Medtronic

Clinical Programmes

Medtronic Coronary Stent Systems

ENDEAVOR DES
RESOLUTE DES
DRIVER BMS

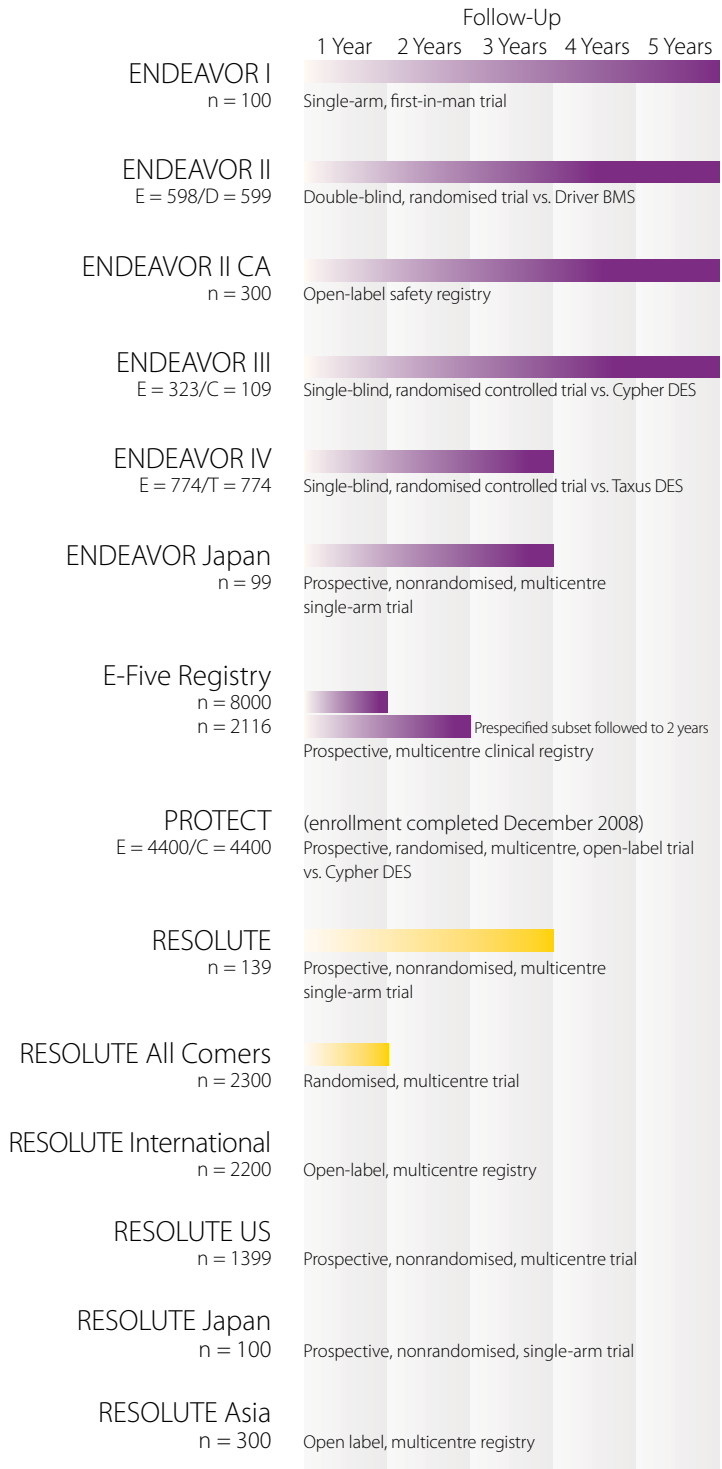
July 2010

Contents

*E I–E IV data analysed at the same data coordinating center and by the same core laboratories.

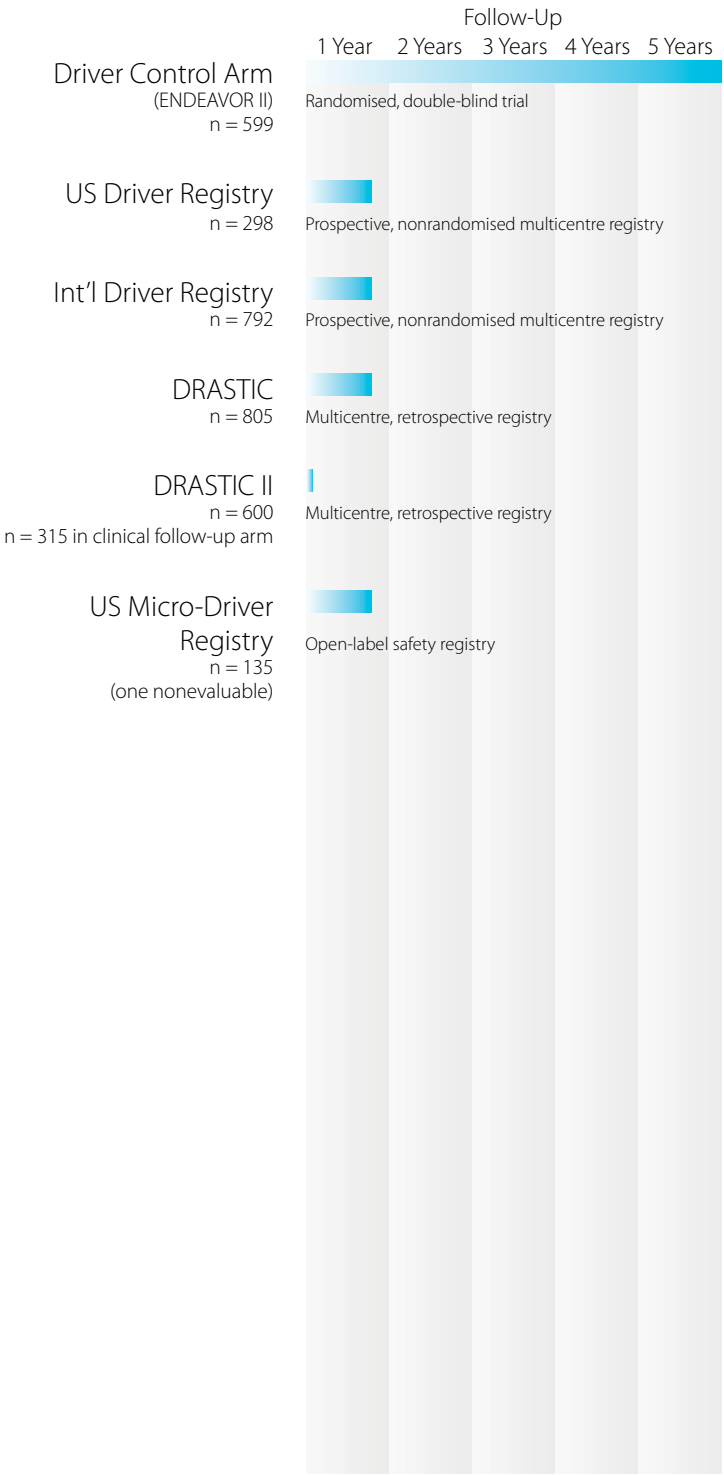
Comprehensive and Robust

Clinical Trials for Drug-Eluting Stents



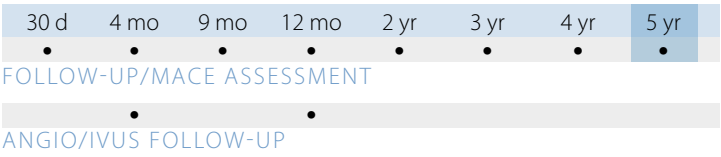
Clinical Programmes

Clinical Trials for Bare Metal Stents



ENDEAVOR I

Single-arm trial
Trial size: 100 patients (100 actual)
Single *de novo* native coronary artery lesions (Type A–B2)
Reference vessel diameter: 3.0–3.5 mm
Lesion length: <15 mm
Stent sizes: 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
Male gender (%)	79.0
Diabetes mellitus (%)	16.0
B2/C lesions (%)	49.0
Lesion location: LAD (%)	43.0

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

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

Postprocedure MLD	n = 100
In-stent MLD (mm)	2.84 ±0.35
In-segment MLD (mm)	2.52 ±0.42

Primary Endpoint (30 days)	n = 100
MACE (%)	1.0

Clinical Follow-Up	12 mo n = 99	24 mo n = 99	36 mo n = 98	48 mo n = 97	60 mo n = 97
MACE (%)	2.0	3.0	6.1	7.2	7.2
Death (all)	0	1.0	3.1	4.1	4.1
Cardiac death	0	0	0	0	0
MI (all)	1.0	1.0	1.0	1.0	1.0
Q-wave	0	0	0	0	0
Non-Q-wave	1.0	1.0	1.0	1.0	1.0
TLR	2.0	2.0	3.1	3.1	3.1
TVF (%)	2.0	4.0	5.1	5.2	5.2
TVR (non-TL) (%)	0	2.0	2.0	2.1	2.0
Thrombosis (ARC def/prob) (%)	1.0	1.0	1.0	1.0	1.0
Late (>30 days)	0	0	0	0	0

