# DES That is Available and Will be Available in Korea

**Kwang Soo Cha**, *MD, FACC, FSCAI*
Dong-A University Medical Center,
Busan

# DES Available in Korea

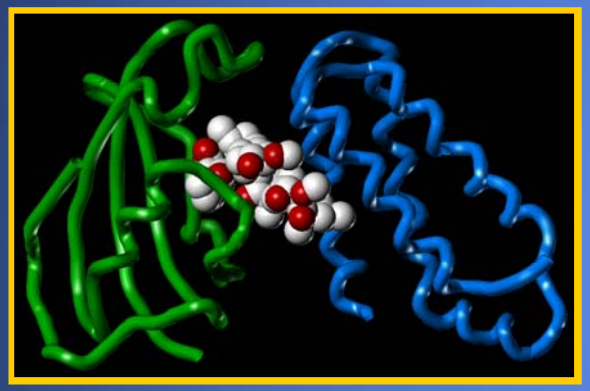
- Sirolimus-eluting (Cypher®)
- Paclitaxel-eluting (Taxus®)
- Zotarolimus-eluting (Endeavor®)
- Pico*Elite* Paclitaxel-eluting
- Coroflex® Please Paclitaxel-releasing

# First Generation
# Drug-eluting Stents in the U.S.

Cordis
a Johnson & Johnson company

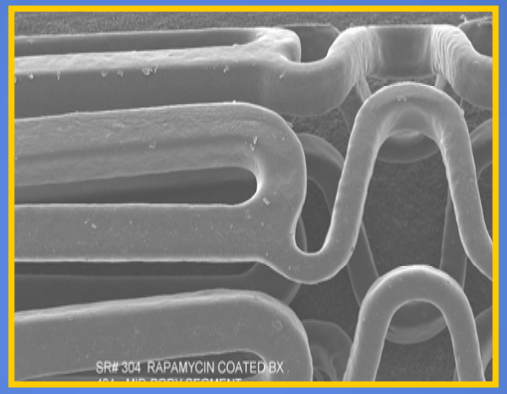
CYPHER SELECT
Sirolimus-eluting coronary Stent

**Cypher**



Sirolimus

**Drug**




PEVA + PBMA blend

**Polymer**

BX Velocity

**Stent**

# CYPHER® Select + Overview

Cordis
a Johnson & Johnson company

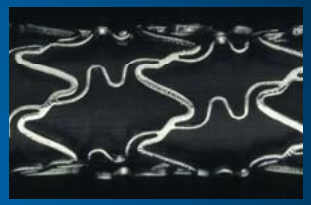
CYPHER SELECT
Sirolimus-eluting coronary Stent

## SDS

Highly Deliverable SDS
- New design and technologies
- Optimized for deliverability and profile from tip through hub

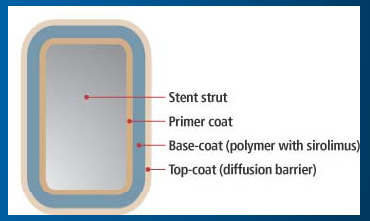
## Stent Design

- Redesigned Platform
  - New level of flexibility and conformability
  - Uniform coverage at every vessel size



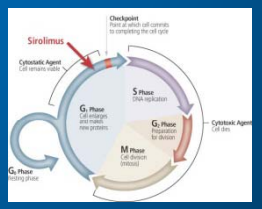
## Stent Material

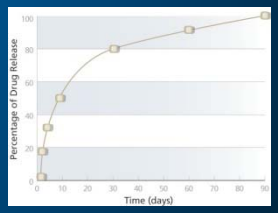
- Stainless Steel
  - High Strength
  - Long record of Biocompatibility




## Drug

- Proven Drug and Release Kinetics
  - Safe, effective Sirolimus
  - Moderate release profile



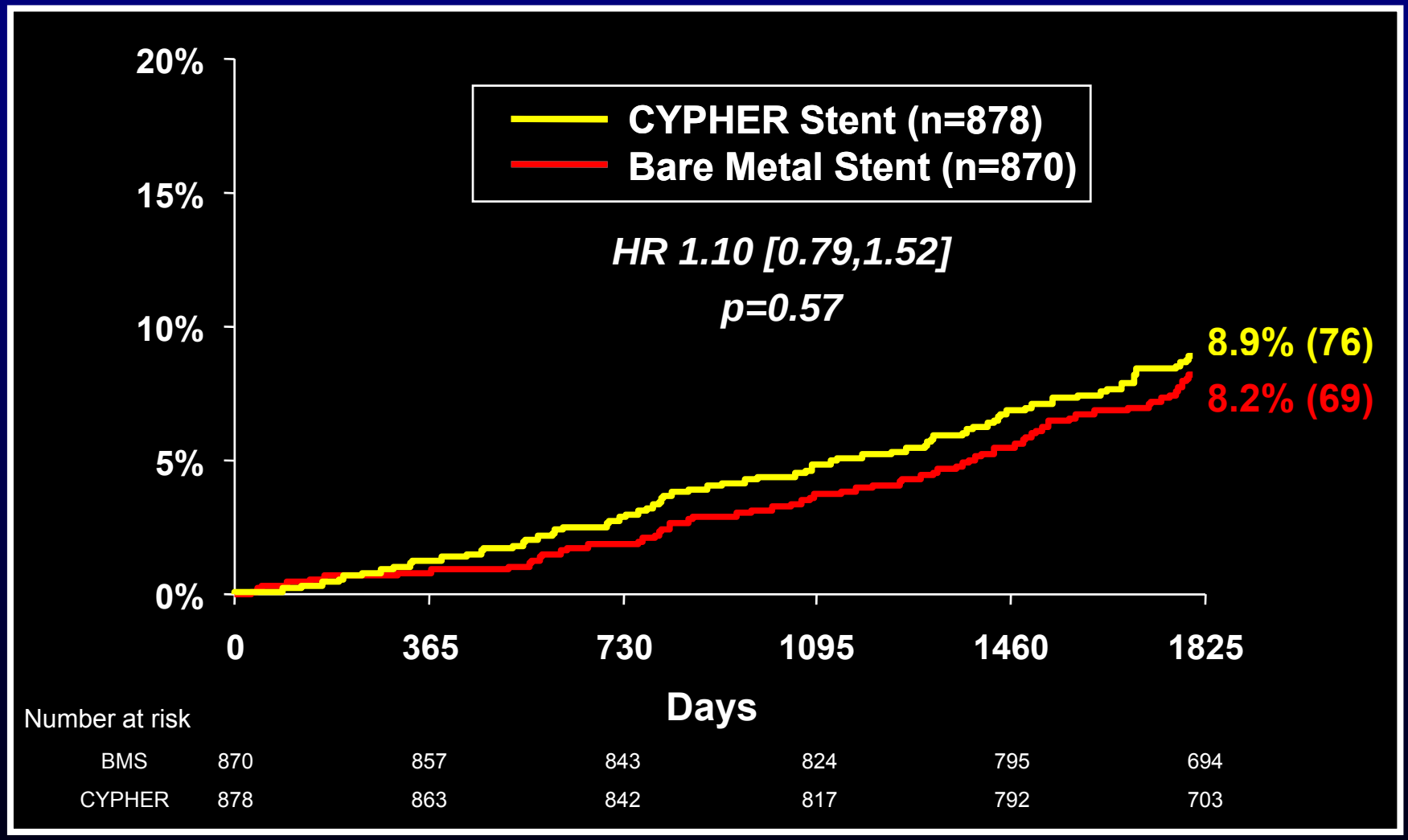

CYPHER® Select + features an advanced SDS lubricious coating technology that further enhances deliverability

# The CYPHER® Stent Trials: Methodology

- Patient-level databases of pivotal RCTs were obtained from Cordis Corporation by the Cardiovascular Research Foundation with permission for unrestricted analyses
  - RAVEL, SIRIUS, E-SIRIUS, C-SIRIUS
    - 5-year data available for all trials
- Analysis Plan (performed by M. Fahy, Sr. Biostatistician)
  - Endpoints
    - Safety:
      - Death (overall, cardiac, non-cardiac); MI (all, QWMI); composites
      - Stent thrombosis: ARC definitions; per protocol
    - Efficacy: TLR and TVR
  - Survival analyses utilized to maximally utilize all available FU information, compared by log-rank test (exact LR if <5 events)

Kirtane A.J., et al., *TCT* 2007; Oral Presentation.

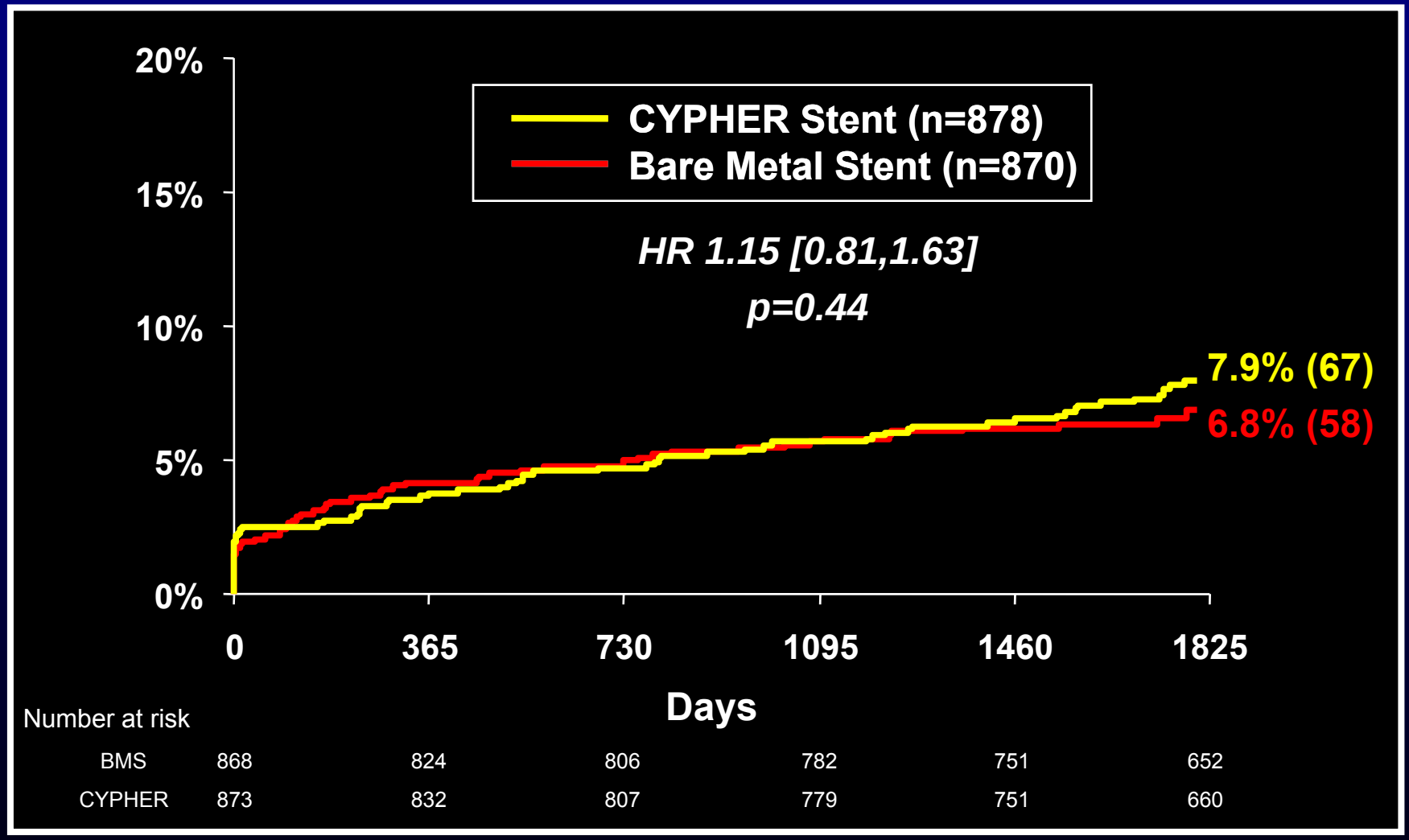
# Death through 5 years: Pooled Analysis of 4 SES vs. BMS RCT's*




** RAVEL, SIRIUS, E-SIRIUS, C-SIRIUS*

Kirtane A.J., et al., *TCT* 2007; Oral Presentation.

# Myocardial Infarction through 5 years: Pooled Analysis of 4 SES vs. BMS RCT's*




** RAVEL, SIRIUS, E-SIRIUS, C-SIRIUS*

Kirtane A.J., et al., *TCT* 2007; Oral Presentation.

# ARC-Defined ST through 5 years: Pooled Analysis of 4 SES vs. BMS RCT's*

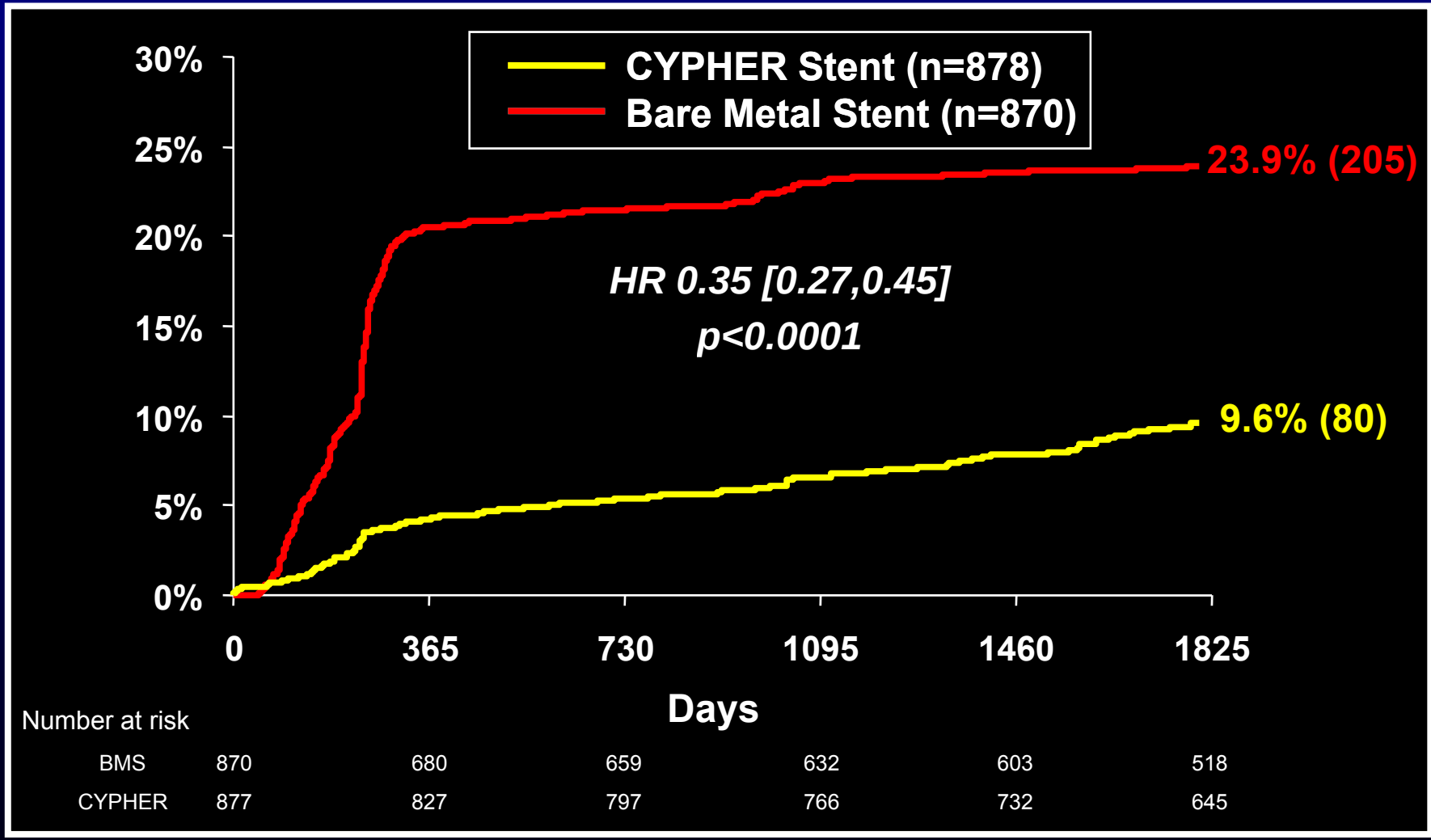
| | CYPHER® (N=878) % (n) | BMS (N=870) % (n) | HR [95% CI] | p- value |
|---|---|---|---|---|
| Definite | 1.6% (13) | 1.0% (8) | 1.62 [0.67,3.91] | 0.28 |
| Probable | 0.5% (4) | 1.0% (9) | 0.44 [0.14,1.43] | 0.16 |
| Possible | 2.5% (21) | 2.5% (20) | 1.05 [0.57,1.94] | 0.88 |
| Def/Probable | 2.1% (17) | 2.0% (17) | 0.99 [0.51,1.95] | 0.99 |
| All | 4.6% (38) | 4.4% (37) | 1.02 [0.65,1.61] | 0.92 |

*Kaplan-Meier estimates*

** RAVEL, SIRIUS, E-SIRIUS, C-SIRIUS*

Kirtane A.J., et al., *TCT* 2007; Oral Presentation.

