

The Future of Xience and the Abbott Vascular DES Pipeline

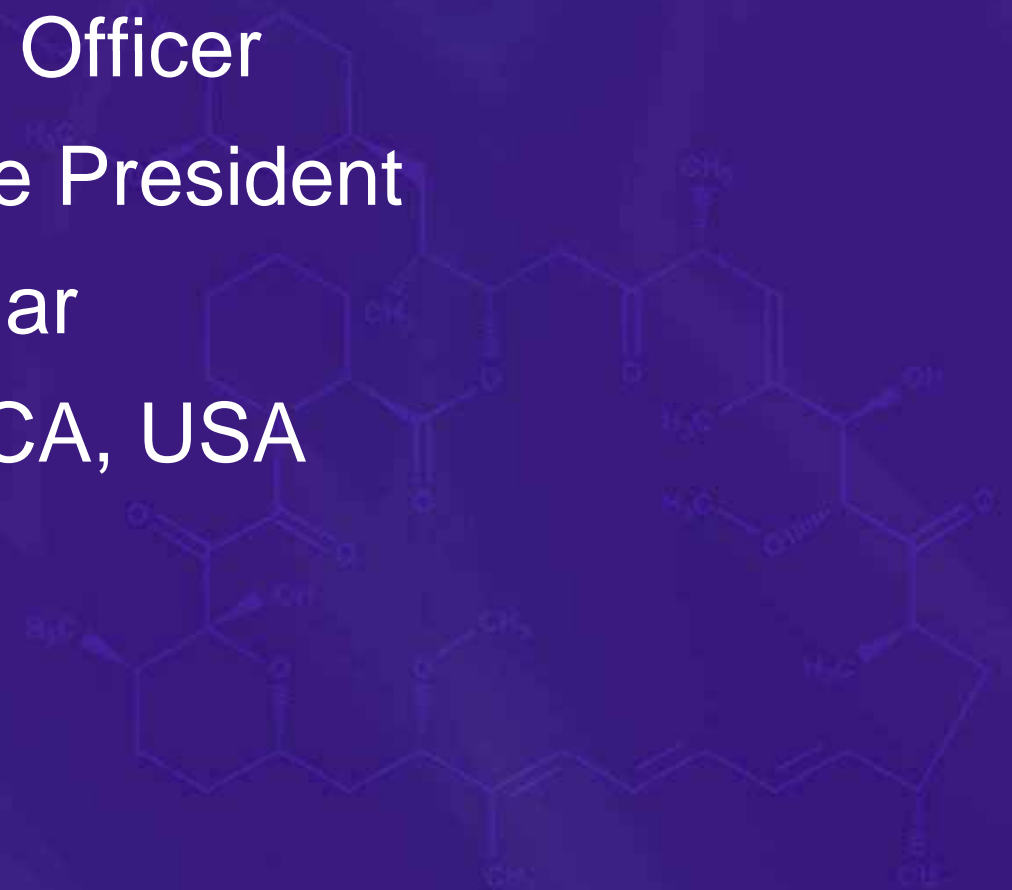
Optimal Balance of Stent Performance and Safety

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Chief Medical Officer
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Angioplasty Summit
TCT-AP
Seoul, Korea 2013