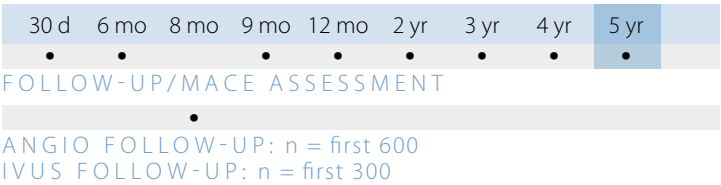
*Late lumen loss

Angiographic Follow-Up	4 mo n = 98	12 mo n = 92
Binary restenosis rate (%)		
In-stent	2.0	4.3
In-segment	3.1	5.4
Minimum luminal diameter (mm)		
In-stent	2.52	2.26
In-segment	2.29	2.08
Late loss (mm)		
In-stent	0.32	0.58
In-segment	0.22	0.43
Diameter stenosis (%)		
In-stent	14.4	21.75
In-segment	22.4	28.0

IVUS Follow-Up	4 mo n = 94	12 mo n = 86
Late incomplete apposition (%)	0	0
NIH volume (mm^3)	6.1	14.2

ENDEAVOR II

Randomised, double-blind trial
Trial size: 1200 patients (1197 actual)
Endeavor stent: n = 600 patients (598 actual)
Control Driver stent: n = 600 patients (599 actual)
Single *de novo* native coronary artery lesions (Type A–C)
Reference vessel diameter: 2.25–3.5 mm
Lesion length: 14–27 mm
Stent sizes: 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 endpoint: TVF (cardiac death, MI, TVR) at 9 months
Antiplatelet therapy for ≥3 months

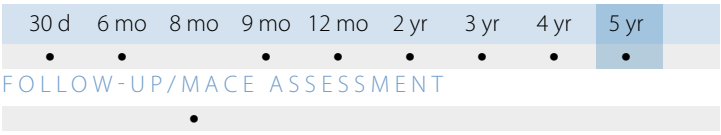
	Endeavor	Driver	*p*-Value
Patient Demographics and Lesion Characteristics	**n = 598**	**n = 599**	
Male gender (%)	77.2	75.3	NS
Diabetes mellitus (%)	18.2	22.2	NS
B2/C lesions (%)	78.5	79.0	NS
Lesion location: LAD (%)	43.2	47.5	NS
Acute Performance Results	**n = 598**	**n = 599**	
Device success (%)	98.8	99.2	NS
Lesion success (%)	99.7	100	NS
Procedure success (%)	96.5	96.4	NS
Baseline Characteristics	**n = 598**	**n = 599**	
Reference vessel diameter (RVD) (mm)	2.73	2.76	NS
Average lesion length (mm)	14.04	14.38	NS
Postprocedure MLD	**n = 598**	**n = 599**	
In-stent MLD (mm)	2.59	2.61	NS
In-segment MLD (mm)	2.21	2.24	NS
Clinical Follow-Up (9 mo)	**n = 592**	**n = 592**	
TVF (%)	7.9	15.0	<0.001
Clinical Follow-Up (12 mo)	**n = 590**	**n = 590**	
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 (ARC def/prob) (%)	0.7	1.2	NS
Late (>30 days)	0.2	0	—

p-Values for outcome differences are not adjusted for multiple comparisons.

	Endeavor	Driver	*p*-Value
Clinical Follow-Up (24 mo)	**n = 588**	**n = 588**	
MACE (%)	9.9	18.0	<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	14.1	<0.001
TVF (%)	11.1	19.7	<0.001
TVR (non-TL) (%)	2.4	4.1	NS
Thrombosis (ARC def/prob) (%)	0.8	1.2	NS
Late (>30 days)	0.1	0	—
Clinical Follow-Up (36 mo)	**n = 585**	**n = 587**	
MACE (%)	12.1	20.6	<0.001
Death	3.6	4.4	NS
MI (all)	3.2	4.3	NS
Q-wave	0.3	1.0	NS
Non-Q-wave	2.9	3.2	NS
TLR	7.2	14.7	<0.001
TVF (%)	12.6	21.3	<0.001
TVR (non-TL) (%)	2.9	4.8	NS
Thrombosis (ARC def/prob) (%)	0.8	1.2	NS
Late (>30 days)	0.1	0	—
Clinical Follow-Up (48 mo)	**n = 583**	**n = 584**	
MACE (%)	13.4	22.1	<0.001
Death (all)	5.0	5.1	NS
Cardiac	2.4	2.6	NS
MI (all)	3.3	4.5	NS
Q-wave	0.3	1.0	NS
Non-Q-wave	2.9	3.4	NS
TLR	7.2	15.8	<0.001
TVF (%)	13.6	22.6	<0.001
TVR (non-TL) (%)	3.4	5.3	NS
Thrombosis (ARC def/prob) (%)	0.8	1.2	NS
Late (>30 days)	0.1	0	—
Clinical Follow-Up (60 mo)	**n = 577**	**n = 582**	
MACE (%)	15.4	24.6	<0.001
Death	6.2	7.6	NS
MI (all)	3.8	4.8	NS
Q-wave	0.3	1.2	NS
Non-Q-wave	3.5	3.6	NS
TLR	7.5	16.3	<0.001
TVF (%)	15.4	24.4	<0.001
TVR (non-TL) (%)	—	—	—
Thrombosis (ARC def/prob) (%)	0.9	1.2	0.29
Late (>30 days)	0.2	0.2	1.00
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 (mm)			
In-stent	1.99	1.62	<0.001
In-segment	1.86	1.56	<0.001
Late loss (mm)			
In-stent	0.62	1.03	<0.001
In-segment	0.36	0.72	<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	—

ENDEAVOR II CA

Single-arm, multicentre registry
Trial size: 300 patients (296 actual, 297 lesions treated)
Single *de novo* native coronary artery lesions
Reference vessel diameter: 2.25–3.5 mm
Lesion length: 14–27 mm
Stent sizes: 2.25–3.5 mm x 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**
15 sites: Europe



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

Patient Demographics and Lesion Characteristics	n = 296
Male gender (%)	75.0
Diabetes mellitus (%)	25.8
B2/C lesions (%)	74.4
Lesion location: LAD (%)	50.5

Acute Performance Results	n = 296
Device success (%)	98.3
Lesion success (%)	99.7
Procedure success (%)	94.9

Baseline Characteristics	n = 296
Reference vessel diameter (RVD) (mm)	2.63
Average lesion length (mm)	16.49

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

Primary Endpoint (30 days)	n = 296
MACE (%)	5.4

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
Late (>30 days)	0

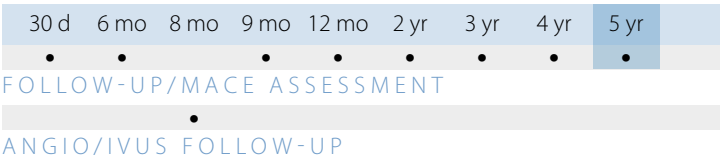
Clinical Follow-Up	12 mo n = 293	24 mo n = 292	36 mo n = 290	48 mo n = 287	60 mo n = 287
MACE (%)	12.3	12.7	13.8	15.3	17.8
Death	0.7	1.4	2.1	3.8	5.9
MI (all)	5.5	5.8	6.2	6.6	7.0
Q-wave	0.3	0.3	0.3	0.3	0.7
Non-Q-wave	5.1	5.5	5.9	6.3	6.6
TLR	6.5	7.2	7.2	7.3	7.3
Emergent CABG	0.3	0.3	1.4	1.4	0.3
TVF (%)	15.7	16.1	17.6	19.2	21.6
TVR (non-TL) (%)	5.8	5.8	6.9	8.4	9.8
Thrombosis (ARC def/prob) (%)	0	0	0	0	0
Early (0–30 days)	0	0	0	0	0
Late (31–360 days)	0	0	0	0	0
Very late (361–1825 days)	0	0	0	0	0

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

IVUS Follow-Up (8 mo)	n = 42
Late incomplete apposition (%)	0

ENDEAVOR III

Randomised, single-blind, prospective trial
Sample size: 436 patients (436 actual)
Endeavor stent: n = 327 patients (323 actual)
Control Cypher stent: n = 109 patients (113 actual)
Single *de novo* native coronary artery lesions
Reference vessel diameter: 2.5–3.5 mm
Lesion length: 14–27 mm
Stent sizes: 2.5–3.5 mm x 18–30 mm (8/9 mm bailout)
Principal investigator: **Martin B. Leon, MD**
29 sites: USA



Primary endpoint: 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
Lesion location: LAD (%)	41.2	39.8	NS
Acute Performance Results	**n = 323**	**n = 113**	
Device success (%)	98.8	94.7	0.02
Lesion success (%)	100	99.1	NS
Procedure success (%)	99.4	91.2	0.01
Baseline Characteristics	**n = 323**	**n = 113**	
Reference vessel diameter (RVD) (mm)	2.75	2.79	NS
Average lesion length (mm)	14.98	14.95	NS
Postprocedure MLD	**n = 323**	**n = 113**	
In-stent MLD (mm)	2.67	2.67	NS
In-segment MLD (mm)	2.27	2.28	NS
Clinical Follow-Up (9 mo)	**n = 321**	**n = 113**	
MACE (%)	7.5	7.1	NS
Death	0.6	0	NS
MI (all)	0.6	3.5	0.04
Q-wave	0	0	—
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 (ARC def/prob) (%)	0.3	0	1.00
Late (>30 days)	0.3	0	1.00
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	—
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 (ARC def/prob) (%)	0.3	0	NS
Late (>30 days)	0.3	0	NS

p-Values for outcome differences are not adjusted for multiple comparisons.

