Medtronic

Endeavor

Medtronic Coronary Stent System
Design For Life™

Clinical Studies

ENDEAVOR I n = 100 48 mo	Single-Arm Trial
ENDEAVOR II n = 1200 36 mo	Double-Blind Randomized Trial *vs.* Driver
ENDEAVOR II CA n = 300 24 mo	Open-Label Safety Registry
ENDEAVOR III n = 436 24 mo	Single-Blind Randomised Controlled Trials *vs.* Cypher
ENDEAVOR IV n = 1548	Single-Blind Randomised Controlled Trials *vs.* Taxus
e-Five n = 8000	Prospective, Multicenter Registry to Evaluate Clinical Performance
PROTECT n = 8800	Prospective, Randomised Multicenter Trial *vs.* Cypher

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Clinical Studies

Endeavor Zotarolimus-Eluting Coronary Stent System

Contents

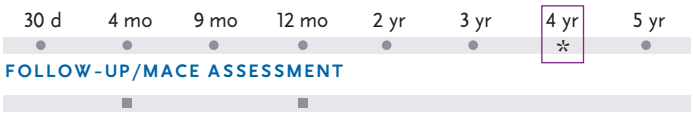
* EI-IV data analyzed at the same data coordinating center and by the same core laboratories.

ENDEAVOR I

Single-arm trial
Sample Size: 100 patients
Endeavor Stent: n = 100 patients

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: **Prof 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	n = 100
Diabetes mellitus	16%
B2/C lesions	49%
Lesion location: LAD	43%

Acute Performance Results	n = 100
Device success	100%
Lesion success	100%
Procedure success	100%

Baseline Characteristics	n = 100
Reference vessel diameter (RVD)	2.96 mm
Average lesion length	10.94 mm

Postprocedure MLD	n = 100
In-stent MLD	2.84 mm
In-segment MLD	2.52 mm

*Late lumen loss

Clinical Follow-Up	n = 99	n = 99	n = 98	n = 97
	12 mo	24 mo	36 mo	48 mo
MACE	2%	3%	6%	7%
Death	0%	1%	3%	4%*
MI (all)	1%	1%	1%	1%
Q-wave	0%	0%	0%	0%
Non-Q-wave	1%	1%	1%	1%
TLR	2%	2%	3%	3%
TVF	2%	4%	5%	5%
TVR (non-TL)	0%	2%	2%	2%
Thrombosis (all)	1%	1%	1%	1%
Late Stent Thrombosis	0%	0%	0%	0%

Angiographic Follow-Up	n = 98	n = 92
	4 mo	12 mo
Binary restenosis rate		
In-stent	2.0%	4.3%
In-segment	3.1%	5.4%
Minimum luminal diameter		
In-stent	2.52 mm	2.26 mm
In-segment	2.29 mm	2.08 mm
Late loss		
In-stent	0.32 mm	0.58 mm
In-segment	0.22 mm	0.43 mm
% Diameter stenosis		
In-stent	14.4%	21.8%
In-segment	22.4%	28.0%