Disclosures

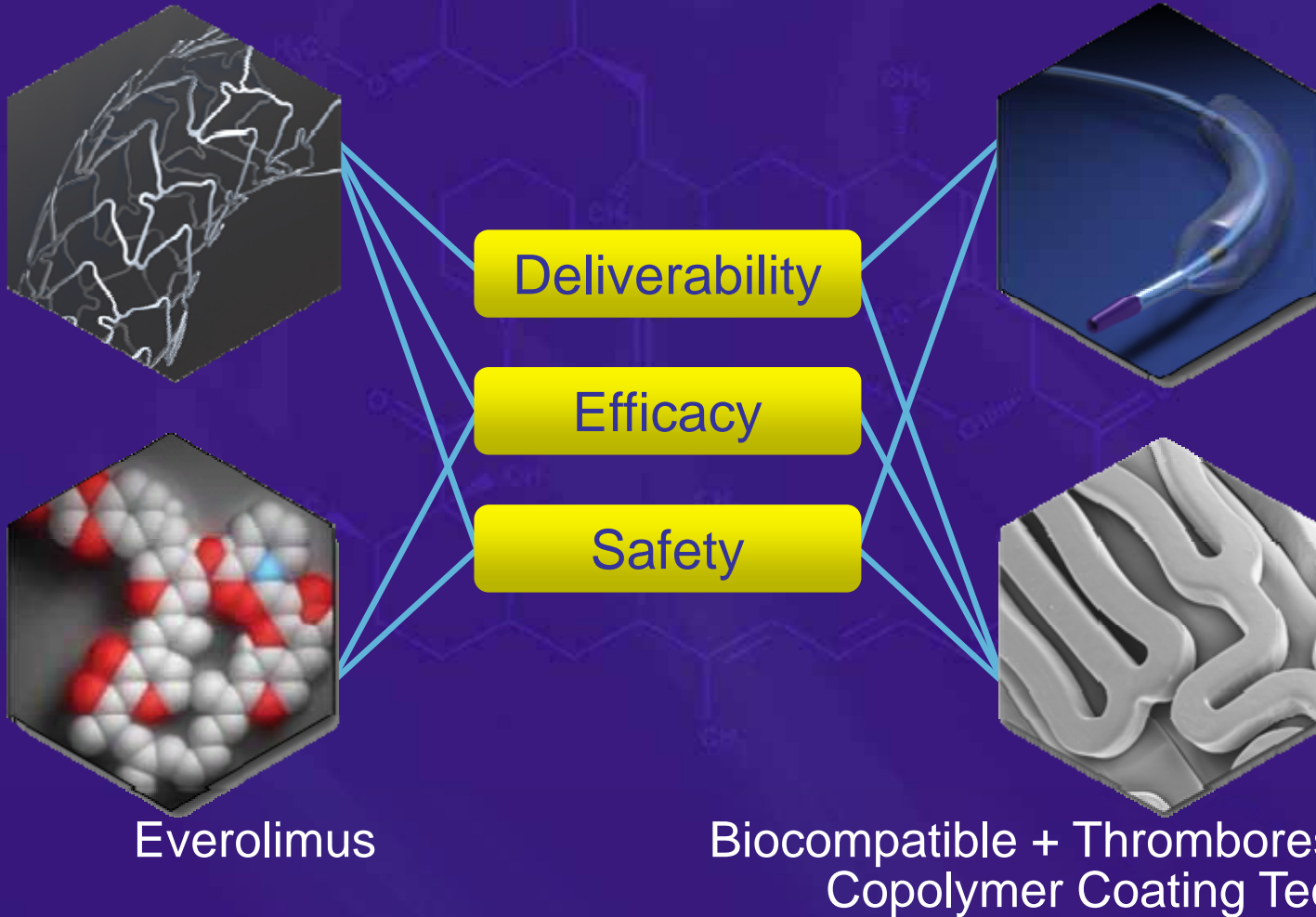
Chief Medical Officer
Divisional Vice President
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Santa Clara, CA, USA



XIENCE V[®] 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

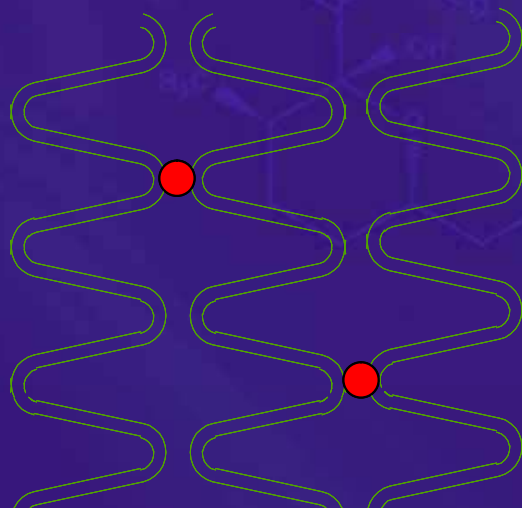
Stent Scaffolding:

