

# The Future of Xience and the Abbott Vascular DES Pipeline

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## Optimal Balance of Stent Performance and Safety

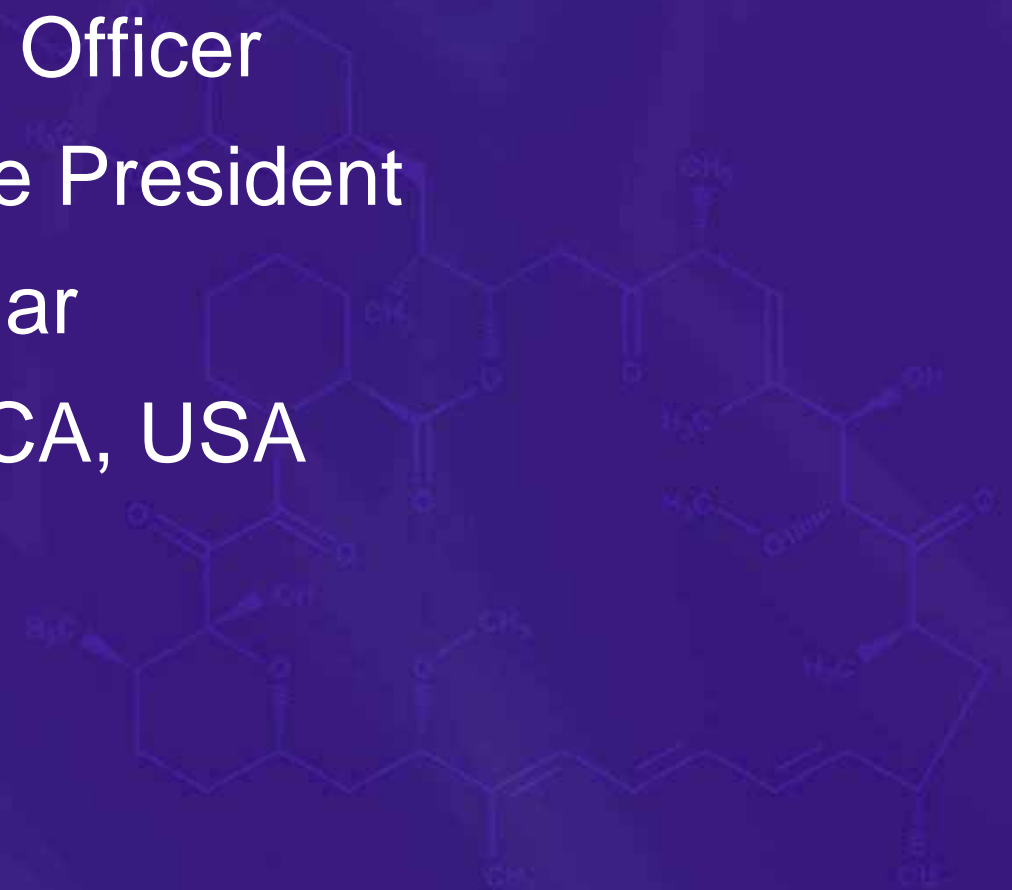
Chuck Simonton MD, FACC, FSCAI  
Chief Medical Officer  
Abbott Vascular  
Santa Clara, CA  
USA

Angioplasty Summit  
TCT-AP  
Seoul, Korea 2013

# Disclosures

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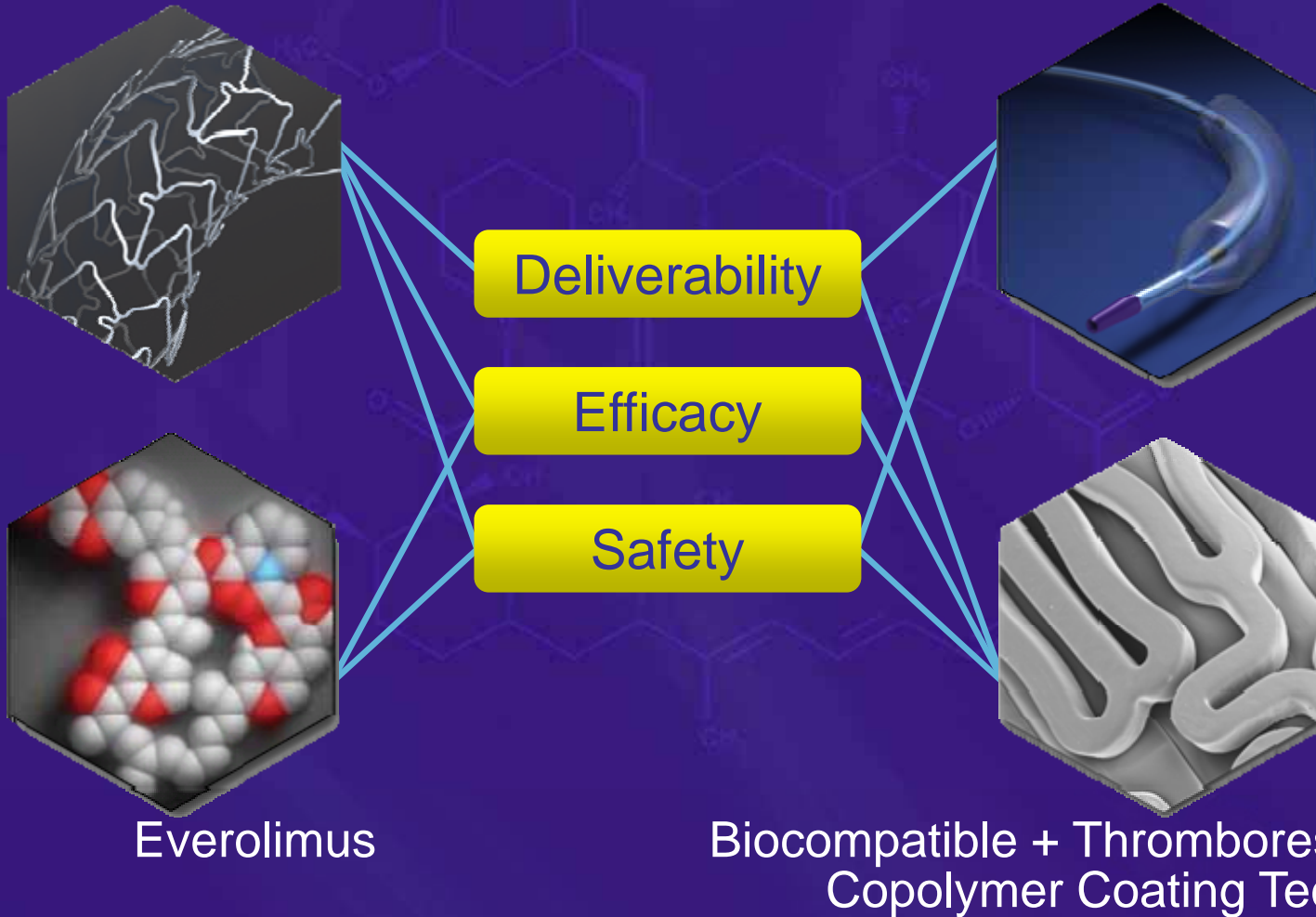
Chief Medical Officer  
Divisional Vice President  
Abbott Vascular  
Santa Clara, CA, USA



# XIENCE V<sup>®</sup> Components: Importance of Design

MULTI-LINK VISION Stent Design

Stent Delivery System



Everolimus

Biocompatible + Thromboresistant Fluoro-Copolymer Coating Technology

Indications: The XIENCE Family of Everolimus Eluting Coronary Stent Systems are indicated for improving coronary luminal diameter in patients with symptomatic heart disease due to *de novo* native coronary artery lesions (XIENCE V and XIENCE nano length  $\leq$  28 mm and XIENCE PRIME and XIENCE PRIME LL length  $\leq$  32 mm) with reference vessel diameters of 2.25 mm to 4.25mm

# Scaffolding Overview & Design Characteristics

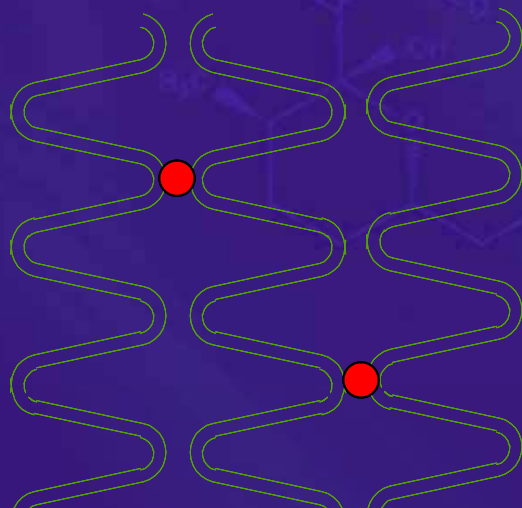
## Stent Scaffolding:

- Provides sound structural support
- Prevent prolapse and secures dissections
- Promote optimal apposition to vessel wall