IVUS Follow-Up	n = 94	n = 86
	4 mo	12 mo
% Late incomplete apposition	0%	0%

*Noncardiac death

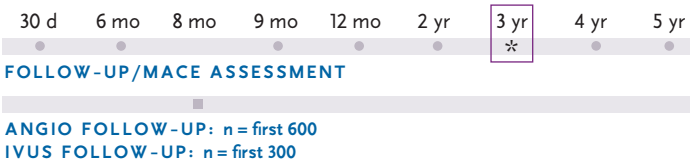
ENDEAVOR II

Randomised, double-blinded 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

	Endeavor	Driver	*p* Value
Patient Demographics and Lesion Characteristics	**n = 598**	**n = 599**	
Diabetes mellitus	18.2%	22.2%	NS
B2/C lesions	78.4%	79.0%	NS
Lesion location: LAD	43.4%	47.6%	NS
Acute Performance Results	**n = 598**	**n = 599**	
Device success	98.8%	99.2%	NS
Lesion success	99.7%	100.0%	NS
Procedure success	97.3%	97.1%	NS
Baseline Characteristics	**n = 598**	**n = 599**	
Reference vessel diameter (RVD)	2.73 mm	2.76 mm	NS
Average lesion length	14.04 mm	14.38 mm	NS
Postprocedure MLD	**n = 598**	**n = 599**	
In-stent MLD	2.59 mm	2.61 mm	NS
In-segment MLD	2.21 mm	2.24 mm	NS
Clinical Follow-up (9 mo)	**n = 592**	**n = 591**	
MACE	7.3%	14.4%	<0.001
Death	1.2%*	0.5%	NS
MI (all)	2.7%	3.9%	NS
Q-wave	0.3%	0.8%	NS
Non-Q-wave	2.4%	3.0%	NS
TLR	4.6%	11.8%	<0.001
TVF	7.9%	15.1%	<0.001
TVR (non-TL)	1.5%	2.2%	NS
Thrombosis (all)	0.5%	1.2%	NS
Late stent thrombosis	0.0%	0.0%	NS

	Endeavor	Driver	*p* Value
Clinical Follow-Up (12 mo)	**n = 590**	**n = 589**	
MACE	8.8%	15.6%	<0.001
Death	1.4%*	0.7%	NS
MI (all)	2.7%	3.9%	NS
Q-wave	0.3%	0.8%	NS
Non-Q-wave	2.4%	3.1%	NS
TLR	5.9%	13.1%	<0.001
TVF	10.0%	16.6%	<0.001
TVR (non-TL)	2.0%	2.5%	NS
Thrombosis (all)	0.5%	1.2%	NS
Late stent thrombosis	0%	0%	NS
Clinical Follow-Up (24 mo)	**n = 587**	**n = 586**	
MACE	9.9%	18.1%	<0.001
Death	2.0%	2.2%	NS
MI (all)	2.9%	3.9%	NS
Q-wave	0.3%	0.9%	NS
Non-Q-wave	2.6%	3.1%	NS
TLR	6.5%	14.2%	<0.001
TVF	11.1%	20.0%	<0.001
TVR (non-TL)	2.4%	4.1%	NS
Thrombosis (all)	0.5%	1.2%	NS
Late stent thrombosis	0.0%	0.0%	NS
Clinical Follow-Up (36 mo)	**n = 577**	**n = 579**	
MACE	12.0%	20.7%	<0.001
Death	3.3%	4.5%	NS
MI (all)	3.3%	4.3%	NS
Q-wave	0.3%	1.0%	NS
Non-Q-wave	2.9%	3.3%	NS
TLR	7.3%	14.7%	<0.001
TVF	12.8%	21.4%	<0.001
TVR (non-TL)	2.9%	4.8%	NS
Thrombosis (all)	0.5%	1.2%	NS
Late stent thrombosis	0.0%	0.0%	
Angiographic Follow-Up (8 mo)	**n = 264**	**n = 265**	
Binary restenosis rate			
In-stent	9.5%	33.2%	<0.001
In-segment	13.3%	34.7%	<0.001
Minimum luminal diameter			
In-stent	1.99 mm	1.62 mm	<0.001
In-segment	1.86 mm	1.56 mm	<0.001
Late loss			
In-stent	0.62 mm	1.03 mm	<0.001
In-segment	0.36 mm	0.72 mm	<0.001
% Diameter stenosis			
In-stent	27.9%	42.2%	<0.001
In-segment	32.7%	44.3%	<0.001
IVUS Follow-Up (8 mo)	**n = 114**	**n = 104**	
% Late incomplete apposition	0%	0%	NS

