

Endeavor

Zotarolimus-Eluting Coronary Stent System
Design for Life

Low Rates of Cardiac Death and
MI out to 4 Years

DES Pooled Programs

Baseline Characteristics and Demographics

	ENDEAVOR ¹ n = 2132 E I, E II, E II CA, E III, E IV	CYPHER ² n = 878 RAVEL, SIRIUS, E-SIRIUS, C-SIRIUS	TAXUS ² n = 1755 TAXUS I, II, IV, V, VI
Age (year)	62	62	62
Male sex (%)	74	72	72
Diabetes (%)	23	22	23
Hypertension (%)	69	64	69
Hyperlipidemia (%)	81	71	71
LAD (%)	44	47	42
RVD (mm)	2.73	2.72	2.74
Lesion length (mm)	14.6	13.8	15.1
DAPT therapy (months)	≥3	≥3	≥6

Results come from separate clinical trials. Data may differ in a head-to-head comparison.

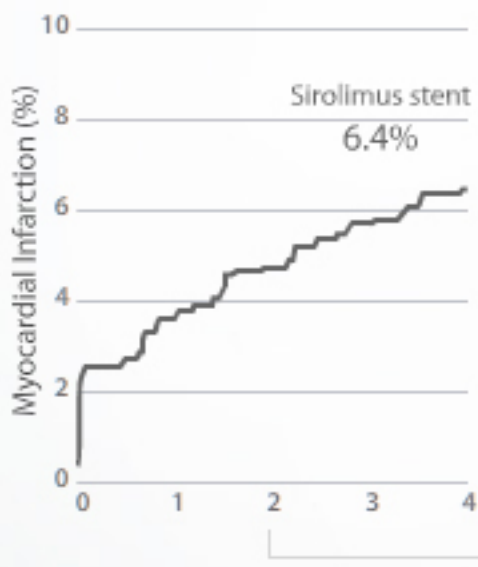
¹ Meredith *et al.*, EuroPCR 2008. Note: DAPT therapy ≥6 months in E IV.

² Stone GW *et al.*, *N Engl J Med*, 356:998–1008, 2007. Note: Taxus V and VI were postmarket trials.

MI Rates from 1 to 4 Years

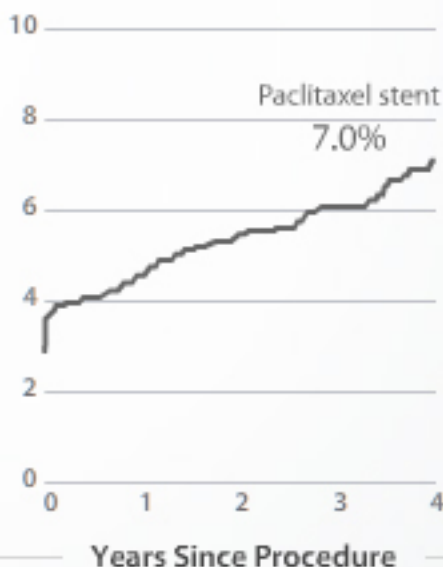
Cypher Pooled¹

RAVEL, SIRIUS, E-SIRIUS, C-SIRIUS
(n = 1748)



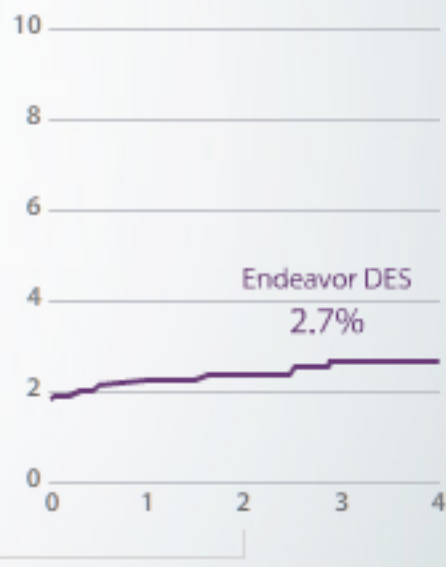
Taxus Pooled¹

TAXUS I, II, IV, V, VI
(n = 3506)