# TLR through 5 years: Pooled Analysis of 4 SES vs. BMS RCT's*




** RAVEL, SIRIUS, E-SIRIUS, C-SIRIUS*

Kirtane A.J., et al., *TCT* 2007; Oral Presentation.

# On-Label CYPHER® Stent Trials: Conclusions through 5-year Follow-up

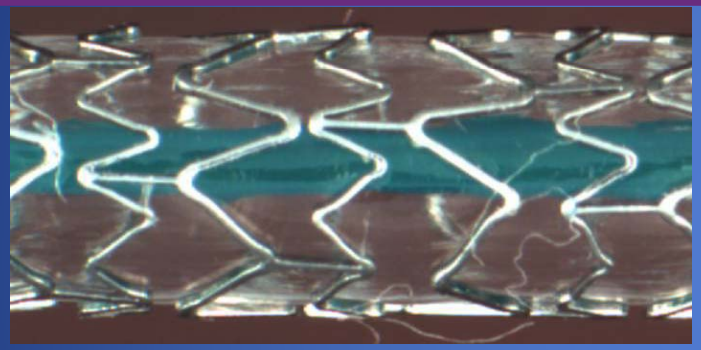
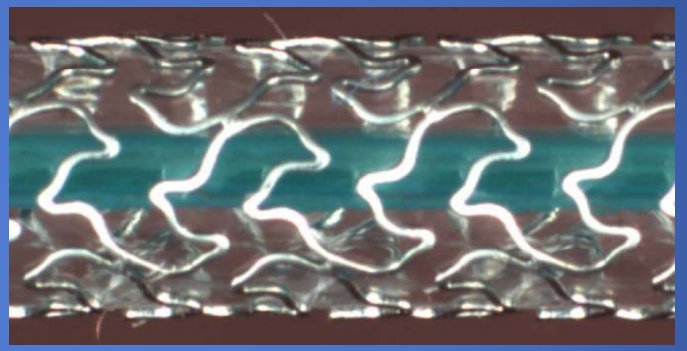
- From this independent, patient-level meta-analysis from the 4 principal CYPHER® Stent trials it may be concluded that at 5-year follow-up of patients with single de novo native coronary lesions 2.5 – 3.5 mm in diameter and ≤30 mm in length, polymer-based sirolimus-eluting stents compared to otherwise equivalent bare metal stents result in:
  - No significant increase in stent thrombosis
    - No significant increase in late stent thrombosis by ARC definitions
  - No significant differences in death or myocardial infarction at any time period
  - Sustained reduction in target lesion and target vessel revascularization

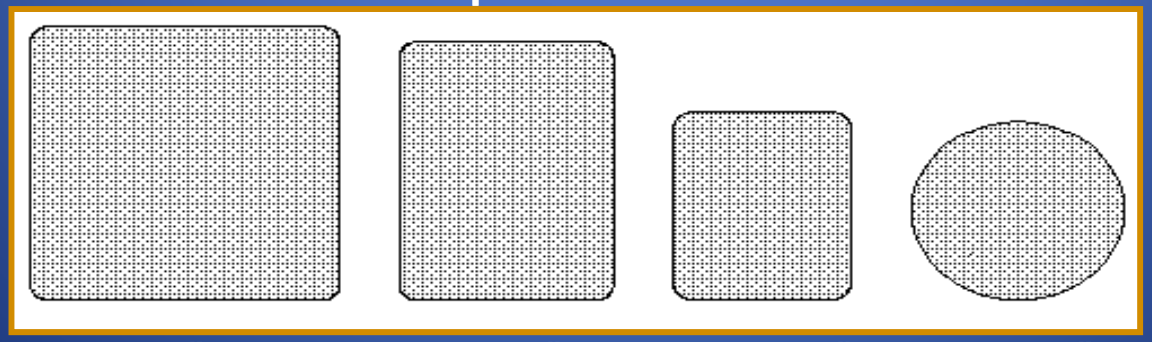
Kirtane A.J., et al., *TCT* 2007; Oral Presentation.

# TAXUS™ Stent Platforms:

## Switching from Express²™ stent design to Liberté™ stent design


TAXUS™ Liberté™
Paclitaxel-Eluting Stent

| Express²™ Stent Design | Liberté™ Stent Design |
|---|---|
|  |  |
| Alternating macro & micro elements | Uniform, repeating cell geometry |




| | Cypher® Select | TAXUS Express® | Liberté™ | Driver® |
|---|---|---|---|---|
| Material Thickness | 0.0055” SST | 0.0052” SST | 0.0038” SST | 0.0036” MP35N |

# Expanding the TAXUS™ Stent Program

**Paclitaxel-Euting NIRx™/ TAXUS Express² ™ Stent**
**>16,000 patients**

**TAXUS™ Liberté™ Stent**
**28,000 patients planned**

| | | NAME | STATUS | N | NAME | STATUS | N |
|---|---|---|---|---|---|---|---|
| Registries | Real World | WISDOM | Completed | 778 | OLYMPIA | | |
| | | | | | • Phase I | Completed | 529 |
| | | MILESTONE II | Completed | 3688 | • Phase II | Enrolling | 5504/10000 |
| | | ARRIVE 1 | Follow-up | 2585 | • Phase III | Enrolling | 10521/15000 |
| | | ARRIVE 2 | Follow-up | 5007 | • Phase IV | Planned | 2500 |
| Studies | Expansion | TAXUS V-DN | Follow-up | 1156 | TAXUS ATLAS | | |
| | | TAXUS V-ISR | Follow-up | 421 | • Direct stent | Follow-up | 247 |
| | | SYNTAX (3VD & LM) | Enrolling | 1548/1800 | • Long lesion | Follow-up | 150 |
| | | | | | • Small vessel | Follow-up | 261 |
| Studies | Foundation | TAXUS II | Follow-up | 536 | TAXUS ATLAS | | |
| | | TAXUS III | Follow-up | 28 | • De novo | Follow-up | 871 |
| | | TAXUS IV | Follow-up | 1314 | | | |
| | | TAXUS VI | Follow-up | 446 | | | |

# TAXUS ATLAS Trial: Study Design

871 patients with coronary heart disease and de novo lesions 10-28 mm long with reference vessel diameter of 2.5-4.0 mm treated with a single stent

Treatment with TAXUS Liberté paclitaxel - eluting stent during PCI N=871

↓

Angiographic follow up at 9 - months

Historical control data from TAXUS IV and TAXUS V trials (TAXUS Express stent) N=991

↓

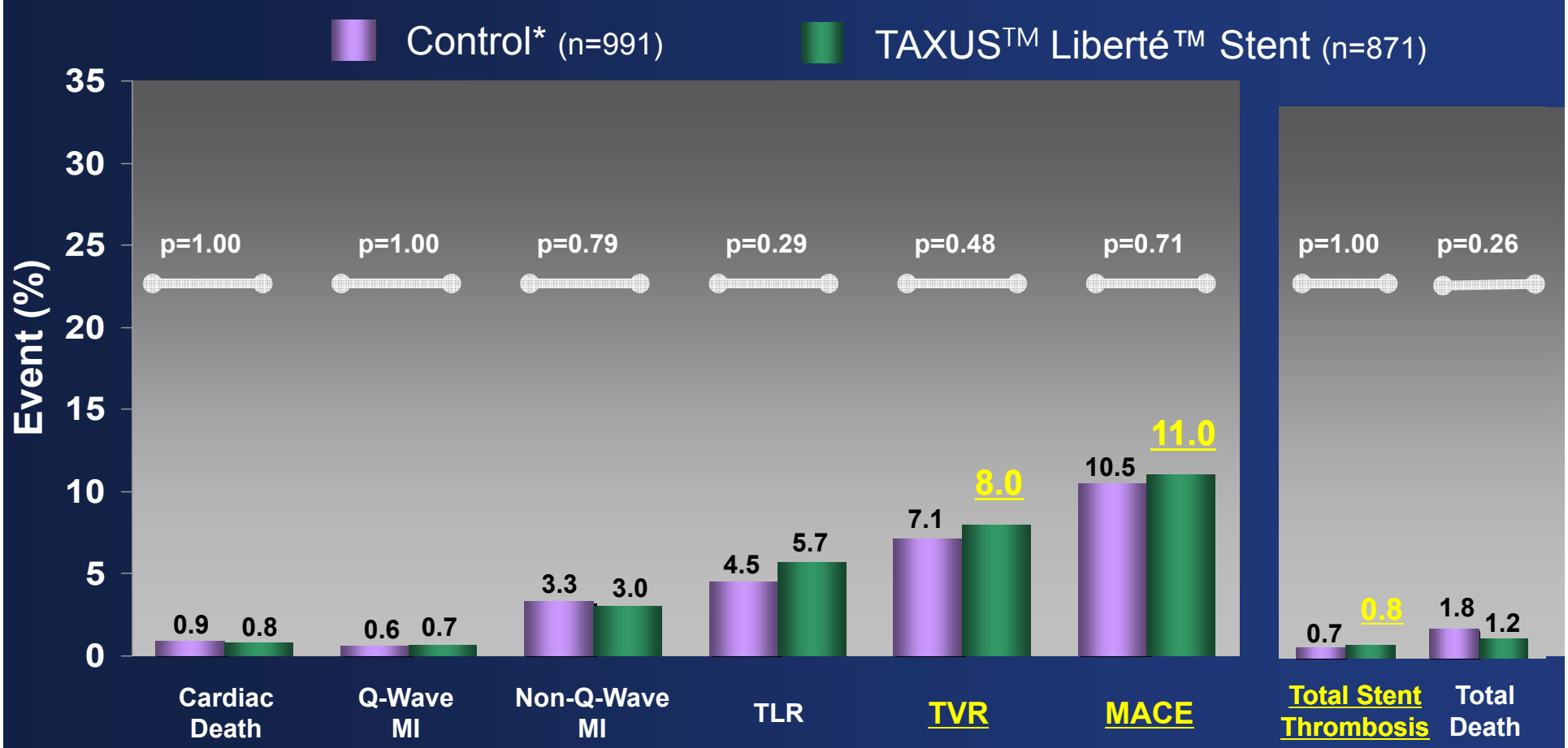
Historical control data of Angiographic follow up at 9 – months

- Primary Endpoint: Target vessel revascularization (TVR) at 9 months, evaluated for non-inferiority compared with historical controls from the TAXUS IV and V trials



*Presented at EuroPCR May 2006*

# TAXUS ATLAS
# Overall MACE Results at 9 months




TAXUS ATLAS 9-month Results, Mark Turco, EuroPCR 2006.

*TAXUS™ Express™ Stent in the TAXUS IV Trial and TAXUS™ Express2™ Stent in the TAXUS V Trial. TAXUS™ Express™ Stent is an investigational device and is not for sale in the EEA.

# TAXUS ATLAS Trial: Summary

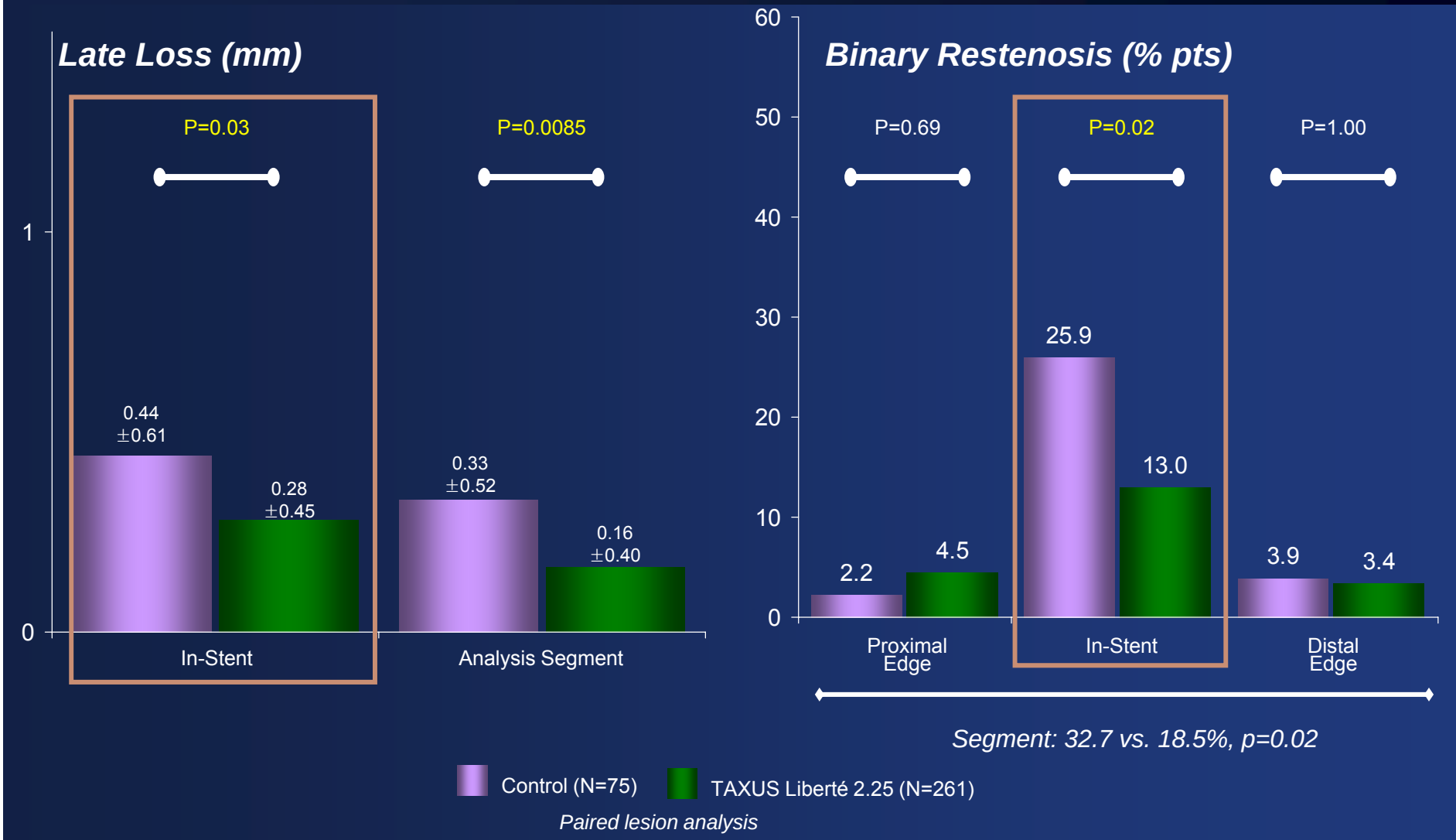
- Among patients with de novo lesions undergoing PCI, use of the Taxus Liberté stent paclitaxel-eluting stent was non-inferior when compared with historical controls form the TAXUS IV and TAXUS V trials, which used the Taxus Express stent.
- When compared to the Taxus Express stent, the Taxus Liberté has thinner struts which aids in flexibility and a lower profile.
- The Taxus Liberté stent is currently also involved in trials of direct stenting, small vessels and long lesions
- Results of the TAXUS ATLAS study should be interpreted with caution as it was a single arm registry study, and the Taxus Liberté stent was not compared to an active control arm but to historical data.