## Links per Ring:

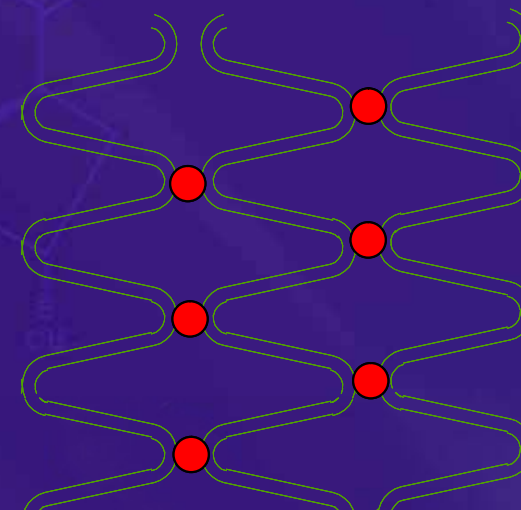
### Fewer

- More Flexible
- Less Scaffolding



### More

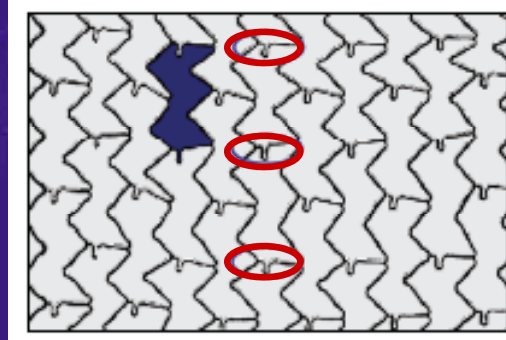
- Less Flexible
- More Scaffolding



# Scaffolding: Optimal with Xience / Prime

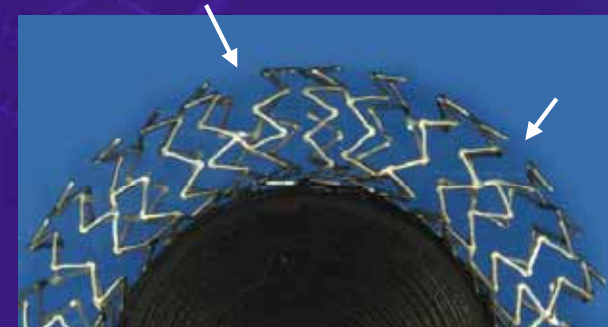
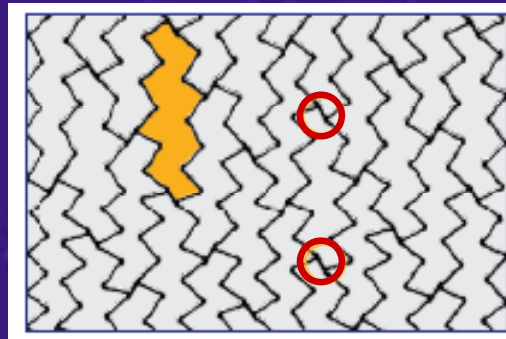
## Xience™ platform

- Peak to valley
- Long links
- 3 links per ring



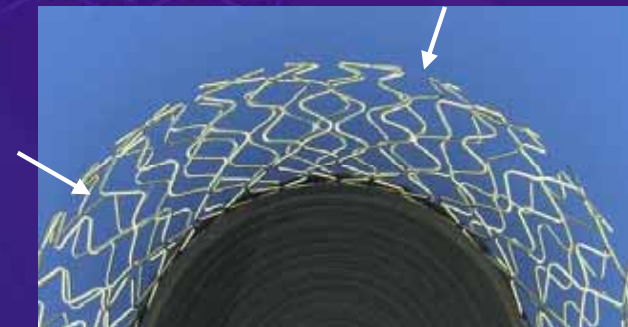
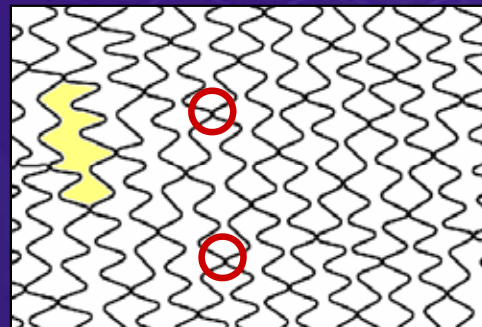
## Element™ platform

- Off-set peak to peak
- Short connectors
- 2 per ring



## Integrity™ platform

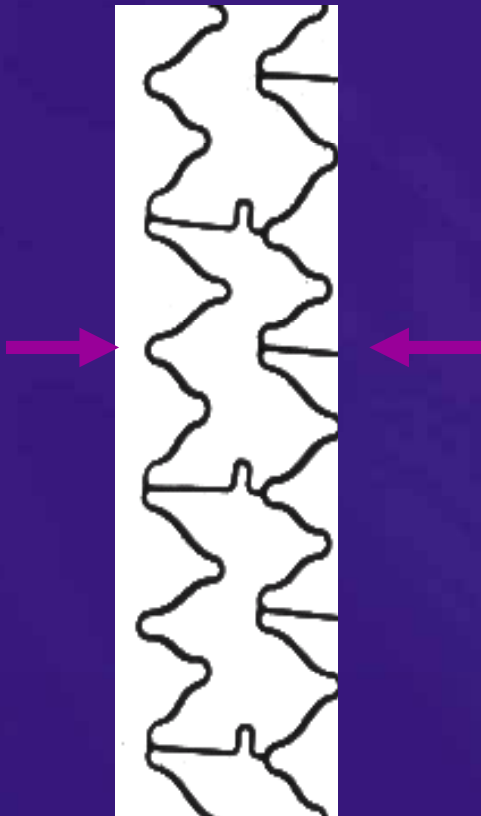
- Peak to peak
- Welds
- Every 4<sup>th</sup> crest



# Longitudinal Stability: Compression

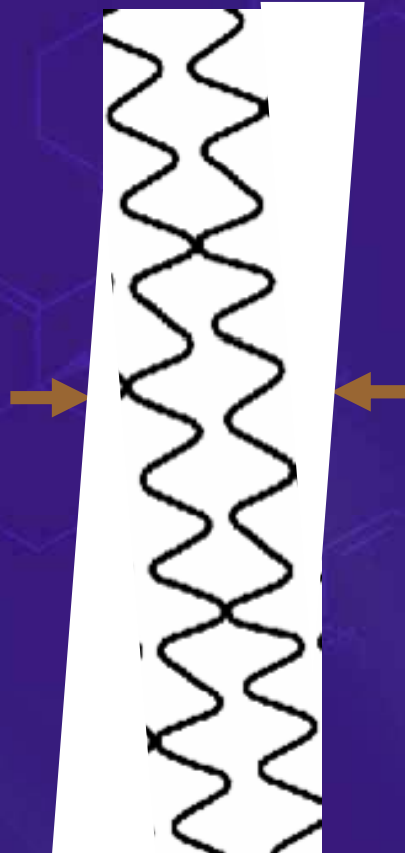
**Xience™ platform**

**Peak-to-Valley**  
3 Long Links



**Integrity™ platform**

**Peak-to-peak**  
2 & 3 Welds



**Element™ platform**

**Offset Peak-to-peak**  
2 Short Connectors



**Most Vulnerable  
to Compression**

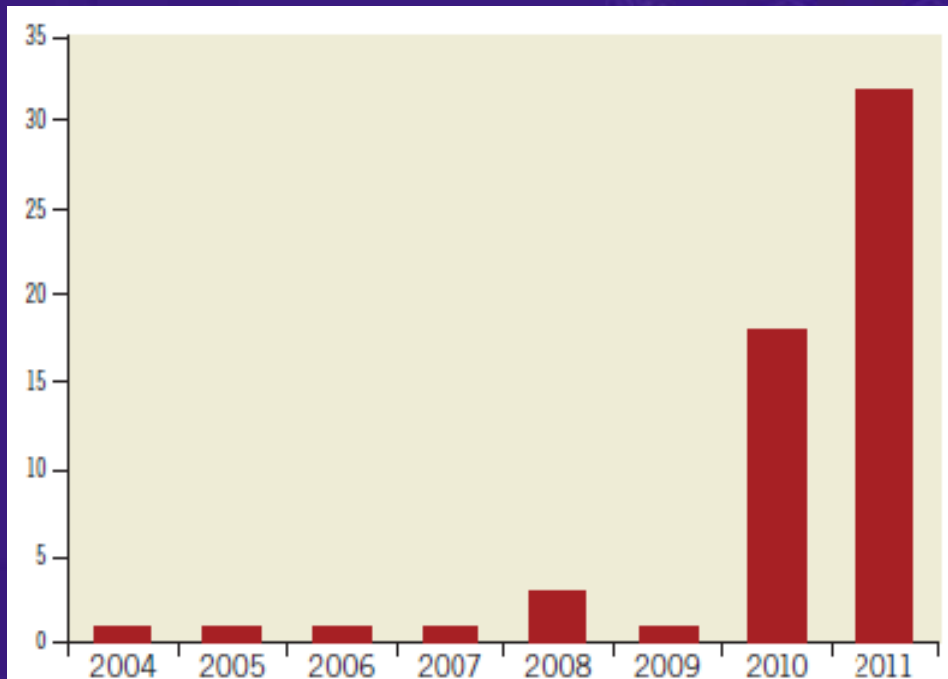
# Longitudinal stent deformation: insights on mechanisms, treatments and outcomes from the Food and Drug Administration Manufacturer and User Facility Device Experience database

Mamas A. Mamas<sup>1,2\*</sup>, MA, DPhil, BM, BCh; Paul D. Williams<sup>1</sup>, MA, BM, BCh, MD

*1. Manchester Heart Centre, Manchester Royal Infirmary, Manchester, United Kingdom; 2. Manchester Academic Health Science Centre, University of Manchester, Manchester, United Kingdom*