	Endeavor	Cypher	*p*-Value
Clinical Follow-Up (24 mo)	**n = 323**	**n = 113**	
MACE (%)	9.2	11.6	NS
Death	1.6	4.5	NS
MI (all)	0.6	3.6	0.04
Q-wave	0	0	—
Non-Q-wave	0.6	3.6	0.04
TLR	7.0	4.5	NS
TVF (%)	14.2	13.4	NS
TVR (non-TL) (%)	8.3	6.3	NS
Thrombosis (ARC def/prob) (%)	0.3	0	NS
Very late (366–730 days)	0	0	NS
Clinical Follow-Up (36 mo)	**n = 304**	**n = 110**	
MACE (%)	11.5	14.5	NS
Death	3.3	7.3	NS
MI (all)	0.6	4.5	0.01
Q-wave	0	0.9	NS
Non-Q-wave	0.6	3.6	0.04
TLR	7.6	4.5	NS
TVF (%)	16.1	14.5	NS
TVR (non-TL) (%)	9.5	7.3	NS
Thrombosis (ARC def/prob) (%)	0.3	0.9	—
Very late (366–1095 days)	0	0.9	0.46
Clinical Follow-Up (48 mo)	**n = 307**	**n = 110**	
MACE (%)	12.7	19.1	0.11
Death	4.2	10.0	0.03
MI (all)	1.0	4.5	0.33
Q-wave	0.3	0.9	0.46
Non-Q-wave	0.7	3.6	0.04
TLR	7.8	6.4	0.83
TVF (%)	15.6	16.4	1.00
TVR (non-TL) (%)	10.1	7.3	0.45
Thrombosis (ARC def/prob) (%)	0.7	0.9	1.00
Very late (366–1460 days)	0.3	0.9	0.45
Clinical Follow-Up (60 mo)	**n = 323**	**n = 113**	
MACE (%)	14.0	22.2	0.05
Death	5.2	13.0	0.02
MI (all)	1.0	4.6	0.03
Q-wave	0.3	0.9	0.45
Non-Q-wave	0.7	3.7	0.04
TLR	8.1	6.5	0.68
TVF (%)	17.9	18.5	0.89
TVR (non-TL) (%)	11.4	8.3	0.47
Thrombosis (ARC def/prob) (%)	0.7	0.9	1.00
Very late (366–1800 days)	0.3	0.9	0.45
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 (mm)			
In-stent	2.06	2.52	<0.001
In-segment	1.91	2.16	<0.001
Late loss (mm)			
In-stent	0.62	0.15	<0.001
In-segment	0.36	0.13	<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

ENDEAVOR IV

Randomised, single-blind, prospective trial
Trial size: 1548 patients (1548 actual)
Endeavor stent: n = 774 patients (773 actual)
Control Taxus stent: n = 774 patients (775 actual)
Single *de novo* native coronary artery lesions (Type A–C)
Reference vessel diameter: 2.5–3.5 mm
Lesion length: ≤27 mm
Stent sizes: 2.5–3.5 mm x 18–30 mm (8/9 mm bailout)
Principal investigator: **Martin B. Leon, MD**
80 sites: USA

30 d	6 mo	8 mo	9 mo	12 mo	2 yr	3 yr	4 yr	5 yr
•	•	•	•	•	•	•	•	•

FOLLOW-UP/MACE ASSESSMENT

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ANGIO/IVUS FOLLOW-UP

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

	Endeavor	Taxus	*p*-Value
Patient Demographics and Lesion Characteristics	**n = 773**	**n = 775**	
Male gender (%)	66.9	68.5	NS
Diabetes mellitus (%)	31.2	30.5	NS
B2/C lesions (%)	69.6	70.9	NS
Lesion location: LAD (%)	42.2	41.5	0.791
Acute Performance Results	**n = 773**	**n = 775**	
Device success (%)	97.3	97.9	NS
Lesion success (%)	99.6	99.2	NS
Procedure success (%)	98.7	96.8	0.02
Baseline Characteristics	**n = 773**	**n = 775**	
Reference vessel diameter (RVD) (mm)	2.73	2.70	NS
Average lesion length (mm)	13.41	13.80	NS
Postprocedure MLD	**n = 770**	**n = 772**	
In-stent MLD (mm)	2.62	2.61	NS
In-segment MLD (mm)	2.22	2.19	NS
Primary Endpoint (9 mo)	**n = 758**	**n = 749**	
TVF (%)	6.6	7.2	NS
Clinical Follow-Up (12 mo)	**n = 754**	**n = 751**	
MACE (%)	6.5	6.7	0.92
Death	1.1	1.1	1.0
Cardiac death	0.5	0.5	1.0
MI (all)	1.6	2.7	0.16
Q-wave	0.3	0.1	1.0
Non-Q-wave	1.3	2.5	0.095
Cardiac death and MI	2.1	3.2	0.20
TLR	4.5	3.2	0.23
TVF (%)	7.7	9.6	0.20
TVR (non-TL) (%)	2.5	4.3	0.07
Thrombosis (ARC def/prob) (%)	0.9	0.1	NS
Early (0–30 days)	0.4	0.1	0.62
Late (31–360 days)	0.5	0	0.12

p-Values for outcome differences are not adjusted for multiple comparisons.

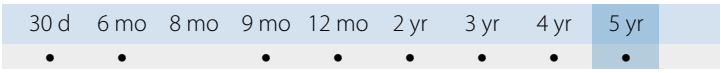
	Endeavor	Taxus	*p*-Value
Clinical Follow-Up (24 mo)	**n = 742**	**n = 739**	
MACE (%)	9.8	10.0	0.93
Death	3.1	2.6	0.64
Cardiac death	1.5	1.2	0.82
MI (all)	2.0	4.1	0.02
Q-wave	0.4	0.5	0.73
Non-Q-wave	1.6	3.5	0.02
Cardiac death and MI	3.4	5.1	0.09
TLR	5.9	4.6	0.29
TVF (%)	11.1	13.1	0.23
TVR (non-TL) (%)	4.2	5.8	0.15
Thrombosis (ARC def/prob) (%)	1.1	0.9	1.00
Early (0–30 days)	0.4	0.1	0.62
Late (31–360 days)	0.5	0	0.12
Very late (361–730 days)	0.1	0.8	0.07
Clinical Follow-Up (36 mo)	**n = 734**	**n = 734**	
MACE (%)	11.4	13.8	0.21
Death	4.0	4.5	0.70
Cardiac death	1.6	2.3	0.45
MI (all)	2.2	4.9	0.01
Q-wave	0.4	0.7	0.73
Non-Q-wave	1.8	4.2	0.01
Cardiac death or MI	3.7	7.1	0.01
TLR	6.5	6.0	0.75
TVF (%)	12.4	16.1	0.05
TVR (non-TL) (%)	4.8	6.8	0.12
Thrombosis (ARC def/prob) (%)	1.1	1.6	0.50
Early (0–30 days)	0.4	0.1	0.62
Late (31–360 days)	0.5	0.0	0.12
Very late (361–1095 days)	0.1	1.5	0.01
Angiographic Follow-Up (8 mo)	**n = 144**	**n = 135**	
Binary restenosis rate (%)			
In-stent	13.3	6.7	NS
In-segment	15.3	10.4	NS
Minimum luminal diameter (mm)			
In-stent	1.95	2.25	<0.001
In-segment	1.80	1.98	0.008
Late loss (mm)			
In-stent	0.67	0.42	<0.001
In-segment	0.36	0.23	0.02
Diameter stenosis (%)			
In-stent	26.41	16.09	<0.001
In-segment	32.28	26.61	0.004
IVUS Follow-Up (8 mo)	**n = 106**	**n = 95**	
Late incomplete apposition (%)	0.9	3.2	NS

Note: ENDEAVOR IV was not specifically powered or designed to evaluate this subset.