ENDEAVOR Pooled²

(E I, E II, E II CA)
(n = 2132)



No. at Risk

Sirolimus stent				
873	827	797	765	704

No. at Risk

Paclitaxel stent				
1725	1619	1492	1053	269

No. at Risk

Endeavor DES				
2132	2014	1219	1186	622

Results come from separate clinical trials. Data may differ in a head-to-head comparison.

¹ Stone GW *et al.*, *N Engl J Med*, 356:998-1008, 2007. Note: Taxus V and VI were postmarket trials.

² Meredith *et al.*, *EuroPCR*, 2008. Note: DAPT therapy ≥ 6 months in E IV.

MI Rates from 1 to 4 Years

Cypher Pooled¹

Taxus Pooled¹

ENDEAVOR Pooled²

Cypher MI rate grew 67% from year 1 to year 4.

Taxus MI rate grew 39% from year 1 to year 4.

Endeavor MI rate grew 10% from year 1 to year 4.

4-year MI rates:

Cypher = 6.4%

Taxus = 7.0%

Endeavor DES = 2.7%

Myocardial Infarction (%)

NO. at RISK

Sirolimus stent

873 827 797 765 704

NO. at RISK

Paclitaxel stent

1725 1619 1492 1053 269

NO. at RISK

Endeavor DES

2132 2014 1219 1186 622

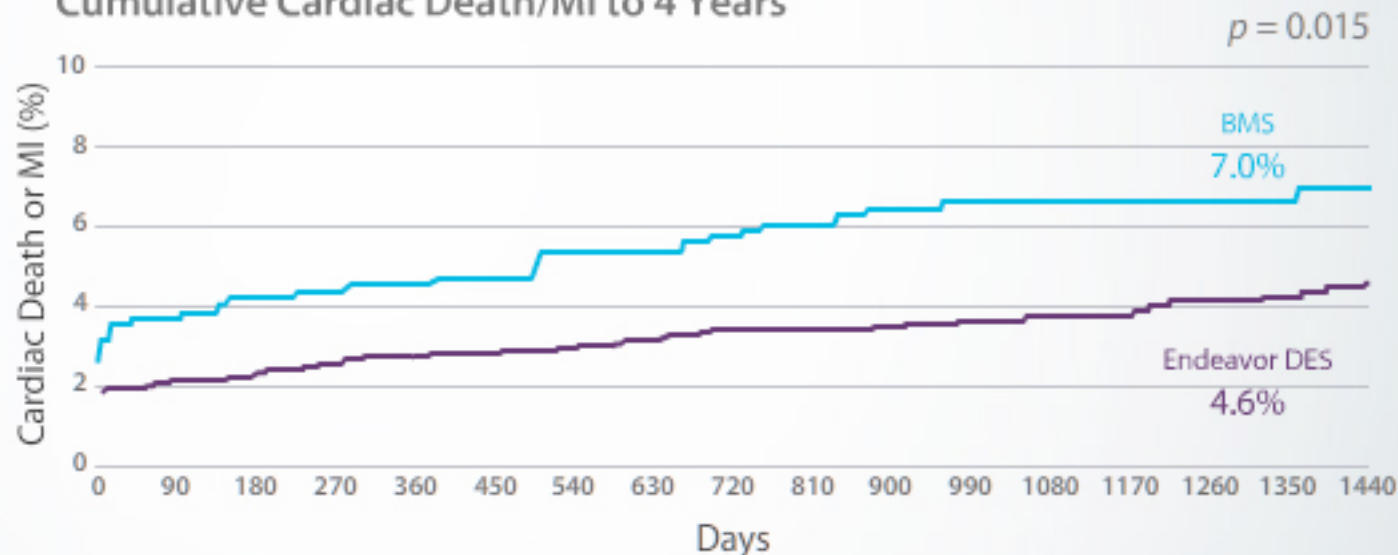
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ENDEAVOR Pooled Safety Analysis Shows a Significant Reduction in Cardiac Death/MI vs. BMS