*Presented at EuroPCR May 2006*

# Angiographic Outcomes at 9 month

## Clinical Data for TAXUS™ Liberté™ **2.25 mm Stent**



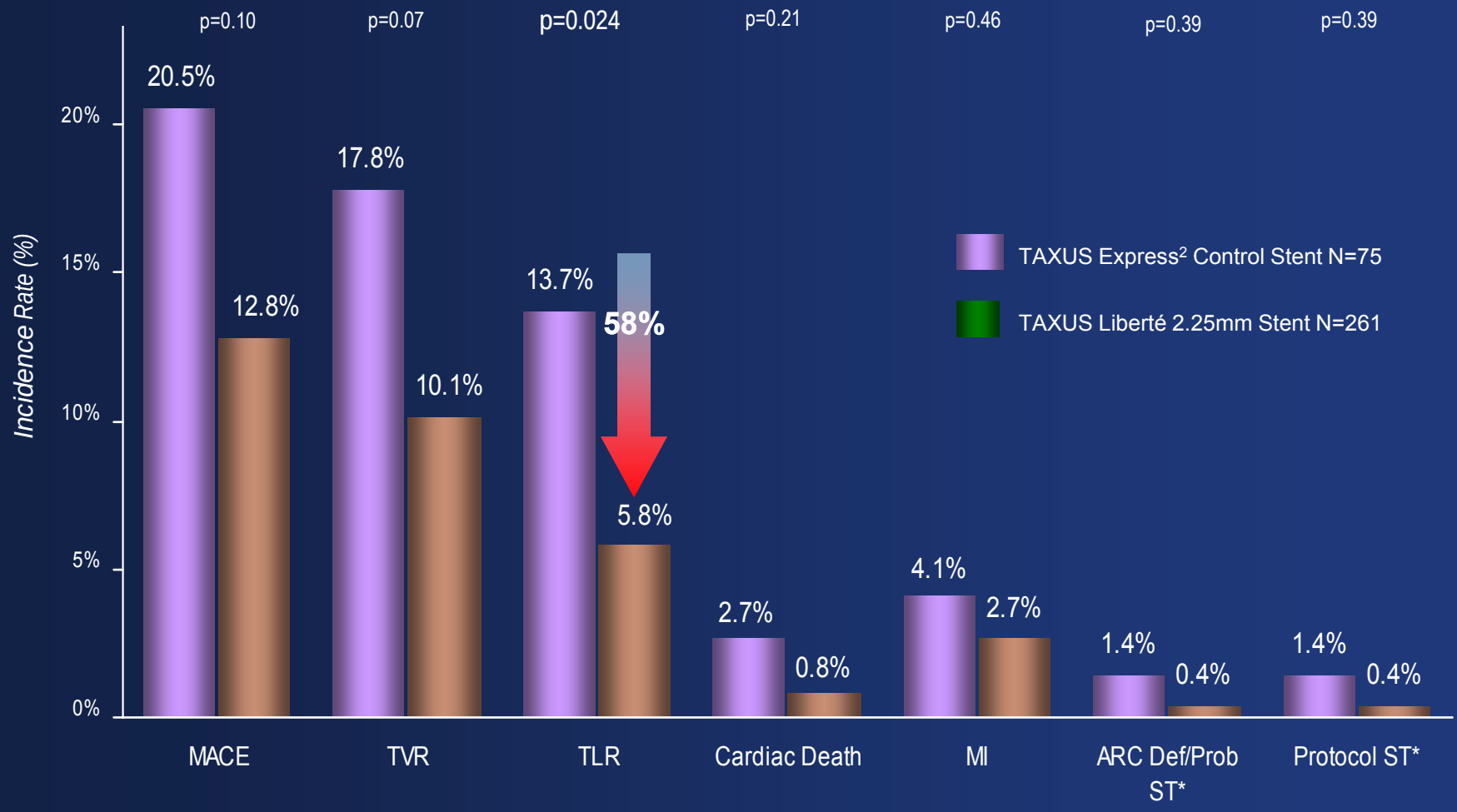

TAXUS ATLAS small vessel study - Data presented by Dr. Mark Turco, TCT 2007.

Control: TAXUS V study pts with RVD≤2.5mm, lesion 28mm Single planned 2.5 or 2.25mm study stent; non-inferiority comparison to TAXUS Express[2] Stent; and superiority to Express[2] BMS.

# TAXUS ATLAS Small Vessel Study

*9-Month Clinical Events*

## TAXUS™ Liberté ™ 2.25mm Stent significantly **reduces TLR** compared with TAXUS Express²™ 2.25mm Stent.

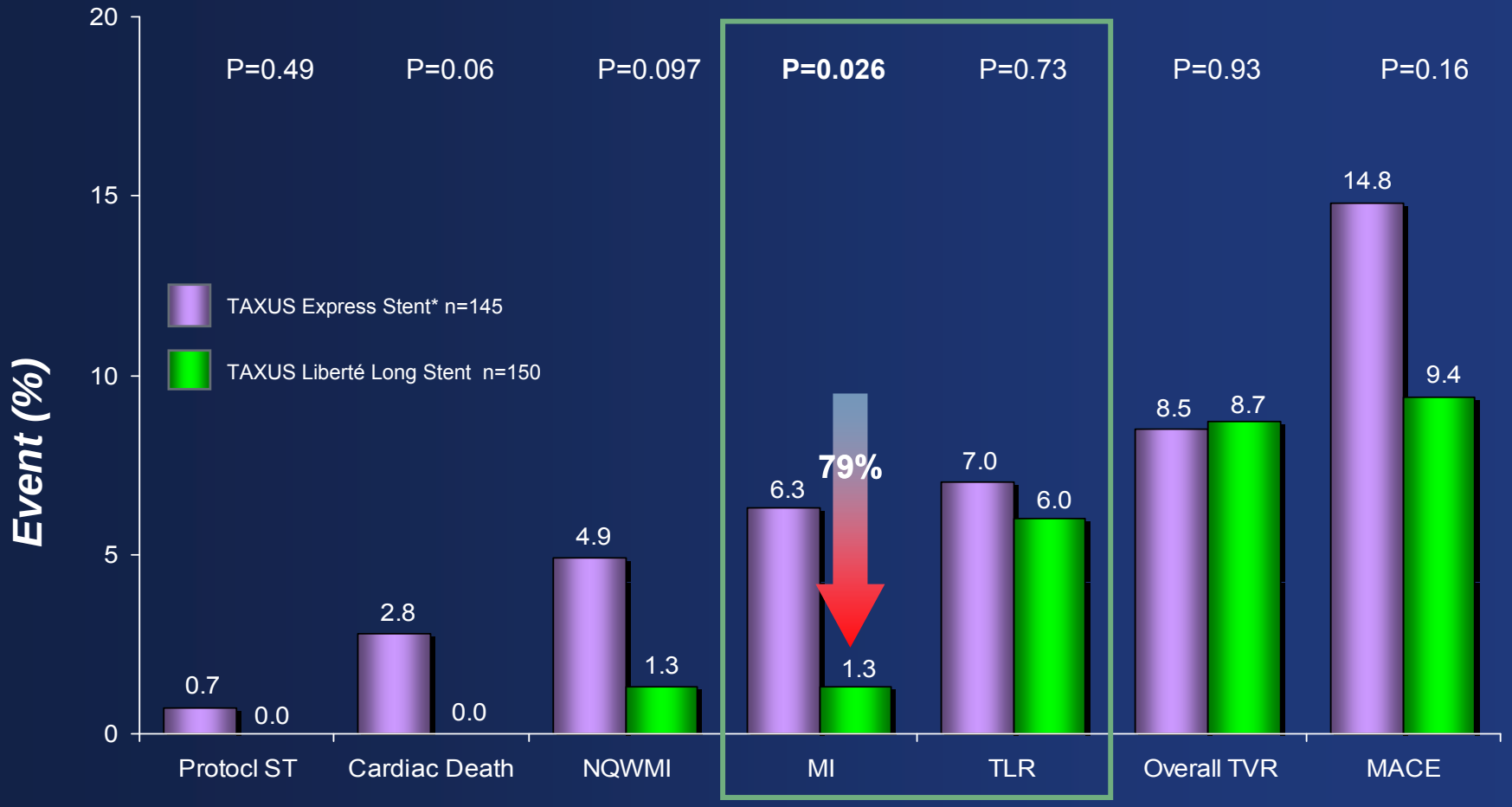



*Stent Thrombosis value was the same for both protocol and ARC Def/Prob

# TAXUS ATLAS Long Lesion Study:

*TAXUS™ Liberté™ Long (38mm) Stent is as effective as TAXUS Express™ Stent* while reducing the risk of MI*

## TAXUS Liberté Long Stent had significantly lower MI

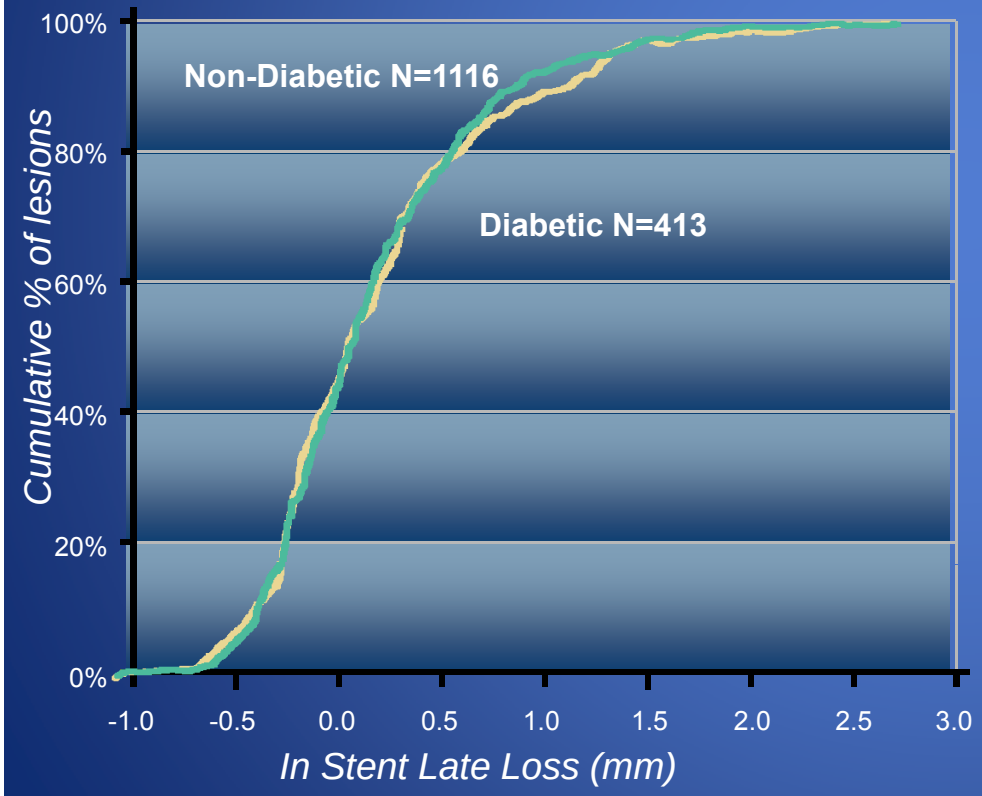


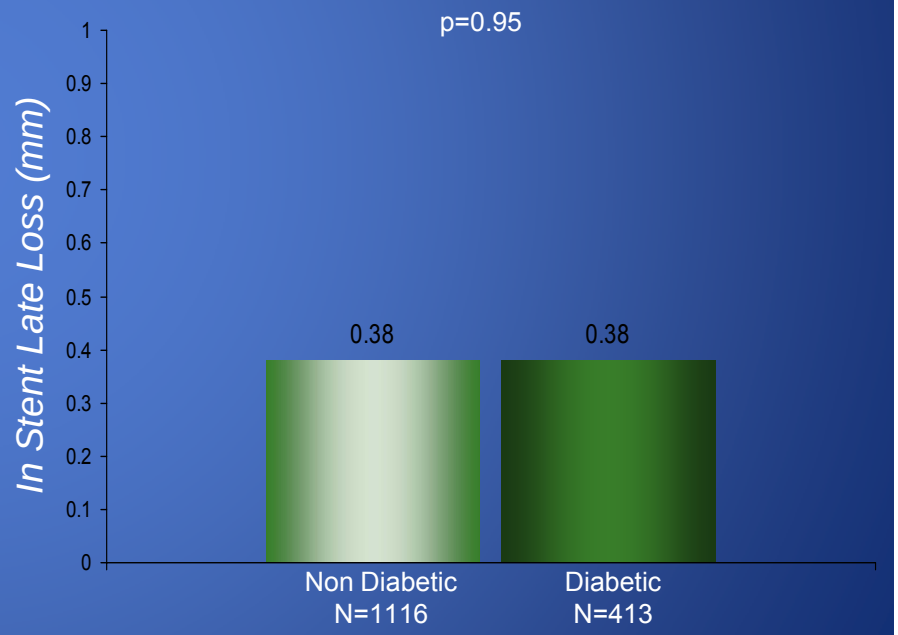

1. In patients with no non-target lesion. *TAXUS Express Stent in the TAXUS IV Trial and TAXUS Express[2] Stent in the TAXUS V Trial. TAXUS Express Stent is an investigational device not for sale in the European Economic Area (EEA) .

# TAXUS ATLAS Study diabetic analysis:

## *The TAXUS™ Liberté™ Stent attenuates the risk of restenosis in diabetic patients[1]*

The TAXUS Stent has the same performance in both diabetics and non-diabetics




1.Risk of Restenosis in Diabetics and Non-diabetics: Results from the TAXUS ATLAS Program, eposter presented by Dr J Ormiston, TCT 2007

Source: TAXUS ATLAS Diabetic Analysis e-poster

# Expanding the TAXUS™ Stent Program

**Paclitaxel-Euting NIRx™/ TAXUS Express² ™ Stent**
**>16,000 patients**

**TAXUS™ Liberté™ Stent**
**28,000 patients planned**

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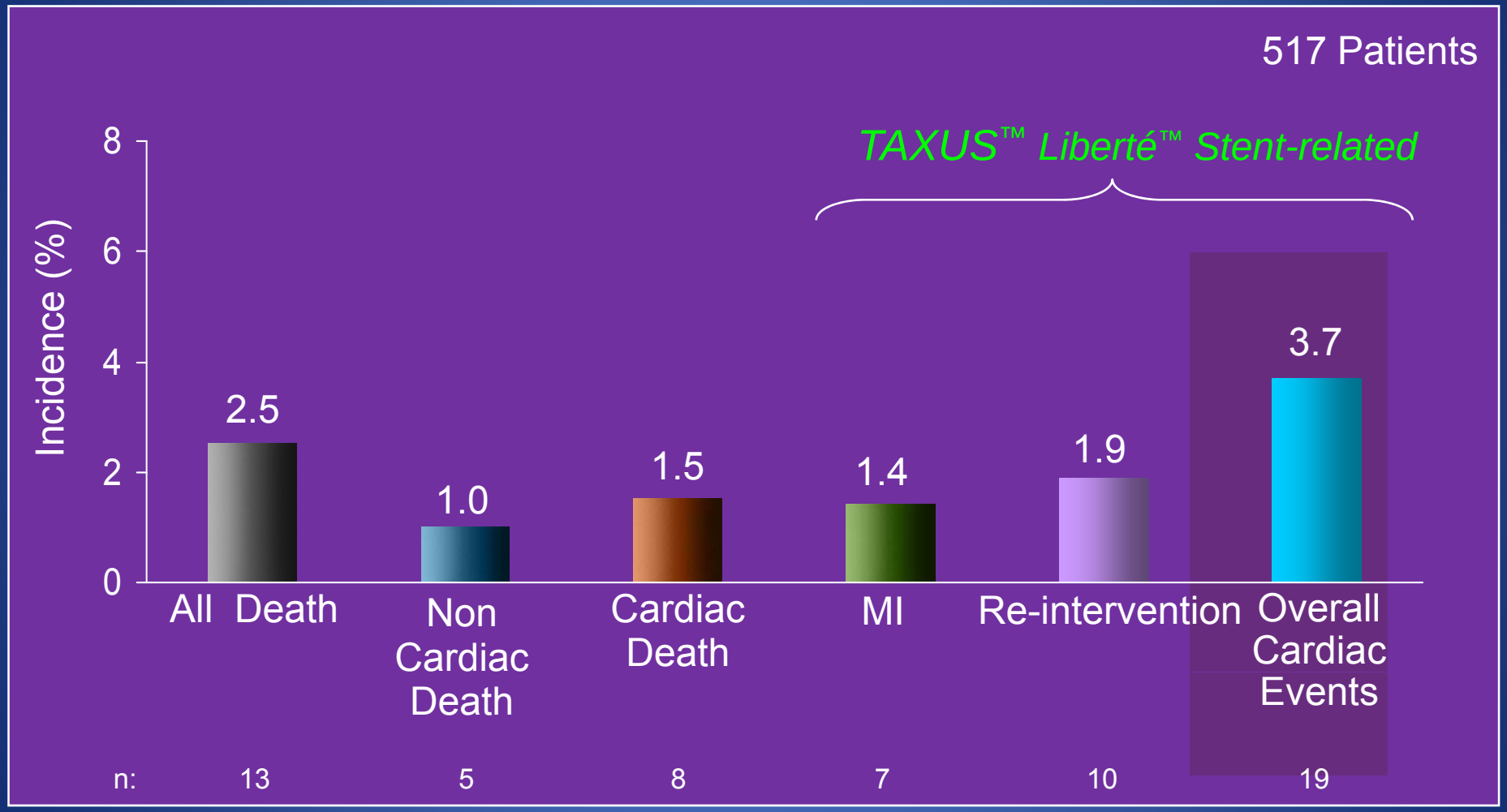
# TAXUS™ OLYMPIA Phase I Results
## 12-Month Cardiac Events