Diabetics	Endeavor	Taxus	*p*-Value
Clinical Follow-Up (36 mo)	**n = 224**	**n = 218**	
Cardiac death and MI (%)	2.7	7.3	0.03
TLR (%)	9.8	8.7	0.74
TVF (%)	15.6	21.6	0.11

ENDEAVOR Pooled Safety Analysis*

ENDEAVOR I, E II, E II CA, E III, E IV and E pK
KM cumulative incidence of safety endpoints to 1880 days (*post hoc* analysis)
Sample size: 2728 patients
Endeavor stent: n = 2132
Control Driver stent: n = 596
Single *de novo* native coronary artery lesions (Type A–C)
Principal investigator: **Laura Mauri, MD**



FOLLOW-UP/MACE ASSESSMENT

Antiplatelet therapy for ≥3 months in all trials except E IV (antiplatelet therapy for ≥6 months)

	Endeavor	Driver†
Patient Demographics and Lesion Characteristics	**n = 2132**	**n = 596**
Male gender (%)	71.5	75.3
Diabetes mellitus (%)	26.1	22.2
B2/C lesions (%)	71.3	79.0
Baseline Characteristics	**n = 2132**	**n = 596**
Reference vessel diameter (RVD) (mm)	2.73	2.76
Average lesion length (mm)	14.16	14.38
Dual Antiplatelet Therapy Usage‡		
1 yr (%)	38.8	29.0
2 yr (%)	31.0	13.5
3 yr (%)	23.7	9.1
4 yr (%)	7.9	9.2
5 yr (%)	7.5	8.6

Clinical Follow-Up (60 mo) Cumulative Incidence	Endeavor n = 2132	Driver n = 596	Difference (95% CI)
MACE (%)	14.3	24.3	-10.02 (-14.36, -5.68)
Death	6.1	7.6	-1.55 (-4.30, 1.19)
Cardiac death	2.2	3.7	-1.51 (-3.42, 0.41)
MI (all)	3.2	4.8	-1.56 (-3.81, 0.68)
Cardiac death and MI	5.2	8.4	-3.25 (-6.09, -0.40)
TLR	7.0	16.5	-9.49 (-13.31, -5.67)
TVF (%)	16.0	24.2	-8.29 (-12.77, -3.81)
TVR (%)	12.6	20.2	-7.6 (-11.82, -3.38)
Thrombosis (ARC def/prob) (%)			
Early/late (0–360 days)	0.6	1.4	-0.73 (-1.73, 0.27)
Very late (361–1800 days)	0.2	0.4	-0.19 (-0.80, 0.43)
Cumulative to 1800 days	0.8	1.7	-0.92 (-2.23, 0.40)

Important Safety Subsets*

Diabetics	Endeavor	Driver	Difference (95% CI)
Clinical Follow-Up (60 mo) Cumulative Incidence	**n = 555**	**n = 132**	
Death (%)	5.45	14.74	-9.29 (-16.69, -1.90)
Cardiac death	1.87	8.76	-6.90 (-12.78, -1.01)
MI (%)	2.61	4.59	-1.98 (-6.78, 2.82)
Cardiac death and MI (%)	4.09	13.26	-9.17 (-16.33, -2.01)
Thrombosis (protocol) (%)	0.54	2.27	-1.73 (-4.96, 1.50)
Thrombosis (ARC def/prob) (%)	1.11	3.07	-1.96 (-5.79, 1.86)

Small Vessels RVD ≤2.5 mm

Clinical Follow-Up (60 mo) Cumulative Incidence	n = 725	n = 190	
Death (%)	6.13	7.98	-1.86 (-6.79, 3.07)
Cardiac death	2.74	5.35	-2.61 (-6.59, 1.37)
MI (%)	2.29	6.39	-4.10 (-8.42, 0.21)
Cardiac death and MI (%)	4.87	11.68	-6.81 (-12.40, -1.21)
Thrombosis (protocol) (%)	0.28	2.63	-2.36 (-5.03, 0.32)
Thrombosis (ARC def/prob) (%)	0.42	3.71	-3.29 (-6.46, -0.12)

Long Lesions ≥20 mm

Clinical Follow-Up (60 mo) Cumulative Incidence	n = 324	n = 91	
Death (%)	4.93	13.64	-8.71 (-17.02, -0.40)
Cardiac death	2.04	4.76	-2.71 (-8.14, 2.71)
MI (%)	5.08	15.62	-10.54 (-19.87, -1.21)
Cardiac death and MI (%)	6.78	20.2	-13.42 (-23.53, -3.31)
Thrombosis (protocol) (%)	0	3.51	-3.51 (-7.94, 0.92)
Thrombosis (ARC def/prob) (%)	0.8	4.65	-3.84 (-9.09, 1.40)

Note: The ENDEAVOR pooled safety analysis was not specifically powered or designed to evaluate these subsets. The Endeavor stent is not specifically indicated for use in RVD <2.25 mm or lesion lengths >27 mm.

KM = Kaplan-Meier
CI = confidence interval
*ENDEAVOR pooled: E I 5 yr, E II 5 yr, E II CA 5 yr, E III 5 yr, E IV 3 yr and E pK 3 yr
†Driver arm existed in E II only.
‡DAPT usage based on case report forms. The optimal duration of dual antiplatelet therapy, specifically clopidogrel, is unknown and DES thrombosis may still occur despite continued therapy.

ENDEAVOR Japan

Prospective, nonrandomised, multicentre, single-arm trial
Trial size: 99 patients (99 actual)
Single *de novo* native coronary artery lesions (Type A–C)
Reference vessel diameter: 2.25–3.5 mm
Lesion length: 14–27 mm
Stent sizes: 2.25–3.5 mm x 18–30 mm (8/9 mm bailout)
Principal investigator: **Shigeru Saito, MD**
11 sites: Japan

30 d	6 mo	8 mo	9 mo	12 mo	2 yr	3 yr	4 yr	5 yr
•	•		•	•	•	•	•	•

FOLLOW-UP/MACE ASSESSMENT

		•						

ANGIO/IVUS FOLLOW-UP: n = 99

Primary endpoint: TVF (cardiac death, MI, TVR) at 9 months
Antiplatelet therapy for 3 months (ticlopidine, aspirin)

Patient Demographics and Lesion Characteristics	n = 99
Male gender (%)	67.7
Diabetes mellitus (%)	38.4
B2/C lesions (%)	88.9
Lesion location: LAD (%)	39.4

Acute Performance Results	n = 99
Device success (%)	97.0
Lesion success (%)	100
Procedure success (%)	98.0

Baseline Characteristics	n = 99
Reference vessel diameter (RVD) (mm)	2.78
Average lesion length (mm)	13.90

Postprocedure MLD	n = 99
In-stent MLD (mm)	2.68
In-segment MLD (mm)	2.23

Clinical Follow-Up (9 mo)	n = 99
MACE (%)	5.1
Death	0
MI (all)	2.0
Q-wave	0
Non-Q-wave	2.0
TLR	3.0
TLR-CABG	0
TLR-PCI	3.0
Emergent CABG	0
TVF (%)	5.1
TVR (non-TL) (%)	0
Thrombosis (ARC def/prob) (%)	0

Clinical Follow-Up (12 mo)	n = 95
MACE (%)	7.4
Death	1.1
MI (all)	2.1
Q-wave	0
Non-Q-wave	2.1
TLR	4.2
Emergent CABG	0
TVF (%)	7.4
TVR (non-TL) (%)	0
Thrombosis (ARC def/prob) (%)	0

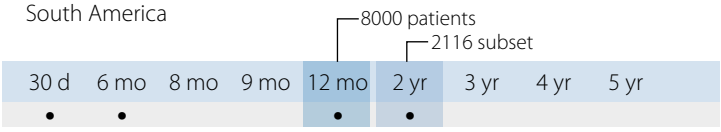
Clinical Follow-Up (24 mo)	n = 94
MACE (%)	9.8
Death	2.1
MI (all)	2.1
Q-wave	0
Non-Q-wave	2.1
TLR	5.3
Emergent CABG	0
TVF (%)	8.5
TVR (non-TL) (%)	0
Thrombosis (ARC def/prob) (%)	0

Clinical Follow-Up (36 mo)	n = 94
MACE (%)	10.6
Death	2.1
MI (all)	2.1
Q-wave	0
Non-Q-wave	2.1
TLR	5.3
TVF (%)	9.6
TVR (non-TL) (%)	1.1
Thrombosis (ARC def/prob) (%)	0

Angiographic Follow-Up (8 mo)	n = 98
Binary restenosis rate (%)	
In-stent	8.2
In-segment	8.2
Minimum luminal diameter (mm)	
In-stent	2.15
In-segment	2.00
Late loss (mm)	
In-stent	0.53
In-segment	0.23
Diameter stenosis (%)	
In-stent	23.7
In-segment	29.2

E-Five Registry

Prospective, multicentre registry
Trial size: 8000 patients (8314 actual) followed to 1 year
Prespecified subset: 2116 patients followed to 2 years
All-comers, single and multiple coronary artery lesions
Stent sizes: 2.25–4.0 mm x 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 and South America