Cumulative Cardiac Death/MI to 4 Years



Days	0	30	270	360	720	1080	1440
Endeavor DES	2132	2102	2080	2033	2001	1616	1056
% CI	1.4	2.0	2.6	2.8	3.4	3.8	4.6
BMS	596	581	573	561	555	544	529
% CI	2.5	3.5	4.4	4.5	5.8	6.6	7.0

ENDEAVOR pooled safety: Mauri, TCT 2008. E I (4 yr), E II (4 yr), E II CA (4 yr), E III (3 yr), E IV (2 yr) and E pK (1 yr).

p -Values are unadjusted for multiple comparisons.

Pooled Kaplan-Meier analysis.

CI = cumulative incidence.

Endeavor DES Shows Consistent and Durable Efficacy¹

¹ Fajadet J *et al.*, *Circulation*, 114:798–806, 2006. Fajadet J *et al.*, EuroPCR 2008. E-Five 12-month data: Rothman *et al.*, EuroPCR 2008.

ENDEAVOR II, SIRIUS, TAXUS IV

Study Design

ENDEAVOR II¹

Primary endpoint:
9-month TVF
International trial

Core lab:
HCRI

Inclusion criteria:

- Single *de novo* native lesions
- Target lesion 14–27 mm
- Target RVD ≥ 2.25 mm and ≤ 3.5 mm
- Dual antiplatelet therapy for ≥ 3 months

SIRIUS²

Primary endpoint:
9-month TVF
US trial

Core lab:
HCRI

Inclusion criteria:

- Single *de novo* native lesions
- Target lesion 15–30 mm
- Target RVD ≥ 2.5 mm and ≤ 3.5 mm
- Dual antiplatelet therapy for ≥ 3 months

TAXUS IV³

Primary endpoint:
9-month TVR
US trial

Core lab:
HCRI

Inclusion criteria:

- Single *de novo* native lesions
- Target lesion 10–28 mm
- Target RVD ≥ 2.5 mm and ≤ 3.75 mm
- Dual antiplatelet therapy for ≥ 6 months

Results come from separate clinical trials. Data may differ in a head-to-head comparison.

¹ Fajadet J *et al.*, *Circulation*, 114:798–806, 2006.

² Moses JW *et al.*, *N Engl J Med*, 349:1315–23, 2003.

³ Stone GW *et al.*, *N Engl J Med*, 350:221–31, 2004.