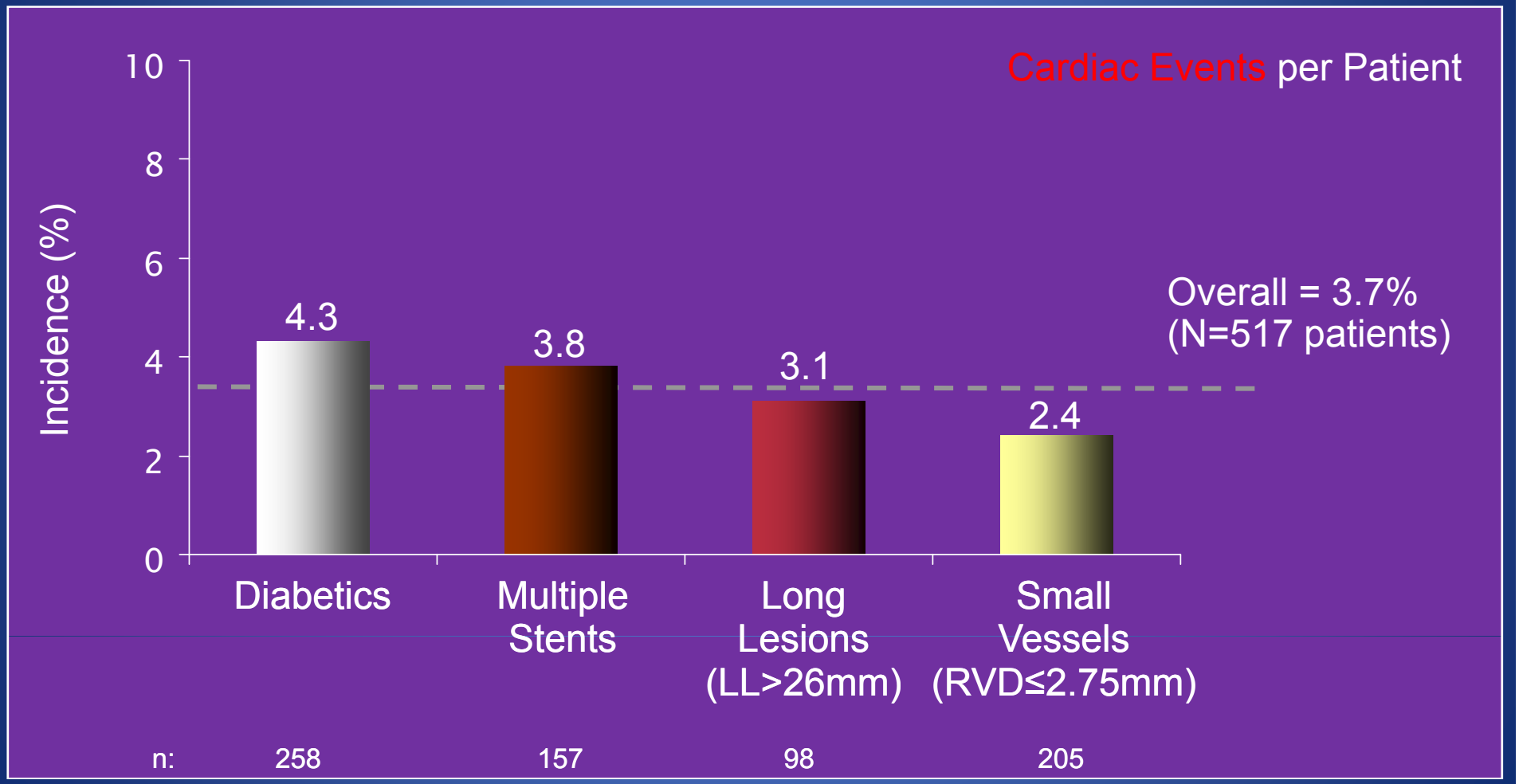



Low cardiac event rates in overall patient population



Refer to glossary

# TAXUS™ OLYMPIA Registry
## Phase I 12-Month Results
### TAXUS™ Liberté™ Stent-Related **Cardiac Events**: High Risk Subsets




Low cardiac event rates in high-risk subsets

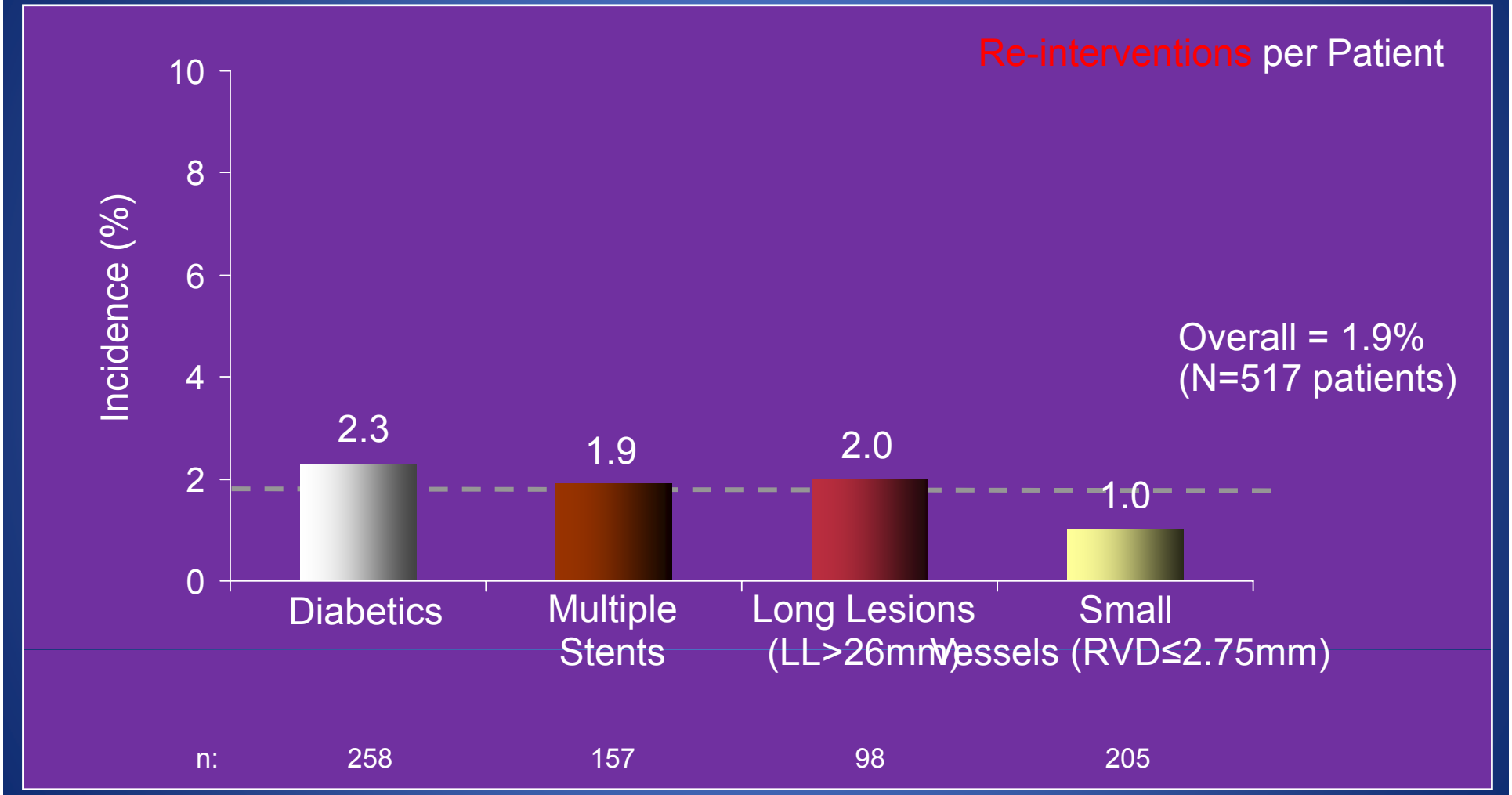


Refer to glossary

# TAXUS™ OLYMPIA Registry Phase I Results

## 12-Month TAXUS™ Liberté™ Stent-Related

## **Re-interventions**: High-Risk Subsets




Rates in high-risk subsets similar to overall population

# TAXUS™ OLYMPIA Registry Summary

## Phase I 12-Months and Preliminary Phase III 6-Months

Complex usage patterns reflecting evolving "real-world" practice

| | Phase I | Phase III |
|---|---|---|
| Diabetics | 50% | 32% |
| Multiple Stenting | 30% | 32% |
| Long Lesions (>26mm) | 19% | 15% |
| Small Vessel (≤2.75mm) | 40% | 40% |

Low occurrence of **cardiac events**

| | 12 Months | 6 Months |
|---|---|---|
| Cardiac Death | 1.5% | 0.9% |
| MI | 1.4% | 0.9% |
| Re-intervention | 1.9% | 1.8% |

Low **stent thrombosis** rates

| 12 Months | 6 Months |
|---|---|
| 1.7% | 0.5% |

TAXUS™ and Liberté™ are registered trademarks by Boston Scientific Corporation; TAXUS OLYMPIA is a registry sponsored by Boston Scientific Corporation. TAXUS™ Liberté™ stent is not approved for use in RVD< 2.25mm. TAXUS™ Liberté™ Stent is not approved for use in patients with lesions longer than 32mm.

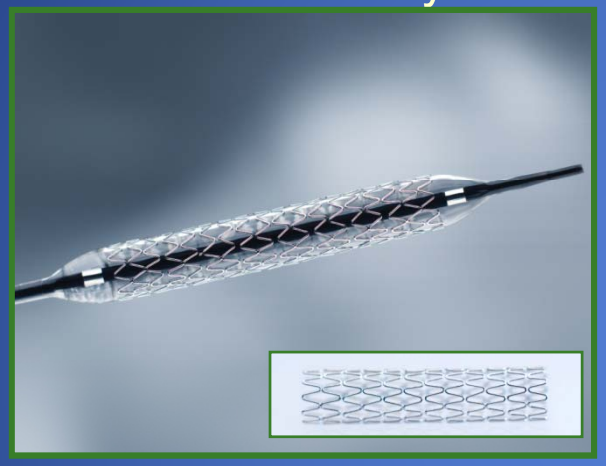
Refer to glossary PSST 3837

# Components of the Endeavor DES System

Medtronic
Schmerzen lindern · Heilung fördern · Leben verlängern

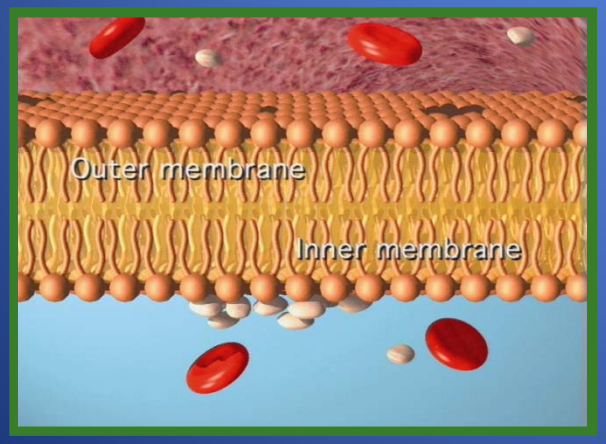
**Endeavour™**
**Zotarolimus-coated stent**

