

# Xience Sierra

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## Current Status of DES and DES Failure

**Tae-Hyun Yang, MD**

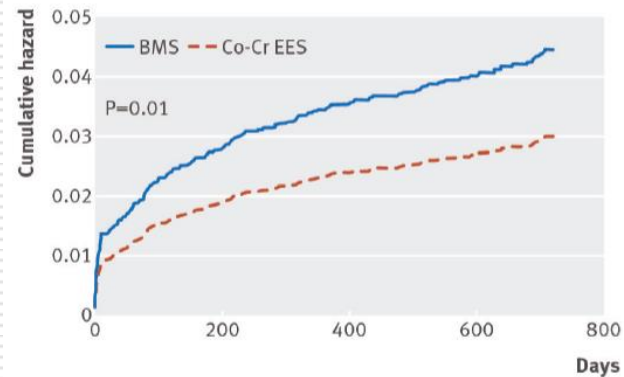
*Professor of Medicine/Cardiology*

Inje University Busan Paik Hospital

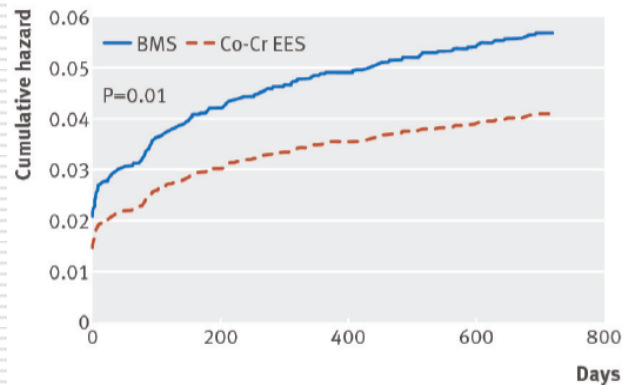


# EES or BMS: Patient Level Meta-Analysis (5 RCTs and 4,896 Patients)

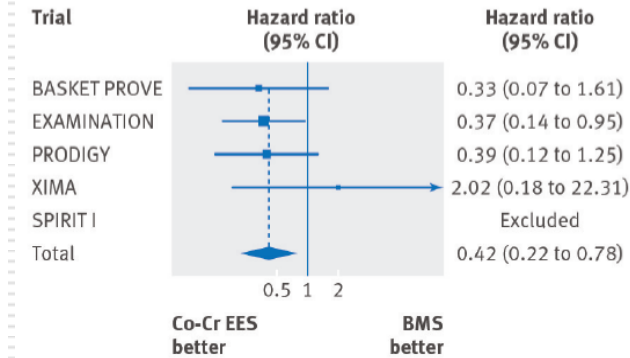
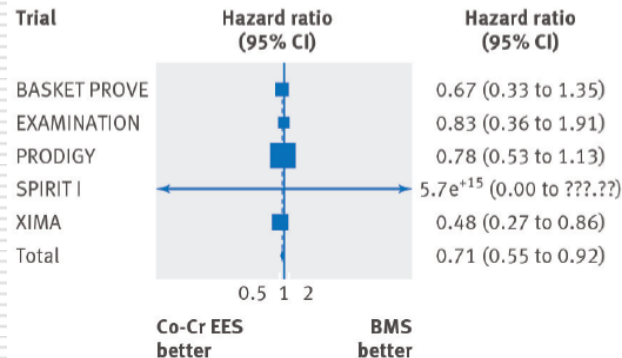
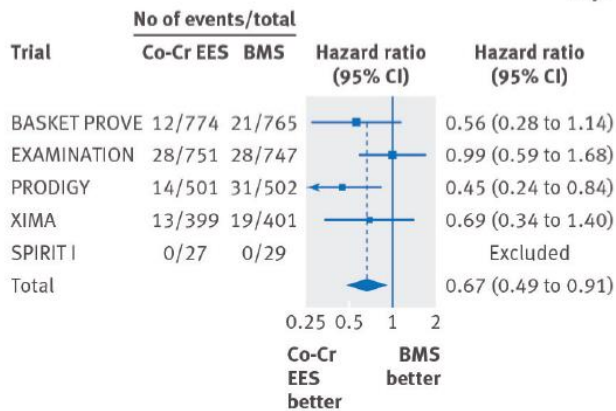
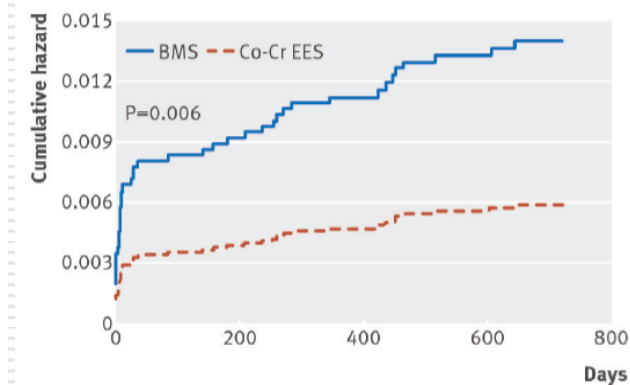
## Cardiac Death



