			
TVR	8.9%	28.1%	0.002
Stent Thrombosis	0.3%	0.6%	0.65

*Control is the TAXUS Express Stent.

Caution - Investigational Device. Limited by US Federal Law to Investigational Use. Not for Sale in the US.

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