Driver Cobalt Alloy Stent

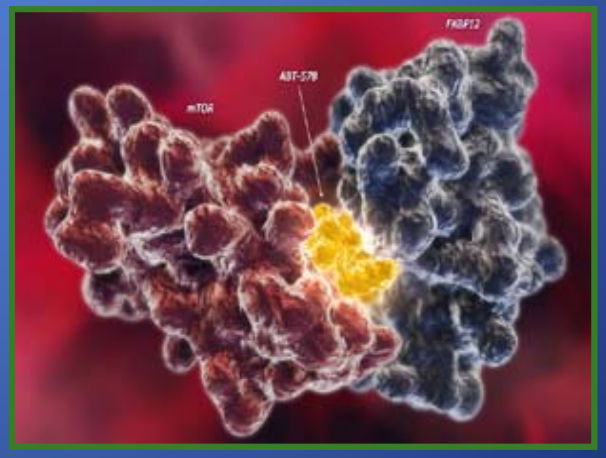


Stent Delivery

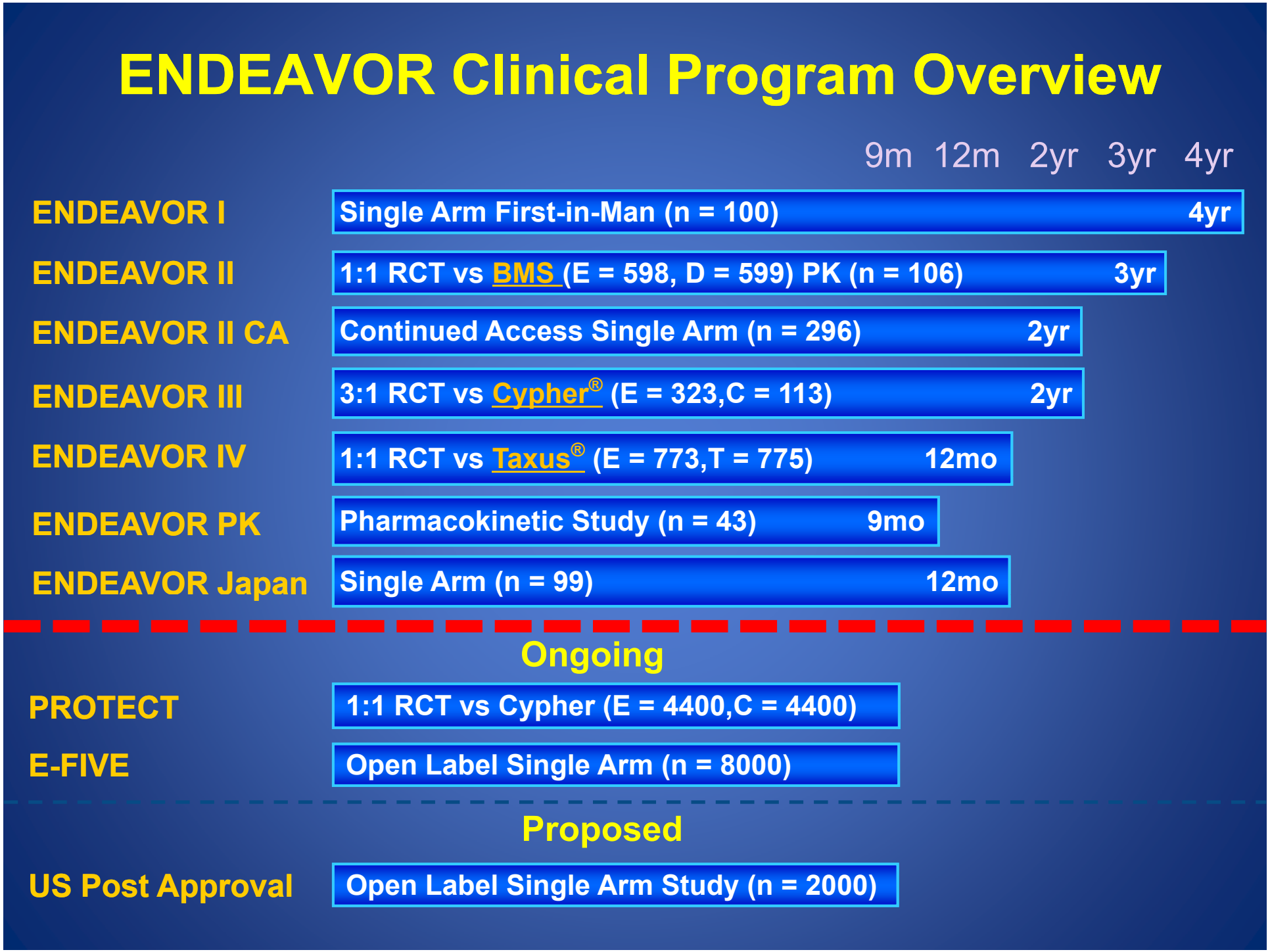
PC Technology




Drug: Zotarolimus



# ENDEAVOR Clinical Program Overview

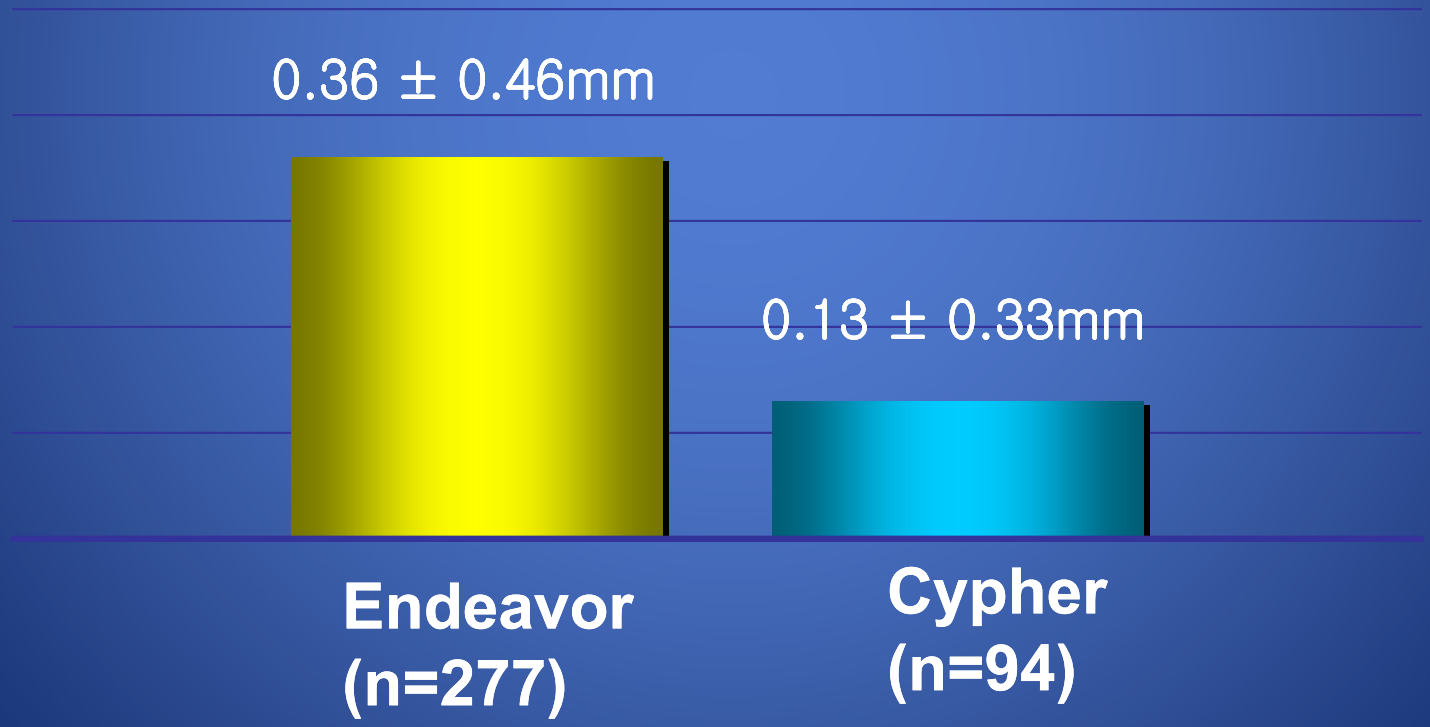


# ENDEAVOR III

## Primary Endpoint Result

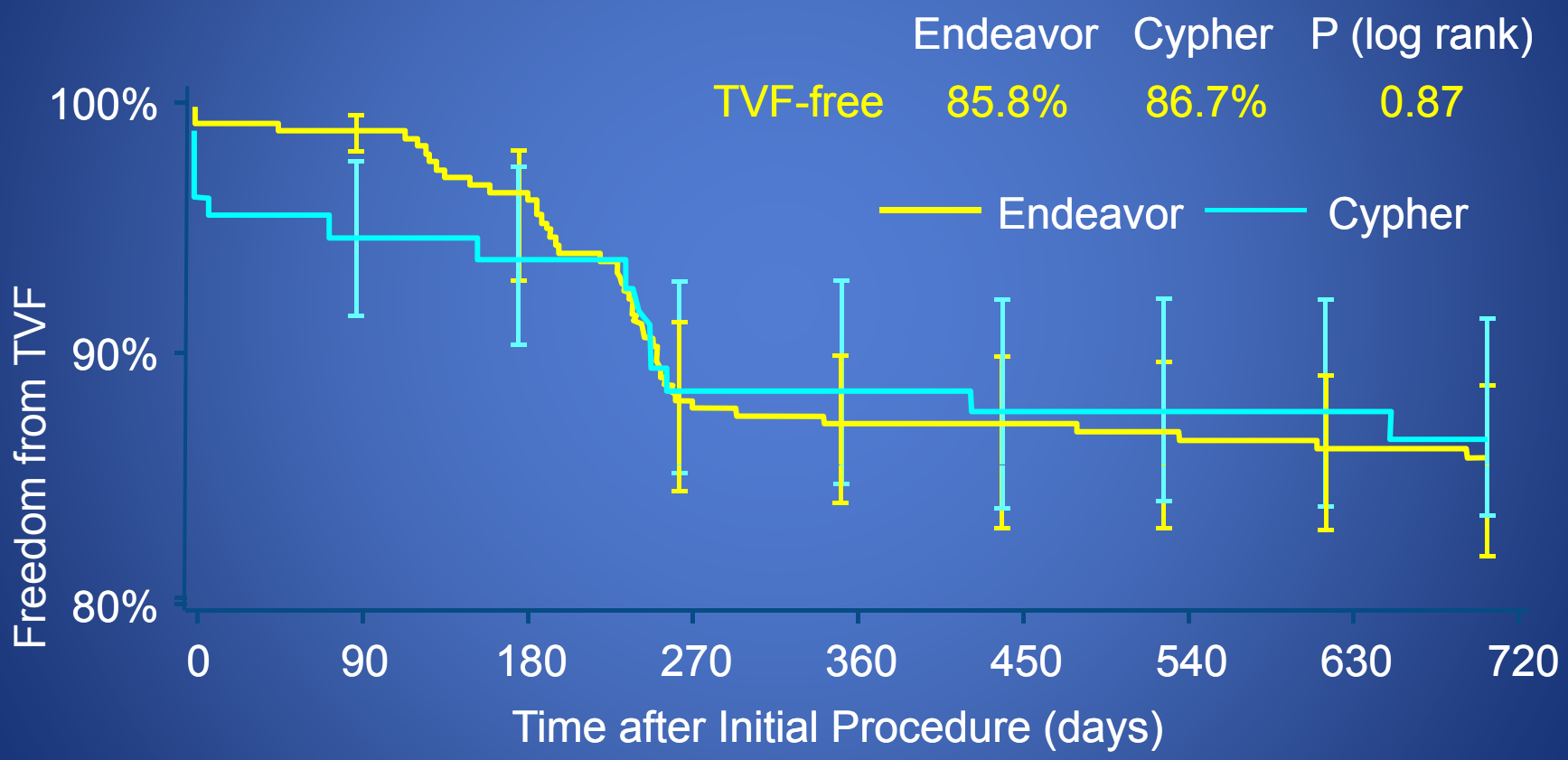
## In-segment Late Loss at 8 months

**P for Non-Inferiority 0.791**
**P for Difference = <0.001**



# ENDEAVOR III

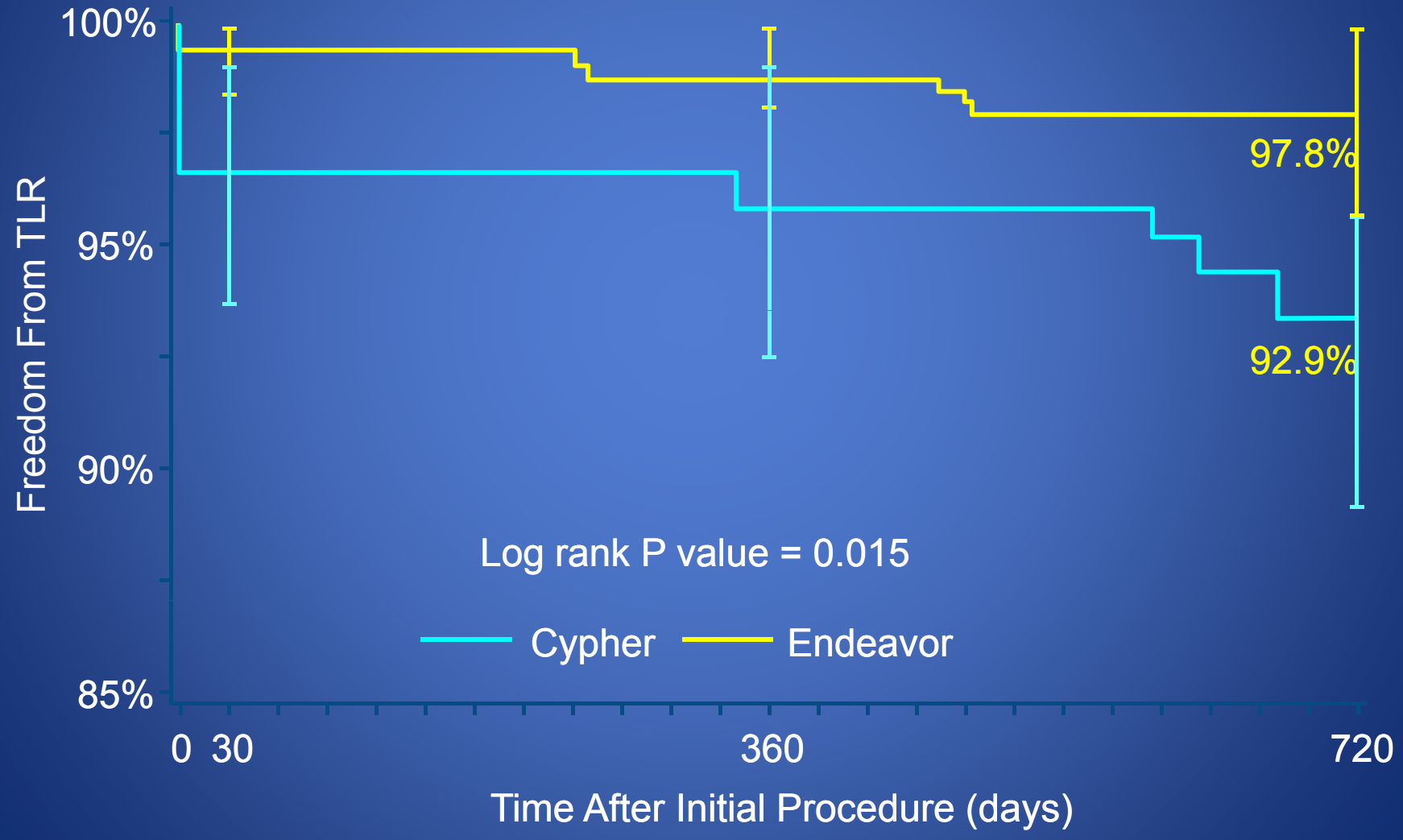
## TVF Event Free Survival to 720 days




 Error bars represent ±1.5SE estimated by Peto formula

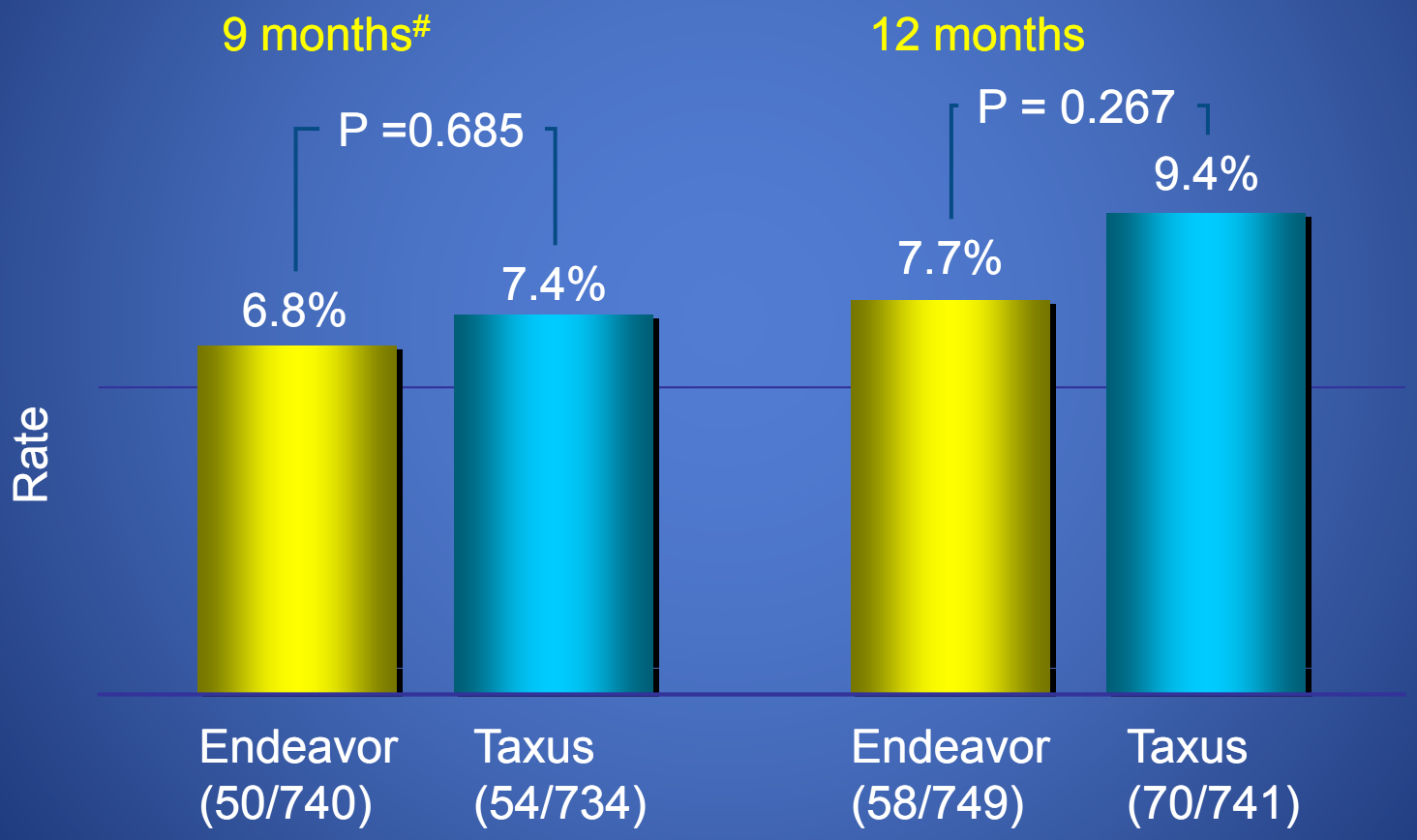
# ENDEAVOR III Safety Analysis

## All Cause Mortality/MI



# ENDEAVOR IV

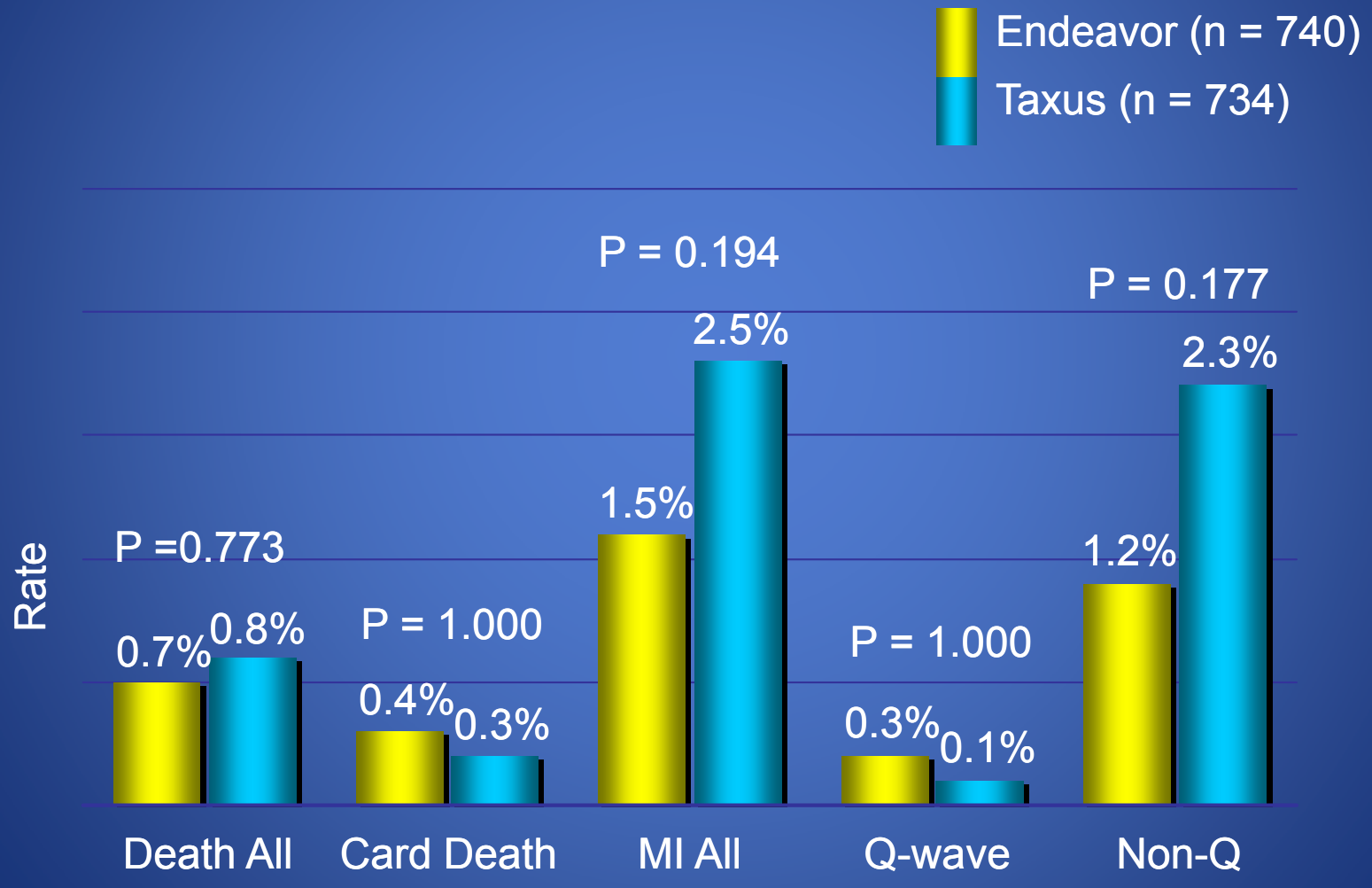
## Target Vessel Failure




 # EIV analysis done using 9-month data set presented to the FDA October 2007

# ENDEAVOR IV

## Death and MI at 9 Months#




 # EIV analysis done using 9-month data set presented to the FDA October 2007


amg
International
PICO Elite
Paclitaxel-Eluting Coronary Stent

# ELITE Registry Europe - *Study Design*

362 patients enrolled, with ≥ 50% stenosis in de novo lesions
in native coronary vessels between 2.0 and 4.0 mm in diameter
multi-center study at 10 sites