## Myocardial Infarction

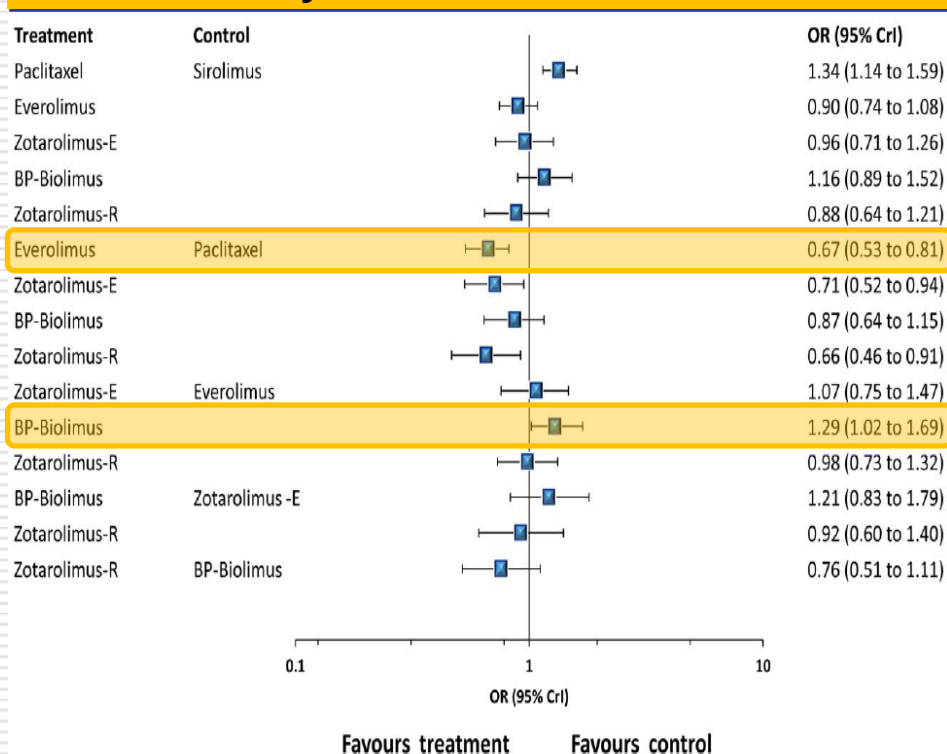


## Definite ST

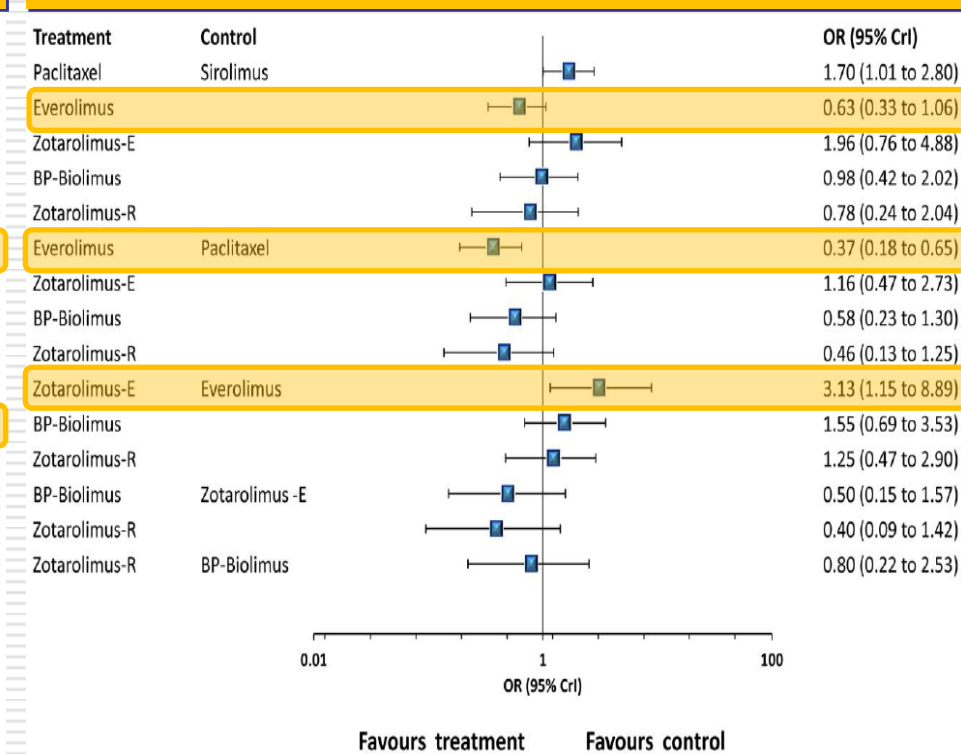


# DP-DES and BP-BES: Network Meta-Analysis (60 RCTs and 63,242 Patients)

## Myocardial Infarction

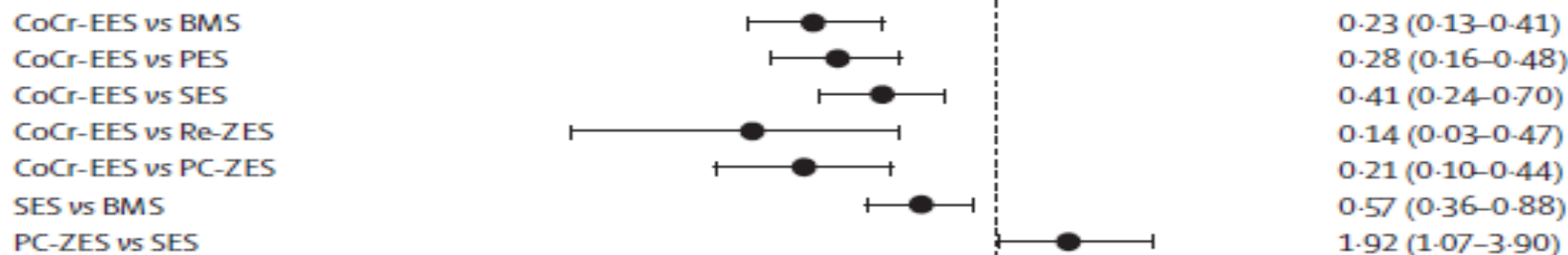


## Definite/Probable Stent Thrombosis

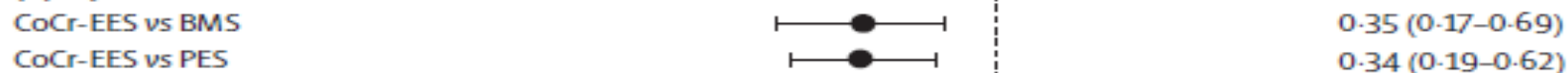


# Stent Thrombosis: Network Meta-Analysis (49 RCTs and 50,844 Patients)

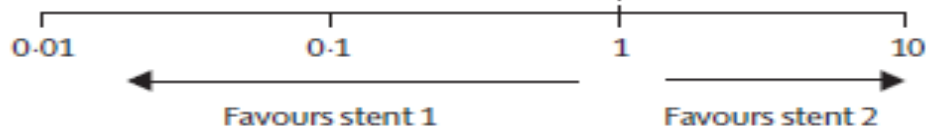
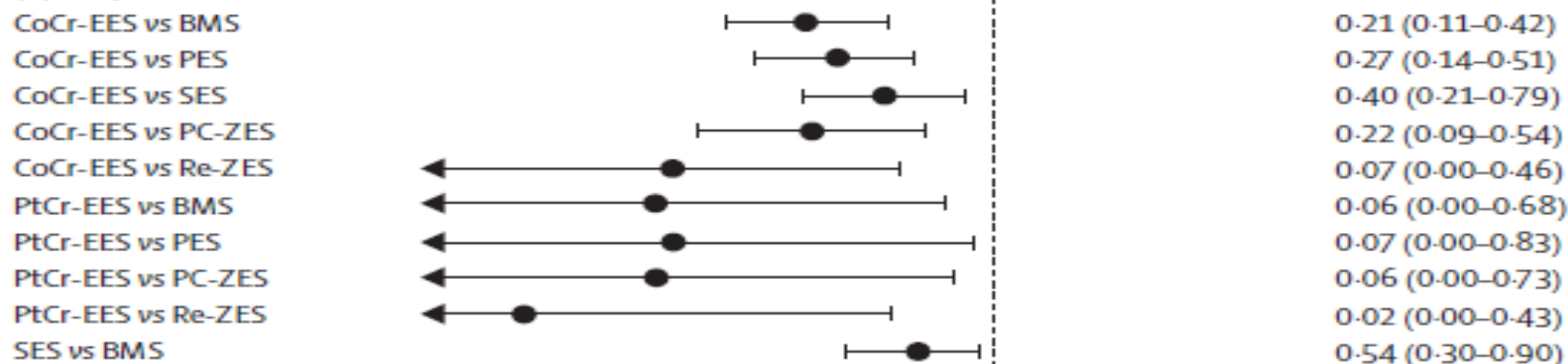
## (A) 1-year definite thrombosis



## (B) 2-year definite thrombosis

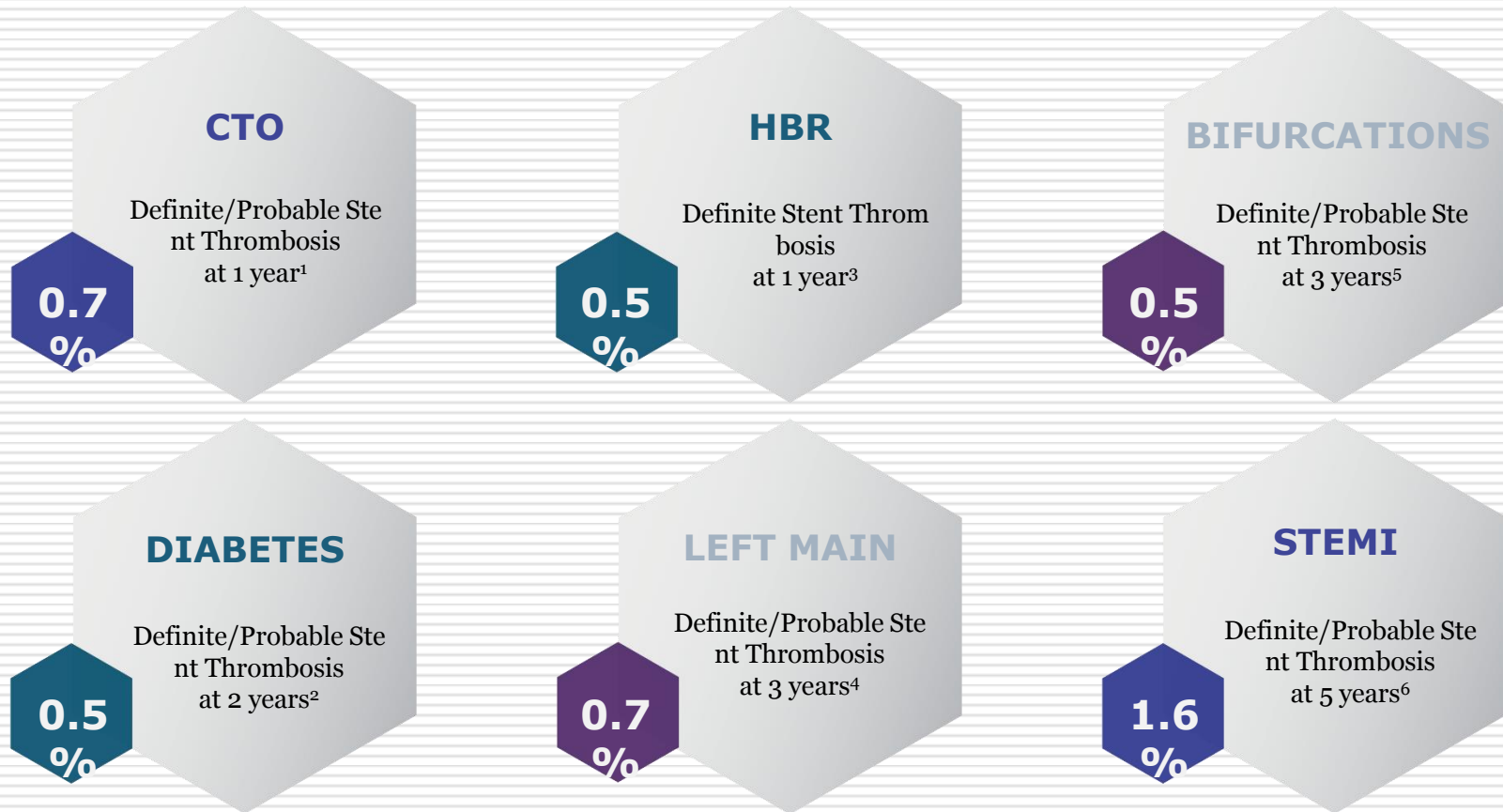


## (C) Early definite thrombosis



# Xience Demonstrated A Consistent Trend of Low ST Rates in Complex Patients

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1: JACC Cardiovasc Interv 2017(PRISON IV); 2: TCT 2016(TUXEDO); 3: JACC 2014(XIMA);  
4: NEJM 2016(EXCEL); 5: Am Heart J 205(TWENTE); 6: ESC 2015(EXAMINATION)