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

Links per Ring:

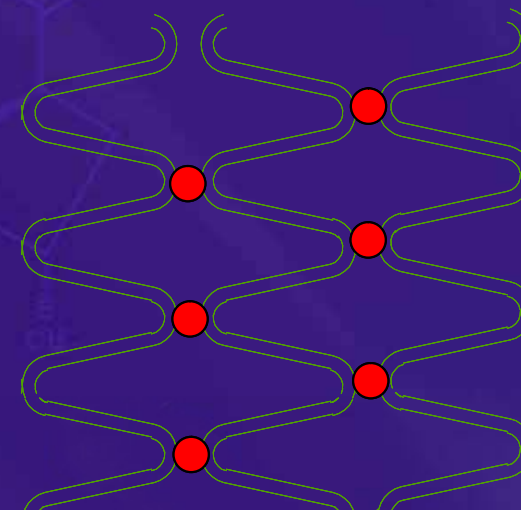
Fewer

- More Flexible
- Less Scaffolding



More

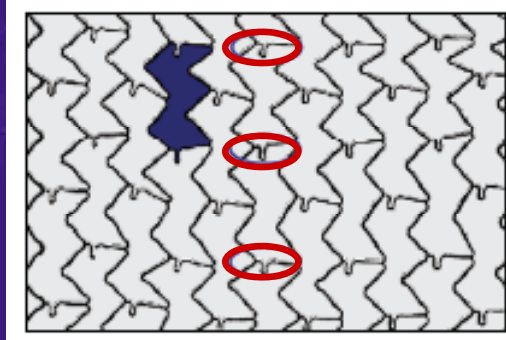
- Less Flexible
- More Scaffolding



Scaffolding: Optimal with Xience / Prime

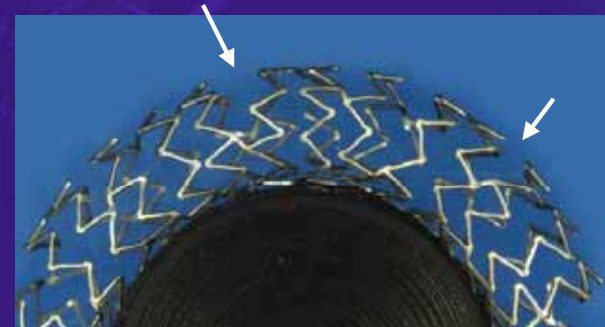
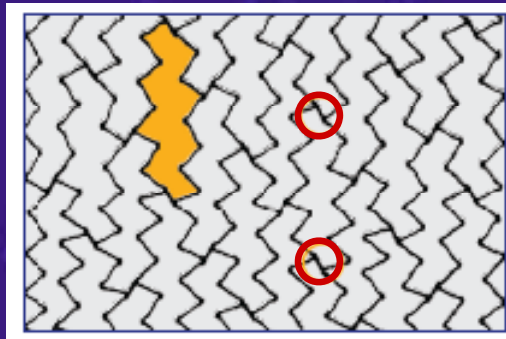
Xience™ platform

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



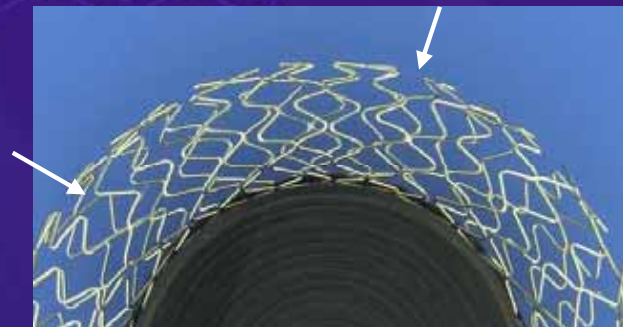
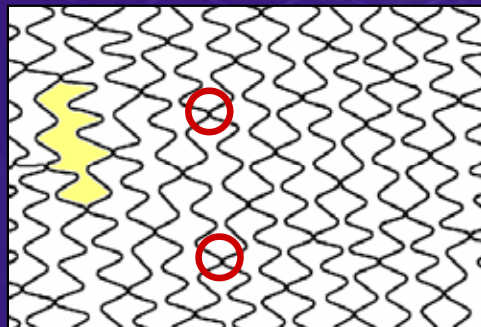
Element™ platform