Non Randomized

· Primary Endpoint: Efficacy
MACE & Angiographic TVF at 6, 12, 18, 24 months

· Second Endpoint: Safety
Acute Stent Thrombosis
MACE at 6, 12, 18, 24 months
Acute success, TVF in hospital at 1, 6, 9months,
Restenosis Rate

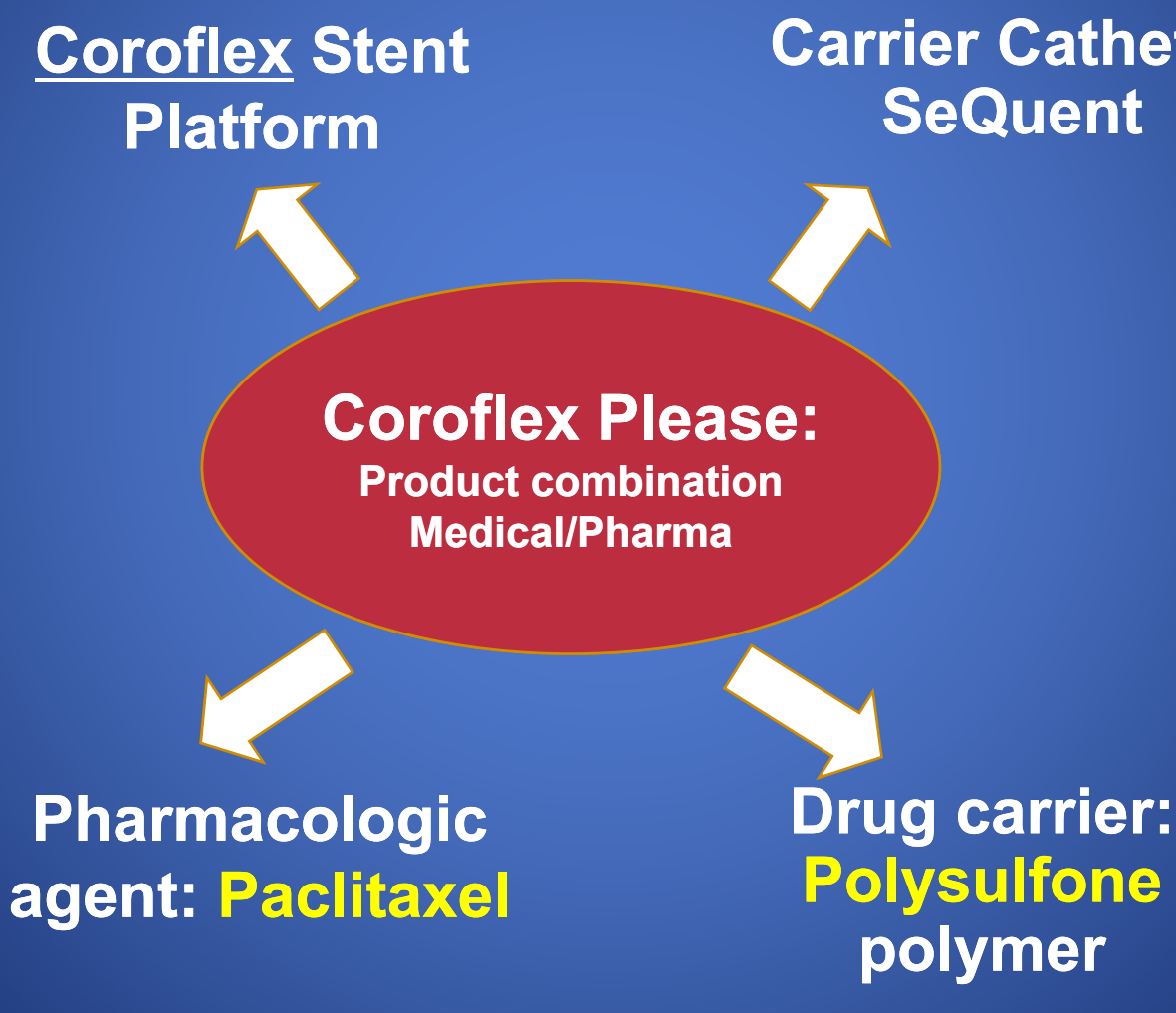
*Dr. D. Glogar (in Wien University clinic in Austria) et al. in 10 European centers*

# 6 months follow-up

| No. of patients | 217 patients |
|---|---|
| Acute stent thrombosis | 0 |
| Acute MI | 0 |
| TVR | 2.3 % |
| MACE | 4.6 % |
| Binary Restenosis | 6.9 % |

*Dr. D. Glogar (in Wien University clinic in Austria) et al. in 10 European centers*

# Coroflex® Please ; Paclitaxel-releasing Coronary Stent System



# Coroflex Please – superior coating quality and integrity

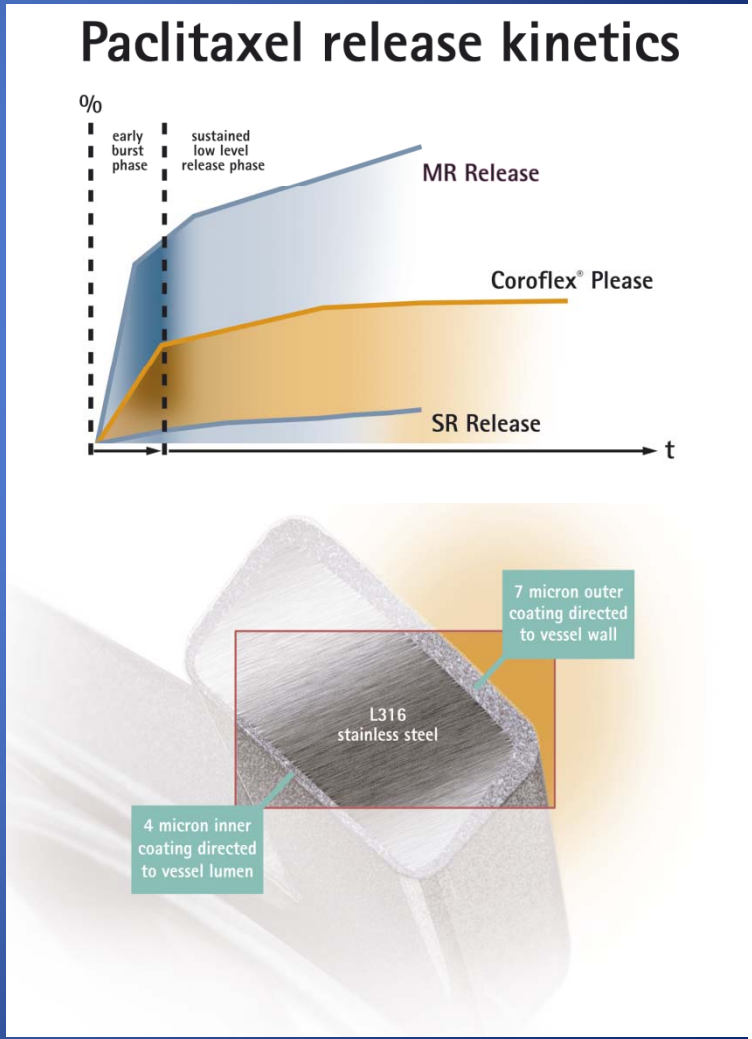
**Polysulfone:**

- uniform
- reproducible
- consistent release of paclitaxel from the stent

➔ **equivalent to TAXUS**

**Destinctive features: asymetric coating**

- targeted drug release -> directed to vessel wall
- no drug loss towards growing endothelium
- stable, non thrombogenic surface

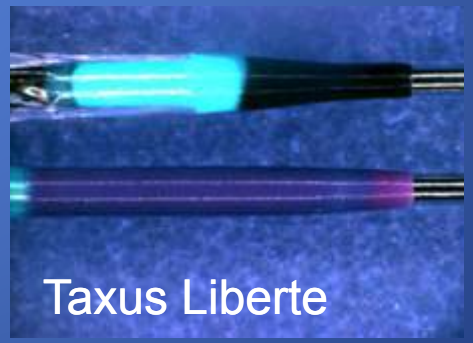


# …superior technical features compared to TAXUS

| | Tip Profile |
|---|---|
| Coroflex | 0.017” |
| Please | 0.019” |
| Taxus Liberté | 0.019” |
| Endeavor | 0.020” |
| Cypher Select | |

- lowest lesion entry profile for Coroflex Please
- the more thinner and more flexible tip design of Coroflex Please facilitates systems crossing for an improved lesion access






* based on measurements of 3.0mm diameter stents. Data on file.

# Pilot Study: PECOPS I

## PECOPS I

The Paclitaxel-eluting Coroflex Please Stent a Pilot Study

**M. Unverdorben, R. Degenhardt, W. Bocksch, D. Horstkotte, C. Nienaber, H. Schneider, C. Vallbracht, M. Wiemer**

A prospective non-randomized, one-armed multi-center trial on safety and efficacy of Coroflex® Please

# PECOPS I- TAXUS II at 6 months

| | Please | SR | MR |
|---|---|---|---|
| MI | 1,1 | | |
| Thrombosis (%) | 1,1 | | |
| TLR (%) | 5,7 | 4,6 | 3,1 |
| MACE (%) | 8,0 | 8,5 | 7,8 |
| Late Loss (mm) | 0,47 | 0,31 | 0,30 |
| Restenosis rate In-stent (%) | 3,9 | 2,3 | 4,7 |
| Restenosis rate In-segment (%) | 7,8 | 5,5 | 8,6 |

**➔ 6 month results are comparable to TAXUS**

# Comparison PECOPS I- TAXUS II at 1 Year

| | Please | SR | MR | |
|---|---|---|---|---|
| Thrombosis (%) | 1,1 | | | |
| PCI | 7,0 | | | |
| CABG | 2,3 | | | |
| MI | 1,2 | | | |
| Death | 1,2 | | | |
| **Total MACE** | **12,8** | 10,9 | 9,9 | n.s. |

➔ **Four MACE events between 6 and 12 months**

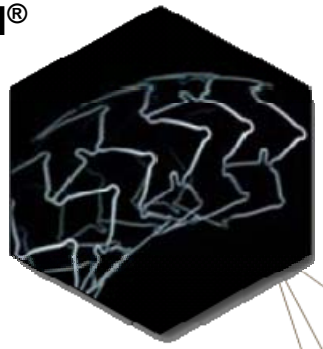
➔ **No additional thrombosis**

# DES That Will Be Available in Korea

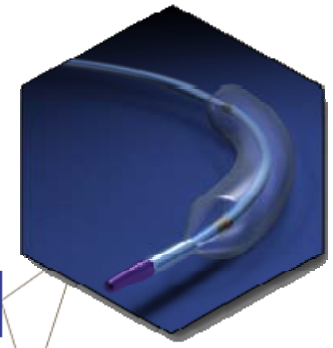
- Everolimus-eluting (Xience®/ Promus®)
- Zotarolimus-eluting (Endeavor Resolute®)
- Biolimus-eluting (Nobori®, Terumo)
- Conor® Sirolimus-eluting
- Bioabsorbable DESs
- .....
-

# XIENCE™ V / PROMUS™ : Optimizing DES Components

**MULTI-LINK VISION®**
**Stent**



**MULTI-LINK VISION®**
**Stent Delivery System**

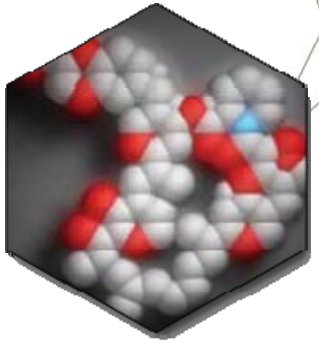


**Deliverability**

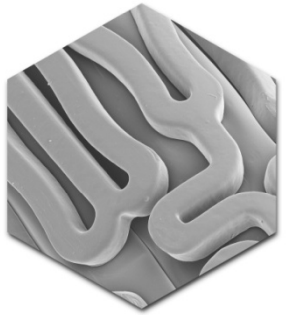
**Efficacy**

**Safety**

**Everolimus**



**Fluorinated Co-Polymer**



Xience™ V

CAUTION: XIENCE™ V is an investigational device. Limited by Federal (U.S.) law to investigational use only.





AP2926938 Rev. A



Abbott Vascular

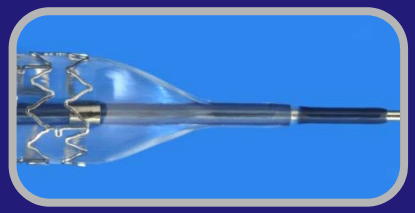
# XIENCE V / PROMUS™
## Built On The Proven MULTI-LINK VISION Stent Platform

### Cobalt Chromium Technology
- Allows for thinner struts without compromise to radiopacity or radial strength[1]

### Thin Strut Stent Design
- Outstanding flexibility and conformability
- .0032” (0.081 mm) strut thickness[2]

### Low System Profile
- Excellent deliverability

### ML VISION® Stent Delivery System
- Soft, highly flexible Pebax balloon material
- Short tapers



1. As compared to stainless steel. Source: ASTM International.
2. Tests performed by and data on file at Abbott Vascular.

Xience™ V

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AP2926938 Rev. A



Abbott Vascular

# SPIRIT Family of Trials

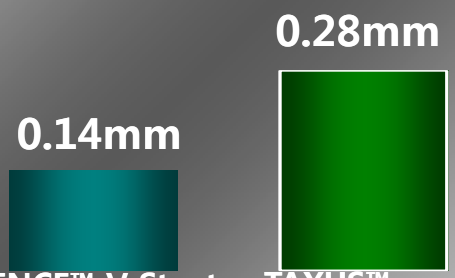
| | SPIRIT FIRST | SPIRIT II | SPIRIT III | SPIRIT IV | SPIRIT V |
|---|---|---|---|---|---|
| **Trial Objective** | Safety and Performance | Clinical Support for CE Launch | Pivotal Study: US & Japan Approval | US Peri-Approval | Post-CE Mark Approval |
| **Location & Participants** | Europe n=**60** | International n=**300** | US: 1,292<br>RCT: **1,002** (80 sites)<br>Japan: 88 (12 sites)<br>n=1,380 | US n=1,125 40 sites | International n~3000<br>Diabetic Study n~300<br>Registry n=2,700 |
| **Enrollment Status** | Completed | Completed November 2005 | US RCT: completed Mar 2006<br>SV: Began Q4 2006 | Began August 2006 | Not Yet Reported |
| **Devices Compared** | XIENCE™ V (PROMUS™) Stent compared to **Multi-Link VISION™ BMS** | XIENCE™ V (PROMUS™) Stent compared to **TAXUS™ Express²™** Stent | XIENCE™ V (PROMUS™) Stent compared to **TAXUS™ Express²™** Stent | XIENCE™ V (PROMUS™) Stent compared to TAXUS™ Express²™ Stent | XIENCE™ V (PROMUS™) Stent compared to TAXUS™ Express²™ Stent |