# DES Consists of 3 Components

A metallic platform, a polymer, and a drug, all influencing acute and long-term results both in safety and efficacy



## Fluoropolymer

- Durability, flexibility, and elasticity for stent coating use
- Biocompatible for cardiovascular implants<sup>4,5,6</sup>
  - Attracts albumin to surface for thromboresistance<sup>8</sup>
  - Minimal inflammation<sup>4</sup>
  - Fast and functional endothelialization<sup>5,9,10</sup>



## CoCr MULTI-LINK Stent Design

- Flexible for conformability, less injury<sup>1</sup>
- Low metal-to-artery ratio reduces injury, inflammation<sup>7</sup>
- Thin, well-apposed struts for rapid re-endothelialization, healing; and reduced thrombogenicity<sup>2,3,4</sup>



## Everolimus

- Elution rate matched to restenosis cascade<sup>11</sup>
- Low drug dose<sup>11,12</sup>
- Broad therapeutic range<sup>11</sup>

# Fluoropolymer Attracts Albumin, Limits Platelet Adhesion, Speeds Endothelization

WITHOUT FLUOROPOLYMER

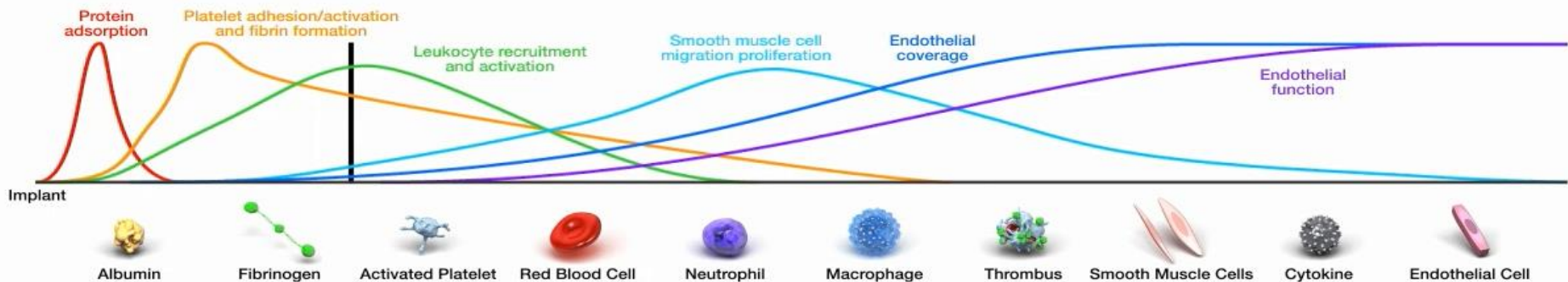


Platelets recruit and activate leukocytes (including neutrophils and macrophages), leading to an inflammatory response.<sup>1</sup>

WITH FLUOROPOLYMER



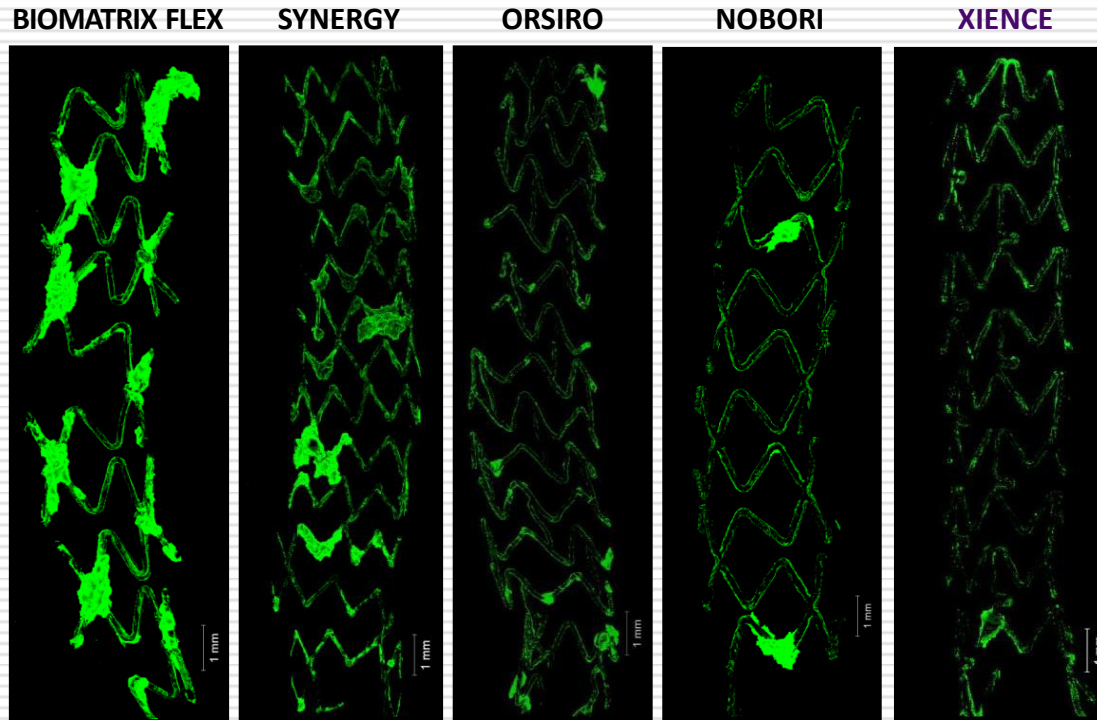
Fewer activated platelets on the fluorinated surface leads to a low inflammatory response.<sup>2,3</sup>



The animations are artists' illustrations of blood and tissue compatibility concepts derived from the long-known benefits of fluorinated surfaces for cardiovascular implants.  
 1. Zarbock, A, et al, Platelet-neutrophil-interactions: Linking hemostasis and inflammation, Blood Reviews (2007) 21, 99-111. 2. Ao, P.Y., et al. Development of Intima Hyperplasia in Six Different Vascular Prostheses. Eur J Vasc Endovasc Surg 20, 241-249 (2000). 3. Paton et al.; US Patent 5,356,668.

# Fluoropolymer Has Least Thrombus in Porcine Model

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Representative confocal photomicrographs showing least thrombus area on DP-EES (GREEN = Platelets) vs. BP-DESs in porcine model



# Fluoropolymer Has Lowest Inflammation During Healing in Porcine Model

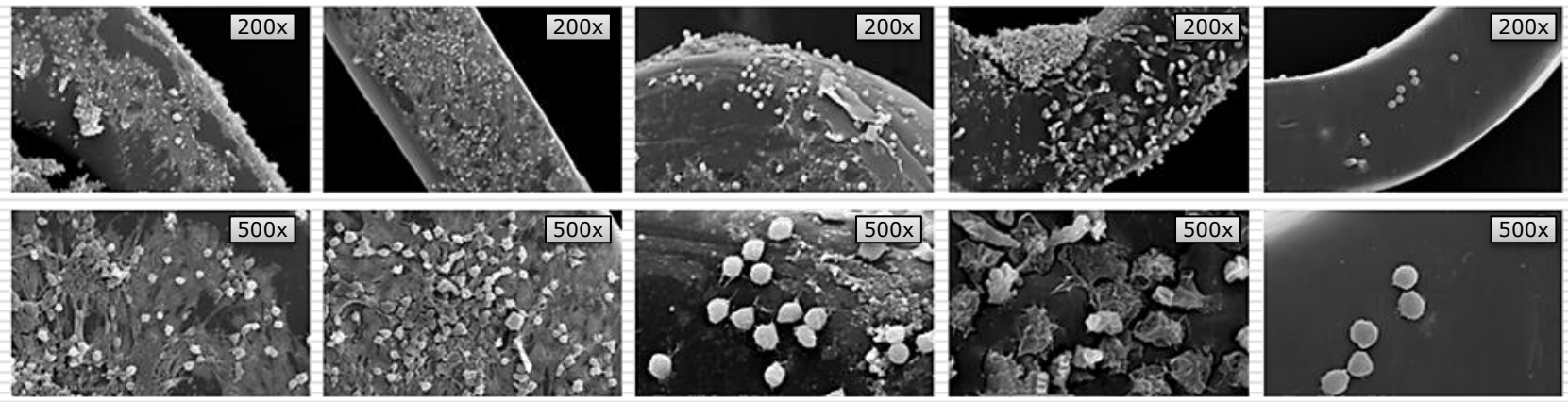
**BIOMATRIX  
FLEX**

**SYNERGY**

**NOBORI**

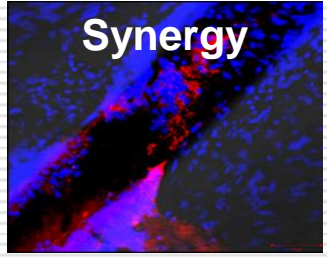
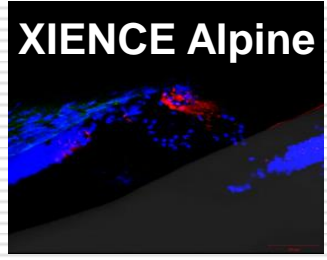
**ORSIRO**