Mamas et al, Eurointervention March 2012

# Rise in Longitudinal Case Complication Reports



**Figure 2.** Number of cases of longitudinal stent deformation submitted to MAUDE website according to year.

**Table 1.** Number of longitudinal stent deformation cases found on the MAUDE database according to stent platform.

Stent platform	Stent type	Number of cases (%)
Element (Boston Scientific)	Promus Element	34 (59.6%)
	Ion/TAXUS Element	8 (14.0%)
	Omega	3 (5.3%)
	Total	45 (78.9%)
Driver (Medtronic)	Endeavor	3 (5.3%)
	Driver	1 (1.8%)
	MicroDriver	1 (1.8%)
	Total	5 (8.9%)
CYPHER (Cordis)	CYPHER	3 (5.3%)
Nobori (Terumo)	Nobori	1 (1.8%)
Liberté (Boston Scientific)	TAXUS Liberté	1 (1.8%)
Multi-link Vision (Abbott Vascular)	XIENCE V	1 (1.8%)
Unidentified		1 (1.8%)

Mamas et al, Eurointervention March 2012



# Xience Stent Design Summary

## Multi-Link Geometry Advantages

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**Excellent Deliverability**

**Without Sacrificing:**

**Scaffolding**

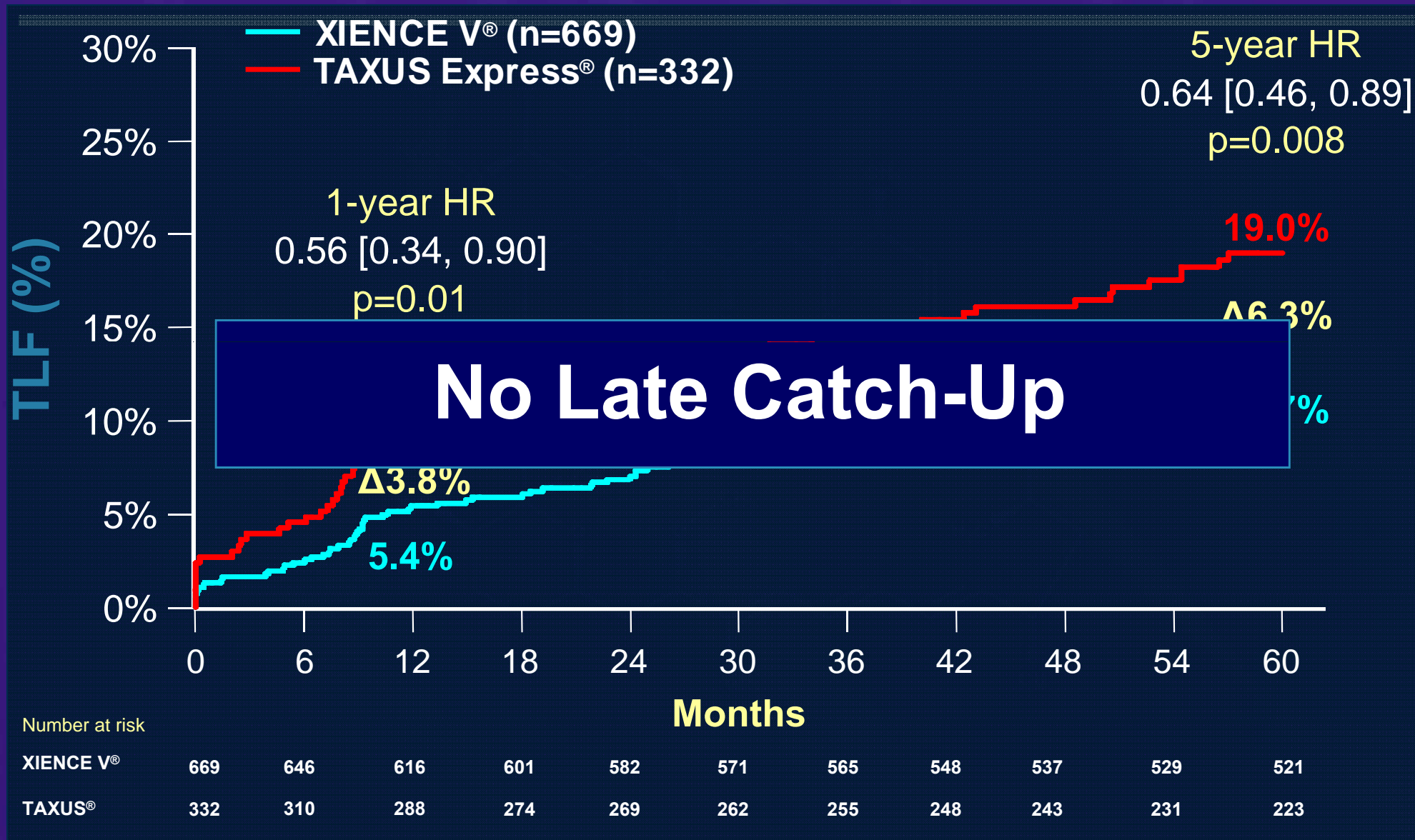
**Longitudinal Strength**

# XIENCE® : Growing Body of Data: Over 40,000 Pts

Follow-Up: Trial	1-Year Purpose	2-Year	3-Year	4-Year	5-Year
Abbott-Sponsored Trials					
SPIRIT FIRST n = 60	Safety & Performance				
SPIRIT II n = 300	Clinical Support for CE Launch				ACC-11
SPIRIT III n = 1,002	U.S. & Japan Approval				TCT-11
SPIRIT IV n = 3,690	U.S. Peri-Approval		TCT-11		
SPIRIT V n = 2,663	Post CE-Mark Continued Follow-up				
XIENCE V USA n = 5,054 + 3000	Real World Registry	TCT-11			
SPIRIT WOMAN n = 1,572	Real World Single Arm Study	TCT-11			
SPIRIT PRIME Registry	TCT-11				

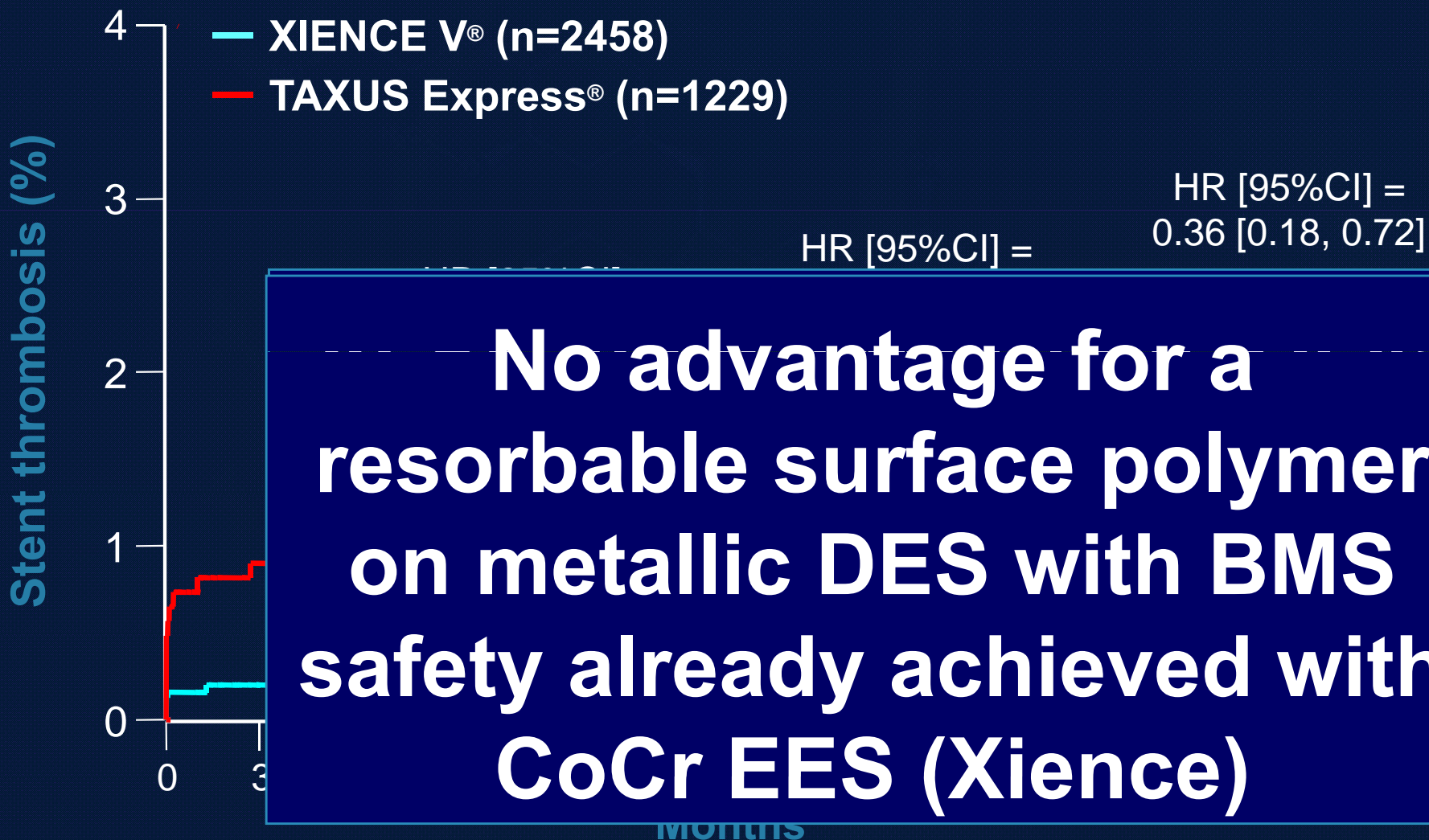
■ New 2011 Data

# SPIRIT III: Target Lesion Failure at 5 Yrs



# SPIRIT IV

## Stent Thrombosis (ARC Def or Prob)



Number at risk

XIENCE V®	2458	2427	2413	2387	2358	2331	2319	2311	2296	2272	2263	2254	2242
TAXUS®	1229	1196	1186	1175	1157	1137	1131	1127	1115	1106	1098	1086	1073