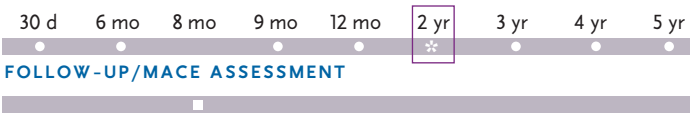
ENDEAVOR II CA

Single-arm, multicenter registry
Sample Size: 300 patients
Endeavor Stent: n = 300 patients

Single *de novo* native coronary artery lesions
Reference vessel diameter: 2.25–3.5 mm
Lesion length: 14–27 mm
Stent diameters: 2.25–3.5 mm
Stent lengths: 18–30 mm (8/9 mm bailout)
Direct stenting for lesions ≤20 mm per investigator discretion

Principal Investigators: **Jean Fajadet, MD, William Wijns, MD, PhD**

Study: 15 sites Europe



Primary endpoint: MACE at 30 days
Antiplatelet therapy for ≥3 months

Patient Demographics and Lesion Characteristics	
Diabetes mellitus	25.8%
B2/C lesions	74.4%
Lesion location: LAD	50.5%

Acute Performance Results	n = 297
Device success	98.3%
Lesion success	99.7%
Procedure success	94.9%

Baseline Characteristics	n = 297
Reference vessel diameter (RVD)	2.63 mm
Average lesion length	16.49 mm

Postprocedure MLD	n = 297
In-stent MLD	2.56 mm
In-segment MLD	2.24 mm

Clinical Follow-up (9 mo)	n = 293
MACE	10.6%
Death	0.7%
MI (all)	5.1%
Q-wave	0.3%
Non-Q-wave	4.8%
TLR	5.1%
Emergent CABG	0.3%
TVF	13.0%
TVR (non-TL)	4.1%
Thrombosis (all)	0.0%
Late stent thrombosis	0.0%

*One patient had two lesions

Clinical Follow-Up (12 mo)	n = 292
MACE	12.3%
Death	0.7%
MI (all)	5.5%
Q-wave	0.3%
Non-Q-wave	5.1%
TLR	6.5%
Emergent CABG	0.3%
TVF	15.8%
TVR (non-TL)	5.8%
Thrombosis (all)	0.0%
Late stent thrombosis	0.0%

Clinical Follow-Up (24 mo)	n = 288
MACE	12.8%
Death	1.4%
MI (all)	5.9%
Q-wave	0.3%
Non-Q-wave	5.6%
TLR	7.3%
Emergent CABG	0.3%
TVF	16.3%
TVR (non-TL)	5.9%
Thrombosis (all)	0.0%
Late stent thrombosis	0.0%

Angiographic Follow-Up (8 mo)	n = 117
Binary restenosis rate	
In-stent	15.4%
In-segment	17.1%
Minimum luminal diameter	
In-stent	1.92 mm
In-segment	1.81 mm
Late loss	
In-stent	0.58 mm
In-segment	0.39 mm
% Diameter stenosis	
In-stent	27.7%
In-segment	31.9%

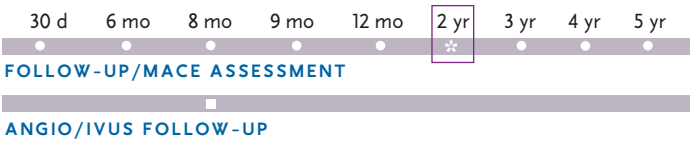
IVUS Follow-up (8 mo)	n = 42
% Late incomplete apposition	0.0%

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
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 Investigator: **Martin B. Leon, MD**
29 sites: US



Primary endpoints: In-segment late lumen loss by QCA at 8 months
Antiplatelet therapy for ≥3 months