Pivotal Trials Patients: DES Arms

Baseline Characteristics and Demographics

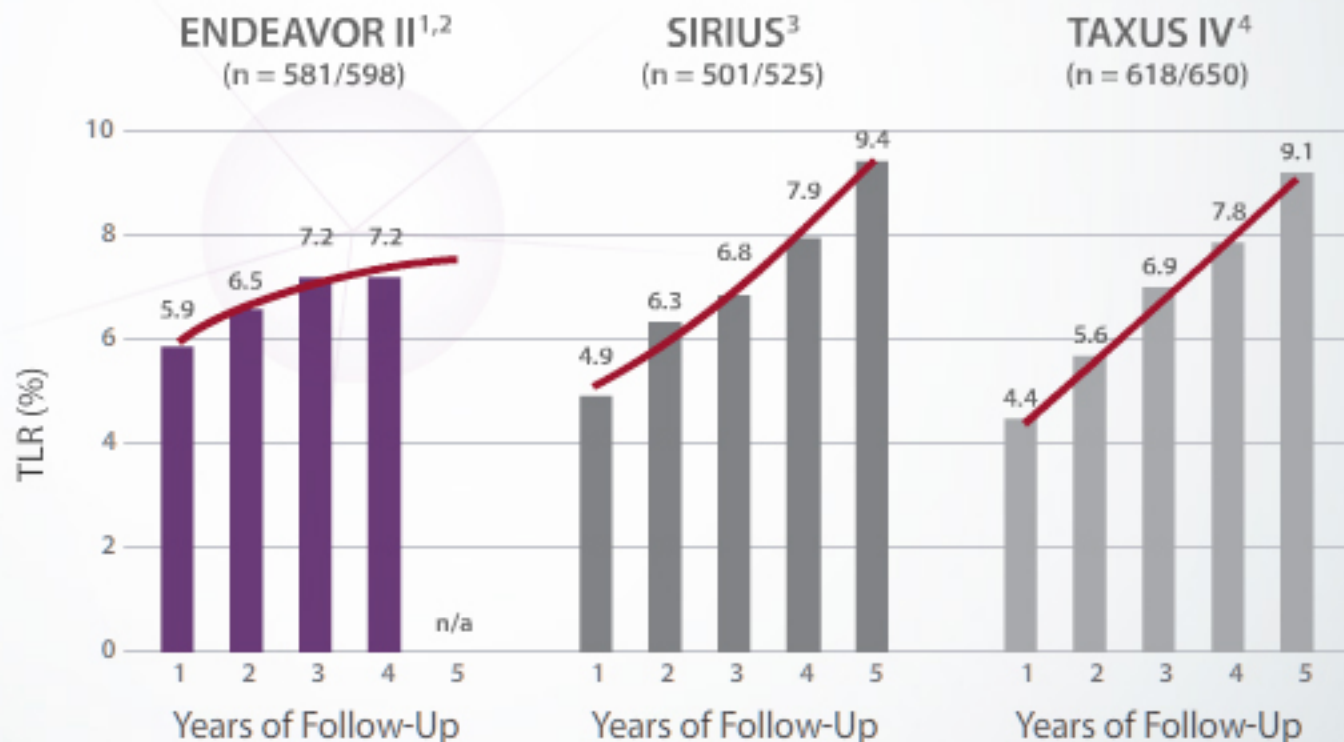
	ENDEAVOR II n = 598	TAXUS IV n = 662	SIRIUS n = 533
RVD (mm)	2.73	2.75	2.78
Lesion length (mm)	14.0	13.4	14.4
Stent-to-lesion length ratio	1.84	1.58	1.40
B2/C lesions (%)	78.5	50.8	58.6
Diabetes mellitus (%)	18.2	24.4	25.0
LAD (%)	43	40	44
Recommended Plavix/Ticlid LOT (month)	3	6	3
Inclusion 2.25-mm vessels	Yes	No	No

Holmes *et al.*, SIRIUS Trial, *Circulation*, 2004.

Stone *et al.*, TAXUS IV, *Circulation*, 2004.

Endeavor TLR Plateaus at 3 Years

Pivotal DES Trials, Historical TLR Rates



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Endeavor TLR Plateaus at 3 Years

Pivotal DES Trials, Historical TLR Rates

Cypher TLR rate grew 61% from year 1 to year 4.

Taxus TLR rate grew 77% from year 1 to year 4.

Endeavor TLR rate grew 22% from year 1 to year 4.

Endeavor TLR plateaus at year 3.

4-year TLR rates:

Cypher = 7.9%

Taxus = 7.8%

Endeavor DES = 7.2%

Results come from separate clinical trials. Data may differ in a head-to-head comparison.

¹ Fajadet J *et al.*, *Circulation*, 114:798–806, 2006.

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Reassurance of Long-Term Safety

4-year MI rates:

Cypher = 6.4%, Taxus = 7.0% and Endeavor DES = 2.7%

ENDEAVOR pooled safety analysis shows a significant reduction in cardiac death/MI vs. BMS

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Efficacy Proven. Safety Delivered.



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For distribution only in markets where Endeavor stent has been approved. Not for distribution in the USA or Japan.

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