# euro PCR 2011

## Impact of the Everolimus-Eluting Drug Eluting Stent on Stent Thrombosis: A Meta-Analysis of 13 Randomized Trials involving 17,074 Patients

*Usman Baber<sup>a</sup> MD MS, Roxana Mehran<sup>a</sup> MD, Samin K. Sharma<sup>a</sup> MD, Somjot Brar<sup>b</sup> MD MPH, Jennifer Yu<sup>a</sup> MD, Jung-Won Suh<sup>d</sup>, Hyo-Soo Kim<sup>d</sup> MD, Seung-Jung Park<sup>e</sup> MD PhD, Antoinette de Waha MD<sup>f</sup>, Prakash Krishnan<sup>a</sup> MD, Pedro Moreno<sup>a</sup> MD, Joseph Sweeny<sup>a</sup> MD, Michael C. Kim<sup>a</sup> MD, Javed Suleman<sup>a</sup> MD, Robert Pyo<sup>a</sup> MD, Jose Wiley<sup>a</sup> MD, Jason Kovacic<sup>a</sup> MD PhD, Annapoorna S. Kini<sup>a</sup> MD, George D. Dangas<sup>a</sup> MD PhD*

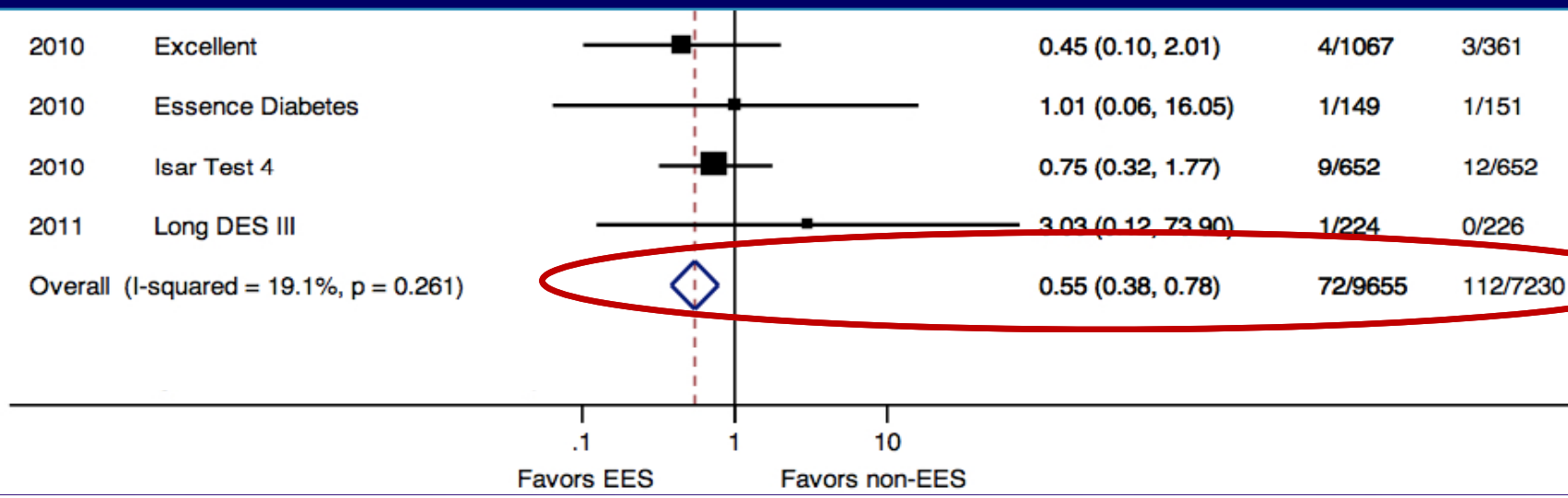
<sup>a</sup>Mount Sinai Medical Center, New York, NY <sup>b</sup>Kaiser Permanente, Pasadena, CA <sup>c</sup>Cardiovascular Research Foundation, New York, NY <sup>d</sup>Seoul National University Hospital, Seoul, Korea <sup>e</sup>Asan Medical Center, Seoul, Korea <sup>f</sup>Deutsches Herzzentrum, Technische Universität, Munich, Germany

# Stent Thrombosis

## Xience/Promus EES in RCT's

YEAR	STUDY	RR (95% CI)	Events, EES	Events, non-EES
2010	Resolute All Comers	0.52 (0.25, 1.07)	11/1152	21/1140
2010	Spirit IV	0.33 (0.15, 0.74)	10/2458	15/1229

**45% Relative Risk Reduction of ARC Definite/Probable Stent Thrombosis**



# Large Body of XIENCE DAPT Data

More than 13,000 Patients Out to 2 Years



**ACC 2012**  
**SPIRIT-  
COMPARE**  
Dr. Elvin Kedhi

**PCR 2010**  
**XIENCE V USA:  
DAPT Analysis**  
Dr. James Hermiller

**PCR 2012**  
**3 Months DAPT  
Analysis**  
Dr. Tullio Palmerini

**TCT 2011**  
**ST & DAPT  
Mega-Meta  
Analysis**  
Dr. Gregg Stone

# XIENCE V USA: Large U.S. Registry with a Highly Complex, Real-World Patient Population

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## XIENCE V USA

- Single-arm registry of **5,054 real-world patients**
- Primary endpoint of ARC Def/Prob stent thrombosis at 1 year

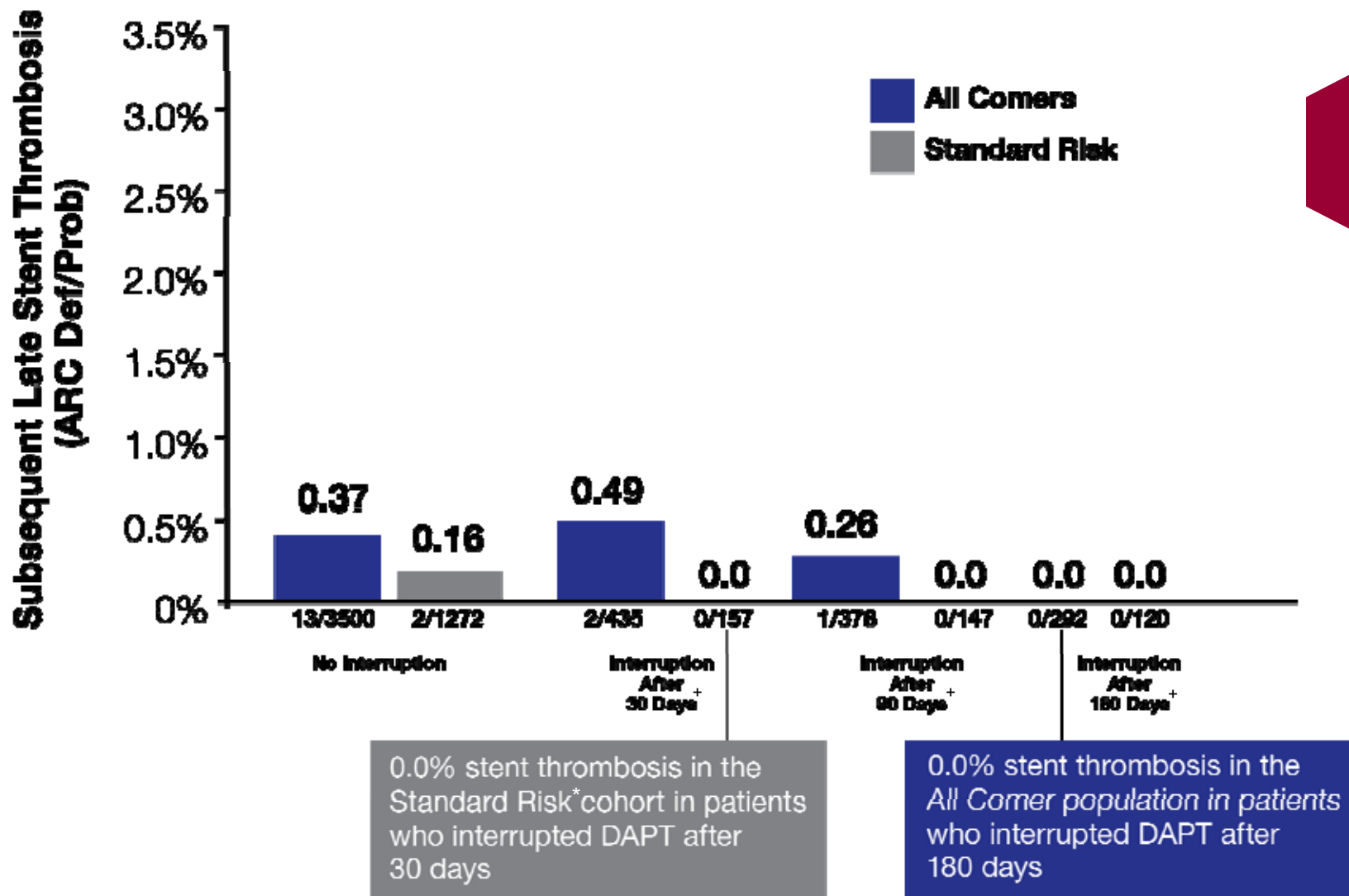
### Patient and Lesion Distribution:

- |                              |                            |
|------------------------------|----------------------------|
| ✓ Left Main: 1.6%            | ✓ CTO Lesions: 2.5%        |
| ✓ AMI: 18.1%                 | ✓ EF <30%: 3.4%            |
| ✓ ACS: 37.5%                 | ✓ Graft Lesions: 4.8%      |
| ✓ Diabetes: 35.6%            | ✓ Restenotic Lesions: 9.5% |
| ✓ Multivessel Disease: 40.8% | ✓ Ostial Lesions: 11.9%    |
| ✓ Multivessel Treated: 13.8% | ✓ Bifurcations: 9.0%       |
| ✓ Renal Insufficiency: 11.1% | ✓ Direct Stenting: 38.7%   |

Source: Derived from J Hermiller, XIENCE V USA 1-Year Results, PCR 2010.