	Endeavor	Cypher	*p* Value
Patient Demographics and Lesion Characteristics	**n = 323**	**n = 113**	
Male gender	65.3%	81.4%	0.001
Diabetes mellitus	29.7%	28.3%	NS
B2/C lesions	67.2%	56.6%	NS
Lesions location: LAD	41.2%	39.8%	NS
Baseline Characteristics	**n = 323**	**n = 113**	
Reference vessel diameter (RVD)	2.75 mm	2.79 mm	NS
Average lesion length	14.96 mm	14.95 mm	NS
Postprocedure MLD	**n = 323**	**n = 113**	
In-stent MLD	2.67 mm	2.67 mm	NS
In-segment MLD	2.27 mm	2.28 mm	NS
Acute Performance Results	**n = 323**	**n = 113**	
Device success	98.8%	94.7%	0.02
Lesion success	100.0%	99.1%	NS
Procedure success	99.4%	95.6%	0.02
Clinical Follow-up (30 day)	**n = 323**	**n = 113**	
MACE	0.6%	3.5%	0.04
Death	0.0%	0.0%	NS
MI (all)			
Q-wave	0.0%	0.0%	NS
Non-Q-wave	0.6%	3.5%	0.04
TLR	0.0%	0.0%	NS
TVF	0.6%	4.4%	0.01
TVR (non-TL)	0.0%	0.9%	NS
Thrombosis (all)	0.0%	0.0%	NS
Late stent thrombosis	0.0%	0.0%	NS

	Endeavor	Cypher	*p* Value
Clinical Follow-up (9 mo)	**n = 321**	**n = 113**	
MACE	7.5%	7.1%	NS
Death	0.6%*	0.0%	NS
MI (all)	0.6%	3.5%	0.04
Q-wave	0.0%	0.0%	NS
Non-Q-wave	0.6%	3.5%	0.04
TLR	6.2%	3.5%	NS
TVF	11.8%	11.5%	NS
TVR (non-TL)	5.9%	5.3%	NS
Thrombosis (all)	0.0%	0.0%	NS
Late stent thrombosis	0.0%	0.0%	NS
Clinical Follow-Up (12 mo)	**n = 320**	**n = 112**	
MACE	7.8%	8.0%	NS
Death	0.6%*	0.9%	NS
MI (all)	0.6%	3.6%	0.04
Q-wave	0.0%	0.0%	NS
Non-Q-wave	0.6%	3.6%	0.04
TLR	6.6%	3.6%	NS
TVF	12.8%	11.6%	NS
TVR (non-TL)	6.6%	5.4%	NS
Thrombosis (all)	0.0%	0.0%	NS
Late stent thrombosis	0.0%	0.0%	NS
Clinical Follow-Up (24 mo)	**n = 313**	**n = 112**	
MACE	9.3%	11.6%	NS
Death	1.6%*	4.5%	NS
MI (all)	0.6%	3.6%	0.04
Q-wave	0.0%	0.0%	NS
Non-Q-wave	0.6%	3.6%	0.04
TLR	7.0%	4.5%	NS
TVF	14.4%	13.4%	NS
TVR (non-TL)	8.3%	6.3%	NS
Thrombosis (all)	0.0%	0.0%	
Late stent thrombosis	0.0%	0.0%	
Angiographic Follow-Up (8 mo)	**n = 277**	**n = 94**	
Binary restenosis rate			
In-stent	9.7%	2.1%	0.01
In-segment	12.3%	4.3%	0.03
Minimum luminal diameter			
In-stent	2.06 mm	2.52 mm	<0.001
In-segment	1.91 mm	2.16 mm	<0.001
Late loss			
In-stent	0.62 mm	0.15 mm	<0.001
In-segment	0.36 mm	0.13 mm	<0.001
Diameter stenosis %			
In-stent	24.9%	11.0%	<0.001
In-segment	30.4%	23.9%	<0.001
IVUS Follow-Up (8 mo)	**n = 189**	**n = 68**	
Late incomplete apposition %	0.5†	5.9	0.02

*Noncardiac deaths (lung cancer, cerebral hemorrhage)

†Thrombus at baseline, resolved during follow-up. No aneurysmal remodeling.