**XIENCE**



Representative scanning electron micrographs of stents evaluated in ex vivo porcine shunt model<sup>1</sup>

XIENCE demonstrates **significantly lower macrophage adherence** versus Synergy



Images from rabbit iliac arteries. Red = RAM11 = macrophages

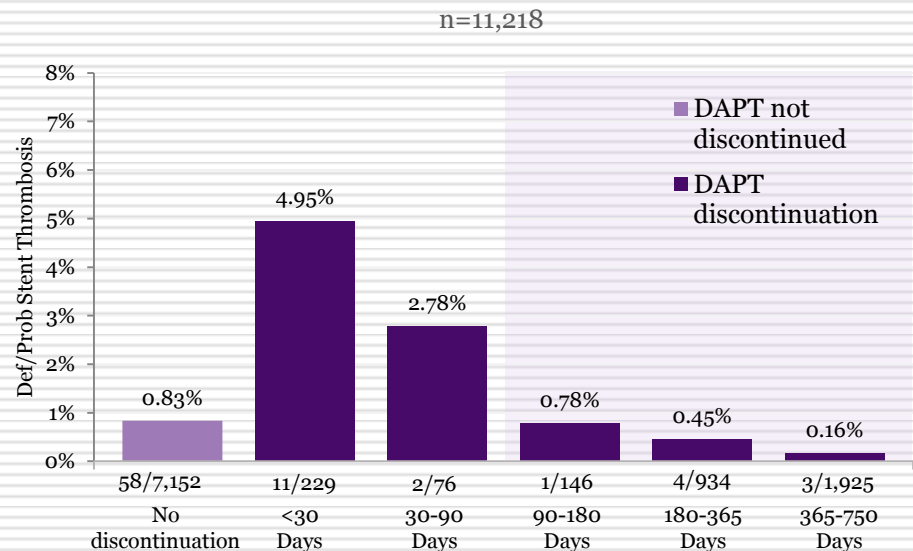
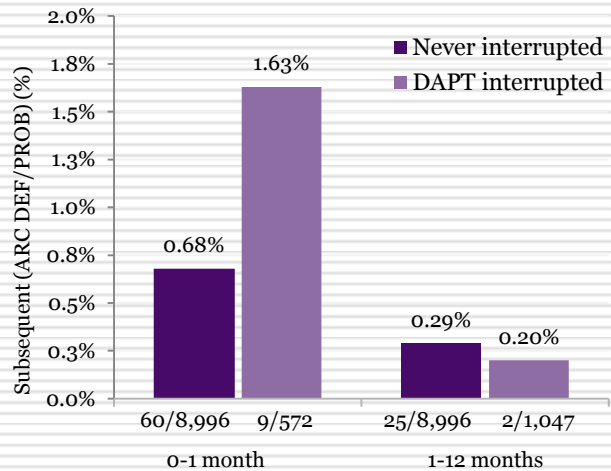
# Fast, Functional Healing Allows Xience to Demonstrate Safety with Its DAPT Data

Post-hoc pooled analysis from the Everolimus stent family trials

## INTERRUPTION\*

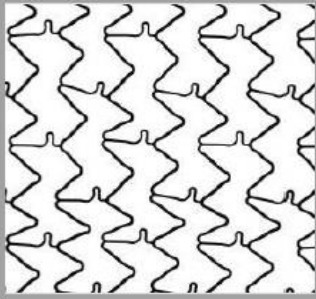
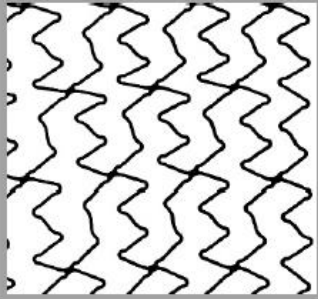
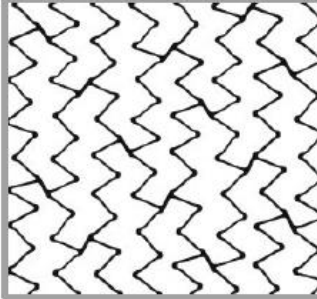
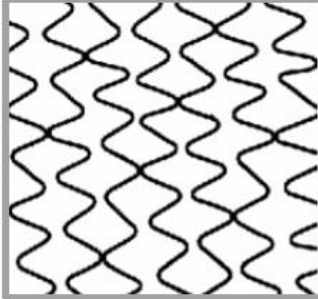

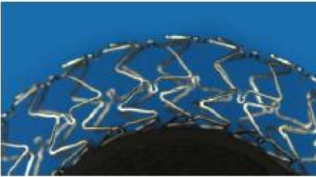




## DISCONTINUATION\*\*

TIMING OF FIRST DAPT INTERRUPTION AND STENT THROMBOSIS



\*Including patients with no DAPT Interruption except possibly after Stent Thrombosis through 365 days. DAPT was considered to be interrupted if aspirin or a thienopyridine was not taken for at least 24 hours during the 2-year follow-up period for any reason. \*\*Permanent DAPT discontinuation was considered if DAPT was never resumed after discontinuation or never resumed before a ST event (if a ST occurred after DAPT discontinuation). Patients who experience early discontinuation of antiplatelet therapy should be monitored carefully for cardiac events. At the discretion of the treating physician, the antiplatelet therapy should be restarted as soon as possible per patient needs. Ultimately the DAPT regimen is up to the discretion of the treating physician. This is a post-hoc, pooled analysis.

# Stent Design

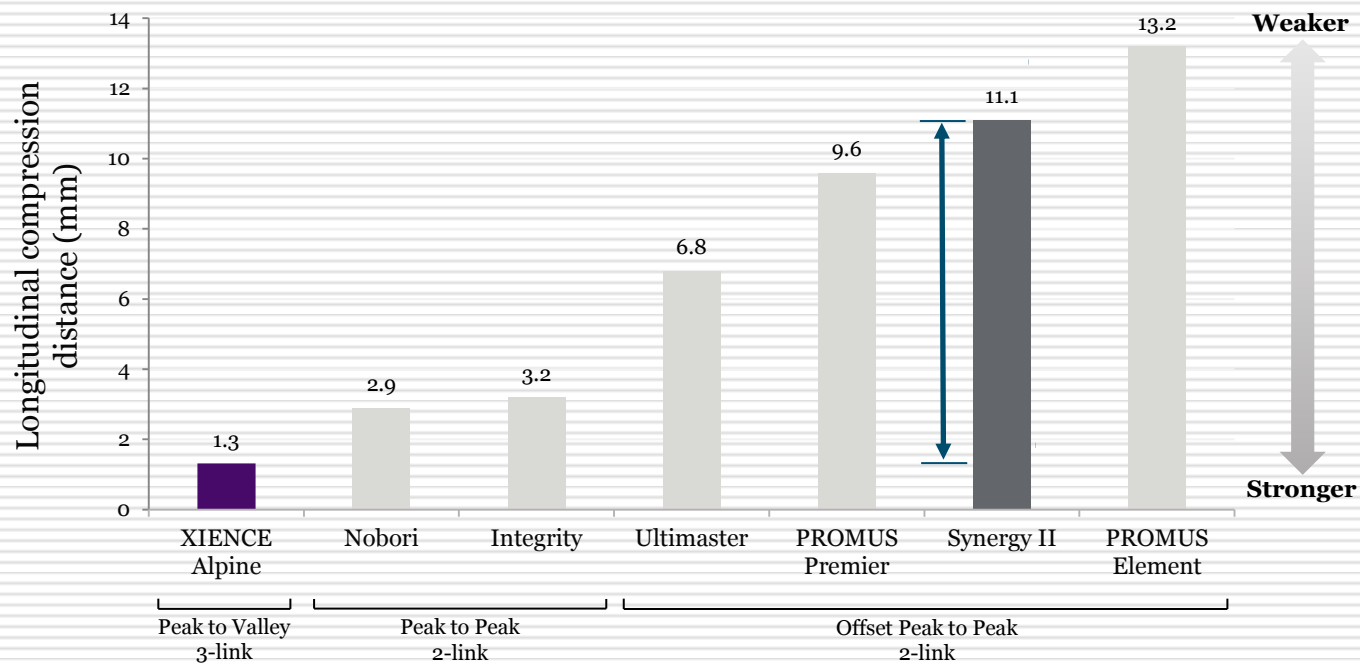
XIENCE Xpedition	Ultimaster	Synergy	R-Integrity	NOBORI
Peak-to-Valley	Offset Peak-to-Peak	Offset Peak-to-Peak	Peak-to-Peak	Peak-to-Peak
				