# XIENCE V USA: 0% Stent Thrombosis with DAPT Interruption After 6 Months



Data Published in JACC Dec 2011


\*Standard Risk patients in XIENCE V USA are those patients treated per labeling for XIENCE V in the U.S.

<sup>+</sup> Out to 1-year. Source: Derived from Hermiller, J. PCR 2010.

# DES Pipeline from Abbott Vascular

## Continuing to Innovate

### The Next Generations of DES

	<b>XIENCE PRIME®</b>	<b>†XIENCE® Side-Branch Access</b>	<b>†Thinman DES</b>	<b>†4<sup>th</sup> Revolution ABSORB™</b>
	<b>XIENCE XPEDITION®</b> <b>CE 2012 US 2013</b>			
<b>E.U. 2006</b> <b>U.S. 2008</b>	<b>E.U. 2009</b> <b>U.S. 2011</b>	<b>2012+</b>	<b>2014+</b>	<b>CE 2011</b> <b>U.S. 2015</b>

†Pipeline products currently in development. Not available for sale.

# XIENCE Xpedition: Most Agile Xience

*Designed to DELIVER*






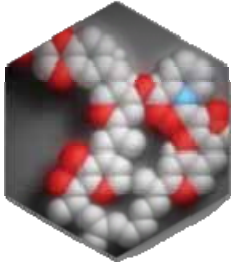

•The most agile XIENCE. Ever.

**Coming Soon!**  
**Pending CE Mark**

Pipeline product currently in development at Abbott Vascular. Not available for sale.

# XIENCE Xpedition

*Designed for improved acute performance*

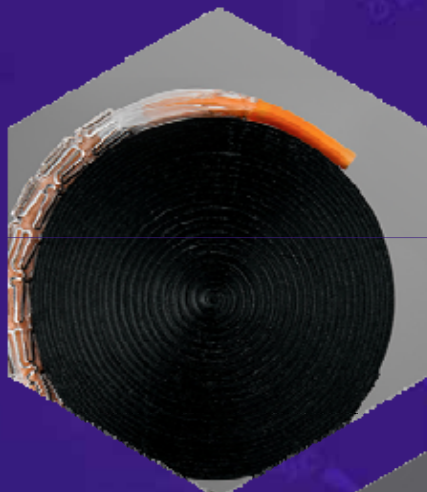
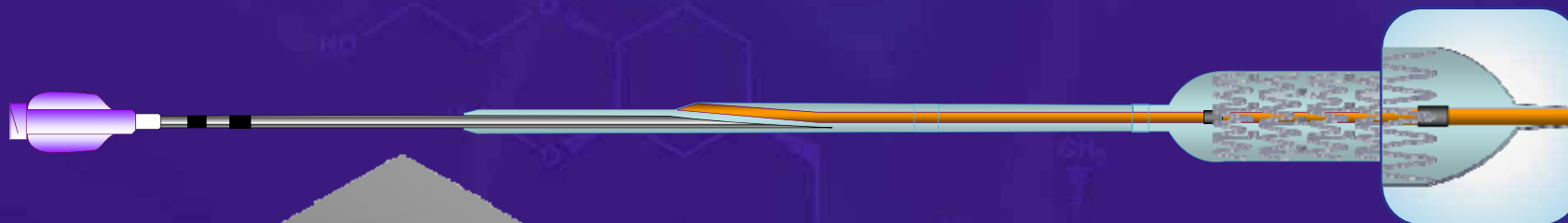
	 <b>Delivery System</b>	 <b>Balloon</b>	 <b>Stent Design and Material</b>	 <b>Drug/Dose</b>	 <b>Polymer</b>
<b>XIENCE PRIME</b>	XIENCE PRIME Delivery System	Single-Layer Balloon	MULTI-LINK 8 Cobalt Chromium	Everolimus 88 µg	Biocompatible Coating Technology
<b>XIENCE Xpedition</b>	<b>NEW!</b> Smooth Transitions Delivery Optimized for Acute Performance	<b>NEW!</b> Multi-Layer Balloon for flatter	↓	↓	↓

Pipeline product currently in development at Abbott Vascular. Not available for sale.

**Coming Soon! Pending CE Mark**

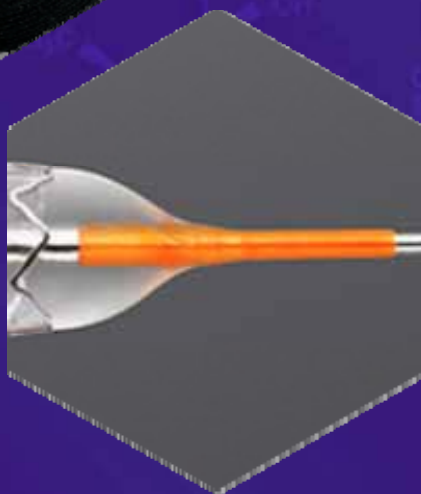
# XIENCE Xpedition

Designed to be **TRACKABLE**



## Integrated Tip

- Smooth tracking around sharp bends in tortuous anatomy



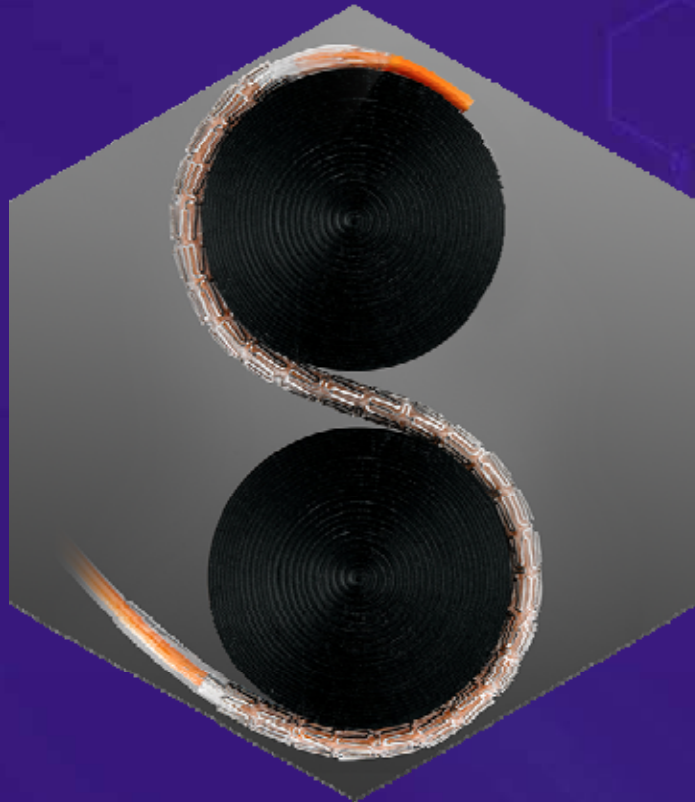
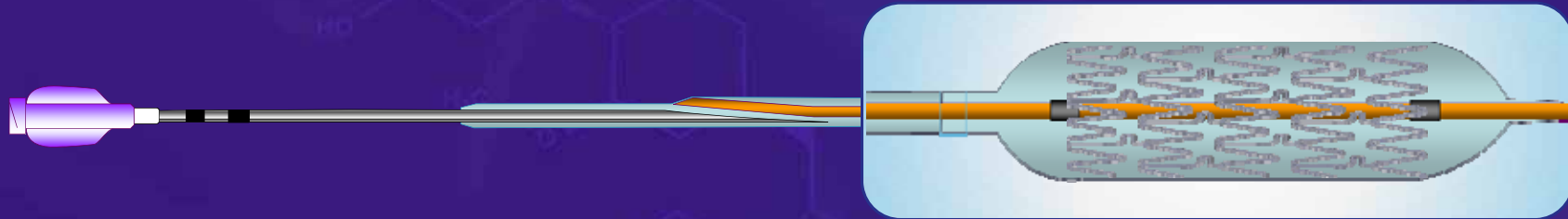
## Slim Seal Technology

- Flexible, ultra low distal seal profile for outstanding crossability

Pipeline product currently in development at Abbott Vascular. Not available for sale.