# SPIRIT III Clinical Trial
## Primary and Major Secondary Endpoints

### *Primary and Secondary Endpoint Met*
***XIENCE™ V/ PROMUS™ Stent non-inferior to TAXUS Stent***

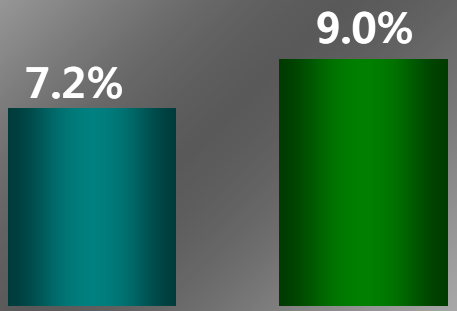
**In-Segment Late Loss at 8 months**

$P_{Non\text{-}Inferiority} < 0.0001$
$P_{Superiority} = 0.004$




**Target Vessel Failure at 9 months**

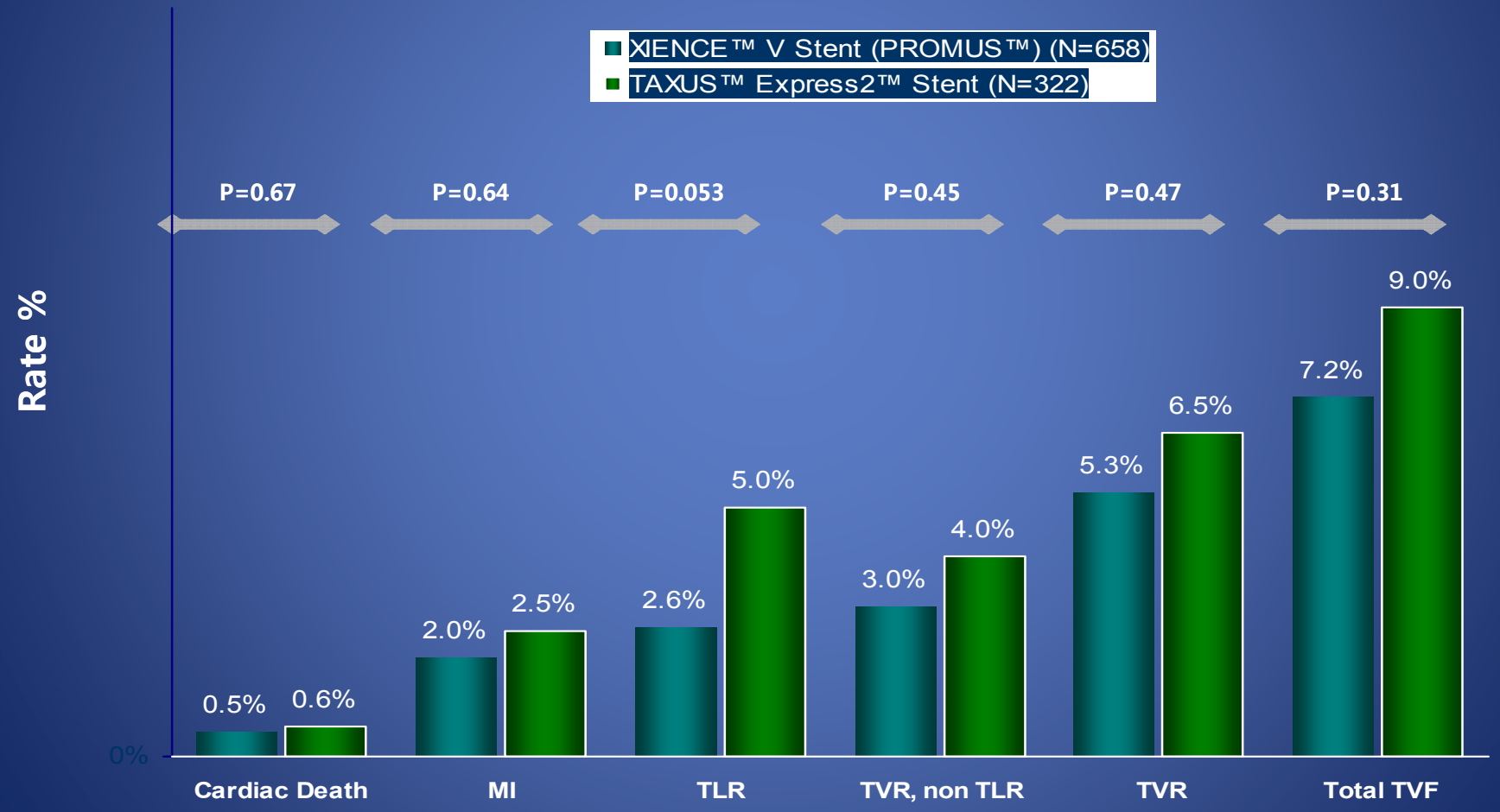
$P_{Non\text{-}Inferiority} < 0.0001$
$P_{Superiority} = 0.31$




**Target Vessel Failure:**
*Cardiac death, MI, Ischemia-driven TVR*

# SPIRIT III Clinical Trial

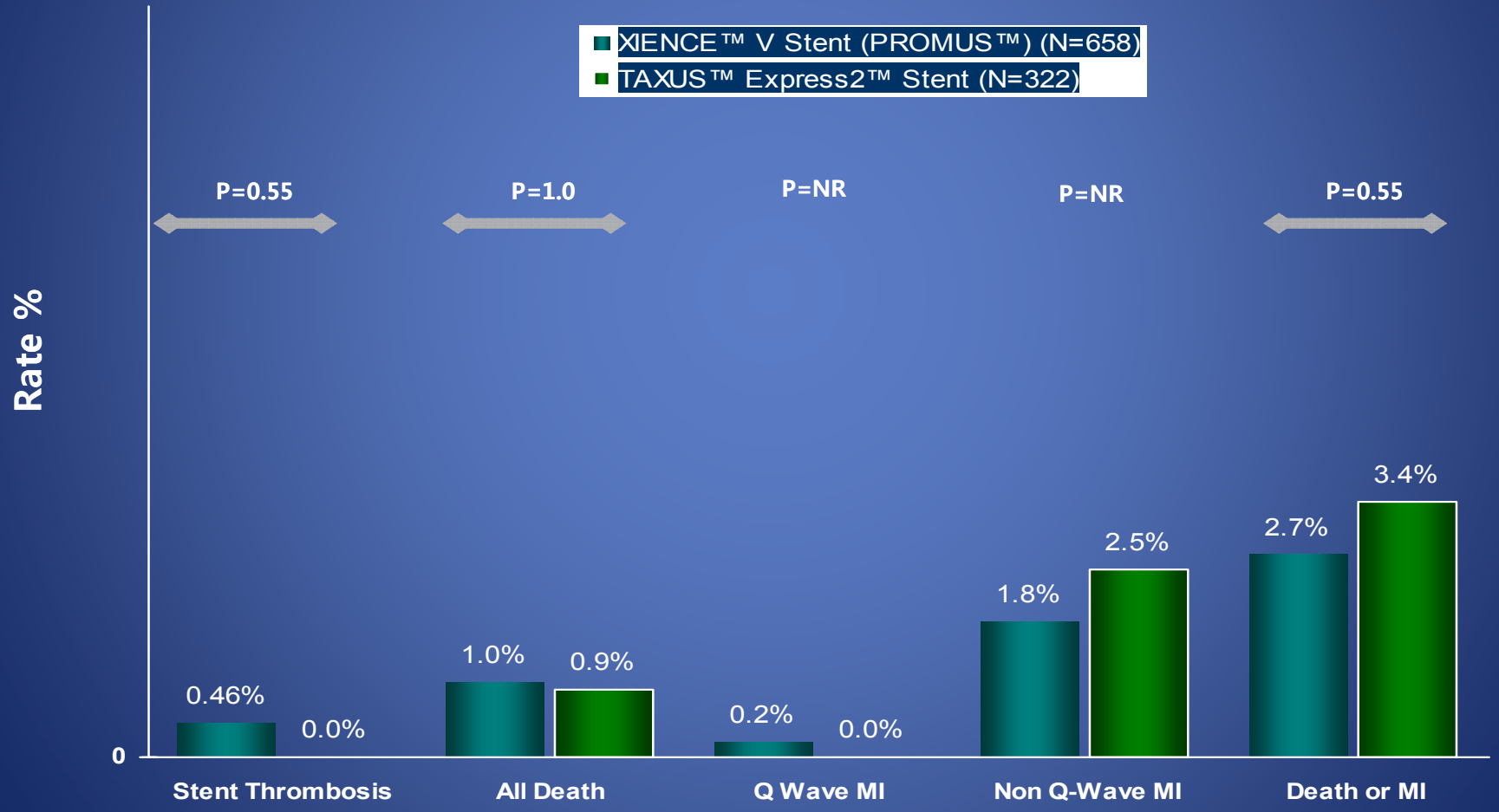
## Clinical Results at 9 Months



# SPIRIT III Clinical Trial

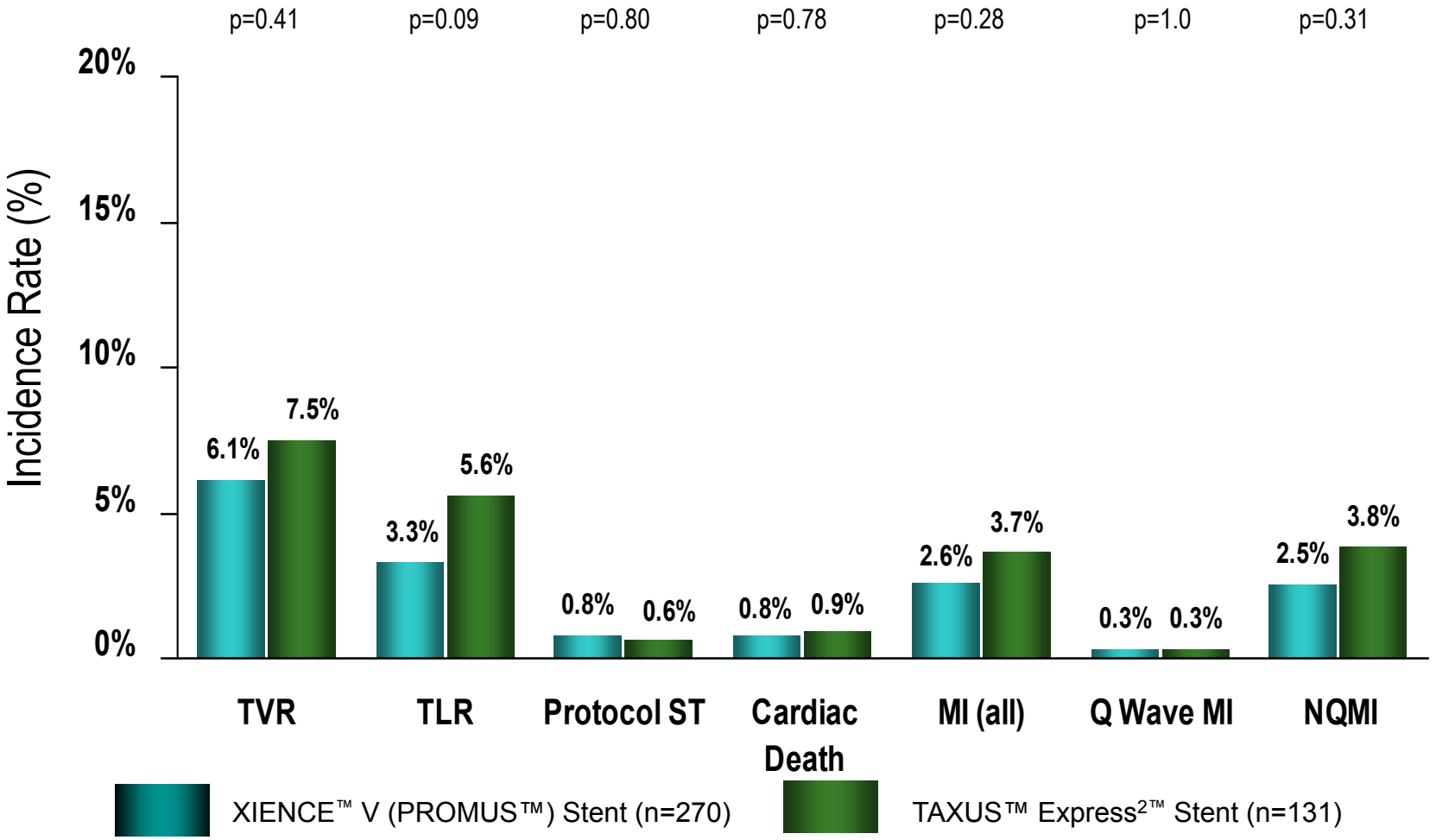
## Safety at 9 Months

**SPIRIT III reinforces the positive safety profile of TAXUS™ Stent & PROMUS™ Stent**

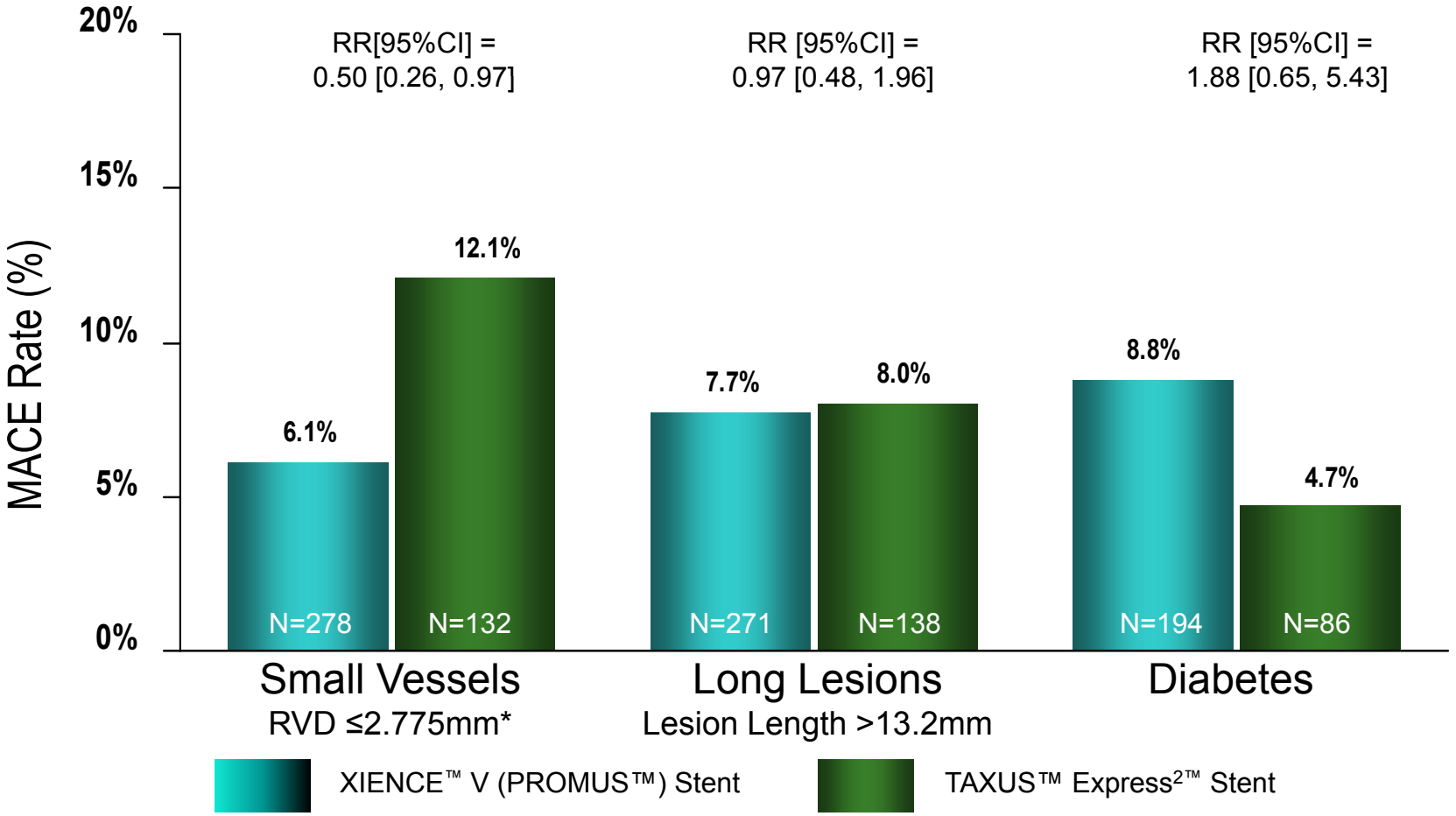


# SPIRIT III Study
## *1-Year* Clinical Results*

*No significant differences between stents on clinical endpoints*



# SPIRIT III Study
## *1-Year MACE in High-Risk Subgroups*




MACE = cardiac death, MI, or ischemia-driven TLR

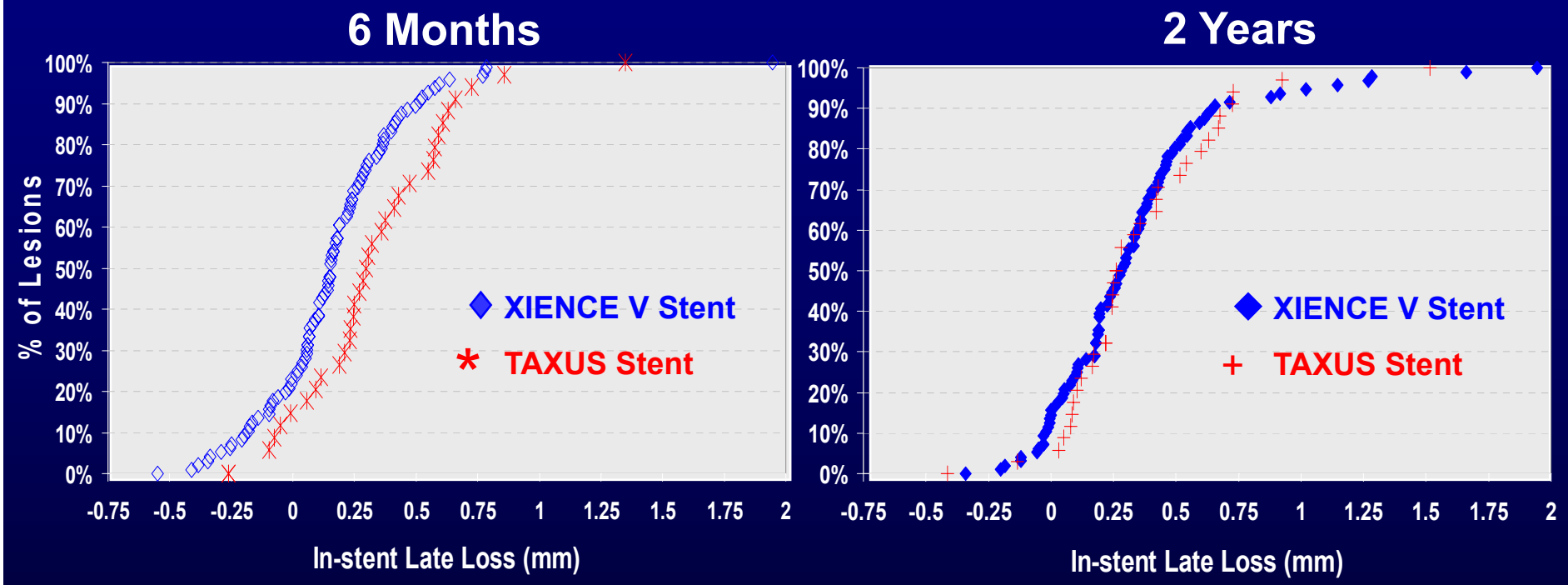
# The **SPIRIT II** Study - A Clinical Evaluation of the XIENCE™ V Everolimus Eluting Coronary Stent System in the Treatment of Patients With *De Novo* Native Coronary Artery Lesions