				
3 Link	2 Link			

XIENCE's 3-flexible, non-linear link and peak-to-valley (in phase) design provides flexibility and scaffolding, minimizes unsupported surface area, prevents longitudinal stent deformation, and ensures even drug distribution

# Xience Demonstrates Excellent Longitudinal Strength

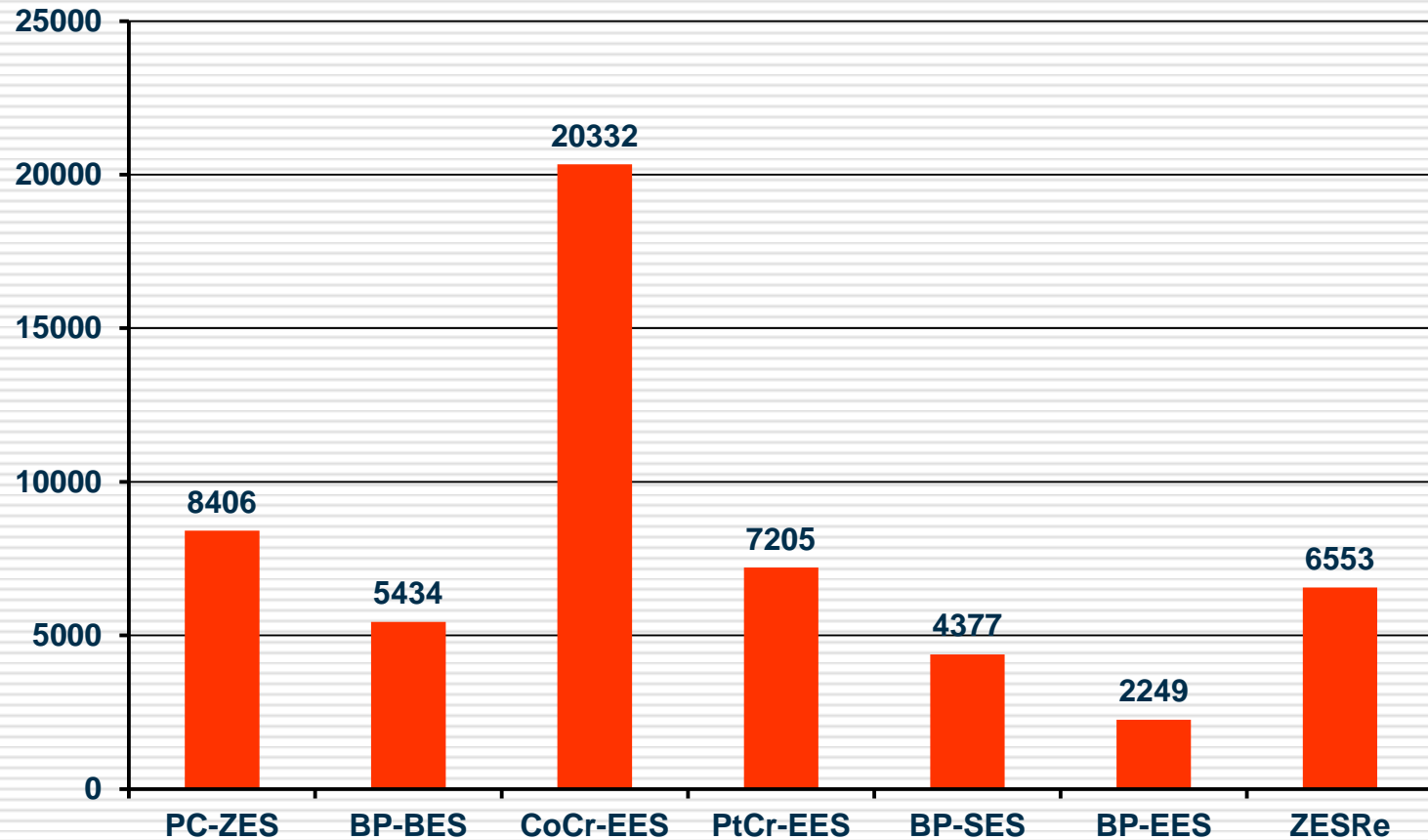
Xience's Peak-to-Valley 3-link design has greater longitudinal strength than Peak-to-Peak 2-link designs, without sacrificing deliverability or SB access