# XIENCE Xpedition

Designed to be **FLEXIBLE**



## More Flexible Balloon with Flatter Compliance

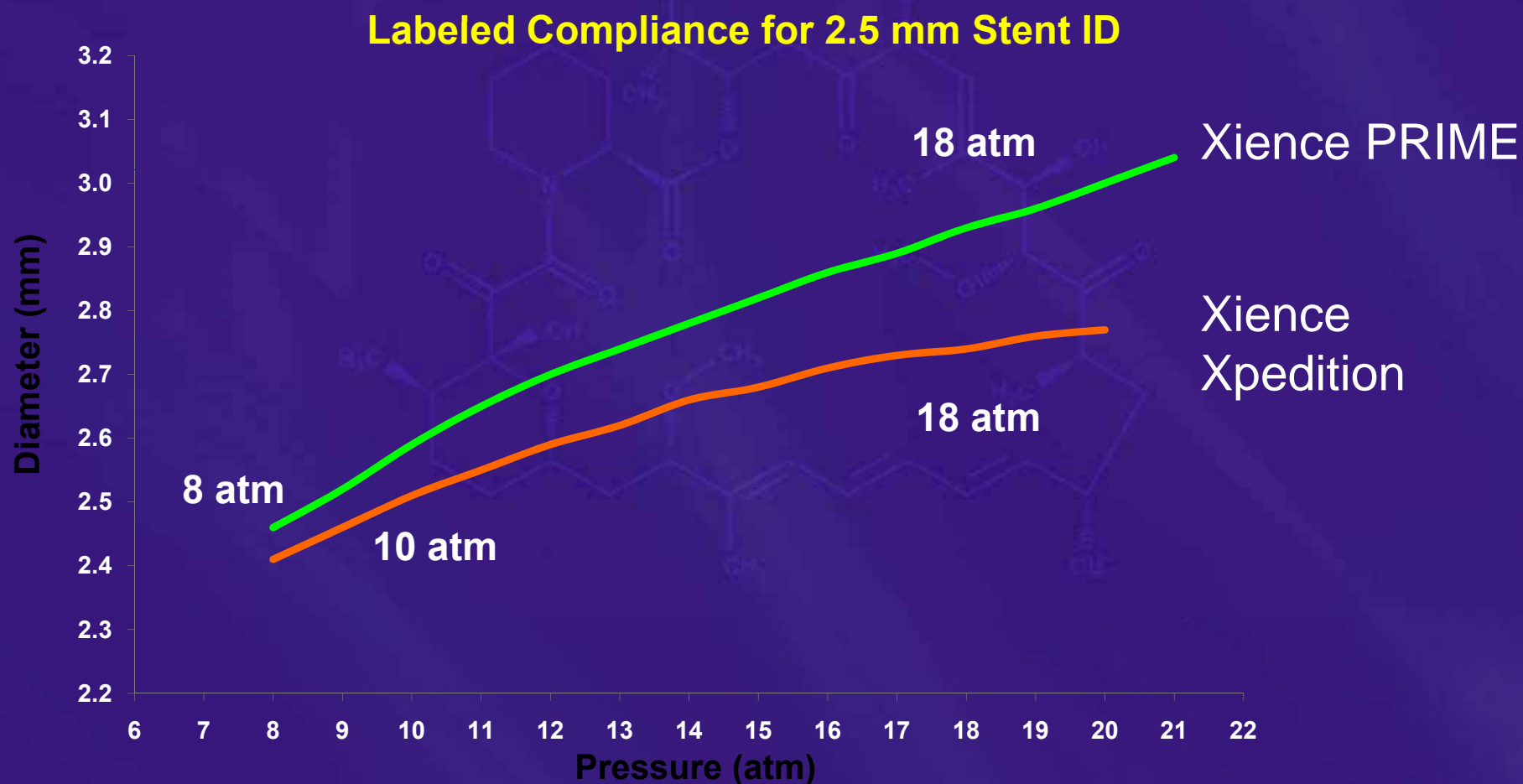
- Thin, multi-layered balloon walls for superb deliverability
- Taper optimized for balloon refold

Pipeline product currently in development at Abbott Vascular. Not available for sale.

# Xience Xpedition

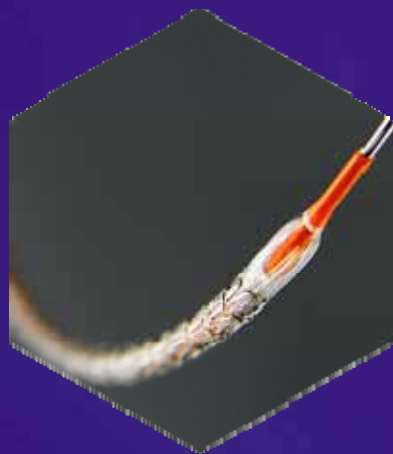
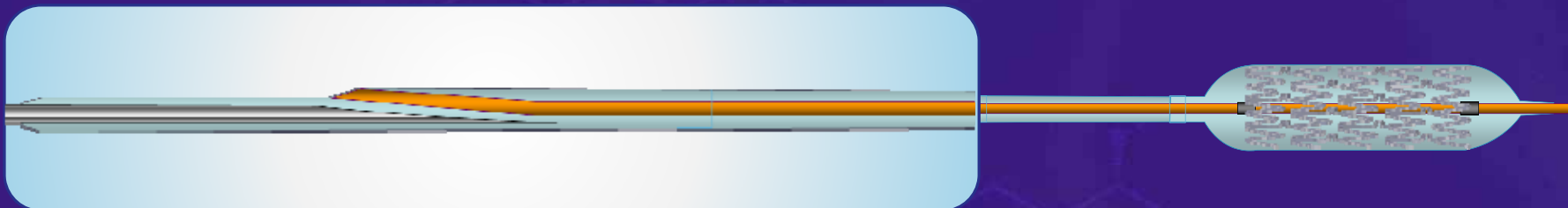
## Flatter Balloon Compliance

Flatter compliance enables higher pressure deployment for improved stent expansion in complex anatomy



# XIENCE Xpedition

Designed to be **PUSHABLE**



## Fewer and smoother transitions across entire system for more efficient force transfer

- Cross challenging anatomy with less force
- Excellent tactile feedback
- Strong and flexible distal shaft

## Skive Transition for Improved Support

- Smooth transition between hypotube and distal shaft
- Reduced guide wire notch profile

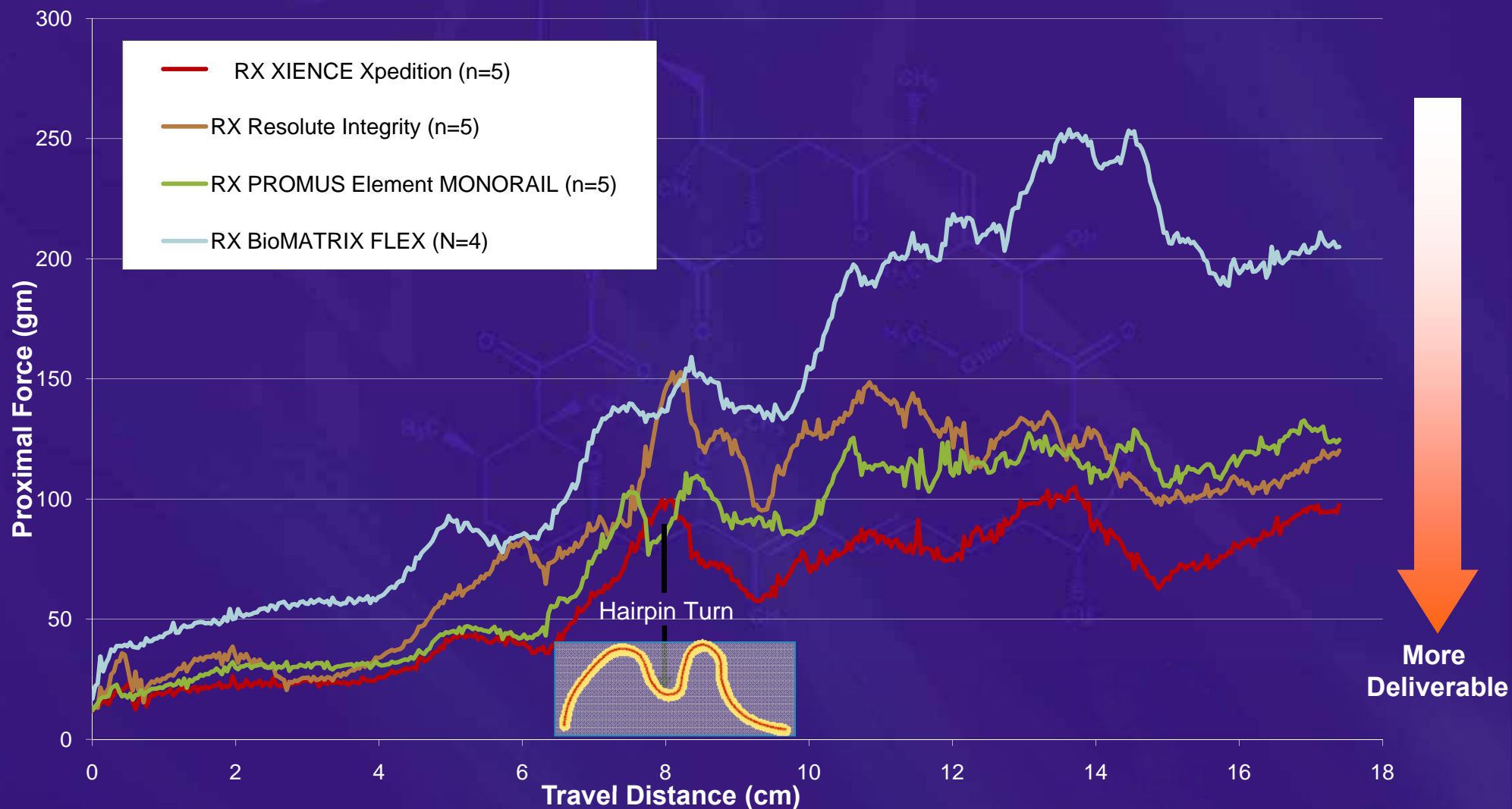
Pipeline product currently in development at Abbott Vascular. Not available for sale.