FOLLOW-UP/MACE ASSESSMENT

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

Patient Demographics and Lesion Characteristics	n = 8314	2 Yr Subset* n = 2116
Male gender (%)	76.7	77.3
Age (yr)	63.29 ±11.06	62.1 ±11.0
Diabetes mellitus (%)	32.7	30.1
B2/C lesions (%)	60.2	63.1
Bifurcation lesions (%)	16.5	16.3
Lesion location: LAD (%)	46.6	49.2

Baseline Characteristics	n = 8314
Reference vessel diameter (RVD) (mm)	2.93 ±0.47
Average lesion length (mm)	18.51 ±10.61

Procedure Characteristics	n = 10,339 Lesions
Total stent length (mm)	23.48 ±12.21
Stent:lesion length (mm)	1.36 ±0.69
Long lesions (>20 mm) (%)	3.04
Stent diameter (%)	
2.25 mm	6.9
2.5 mm	21.7
2.75 mm	16.1
3.0 mm	33.1
3.5 mm	17.9
4.0 mm	4.3

Clinical Follow-Up	30 days n = 8243	12 mo n = 7832	24 mo n = 2054
MACE (%)	1.6	7.5	8.5
Death	0.6	2.4	2.9
Cardiac death	0.6	1.7	1.5
MI (all)	0.9	1.6	1.5
Q-wave	0.2	0.4	0.3
Non-Q-wave	0.7	1.3	1.1
TLR	0.4	4.5	5.1
TVF (%)	1.6	7.2	7.9
TVR (non-TL) (%)	0	0.7	1.0
Thrombosis (ARC def/prob) (%)	0.8	1.0	0.1
Late (31–360 days)	—	0.3	0.1
Very late (366–730 days)	—	—	0.1

*Prespecified subset followed to 2 years.

Important Safety Subsets (from 8000-patient cohort)

Diabetics

Clinical Follow-Up	30 days n = 2698	12 mo n = 2563
MACE (%)	2.1	9.7
Death (all)	1.1	4.1
Cardiac death	0.9	2.7
MI (all)	1.0	1.8
Q-wave	0.2	0.5
Non-Q-wave	0.8	1.4
Cardiac death and MI	1.7	4.1
TLR	0.6	5.3
TVF (%)	1.9	8.7
TVR (non-TL) (%)	0.1	0.6
Thrombosis (all) (%)	1.2	1.6
Early (0–30 days)	1.2	1.3
Late (31–360 days)	—	0.3

Small Vessels (RVD ≤2.75 mm)

Clinical Follow-Up	30 days n = 3503	12 mo n = 3336
MACE (%)	2.0	9.1
Death (all)	0.9	3.1
Cardiac death	0.8	2.3
MI (all)	1.0	1.8
Q-wave	0.2	0.4
Non-Q-wave	0.9	1.4
Cardiac death and MI	1.7	3.6
TLR	0.5	5.6
TVF (%)	2.0	8.8
TVR (non-TL) (%)	0.1	0.9
Thrombosis (all) (%)	1.1	1.5
Early (0–30 days)	1.1	1.1
Late (31–360 days)	—	0.4

Long Lesions (>20 mm)

Clinical Follow-Up	30 days n = 3586	12 mo n = 3402
MACE (%)	2.6	9.4
Death (all)	0.9	3.3
Cardiac death	0.8	2.3
MI (all)	1.6	2.4
Q-wave	0.4	0.5
Non-Q-wave	1.3	1.9
Cardiac death and MI	2.3	4.3
TLR	0.6	5.2
TVF (%)	2.6	8.9
TVR (non-TL) (%)	0.1	0.7
Thrombosis (all) (%)	1.1	1.5
Early (0–30 days)	1.1	1.2
Late (31–360 days)	—	0.3

Note: The E-Five registry was not specifically powered or designed to evaluate these subsets. The Endeavor stent is not specifically indicated for use in RVD <2.25 mm or lesion lengths >27 mm.

Important Safety Subsets (from prespecified 2116-patient subset)

Diabetics

Clinical Follow-Up	12 mo n = 628	24 mo n = 614
MACE (%)	9.2	10.9
Death (all)	3.3	5.0
Cardiac death	2.2	2.6
MI (all)	1.4	1.6
Q-wave	0.2	0.2
Non-Q-wave	1.3	1.5
Cardiac death and MI	3.5	3.9
TLR	5.6	6.2
TVF (%)	8.6	9.6
TVR (non-TL) (%)	0.6	0.8
Thrombosis (ARC def/prob) (%)	0.8	0.8
Early (0–30 days)	0.8	0.8
Late (31–365 days)	0.0	0.0
Very late (366–730 days)	—	0.0

Small Vessels (2.25 mm ≤2.75 mm)

Clinical Follow-Up	12 mo n = 1207	24 mo n = 294
MACE (%)	9.1	10.2
Death (all)	3.6	4.4
Cardiac death	2.6	2.0
MI (all)	1.7	1.4
Q-wave	0.4	0.7
Non-Q-wave	1.3	1.7
Cardiac death and MI	4.1	3.1
TLR	5.0	5.4
TVF (%)	8.6	8.2
TVR (non-TL) (%)	0.7	0.7
Thrombosis (ARC def/prob) (%)	1.7	0.7
Early (0–30 days)	1.2	0.3
Late (31–365 days)	0.5	0.0
Very late (366–730 days)	—	0.3

Long Lesions (>20 mm)

Clinical Follow-Up	12 mo n = 956	24 mo n = 934
MACE (%)	7.2	9.1
Death (all)	2.2	3.4
Cardiac death	1.6	1.8
MI (all)	1.6	1.9
Q-wave	0.3	0.3
Non-Q-wave	1.3	1.6
Cardiac death and MI	3.0	3.5
TLR	4.4	4.8
TVF (%)	7.2	8.2
TVR (non-TL) (%)	0.7	1.0
Thrombosis (all) (%)	1.0	1.2
Early (0–30 days)	0.7	0.7
Late (31–360 days)	0.3	0.3
Very late (366–730 days)	—	0.1

Note: The E-Five registry was not specifically powered or designed to evaluate these subsets.

PROTECT

Prospective, multicentre, randomised, open-label trial
Trial size: 8800 patients (enrollment completed December 2008)
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 (The Netherlands)
Prof. Philippe Gabriel Steg (France)
William Wijns, MD, PhD (Belgium)
More than 200 international sites

30 d	6 mo	8 mo	9 mo	12 mo	2 yr	3 yr	4 yr	5 yr
•	•			•	•	•		

FOLLOW-UP

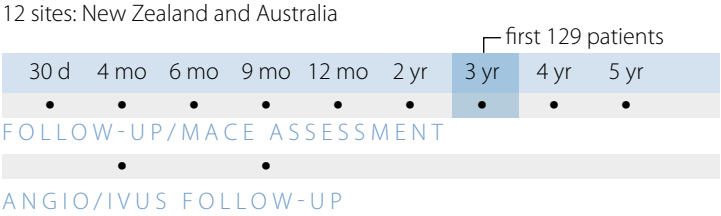
Primary endpoint: definite/probable stent thrombosis (ARC definition) to 3 years

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

Open label: antiplatelet therapy for 3–12 months

RESOLUTE

Prospective, nonrandomised, multicentre, single-arm trial
Trial size: 130 patients (139 actual)
Single *de novo* native coronary artery lesions
Reference vessel diameter: 2.5–3.5 mm
Lesion length: 14–27 mm
Stent sizes: 2.5 mm, 3.0 mm, 3.5 mm x 18 mm, 24 mm, 30 mm (8/9 bailout)
Principal investigator: **Ian Meredith, MD, PhD**
12 sites: New Zealand and Australia



Primary endpoint: late lumen loss (in-stent) at 9 mo by QCA
Antiplatelet therapy for ≥6 months

Patient Demographics and Lesion Characteristics	n = 130
Male gender (%)	75.4
Diabetes mellitus (%)	17.7
B2/C lesions (%)	81.7
Lesion location: LAD (%)	34.4

Acute Performance Results	n = 130
Device success (%)	99.2
Lesion success (%)	100
Procedure success (%)	96.2

Baseline Characteristics	n = 130
Reference vessel diameter (RVD) (mm)	2.81 ±0.41
Lesion length (mm)	15.49 ±6.23

Postprocedure MLD	n = 130
In-stent MLD (mm)	2.75 ±0.39
In-segment MLD (mm)	2.36 ±0.44

