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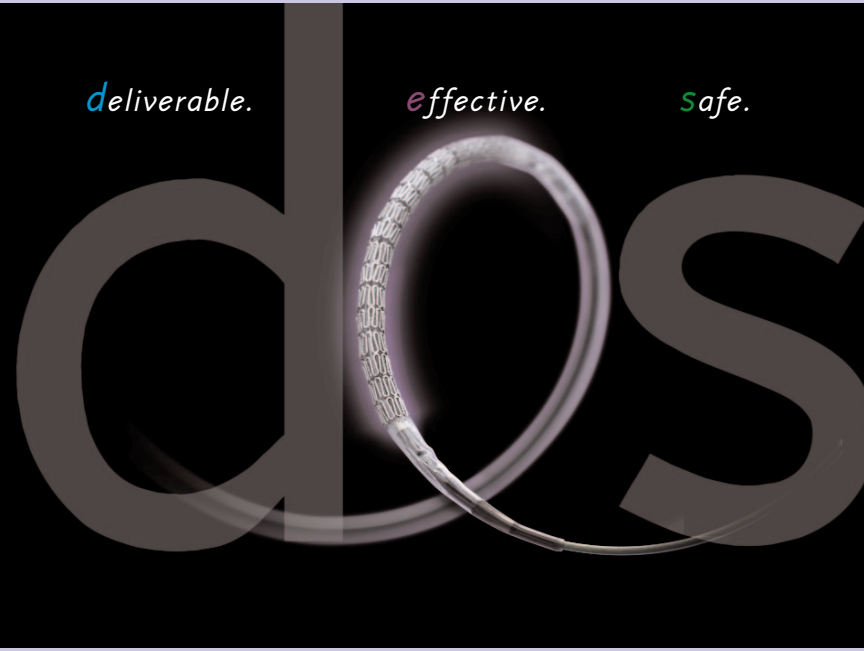
Clinical Reference Guide

ENDEAVOR

Drug Eluting Rapid Exchange Coronary Stent System

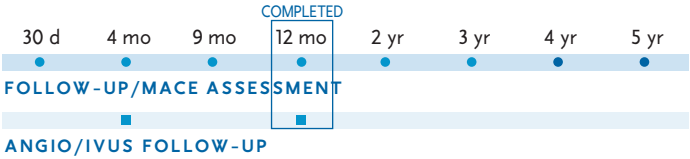


ENDEAVOR I

Single-arm, feasibility trial
Sample Size: 100 patients
Endeavor Stent: n = 100 pat ients

Single *de novo* native coronary artery lesions (Type A-B2)
Reference Vessel Diameter: 3.0–3.5 mm
Lesion Length: ≤15 mm
Stent Size: 3.0–3.5 mm x 18 mm

Principal Investigator: **Professor Ian Meredith, MD, PhD, FACC, FRACP**
8 sites: Australia and New Zealand



Primary endpoints: MACE at 30 days and Late Loss* (QCA) at 4 months
Antiplatelet therapy for ≥3 months

Patient Demographics and Lesion Characteristics	
Diabetes Mellitus	16%
Lesion Type	
A	17%
B1	34%
B2	44%
C	5%
Lesion Location	
LAD	42%
LCX	23%
RCA	35%

Acute Performance Results	
Device Success	100%
Lesion Success	100%
Procedure Success	100%

*Late Lumen Loss

Baseline Characteristics	
Reference Vessel Diameter (RVD)	2.96 mm
Average Lesion Length	10.9 mm

Postprocedure MLD	
In-stent MLD	2.84 mm
In-segment MLD	2.52 mm

Clinical Follow-up	n = 100	n = 100
	4 mo	**12 mo**
MACE*	2%	2%
Death	0%	0%
MI (all)	1%	1%
Q-wave	0%	0%
Non-Q-wave	1%	1%
TLR	1%	1%
TVF	2%	2%
TVR (non-TL)	0%	0%
Thrombosis (All)	1%	1%
Late Stent Thrombosis	0%	0%

Angiographic Follow-up	n = 97	n = 91
	4 mo	**12 mo**
Binary Restenosis Rate		
In-stent	2.1%	5.4%
In-segment	2.1%	5.4%
Minimum Luminal Diameter		
In-stent	2.51 mm	2.24 mm
In-segment	2.30 mm	2.09 mm
Late Loss		
In-stent	0.33 mm	0.61 mm
In-segment	0.21 mm	0.43 mm
% Diameter Stenosis		
In-stent	14.6%	22.4%
In-segment	21.9%	27.8%

IVUS Follow-up	n = 96	n = 87
	4 mo	**12 mo**
% Late Incomplete Apposition	0%	0%

*Hierarchical MACE

ENDEAVOR II

Randomised, double-blinded, prospective trial

Sample Size: 1200 patients

Endeavor Stent: n = 600 patients

Control Driver Stent: n = 600 patients

Single *de novo* native coronary artery lesions (Type A-C)