# Xience Xpedition

## Less Work to Track Through Tortuosity

### Catheter Performance Test



# ABSORB

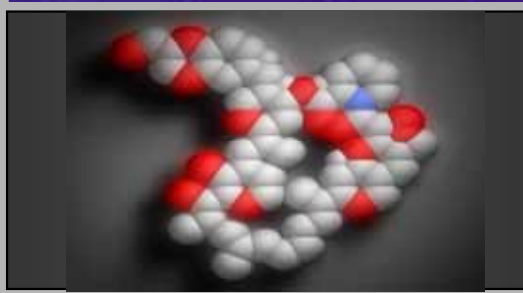
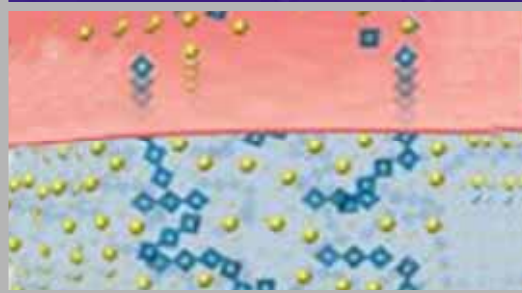
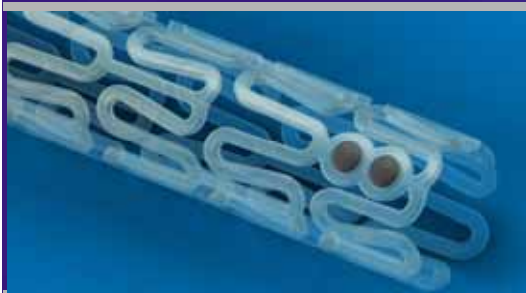
The Fully Bioresorbable Vascular Scaffold

The Fourth Revolution of PCI!



# ABSORB Everolimus-Eluting Bioresorbable Vascular Scaffold Components

Bioresorbable Scaffold	Bioresorbable Coating	Everolimus	XIENCE V Delivery System
<ul style="list-style-type: none"> <li>• Poly(L-lactide) (PLLA)</li> <li>• Naturally resorbed, fully metabolized</li> </ul>	<ul style="list-style-type: none"> <li>• Poly(D,L-lactide) (PDLLA) coating</li> <li>• Naturally resorbed, fully metabolized</li> </ul>	<ul style="list-style-type: none"> <li>• Similar dose density and release rate to XIENCE V</li> </ul>	<ul style="list-style-type: none"> <li>• World-class deliverability</li> </ul>



All illustrations are artists' renditions

# BMS and DES: The Old Rules

## Revascularization

1

- Deliverability
- Enough support to attain max acute gain without injury
  - Conformability
- Good efficacy of drug and tissue dosing profile

## Durable results

2

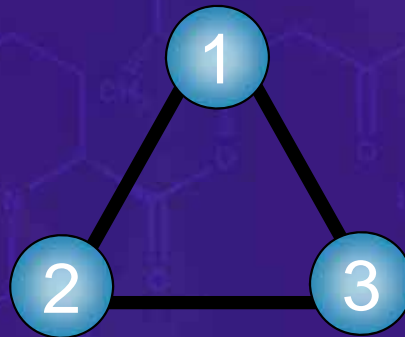
- Biocompatibility
- Thromboresistance or passivation
- Minimal late catch-up after drug is eluted and metabolized
- No fractures that can cause chronic irritation

**For a DES, the goal is the creation and maintenance of acute gain, while hoping for long-term safety.**

# Bioresorbable Vascular Scaffold (BVS): The New Rules



**Revascularization**  
with Transient Support



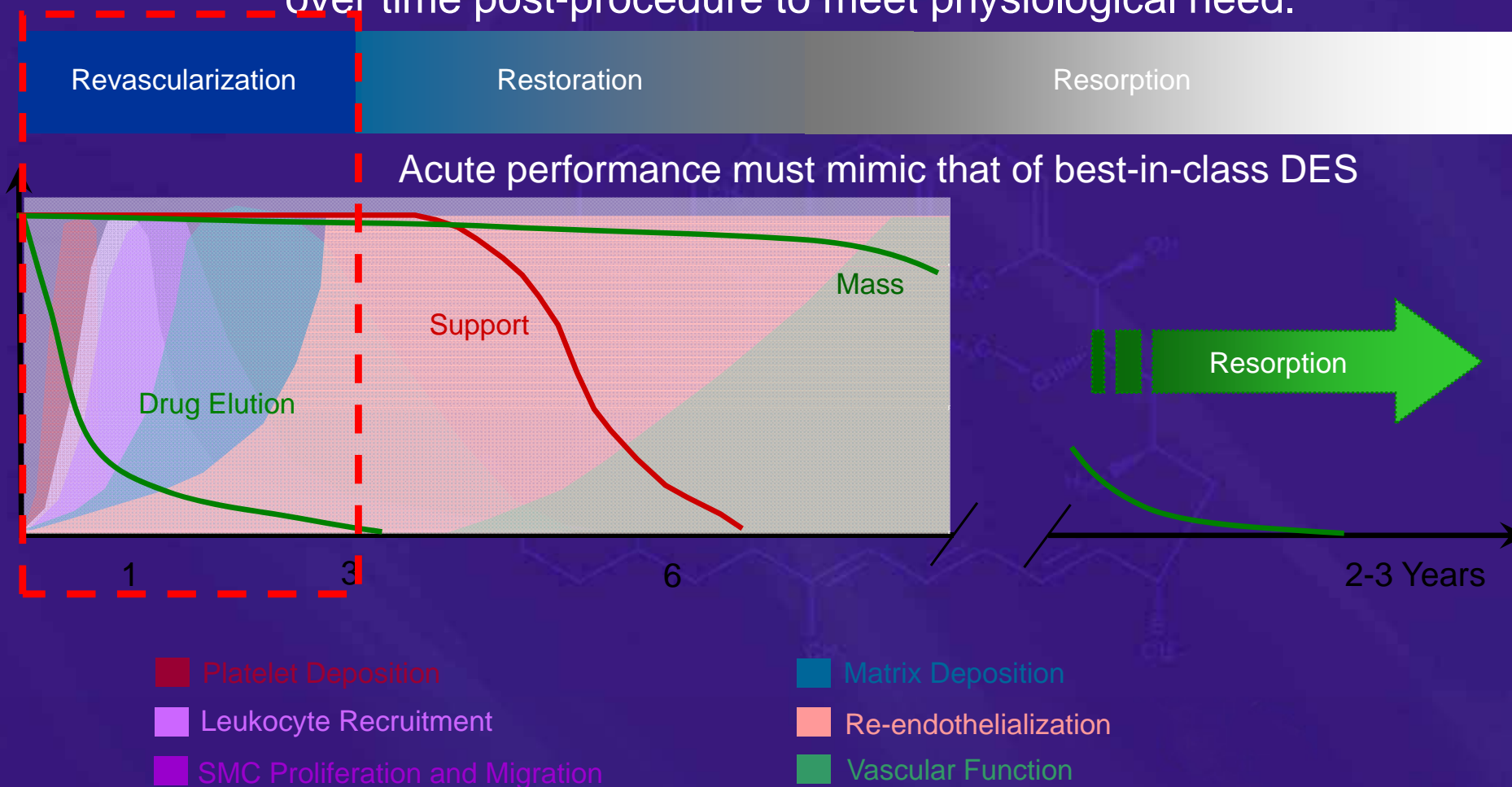
**Restoration** of  
Physiological Environment  
(shear stress, multidirectional  
motion, morphology)

Benign  
**Resorption**

**For a BVS, the goal is to provide temporary vessel support and then allow the physiology to evolve naturally.**

# BVS Performance: Targets vs. Time

A critical element of BVS performance is the manner in which properties evolve over time post-procedure to meet physiological need.