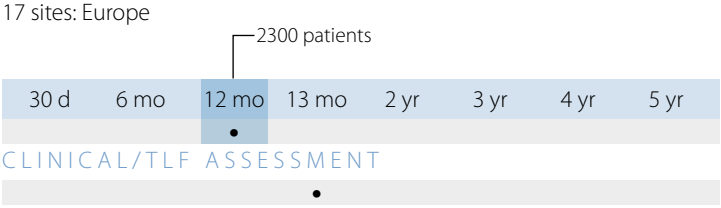
Clinical Follow-Up	12 mo n = 130 131 Lesions	24 mo n = 130 131 Lesions	36 mo n = 129 130 Lesions
MACE (%)	8.5	10.0	11.6
Death (all)	2.3	3.1	4.7
Cardiac death	0.8	0.8	0.8
MI (all)	5.4	5.4	5.4
Q-wave	0	0	0
Non-Q-wave	5.4	5.4	5.4
Cardiac death and MI	6.2	6.2	6.2
TLR	0.8	1.5	1.6
TVR (non-TL) (%)	0	0	0.8
TVR (%)	0.8	1.5	2.3
TVF (%)	6.9	7.7	8.5
Thrombosis (ARC def/prob) (%)	0	0	0
0–30 days	0	0	0
>30 days or LST	0	0	0

Angiographic Follow-Up	4 mo n = 30	9 mo n = 96
Binary restenosis rate (%)		
In-stent	0	1.0
In-segment	0	2.1
Minimum luminal diameter (mm)		
In-stent	2.68 ±0.39	2.51 ±0.48
In-segment	2.38 ±0.40	2.21 ±0.45
Late loss (mm)		
In-stent	0.12 ±0.26	0.22 ±0.27
In-segment	0.05 ±0.20	0.12 ±0.27
Diameter stenosis (%)		
In-stent	7.18 ±7.86	10.13 ±12.63
In-segment	17.74 ±7.57	21.08 ±10.62

IVUS Follow-Up	4 mo n = 24	9 mo n = 88
Volume obstruction (%)	2.23 ±2.43	3.73 ±4.05
Late incomplete apposition (%)	3.3	6.8
NIH volume (mm^3)	3.72 ±4.21	6.55 ±7.83

RESOLUTE All Comers

Prospective, randomised, multicentre trial
Trial size: 2300 patients (2292 actual)
Resolute stent: n = 1150 (1140 actual)
Xience V stent: n = 1150 (1152 actual)
All comers, CAD including UA, NSTEMI and STEMI
No limitations on the number of lesions, vessels or lesion length.
Principal investigators: **Patrick Serruys, MD, PhD**
Sigmund Silber, MD, FACC, FESC
Stephan Windecker, MD
17 sites: Europe



Primary endpoint: TLF (ARC-defined): cardiac death, target vessel MI, clinically indicated TLR at 12 months
Antiplatelet therapy for >6 months (per guidelines)

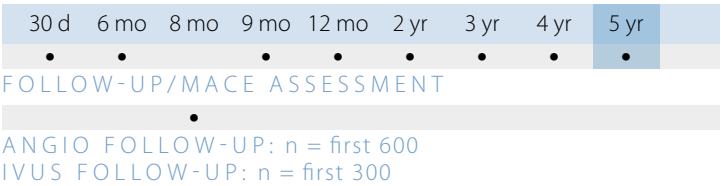
	Resolute	Xience V	*p*-Value
Patient Demographics and Lesion Characteristics	**n = 1140**	**n = 1152**	
Age (yr)	64.4 ±10.9	64.2 ±10.8	*NS*
Male gender (%)	76.7	77.2	*NS*
Diabetes mellitus (%)	23.5	23.4	*NS*
Insulin-treated	8.4	7.1	*NS*
Unstable angina (%)	19.4	18.9	*NS*
AMI (within 12 hr)	15.4	17.8	*NS*
AMI (within 72 hr)	28.9	28.8	*NS*
Complex* (%)	67.0	65.6	*NS*
Baseline Characteristics	**n = 1140** 1661 Lesions	**n = 1152** 1705 Lesions	
Small vessel (RVD ≤ 2.75 mm) (% patients)	67.8	67.4	*NS*
Average lesion length (mm)	11.89 ±7.50	12.15 ±7.86	*NS*
Multivessel disease	58.4	59.2	*NS*
Syntax score	14.8 ±9.3	14.6 ±9.2	*NS*
Procedure Characteristics	**n = 1140** 1661 Lesions	**n = 1152** 1705 Lesions	
Lesions treated per patient	1.46 ±0.73	1.48 ±0.77	*NS*
Lesion length (mm)	11.89 ±7.50	12.15 ±7.86	*NS*
No. of stents per patient	1.9 ±1.2	2.0 ±1.3	0.02
Stent length per patient (mm)	34 ±24	37 ±26	0.02
Prestent balloon dilatation (%)	69.5	70.2	*NS*
Implantation of study stent (%)	98.0	96.9	*NS*
Lesion success (%)	98.9	99.1	*NS*
Device success (%)	97.0	96.6	*NS*
Procedure success (%)	94.6	94.2	*NS*

p-Values for outcome differences are unadjusted for multiple comparisons.
*Complex patient definition: bifurcation, bypass graft, ISR, AMI <72 hr, LVEF <30%, unprotected LM, >2 vessels stented, renal insufficiency or failure (creatinine >140 µmol/L), lesion length >27 mm, >1 lesion per vessel, lesion with thrombus or TO (preprocedure TIMI = 0). With the exception of long lesions (treatable with a single 38-mm length stent), Resolute DES currently is not specifically approved for the patient subsets noted in this complex patient definition.
RESOLUTE All Comers was not specifically designed or powered for complex patient subset analysis.

	Resolute	Xience V	*p*-Value
Clinical Follow-Up (12 mo)	**n = 1119**	**n = 1126**	
TLF (%)	8.2	8.3	0.94
MACE (%)	8.7	9.7	0.42
TVF (%)	9.0	9.6	0.66
TLR (%)	3.9	3.4	0.50
TVR (%)	4.9	4.8	0.92
Death (%)	1.6	2.8	0.08
Cardiac death (%)	1.3	1.7	0.61
Target vessel MI (%)	4.2	4.1	0.92
Thrombosis (ARC def/prob) (%)	1.6	0.7	*NS*
Early (0–30 days)	1.1	0.5	*NS*
Late (31–360 days)	0.6	0.2	*NS*
Angiographic Follow-Up (13 mo)	**n = 191**	**n = 186**	
In-stent diameter stenosis (%) (Powered secondary endpoint)	21.7	19.8	0.21
Complex Patient Subgroup	**n = 752**	**n = 742**	
TLF (%)	8.9	9.7	0.66
MACE (%)	9.2	11.5	0.15
TVF (%)	9.8	11.1	0.45
TLR (%)	4.4	4.0	0.80
Death (%)	1.5	3.4	0.02
Cardiac death (%)	1.3	2.2	0.24
Target vessel MI (%)	4.3	4.4	0.90
Thrombosis (ARC def/prob) (%)	1.7	0.9	0.26

Driver Control Arm (ENDEAVOR II)

Randomised, double-blind trial
Trial size: 1200 patients (1197 actual)
Endeavor stent: n = 600 patients (598 actual)
Control Driver stent: n = 600 patients (599 actual)
Single *de novo* native coronary artery lesions (Type A–C)
Reference vessel diameter: 2.25–3.5 mm
Lesion length: 14–27 mm
Stent sizes: 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 endpoint: TVF (cardiac death, MI, TVR) at 9 months
Antiplatelet therapy for ≥3 months

	Driver
Patient Demographics and Lesion Characteristics	**n = 599**
Male gender (%)	75.3
Diabetes mellitus (%)	22.2
B2/C lesions (%)	79.0
Lesion location: LAD (%)	47.5
Acute Performance Results	**n = 599**
Device success (%)	99.2
Lesion success (%)	100
Procedure success (%)	96.4
Baseline Characteristics	**n = 599**
Reference vessel diameter (RVD) (mm)	2.76
Average lesion length (mm)	14.38
Postprocedure MLD	**n = 599**
In-stent MLD (mm)	2.61
In-segment MLD (mm)	2.24
Clinical Follow-Up (9 mo)	**n = 592**
TVF (%)	15.0
Clinical Follow-Up (12 mo)	**n = 590**
MACE (%)	15.6
Death	0.7
MI (all)	3.9
Q-wave	0.8
Non-Q-wave	3.1
TLR	13.1
TVF (%)	16.6
TVR (non-TL) (%)	2.5
Thrombosis (all) (%)	1.2
Late (>30 days)	0

p-Values for outcome differences are not adjusted for multiple comparisons.