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 Investigator: **Martin B. Leon, MD**
Up to 80 sites: US

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

Out to 3 yrs (KM estimate) under ARC (Academic Research Consortium)

Thrombosis	Endeavor n = 1316	Driver n = 596
Early (any)	4 [0.30%]	7 [1.18%]
Definite	4	7
Probable	0	0
Late (any)	6 [0.46%]	4 [0.68%]
Definite	2	1
Probable	0	0
Possible	4	3
Very Late (any)	2 [0.16%]	5 [0.88%]
Definite	0	0
Probable	1	1
Possible	1	4
Totals	12 [0.92%] (CI 0.40%, 1.45%)	16 [2.74%] (CI 1.42%, 4.07%)

CI = Confidence Interval

e-Five

Prospective, multicenter registry
Sample Size: 8000 patients
Endeavor stent: n = 8000 patients

All-comers, single and multiple coronary artery lesions
Stent diameters: 2.25–4.0 mm
Stent lengths: 8/9–30 mm

Principal Investigators: **Chaim Lotan, MD, Prof Ian Meredith, MD, PhD, FACC, FRACP, Martin Rothman, MD**

200 sites: Asia Pacific, Europe, Israel, New Zealand, South America

FOLLOW-UP/MACE ASSESSMENT

Primary endpoints: MACE at 12 months
Antiplatelet therapy for ≥3 months

Patient Demographics	n = 2015
Male gender	76.6%
Age (years)	63.0 ±11.5
Prior MI	
Non-Q-wave	12.4%
Q-wave	25.0%
Prior PCI	24.0%
Prior CABG	6.7%
Diabetes mellitus	35.2%
Recent MI	21.8%
Unstable angina	31.5%
B2/C lesions	59.9%
Bifurcation lesions	15.7%

Procedure Characteristics	n = 2458
Total stent length (mm)	23.4 ±12.0
Stent: lesion length	1.4 ±0.5
Long lesions (>16 mm)	45.2%
Stent diameter (mm)	
2.25	6.0%
2.5	21.4%
2.75	16.2%
3.0	34.9%
>3.0	21.4%

Clinical Follow-Up (30 days)	All n = 1982	Diabetic n = 698	Bifurcation n = 344	Recent MI n = 432
MACE	1.7%	2.6%	2.6%	3.2%
Death	0.9%	1.4%	1.5%	2.1%
MI (all)				
Q-wave	0.2%	0.6%	0.3%	0.0%
Non-Q-wave	0.6%	0.7%	1.2%	1.2%
TLR	0.4%	0.9%	0.6%	0.7%
Emergent CABG	0.0%	0.0%	0.0%	0.0%
TVF	1.7%	2.4%	2.6%	3.0%

PROTECT

Prospective, multicenter, randomised, open-label trial

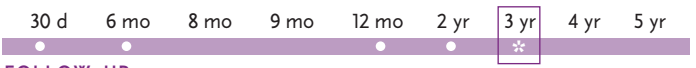
Sample Size: 8800 patients

Endeavor Stent: n = 4400 patients

Cypher Stent: n = 4400 patients

All-comers, single and multiple coronary artery lesions

Principal Investigators: **Edoardo Camenzind, MD (Switzerland), William O'Neill, MD (USA), Prof Patrick Serruys (Netherlands), Prof Philippe Gabriel Steg (France), William Wijns, MD, PhD (Belgium)**



FOLLOW-UP

Primary endpoint: Overall stent thrombosis rate at 3 years, defined as definite and probably according to the ARC definition

Main secondary endpoint: Composite endpoint of total death and number of patients with nonfatal myocardial infarctions at 3 years

Medtronic CardioVascular
3576 Unocal Place
Santa rosa, CA 95403
USA
Telephone: +1.707.525.0111
www.Medtronic.com

Medtronic BV
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
Telephone: +31.45.566.8000
FAX: +31.45.566.8668

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