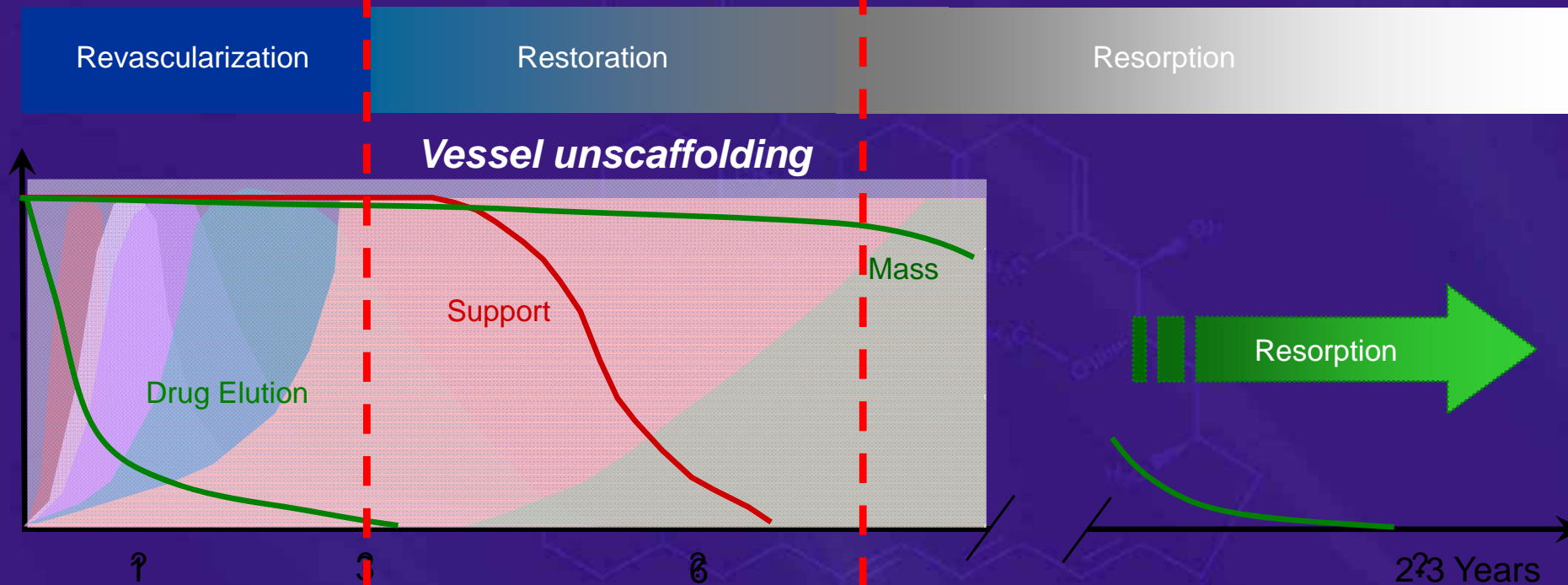


Forrester JS, *et al.*, *J. Am. Coll. Cardiol.* 1991; 17: 758.

Oberhauser JP, *et al.*, *EuroInterv.* 2009; 5: F15.

# BVS Performance: Targets vs. Time

A critical element of BVS performance is the manner in which properties evolve over time post-procedure to meet physiological need.



What is the rationale for these BVS performance time scale targets?

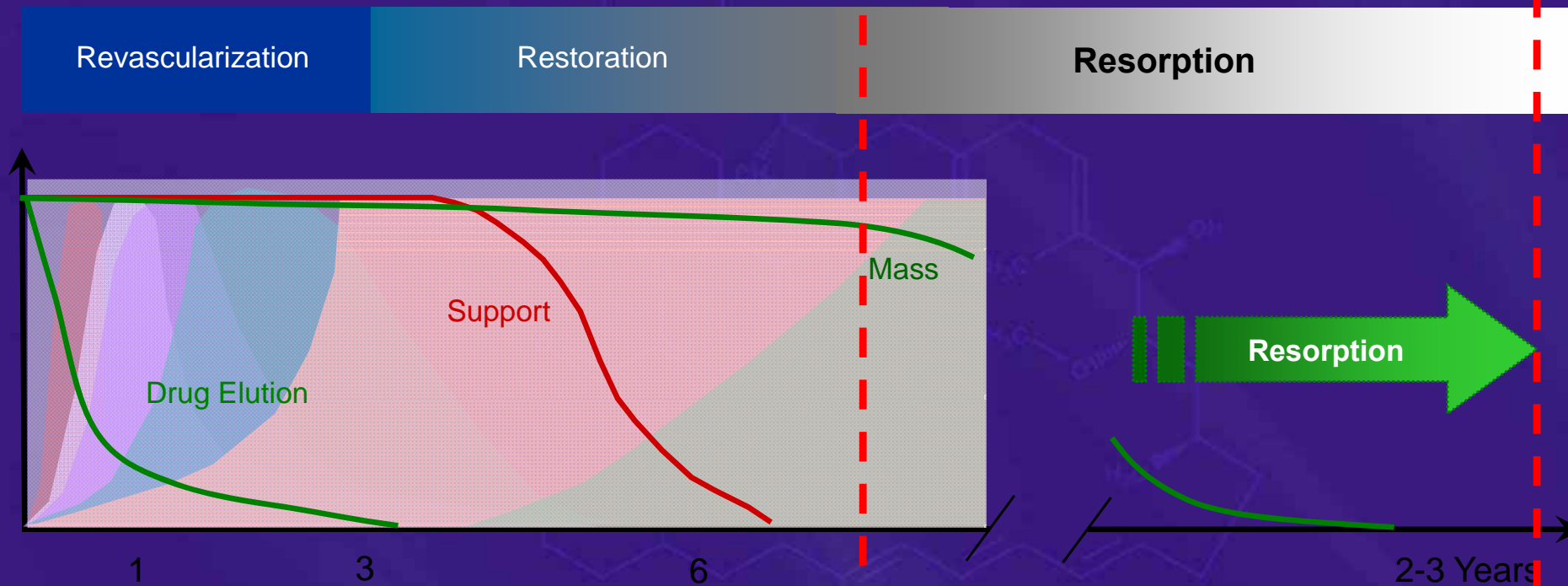
- Platelet Deposition
- Leukocyte Recruitment
- SMC Proliferation and Migration
- Matrix Deposition
- Re-endothelialization
- Vascular Function

Forrester JS, *et al.*, *J. Am. Coll. Cardiol.* 1991; 17: 758.

Oberhauser JP, *et al.*, *EuroInterv.* 2009; 5: F15.

# BVS Performance: Targets vs. Time

A critical element of BVS performance is the manner in which properties evolve over time post-procedure to meet physiological need.



PLLA resorption is a slow, benign process and disconnected from the loss of device functionality.

- Platelet Deposition
- Leukocyte Recruitment
- SMC Proliferation and Migration
- Matrix Deposition
- Re-endothelialization
- Vascular Function

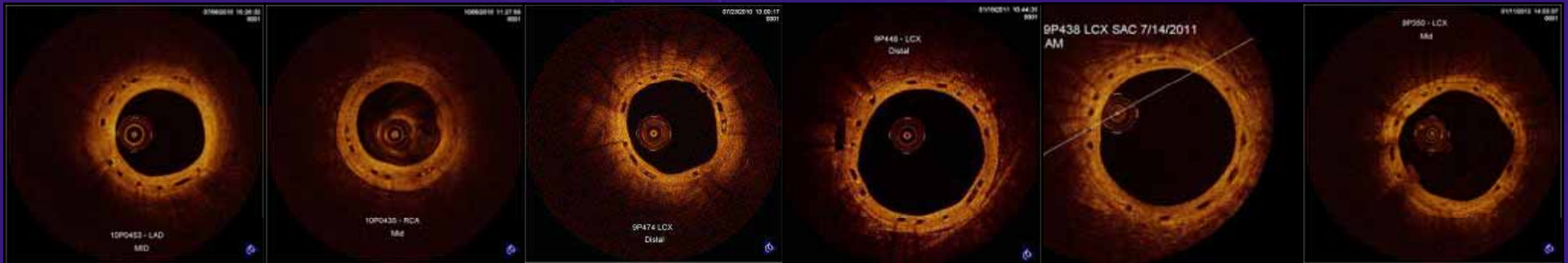
Forrester JS, *et al.*, *J. Am. Coll. Cardiol.* 1991; 17: 758.

Oberhauser JP, *et al.*, *EuroInterv.* 2009; 5: F15.



# OCT Imaging: Absorb BVS

## ABSORB BVS



3 months

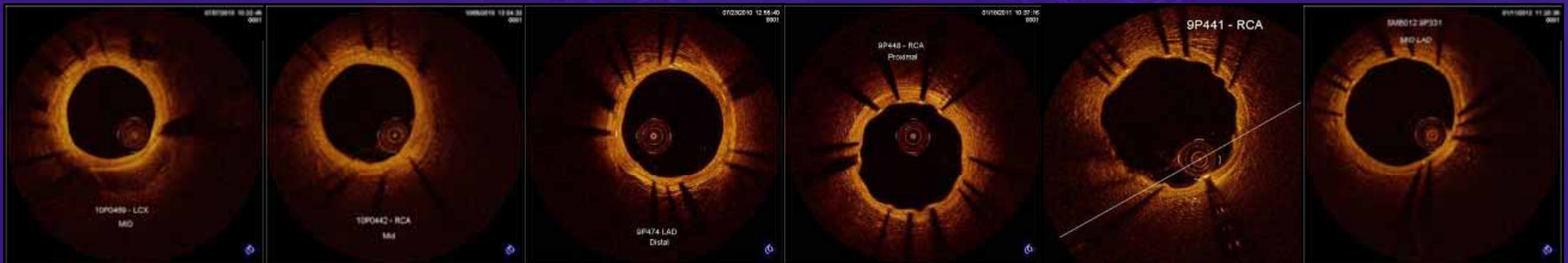
6 months

12 months

18 months

24 months

30 months



## XIENCE V

Representative photomicrographs of porcine coronary arteries (Movat's Pentachrome, 2X magnification)

Representative optical coherence tomography images of porcine coronary arteries

# Summary

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1. The Xience V and Xience PRIME EES family has the best-in-class combination of efficacy, safety and stent design preserving scaffolding and longitudinal strength
2. Leveraging the strong clinical data, future generations of Xience family will bring even more deliverability (Xpedition) and side branch access (Xience SBA)
3. **ABSORB** represents the 4<sup>th</sup> Revolution of PCI, achieving revascularization and vessel restoration due to the return of more normal vessel biology and defenses against atherosclerosis