	Driver
Clinical Follow-Up (24 mo)	**n = 588**
MACE (%)	18.0
Death	2.2
MI (all)	3.9
Q-wave	0.9
Non-Q-wave	3.1
TLR	14.1
TVF (%)	19.7
TVR (non-TL) (%)	4.1
Thrombosis (all) (%)	1.2
Late (>30 days)	0
Clinical Follow-Up (36 mo)	**n = 587**
MACE (%)	20.6
Death	4.4
MI (all)	4.3
Q-wave	1.0
Non-Q-wave	3.2
TLR	14.7
TVF (%)	21.3
TVR (non-TL) (%)	4.8
Thrombosis (all) (%)	1.2
Late (>30 days)	0
Clinical Follow-Up (48 mo)	**n = 584**
MACE (%)	22.1
Death (all)	5.1
Cardiac	2.6
MI (all)	4.5
Q-wave	1.0
Non-Q-wave	3.4
TLR	15.8
TVF (%)	22.6
TVR (non-TL) (%)	5.3
Thrombosis (all) (%)	1.2
Late (>30 days)	0
Clinical Follow-Up (60 mo)	**n = 582**
MACE (%)	24.6
Death	7.6
MI (all)	4.8
Q-wave	1.2
Non-Q-wave	3.6
TLR	16.3
TVF (%)	24.4
TVR (non-TL) (%)	—
Thrombosis (all) (%)	1.2
Late (>30 days)	0.2
Angiographic Follow-Up (8 mo)	**n = 265**
Binary restenosis rate (%)	
In-stent	33.2
In-segment	34.7
Minimum luminal diameter (mm)	
In-stent	1.62
In-segment	1.56
Late loss (mm)	
In-stent	1.03
In-segment	0.72
Diameter stenosis (%)	
In-stent	42.2
In-segment	44.3
IVUS Follow-Up (8 mo)	**n = 104**
Late incomplete apposition (%)	0

US Driver Registry

Prospective, nonrandomised multicentre registry
Trial size: 298 patients (298 actual)
Single *de novo* or restenotic nonstented native coronary artery lesions (Type A–C)

Stent sizes: 3.0–4.0 mm x 9–18 mm

Principal investigator: **Michael H. Sketch Jr., MD, FACC**

23 sites: USA

14 d	30 d	6 mo	8 mo	9 mo
•	•	•		•

FOLLOW-UP/MACE ASSESSMENT

		•		

ANGIO/IVUS FOLLOW-UP

Primary endpoint: MACE at 6 months

Patient Demographics and Lesion Characteristics	n = 298
Male gender (%)	68.1
Diabetes mellitus (%)	27.6
B2/C lesions (%)	50.7
Lesion location: LAD (%)	45.1

Acute Performance Results	n = 298
Device success (%)	100
Lesion success (%)	100
Procedure success (%)	98.3

Baseline Characteristics	n = 298
Reference vessel diameter (RVD) (mm)	3.07 ±0.47
Average lesion length (mm)	11.04 ±4.24

Postprocedure MLD	n = 284
In-stent MLD (mm)	2.90 ±0.41
In-segment MLD (mm)	2.55 ±0.50

Clinical Follow-Up	180 days n = 298	270 days n = 298
MACE (%)	5.7	10.1
Death (all)	0.7	1.3
Cardiac death	0	0
MI (all)	1.7	1.7
Q-wave	0	0
Non-Q-wave	1.7	1.7
TLR	3.4	7.0
TVF (%)	6.7	9.7
TVR (%)	4.4	8.1
Thrombosis (all) (%)	0	0

Angiographic Follow-Up (9 mo)	n = 83
Binary restenosis rate (%)	
In-stent	15.7
In-segment	15.7
Minimum luminal diameter (mm)	
In-stent	1.99 ±0.62
In-segment	1.93 ±0.58
Late loss (mm)	
In-stent	0.94 ±0.54
In-segment	0.62 ±0.56
Diameter stenosis (%)	
In-stent	34.2 ±16.3
In-segment	36.1 ±15.0

International Driver Registry

Prospective, nonrandomised multicentre registry
Trial size: 792 patients (792 actual)
All-comers
Stent sizes: 2.25–4.0 mm x 9–18 mm
Steering committee: **U. Sigwart, University Hospital, Switzerland; B. Chevalier, Center Cardiologique du Nord, France; and A. Kastrati, Deutsches Herzzentrum München, Germany**
29 sites: Europe

14 d	30 d	6 mo	8 mo	9 mo
•	•	•		•

FOLLOW-UP/MACE ASSESSMENT

		•		

ANGIO/IVUS FOLLOW-UP

Primary endpoint: MACE at 9 months
Secondary endpoints: in-hospital MACE; TVF at 9 months

Patient Demographics and Lesion Characteristics	n = 792
Male gender (%)	75.6
Diabetes mellitus (%)	22.0
B2/C lesions (%)	60.9
Lesion location: LAD (%)	33.7
Prior MI (%)	30.2
Prior PCI (%)	23.1

Acute Performance Results	n = 792
Device success (%)	99.4
Procedure success (%)	99.8

Baseline Characteristics	n = 792
Reference vessel diameter (RVD) (mm)	3.06 ±0.52
Average lesion length (mm)	14.16 ±6.83

Clinical Follow-Up (9 mo)	n = 787
MACE (%)	8.9
Cardiac death	1.4
MI (all)	2.2
Q-wave	1.2
Non-Q-wave	0.9
TLR	6.6
TVF (%)	9.9

DRASTIC

(Driver Stent Evaluation in a Real-World Japanese Clinical Setting Through Its Clinical and Angiographic Follow-Up Study)
Multicentre, retrospective registry
Trial size: 805 patients (805 actual)
All-comers

Stent diameters: 3.0 mm, 3.5 mm, 4.0 mm x 9–30 mm

Principal investigator: **S. Nanto, MD**

6 sites: Japan

	30 d	6 mo	8 mo	9 mo
FOLLOW-UP/MACE ASSESSMENT	•	•		•
ANGIO/IVUS FOLLOW-UP		•		

Primary endpoint: TLR at 9 months

Patient Demographics and Lesion Characteristics	n = 805
Male gender (%)	76.4
Diabetes mellitus (%)	33.3
B2/C lesions (%)	81.7
Lesion location: LAD (%)	39.0
Prior MI (%)	33.6
Prior PCI (%)	35.9

Acute Performance Results	n = 805
Device success (%)	99.8
Lesion success (%)	99.0
Procedure success (%)	97.4

Clinical Follow-Up	30 days n = 631	270 days n = 631
MACE (%)	2.7	18.5
Death (all)	1.8	2.6
Cardiac death	1.6	1.9
Q-wave MI	0.2	0.5
Non-Q-wave	0.5	0.2
TLR	0.3	14.7
Thrombosis (all) (protocol) (%)	0.2	0

DRASTIC II

(Driver Stent Evaluation in a Real World Japanese Clinical Setting Through Its Clinical and Angiographic Follow-Up Study II)
Multicentre, retrospective registry
Trial size: 600 patients (315 in clinical follow-up arm)
Single *de novo* native coronary artery lesions
Stent diameters: 3.0 mm, 3.5 mm, 4.0 mm x 8–30 mm
Principal investigator: **S. Nanto, MD**
20 sites: Japan

	30 d	6 mo	8 mo	9 mo	24 mo
FOLLOW-UP/MACE ASSESSMENT	•	•		•	•
ANGIO/IVUS FOLLOW-UP		•			

Primary endpoint: MACE at 24 months

Patient Demographics and Lesion Characteristics	n = 315
Male gender (%)	78.4
Diabetes mellitus (%)	35.2
B2/C lesions (%)	84.4
Lesion location: LAD (%)	37.9

Acute Performance Results	n = 315
Device success (%)	100
Lesion success (%)	100
Procedure success (%)	99.1

Baseline Characteristics	n = 315
Reference vessel diameter (RVD) (mm)	2.84 ±0.73
Average lesion length (mm)	12.4 ±9.1

Clinical Follow-Up	30 days n = 315
MACE (%)	0.9
Death (all)	0.3
Cardiac death	0.3
Q-wave MI	0.3
Non-Q-wave	0
TLR	0.3
Thrombosis (all) (protocol) (%)	0.3

US Micro-Driver Registry

Prospective, nonrandomised, multicentre registry
Trial size: 135 patients (135 actual, one nonevaluable)
Single *de novo* native coronary artery lesions
Stent diameters: 2.25–2.75 mm x 8–24 mm
Principal investigator: **Michael H. Sketch Jr., MD, FACC**
17 sites: USA

30 d	6 mo	8 mo	9 mo
•	•		•

FOLLOW-UP/MACE ASSESSMENT

	•		

ANGIO/IVUS FOLLOW-UP

Primary endpoint: MACE at 30 days

Patient Demographics and Lesion Characteristics	n = 135
Male gender (%)	65.9
Diabetes mellitus (%)	31.9
B2/C lesions (%)	58.2
Lesion location: LAD (%)	26.1

Acute Performance Results	n = 134
Device success (%)	99.3
Lesion success (%)	100
Procedure success (%)	99.3

Baseline Characteristics	n = 134
Reference vessel diameter (RVD) (mm)	2.19
Average lesion length (mm)	9.60 ±3.97

Postprocedure Characteristics	0 days n = 134
MLD (mm)	
In-stent	2.16 ±0.27
In-segment	1.84 ±0.37
Diameter stenosis (%)	
In-stent	3.5 ±10.1
In-segment	18.5 ±8.9

Clinical Follow-Up	180 days n = 123	270 days n = 123
MACE (%)	13	19.5
Death (all)	0.8	0.8
Cardiac death	0.8	0.8
MI (all)	0.8	0.8
Q-wave	0	0
Non-Q-wave	0.8	0.8
TLR	11.4	17.9
Emergent CABG	0	0
TVF (%)	14.6	21.1
TVR (non-TL) (%)	3.3	4.9
Thrombosis (all) (%)	0	0

Angiographic Follow-Up (6 mo)	
Binary restenosis rate (%) (n = 109)	
In-stent	49.5
In-segment	53.2
Minimum luminal diameter (mm) (n = 109)	
In-stent	1.18 ±0.57
In-segment	1.12 ±0.53
Late loss (mm) (n = 108)	
In-stent	0.98 ±0.55
In-segment	0.71 ±0.55
Diameter stenosis (%) (n = 109)	
In-stent	46.4 ±24.5
In-segment	49.2 ±21.8

GLOSSARY

The following definitions and abbreviations were used throughout the ENDEAVOR clinical program.