## Clinical, Angiographic and IVUS **2-year** results

SCAI-ACCi2 Late-Breaking Clinical Trials III: DES

**Serruys PW., ACC LBCT Oral Presentation; 2008.**

# In-stent Late Loss in Patients with Serial 6-Month and 2-Year Angio FU



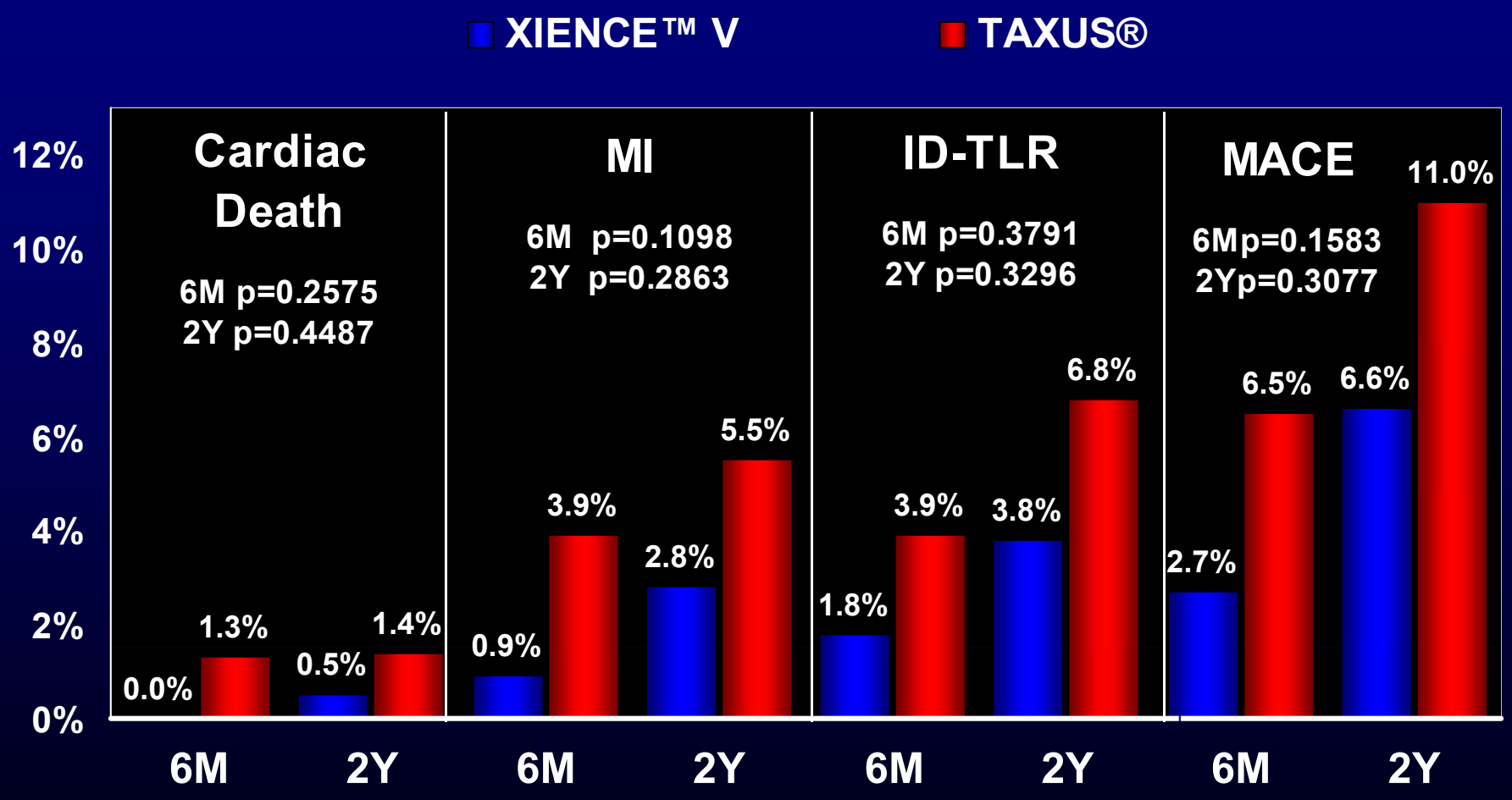

| | |
|---|---|
| XIENCE[M] V Stent: 0.17 ± 0.32 (nL=97) | XIENCE V Stent: 0.33 ± 0.37 (nL=97) |
| TAXUS Stetnt: 0.33 ± 0.32 (nL=35) | TAXUS Stent: 0.34 ± 0.34 (nL=35) |
| P=0.0037 | P=0.6026 |

In this serial analysis, for patients having TLR, values of loss and neo-intimal hyperplasia observed prior to 6-month or 2-year F U were imputed at 6 months and 2 years respectively

CAUTION: XIENCE™ V is an Investigational device. Limited by Federal (U.S.) law to investigational use only.
TAXUS® Paclitaxel-eluting Coronary Stent System is a registered trademark of Boston Scientific or its affiliates.

Serruys PW., ACC LBCT Oral Presentation; 2008.

# 6-Month (6M) and 2-Year (2Y) Clinical Results

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Serruys PW., ACC LBCT Oral Presentation; 2008.

# ARC Stent Thrombosis

| Definite and Probable | XIENCE™ V<br>223 patients | TAXUS ®<br>77 patients |
|---|---|---|
| Acute stent thrombosis (%) | **0.0** | **0.0** |
| Sub-acute stent thrombosis (%) | **0.0** | **1.3** |
| | 220 patients | 77 patients |
| Late stent thrombosis (%) | **0.0** | **1.3** |
| | 211 patients | 73 patients |
| Very late stent thrombosis (%) | **0.9** | **0.0** |
| **Total stent thrombosis (%)** | **0.9** | **1.4** |

Acute: 0 to 24 hours after stent implantation
Subacute: >24 hours to 30 days after stent implantation
Late: >30 days to 1 year after stent implantation
Very late: >1 year after stent implantation
p=NS

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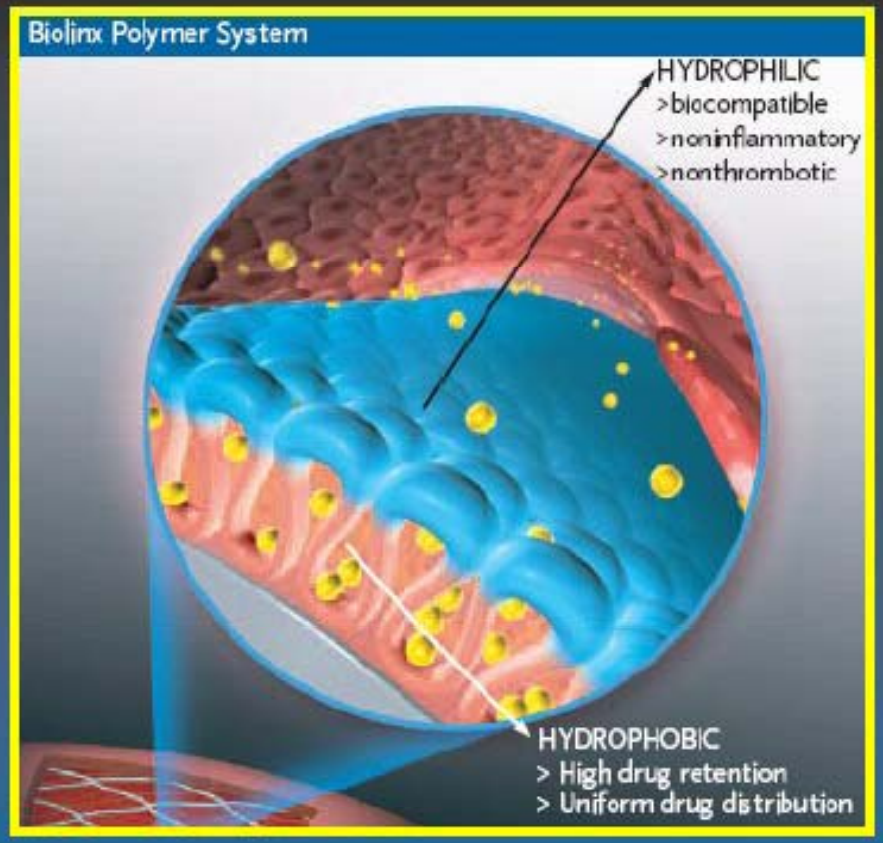
**Serruys PW., ACC LBCT Oral Presentation; 2008.**

# Endeavor Resolute

## *BioLinx Polymer*




*Components of a safe polymer:*

- Mimics the body's chemistry
- Allows reliable drug elution
- Compatible with stent delivery

*Biocompatible BioLinx polymer system design:*

- Non-inflammatory and non-thrombotic
- Rapid and functional endothelial healing

**A biostable polymer that applies the basics of membrane structure will provide sustained drug elution over time while maintaining biocompatibility**

# Angiographic Results

## 9 Month Cohort

| n=96 | In-stent | In-segment |
|---|---|---|
| Pre-procedure RVD (mm) | | 2.79 ± 0.40 |
| Lesion Length (mm) | | 15.87 ± 6.51 |
| MLD (mm) pre | | 0.82 ± 0.35 |
| post | 2.74 ± 0.41 | 2.33 ± 0.44 |
| Acute Gain | 1.91 ± 0.47 | 1.51± 0.50 |
| 9 mo f/u MLD (mm) | 2.51 ± 0.48 | 2.21 ± 0.45 |
| Late Loss (mm) | 0.22 ± 0.27 | 0.12 ± 0.27 |
| Late Loss Index | 0.12 ± 0.16 | 0.08 ± 0.21 |
| 9 mo f/u % DS | 10.13 ± 12.63 | 21.08 ± 10.62 |
| ABR n (%) | 1 (1%) | 2 (2.1%) |

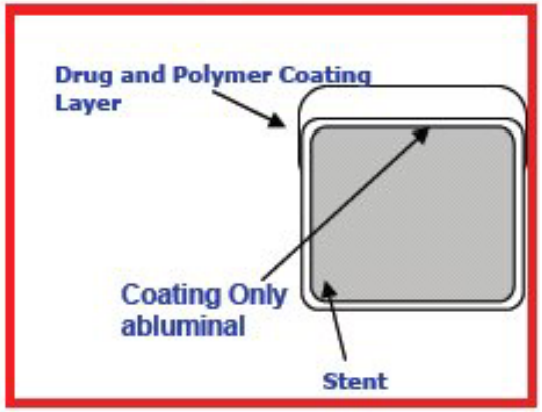
# RESOLUTE

## Clinical Events to 12 months

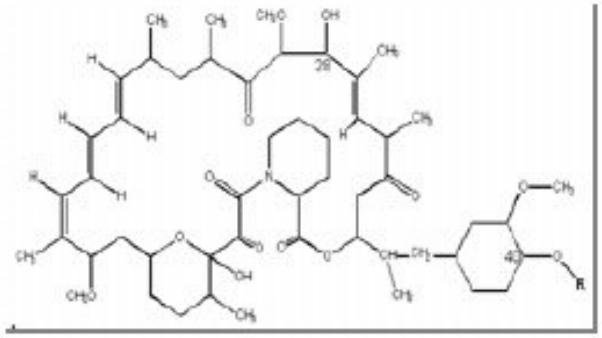
| | 9 months n=130 patients n=131 lesions | 9-12 months n=129, 130 lesions | 12 months n=129 patients, 130 lesions |
|---|---|---|---|
| Death (all) - % (#) | 1.5 (2) | 0.8 (1) | 2.3 (3) |
| Cardiac | 0.8 (1) | 0 | 0.8 (1) |
| MI (all) - % (#) | 5.4 (7) | 0 | 5.4 (7) |
| Q Wave | 0 | 0 | 0 |
| Non Q wave | 5.4 (7) | 0 | 5.4 (7) |
| Death (cardiac) + MI (all) - % (#) | 6.2 (8) | 0 | 6.2 (8) |
| Stent Thrombosis (all) - % () | 0 | 0 | 0 (0) |
| 0-30 days | 0 | 0 | 0 (0) |
| 31-360 days | 0 | 0 | 0 (0) |
| TLR - % (#) | 0 | 0.8 (1) | 0.8 (1) |
| TVR (non-TL) - % (#) | 0 | 0 | 0.0 |
| TVR - % (#) | 0 | 0 | 0.8 (1) |
| MACE - % (#/) | 6.9 (9) | 1.6 (2) | 8.5 (11) |
| TVF - % (#/) | 6.2 (8) | 0.8 (1) | 7.0 (9) |

# Nobori DES Components

**S-Stent™ (stainless steel)**
- Quadrature-link design
- Excellent flexibility and scaffolding
- Reduced turbulence and wall injury




**PLA bioabsorbable Polymer**
- High drug-carrying capacity
- Controlled **biodegradability**
- Simultaneous polymer degradation and release of drug into tissue
- Abluminal Coating



**Biolimus A9™ (rapamycin derivative)**
- A potent new "Limus" designed for stent applications
- Powerful immunosuppressant, anti-inflammatory compound
- Prevents smooth muscle cell proliferation
- Highly lipophylic; elutes fast from stent

# MACE Rate up to 9 Months


| Hierarchical | Nobori ™ 85 Patients | Taxus® 35 Patients |
|---|---|---|
| Cardiac and Non-Cardiac Death (%) | 0 | 0 |
| Myocardial Infarction (/%) | 4.7 | 8.6 |
| • Q-Wave | 0.0 | 0.0 |
| • Non-Q-Wave | 4.7 | 8.6 |
| – CK>2UNL<3UNL | 4.7 | 8.6 |
| – CK>3UNL | 0.0 | 0.0 |
| Clinically and Non-Clinically Driven Target vessel revascularization (%) | 7.0 | 11.4 |
| • CABG | 0.0 | 2.9 |
| • PCI | 7.0 | 8.6 |
| TOTAL MACE | 11.7 | 20.0 |
| Stent Thrombosis (%) | 0 | 0 |

# Clinically Driven Revascularizations up to 9 Months


| | Nobori ™ 85 Patients | Taxus® 35 Patients |
|---|---|---|
| TLR - Clinically Driven % | 0 | 2.9* |
| TVR – non-TLR - Clinically Driven % | 1.2 | 2.9 |
| Total Clinically Driven TVR % | 1.2 | 5.7 |
| TOTAL MACE with Clinically Driven Revascularizations % | 5.9 | 14.3 |

* Emergent CABG during procedure

# DES in Korea

## Available

- Sirolimus-eluting (Cypher®)
- Paclitaxel-eluting (Taxus®)
- Zotarolimus-eluting (Endeavor®)
- Pico*Elite* Paclitaxel-eluting
- Coroflex® Please Paclitaxel-releasing

## Will Be Available

- Everolimus-eluting (Xience®/ Promus®)
- Zotarolimus-eluting (Endeavor Resolute®)
- Biolimus-eluting (Nobori®, Terumo)
- Conor® Sirolimus-eluting
- Bioabsorbable DESs
- .....
-

Endeavour™
Zotarolimus-coated stent

YUKON® Choice®
Drug Eluting Stent

Paclitaxelfreisetzendes koronares Stentsystem

KRAUTH CardioVascular

Axxion™
Medikamentenbeschichteter Koronarstent

SORIN BIOMEDICA

Janus - A unique polymer-free Drug Eluting Stent