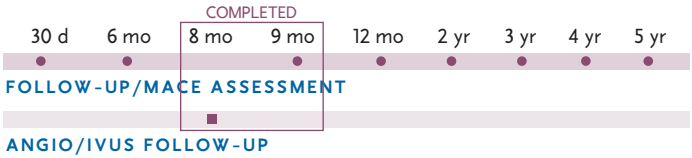
Reference Vessel Diameter: 2.25–3.5 mm

Lesion Length: 14-27 mm

Stent size: 2.25–3.5 mm x 18–30 mm (8/9 mm bailout)

Principal Investigators: **Jean Fajadet, MD, Rick Kuntz, MD, MSc**
William Wijns, MD, PhD

72 sites: Europe, Asia Pacific, Israel, Australia and New Zealand



Primary endpoints: TVF (cardiac death, MI, TVR) at 9 months
Antiplatelet therapy for ≥3 months

Patient Demographics and Lesion Characteristics			
	Endeavor	**Driver**	***p* Value**
Diabetes Mellitus	18.0%	22.2%	NS
Lesion Type			NS
A	2.9%	4.1%	
B1	18.7%	17.0%	
B2	50.7%	54.5%	
C	27.7%	24.4%	
Lesion Location			NS
LAD	43.4%	47.5%	
LCX	22.3%	21.2%	
RCA	34.4%	31.2%	

Acute Performance Results			
	Endeavor	**Driver**	***p* Value**
Device Success	99.3%	99.3%	NS
Lesion Success	99.8%	100.0%	NS
Procedure Success	97.4%	97.1%	NS

Baseline Characteristics	
Reference Vessel Diameter (RVD)	2.74 mm
Average Lesion Length	14.05 mm

Postprocedure MLD	
In-stent MLD	2.59 mm
In-segment MLD	2.21 mm

Clinical Follow-up (9 mo)	n = 582	n = 585	
	Endeavor	**Driver**	***p* Value**
MACE†	7.4%	14.7%	<0.0001
Death	1.2%	0.5%	0.224
MI			
Q-wave	0.3%	0.9%	0.452
Non-Q-wave	2.4%	3.1%	0.591
TLR	4.6%	12.1%	<0.0001
TVF	8.1%	15.4%	<0.0005
TVR	5.7%	12.8%	<0.0001
Thrombosis (All)	0.5%	1.2%	NS
Late Stent Thrombosis	0%	0%	NS

Angiographic Follow-up (8 mo)	n = 298	n = 302	
	Endeavor	**Driver**	***p* Value**
Binary Restenosis Rate			
In-stent	9.5%	32.7%	<0.0001
In-segment	13.3%	34.2%	<0.0001
Minimum Luminal Diameter			
In-stent	1.99 mm	1.63 mm	<0.0001
In-segment	1.86 mm	1.57 mm	<0.0001
Late Loss			
In-stent	0.62 mm	1.03 mm	<0.0001
In-segment	0.36 mm	0.71 mm	<0.0001
% Diameter Stenosis			
In-stent	27.9%	42.1%	<0.0001
In-segment	32.6%	44.3%	<0.0001

IVUS Follow-up (8 mo)	n = 100	n = 83	
	Endeavor	**Driver**	***p* Value**
% Late Incomplete Apposition	0%	0%	NS

†Composite MACE, nonhierarchical

ENDEAVOR III

Randomised, single-blinded, prospective trial

Sample Size: 436 patients

Endeavor Stent: n = 327 patients

Control Cypher Stent: n = 109 patients

Single *de novo* native coronary artery lesions (Type A-B2)

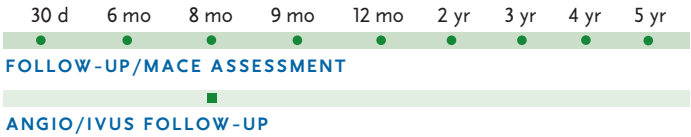
Reference Vessel Diameter: 2.5–3.5 mm

Lesion Length: 14-27 mm

Stent Size: 2.5–3.5 mm x 18–30 mm (8/9 mm bailout)

Principal Investigators: **David E Kandzari, MD, Martin B. Leon, MD**

30 sites: US



Primary endpoints: In-segment Late Loss (QCA) at 8 months

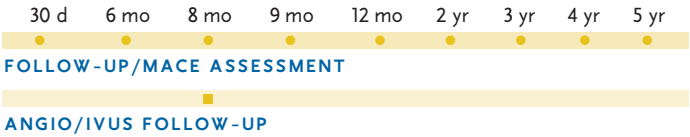
Antiplatelet therapy for ≥3 months

ENDEAVOR IV

Randomised, single-blinded, prospective trial
Sample Size: 1548 patients
Endeavor Stent: n = 774 patients
Control Taxus Stent: n = 774 patients

Single *de novo* native coronary artery lesions (Type A–C)
Reference Vessel Diameter: 2.5–3.5 mm
Lesion Length: ≤27 mm
Stent size: 2.5–3.5 mm x 18–30 mm (8/9 mm bailout)

Principal Investigators: **David E. Kandzari, MD, Martin B. Leon, MD**
Up to 80 sites: US and Canada



Primary endpoints: TVF at 9 months
Antiplatelet therapy for ≥6 months

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