Acute success
- Device success: attainment of <50% in-stent residual stenosis of the target lesion using only the assigned device
- Lesion success: attainment of <50% in-stent residual stenosis of the target lesion using any percutaneous method
- Procedure success: attainment of <50% in-stent residual stenosis of the target lesion and no in-hospital MACE
- Device-specific procedure success: device success and no in-hospital MACE. Device-specific procedure success is utilised to account for procedural successes/failures that are related to the implanted device.

Binary restenosis rate
Percent of patients with a follow-up percent diameter stenosis of ≥50% determined by QCA

Death
Divided into two categories:
- **Cardiac death** is defined as death due to any of the following:
  - Acute myocardial infarction
  - Cardiac perforation/pericardial tamponade
  - Arrhythmia or conduction abnormality
  - Stroke within 30 days of the procedure or stroke suspected of being related to the procedure
  - Death due to complication of the procedure, including bleeding, vascular repair, transfusion reaction or bypass surgery
  - Any death in which a cardiac cause cannot be excluded
- **Noncardiac death** is defined as a death not due to cardiac causes (as defined above).

Diabetes
A patient was considered to have a history of diabetes mellitus if he/she was taking insulin or oral antidiabetic agents or was on a modified diet to control diabetes mellitus. Patients who were taking both oral medications and insulin were considered to be insulin-dependent. Patients with a history of untreated diabetes mellitus (or diabetes mellitus treated with diet only) were classified as having noninsulin-dependent diabetes mellitus.

In-lesion measurement (also in-segment measurement)
Measurements either within the stented segment or within 5 mm proximal or distal to the stent edges

In-stent measurement
Measurements within the stented segment

Late lumen loss
Difference between the postprocedure minimal lumen diameter (MLD) and the follow-up angiography MLD

Major adverse cardiac events (MACE)
Composite of death, MI (Q-wave and non-Q-wave), emergent bypass surgery or TLR (repeat PTCA or CABG)

Myocardial infarction (MI)

A diagnosis of myocardial infarction is made when one of the following criteria is met:

- **Q-wave MI (QWMI):** QWMI requires one of the following criteria:
  - Chest pain or other acute symptoms consistent with myocardial ischemia and new pathological Q-waves in two or more contiguous ECG leads as determined by an ECG core laboratory or independent review of the CEC, in the absence of timely cardiac enzyme data
  - New pathologic Q-waves in two or more contiguous ECG leads as determined by an ECG core laboratory or independent review of the CEC and elevation of cardiac enzymes. In the absence of ECG data, the CEC may adjudicate Q-wave MI based on the clinical scenario and appropriate cardiac enzyme data.
- **Non-Q-wave MI (NQWMI):** Elevated CK >2x the ULN with the presence of elevated CK-MB (any amount above the ULN) in the absence of new pathological Q-waves

Stent thrombosis (per protocol)

A diagnosis of stent thrombosis is made when one of the following criteria is met:

- Angiographic thrombus or subacute closure within the stented vessel at the time of the clinically driven angiographic restudy for documented ischemia (chest pain and ECG changes)
- Any death not attributed to a noncardiac cause within the first 30 days
- Late stent thrombosis is reported according to the following criteria:
  - **Definite late stent thrombosis:** MI >30 days after index and attributable to the target vessel, angiographic documentation (site-reported or by QCA) of thrombus or total occlusion at the target site, and freedom from interim revascularisation of the target vessel
  - **Possible late stent thrombosis:** MI >30 days after index and attributable to the target vessel, no identifiable culprit lesion elsewhere, freedom from interim revascularisation of the target lesion, and freedom from interim bypass grafting of the target vessel

Stent thrombosis (ARC, Academic Research Consortium)

1. Timing:

• Acute stent thrombosis*	0–24 hours poststent implantation
• Subacute stent thrombosis*	>24 hours to 30 days poststent implantation
• Late stent thrombosis†	>30 days to 1 year poststent implantation
• Very late stent thrombosis†	>1 year poststent implantation

2. Level of evidence:

- **Definite stent thrombosis:** considered to have occurred by either angiographic or pathologic confirmation
  - ***Angiographic confirmation of stent thrombosis:*** The presence of a thrombus originating in the stent or in the segment 5 mm proximal or distal to the stent **AND** at least one of the following criteria has been fulfilled within a 48-hour time window:
    1) Acute onset of ischemic symptoms at rest
    2) New ischemic ECG changes suggestive of acute ischemia
    3) Typical rise and fall in cardiac biomarkers (refer to definition of spontaneous MI)
  - ***Pathologic confirmation of stent thrombosis:*** evidence of recent thrombus within the stent determined at autopsy or via examination of tissue retrieved following thrombectomy

*Acute or subacute can also be replaced by the term early stent thrombosis. Early stent thrombosis (0–30 days) is used in this document.

† Including "primary" as well as secondary late stent thrombosis; secondary late stent thrombosis is a stent thrombosis after a target lesion revascularisation.

- **Probable stent thrombosis:** considered to have occurred after intracoronary stenting in the following cases:
  - Any unexplained death within the first 30 days
  - Irrespective of the time after the index procedure, any MI that is related to documented acute ischemia in the territory of the implanted stent without angiographic confirmation of stent thrombosis and in the absence of any other obvious cause
- **Possible stent thrombosis:** considered to have occurred with any unexplained death from 30 days following intracoronary stenting until end of trial follow-up

3. Stent thrombosis after TLR: censored vs. *noncensored:*
Censoring stent thrombosis events that occur post-TLR performed for stent restenosis may be appropriate as the thrombosis may be related to the treatment chosen to treat restenosis (e.g., brachytherapy) rather than the type of stent used in the index procedure. Alternatively, censoring stent thrombosis events that occur after TLR may bias results in favor of devices with higher restenosis risks. Therefore, stent thrombosis data presented in this review report both TLR-censored and TLR-uncensored rates as follows:

- **ARC definite + probable (TLR-censored):** adjudicated stent thrombosis meeting the definite or probable ARC definition with censoring of any definite or probable stent thrombosis events that may have occurred after a TLR
- **ARC definite + probable (TLR-uncensored):** adjudicated stent thrombosis meeting the definite or probable ARC definition, including any definite or probable stent thrombosis events that may have occurred after a TLR

The ARC definitions are available in the following publication: Cutlip DE, et al. Academic Research Consortium, Clinical endpoints in coronary stent trials: A case for standardized definitions. *Circulation.* 2007; 115:2344–2351.

Target lesion revascularisation (TLR): any clinically driven repeat intervention of the target lesion by PCI or CABG of the target vessel. Clinically driven revascularisations are those in which the subject has a positive functional study, ischemic ECG changes at rest in a distribution consistent with the target vessel or ischemic symptoms. Revascularisation of a target lesion with an in-lesion diameter stenosis ≥70% (by QCA) in the absence of the above-mentioned ischemic signs or symptoms is also considered clinically driven. In the absence of QCA data for relevant follow-up angiograms, the clinical need for revascularisation is adjudicated using the presence or absence of ischemic signs and symptoms. Nonclinically driven repeat TLR are those in which the subject undergoes a nonemergent revascularisation for a diameter stenosis <50% (by QCA). Nonemergent repeat TLR for a diameter stenosis <70% (by QCA) in subjects without either a positive functional study or angina are also considered nonclinically driven.

Target vessel failure (TVF): target vessel revascularisation (defined below), Q- or non-Q-wave MI, or cardiac death that could not be clearly attributed to a vessel other than the target vessel. TVF includes any revascularisation or adverse endpoint due to renarrowing of any portion of the target vessel and assumes that the entire vessel is vulnerable to late failures because of guide catheter or guidewire trauma or progression of disease remote from the treatment site.

Target vessel revascularisation (TVR): any clinically driven (as defined for TLR) repeat percutaneous intervention of the target vessel or bypass surgery of the target vessel

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