LONGITUDINAL COMPRESSION BY 50 GRAM APPLIED LOAD<sup>2</sup>

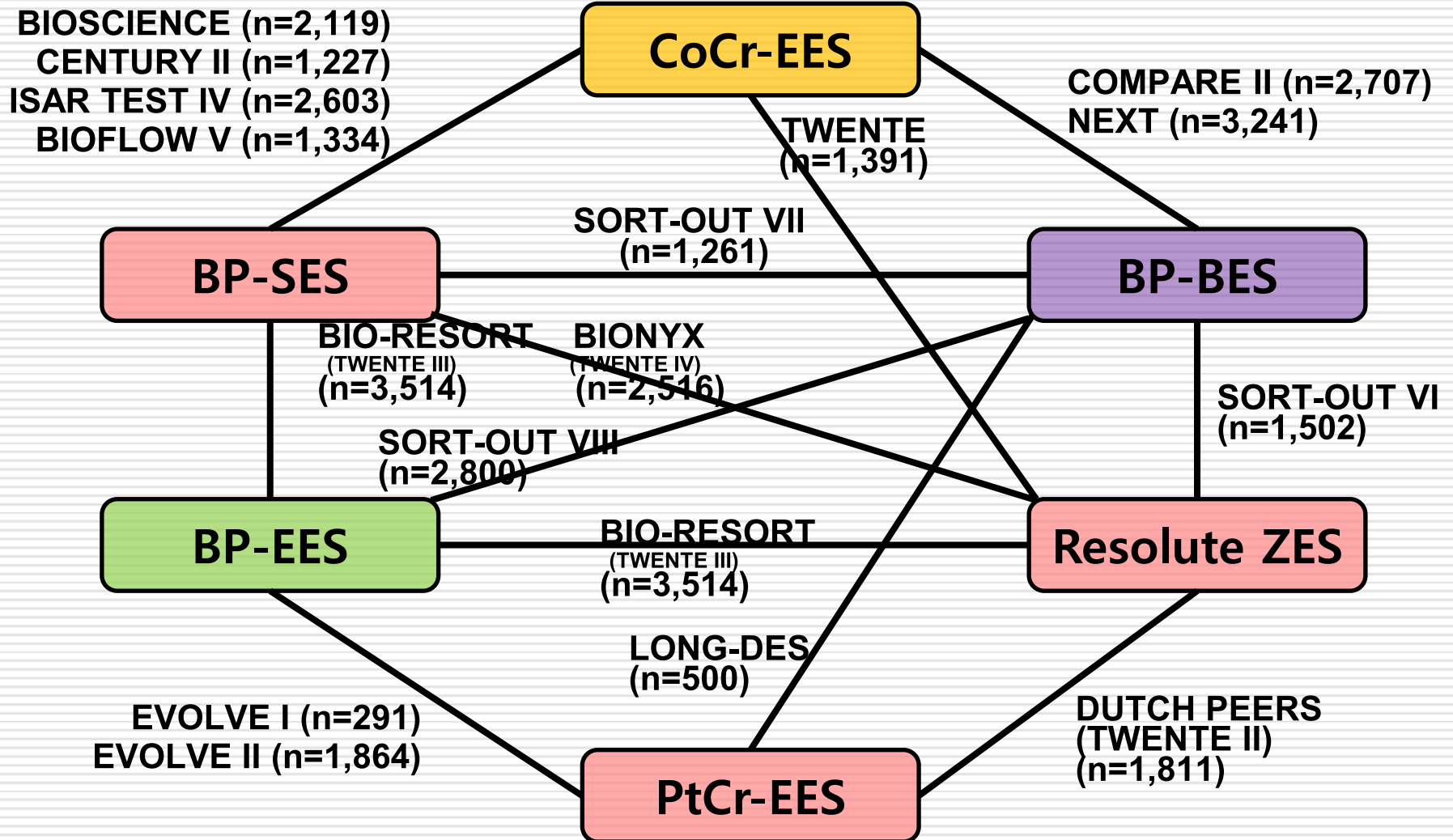


# RCT with New Generation DES

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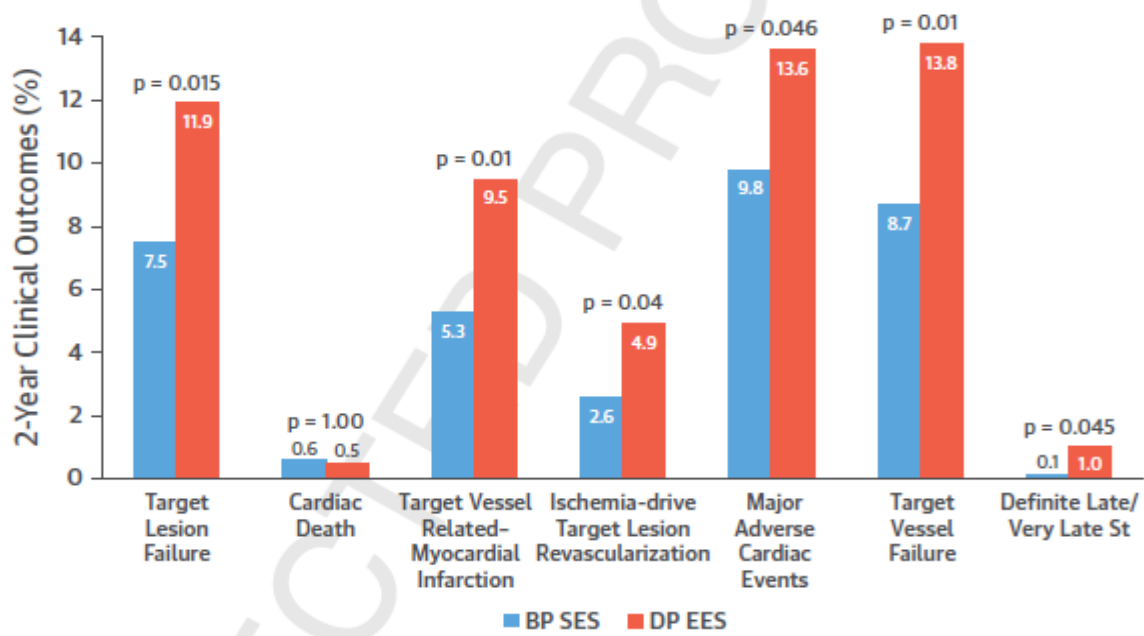
# New Generation DP vs. BP DES



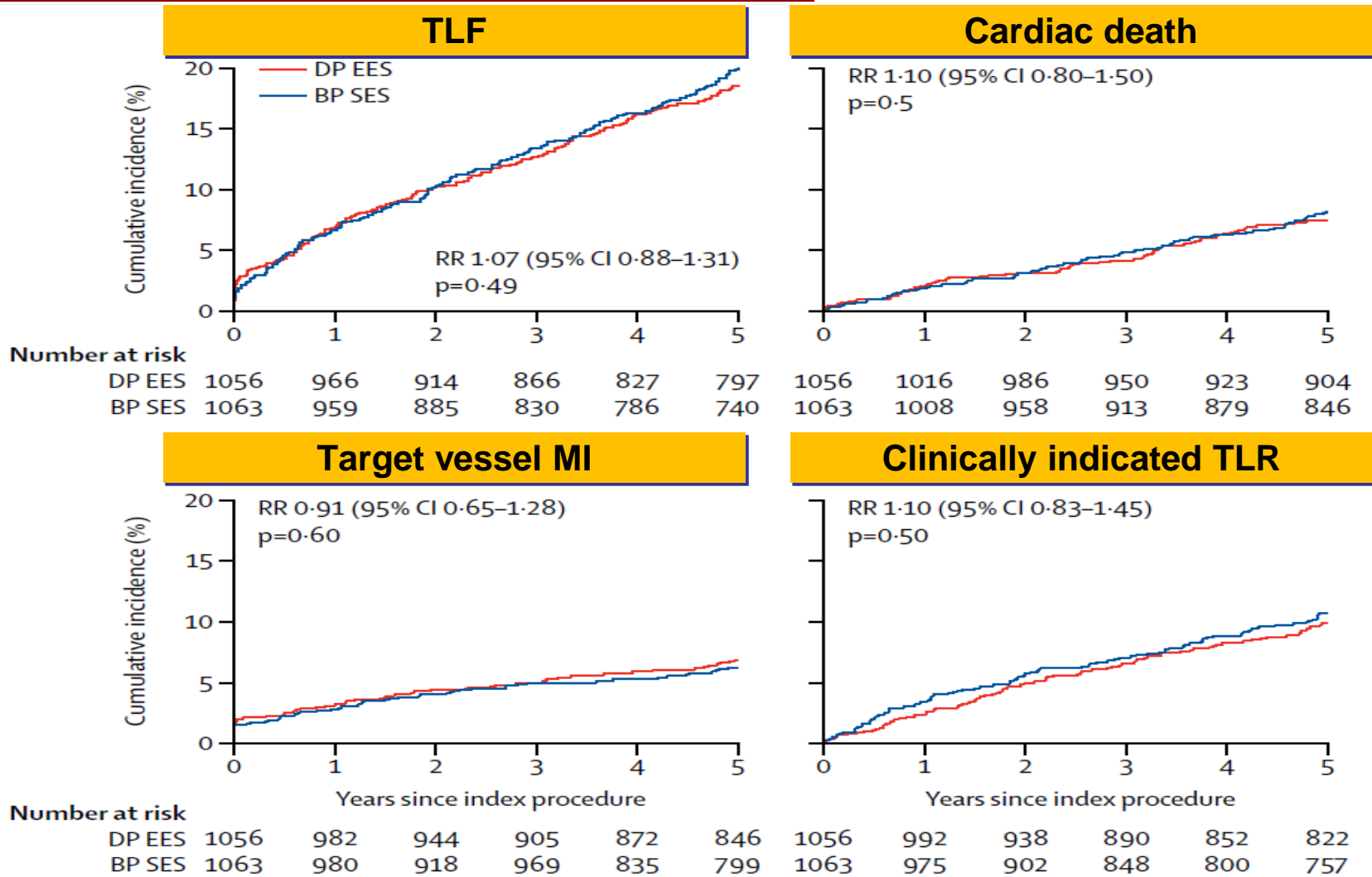
# BIOFLOW V 2-Year Results (DP EES [Xience<sup>®</sup>] vs. BP SES[Orsiro<sup>®</sup>])

Patients With Coronary Artery Disease That Qualify For Percutaneous Coronary Intervention With Stenting (N = 1334 Randomized)

Stent model	Bioresorbable Polymer Sirolimus-Eluting Stents (BP SES) (N = 884)	Durable Polymer Everolimus-Eluting Stents (DP EES) (N = 450)
Stent material <sup>‡§</sup>	L-605 Cobalt-Chromium	L-605 Cobalt-Chromium
Antiproliferative drug <sup>  </sup>	Sirolimus (1.4 $\mu\text{g}/\text{mm}^2$ ), >80% eluted in first 90 days	Everolimus (100 $\mu\text{g}/\text{cm}^2$ ), 100% drug release within 4 months



# BIOSCIENCE 5-Year Outcomes (DP EES [Xience®] vs. BP SES[Orsiro®])





# DP EES vs. BP SES

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- **BIOFLOW V<sup>1</sup>**  
(higher TLF with Xience than Orsiro at 2 year FU)
- **BIOSCIENCE<sup>2</sup>**  
(Similar TLF with Xience and Orsiro at 5 year FU)
- **CENTURY II<sup>3</sup>**  
(Similar TLF with Xience and Ultimaster at 5 year FU)
- **ISAR-TEST 4<sup>4</sup>**  
(Similar MACE with Xience/Yukon Choice PC at 10 year FU)

# DP EES vs. BP BES or Resolute ZES

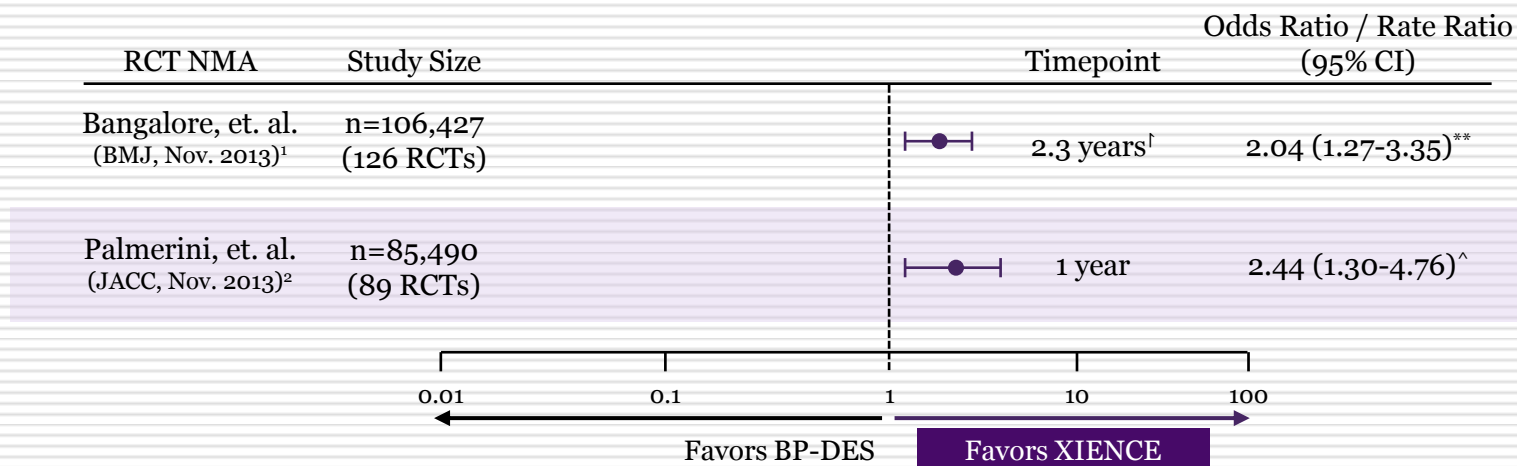
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- **COMPARE II<sup>1</sup>**  
(Nobori is equivalent in TLF and ST compared to the Xience at 5 year FU)
- **NEXT<sup>2</sup>**  
(Nobori is equivalent in safety and efficacy outcomes compared to the Xience/Promus at 5 year FU)
- **TWENTE<sup>3</sup>**  
(Similar safety and efficacy outcomes of Resolute and Xience at 5 year FU)

# Xience Is Safer Than BP-DES with Lower Definite Stent Thrombosis

## RCT Network Meta-Analysis

### ARC DEFINITE STENT THROMBOSIS: XIENCE VS. BIODEGRADABLE POLYMER DES



Bangalore analysis includes Synergy™, Orsiro, BioMatrix Flex™, and Nobori®  
 Palmerini analysis includes Nobori®, Biomatrix™, and BioMatrix Flex™

# Xience Products

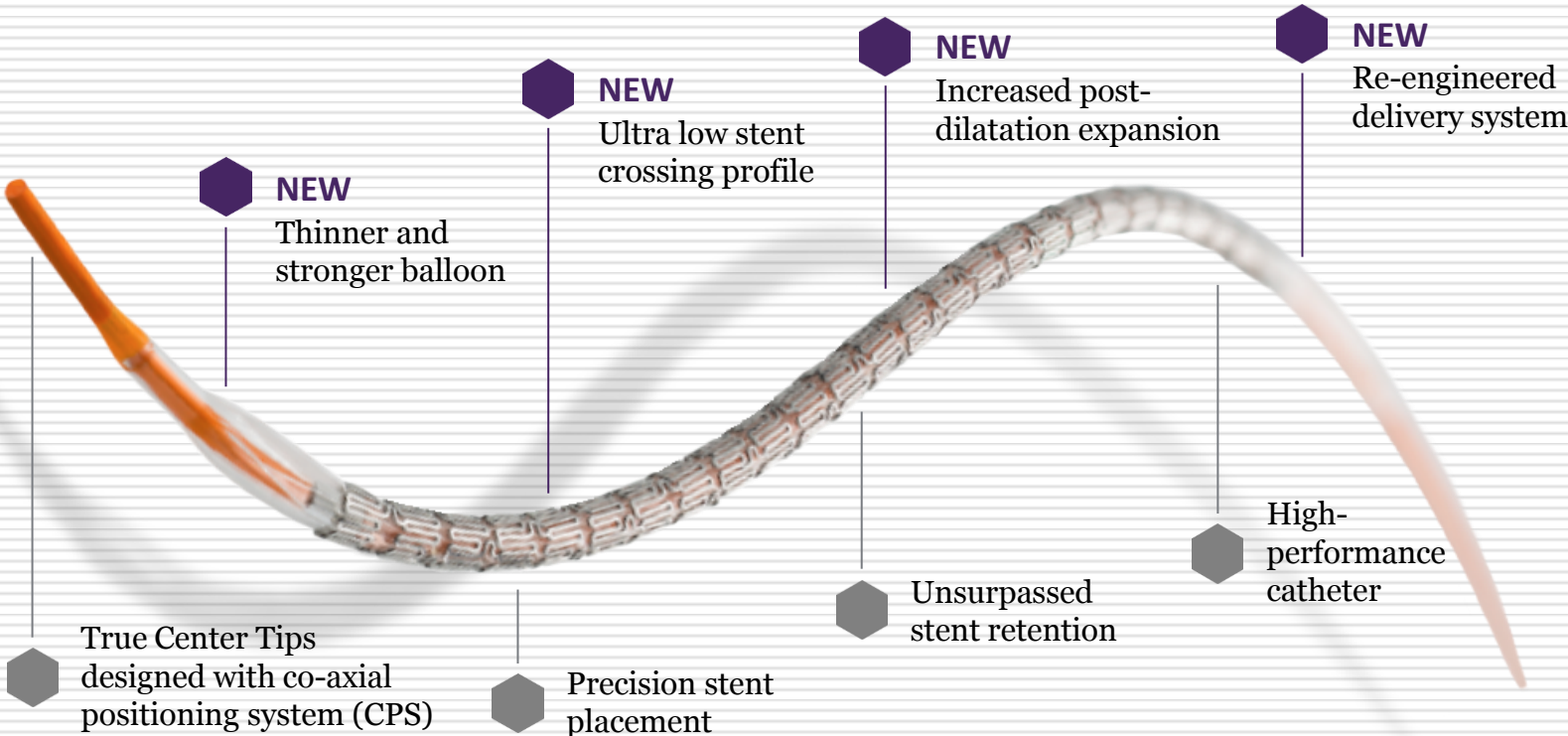
	Catheter Technology	Balloon	Stent Design and Material	Drug/Dose	Coating
<b>XIENCE V</b>	MULTI-LINK VISION Catheter	Single-Layer Balloon	MULTI-LINK VISION Cobalt Chromium	Everolimus 88 µg <sup>1</sup>	Biocompatible Coating Technology
<b>XIENCE PRIME</b>	XIENCE PRIME Catheter	Single-Layer Balloon	MULTI-LINK 8 Cobalt Chromium	↓	↓
<b>XIENCE Xpedition</b>	XIENCE Xpedition Catheter	Thin, Multi-Layer Balloon	↓		
<b>XIENCE Alpine</b>	<b>NEW!</b> Peak Performance in Complex Lesions	↓	↓		

# Xience Sierra

BEST-IN-CLASS  
DELIVERABILITY<sup>1</sup>

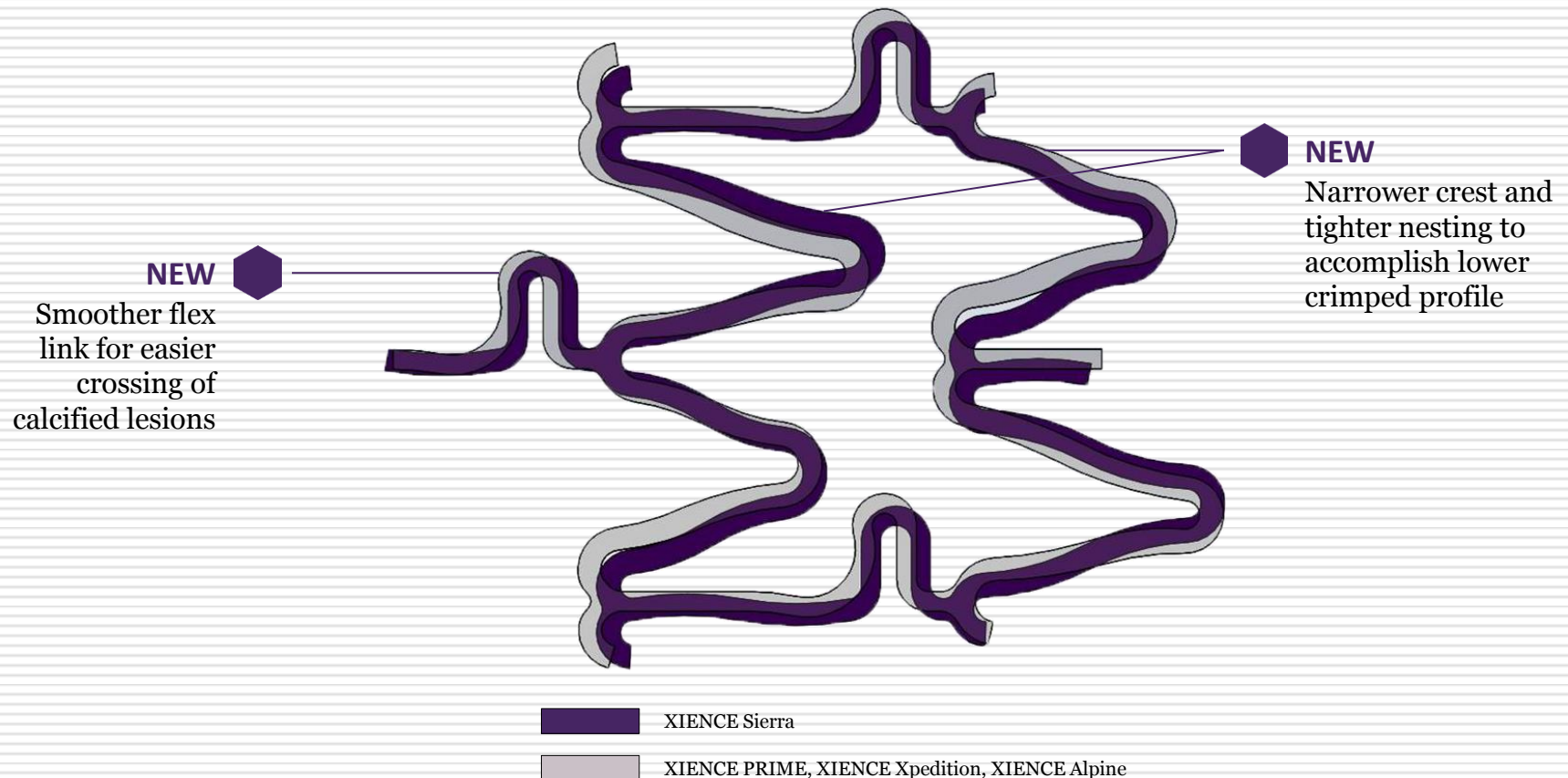
EXPANDED TREATMENT  
OPTIONS<sup>2</sup>

UNPARALLELED SAFETY<sup>3</sup>



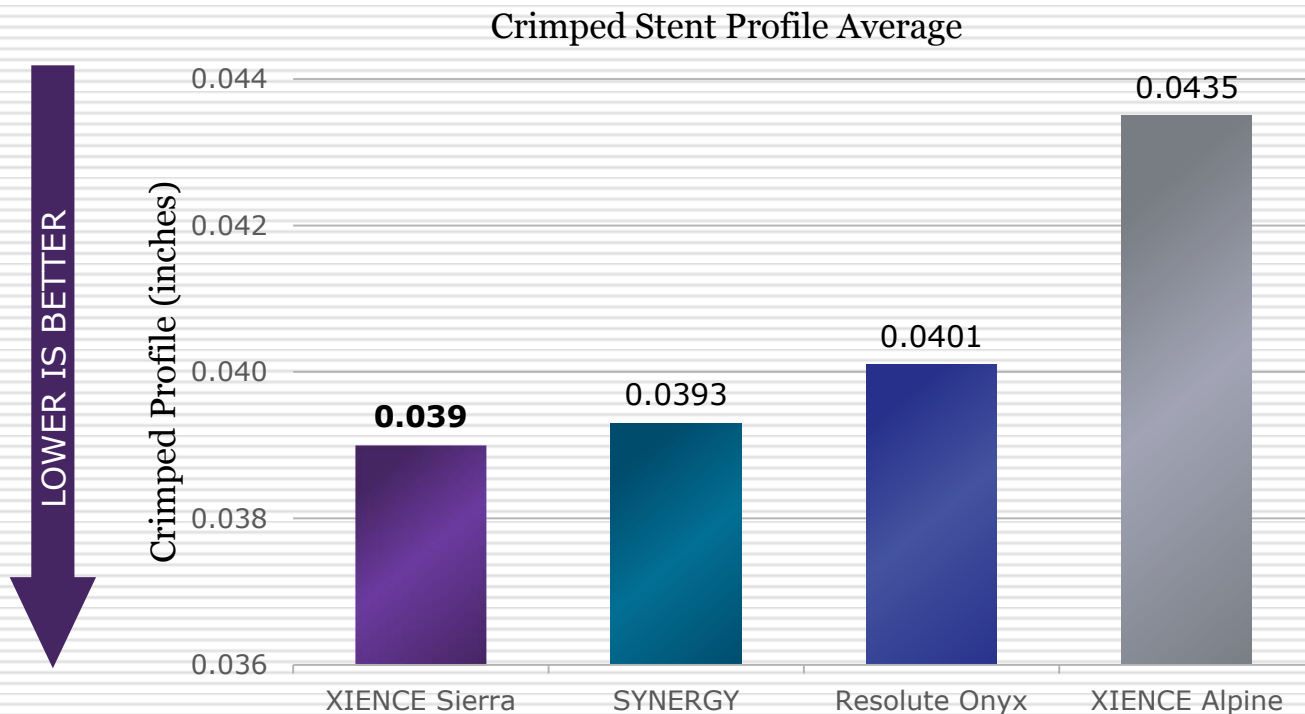
# Enhanced Stent Design Changes Significantly Reduced Crimped Profile for Exceptional Crossing

Small Stent 2.0, 2.25, 2.5, 2.75, 3.0, 3.25 mm  
6-Crest Design



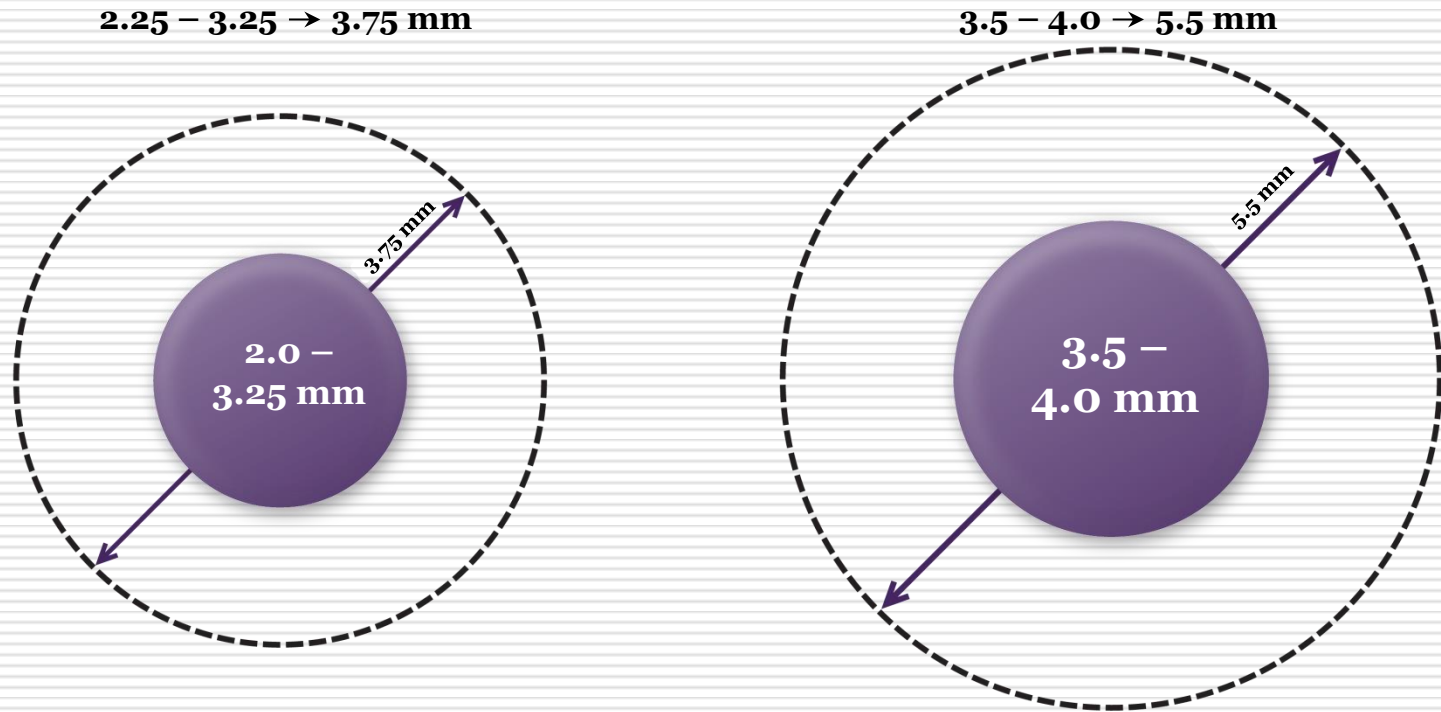
# Ultra Low Stent Crimped Profile of 0.0390" for Crossing Tight Lesions Enabled by The New Stent Design and Balloon Technology

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# Enhanced Stent Design Allows for Post-Dilatation up to 5.5 mm

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# Summary

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- **Across RCTs, meta-analysis and observation studies, the DP-EES (Xience) is the stent which has received the most extensive investigation ever.**
- **Evidence suggests that the Xience stent significantly reduces stent thrombosis not only compared to first generation DES and BMS, but even BP-BES.**
- **With improved safety of the previous version of Xience stent, Xience Sierra might provide enhanced procedural success and outcomes through several technical improvements.**