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



Integrity™ platform

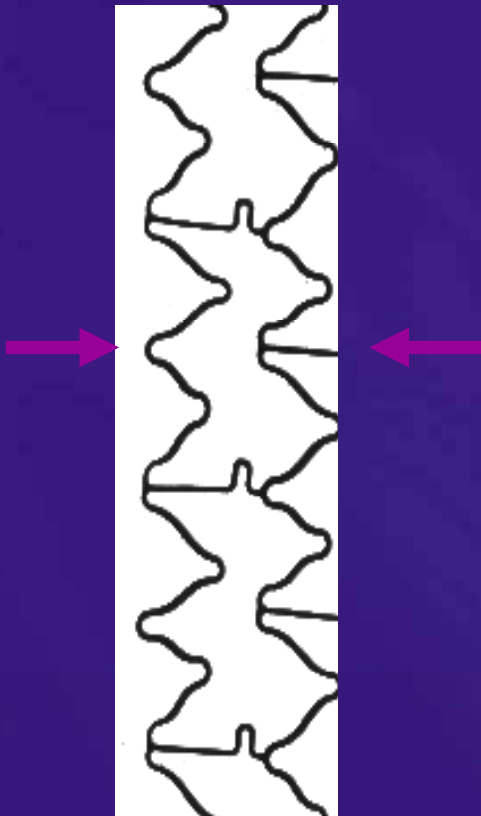
- Peak to peak
- Welds
- Every 4th crest



Longitudinal Stability: Compression

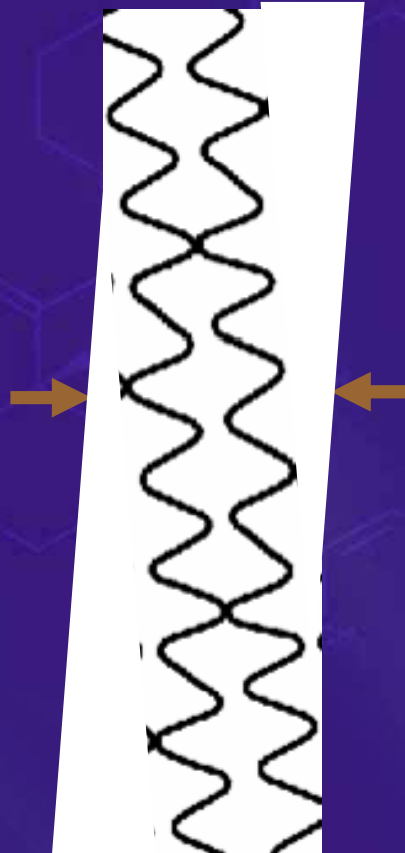
Xience™ platform

Peak-to-Valley
3 Long Links



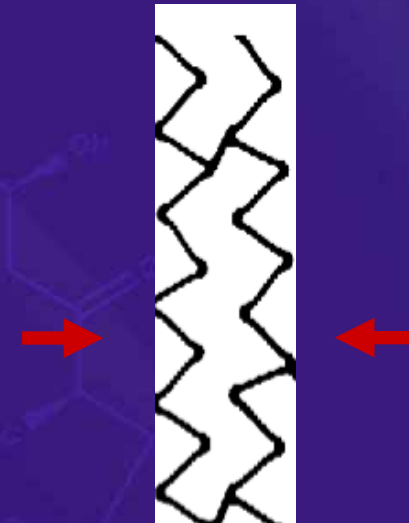
Integrity™ platform

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^{1,2*}, MA, DPhil, BM, BCh; Paul D. Williams¹, 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

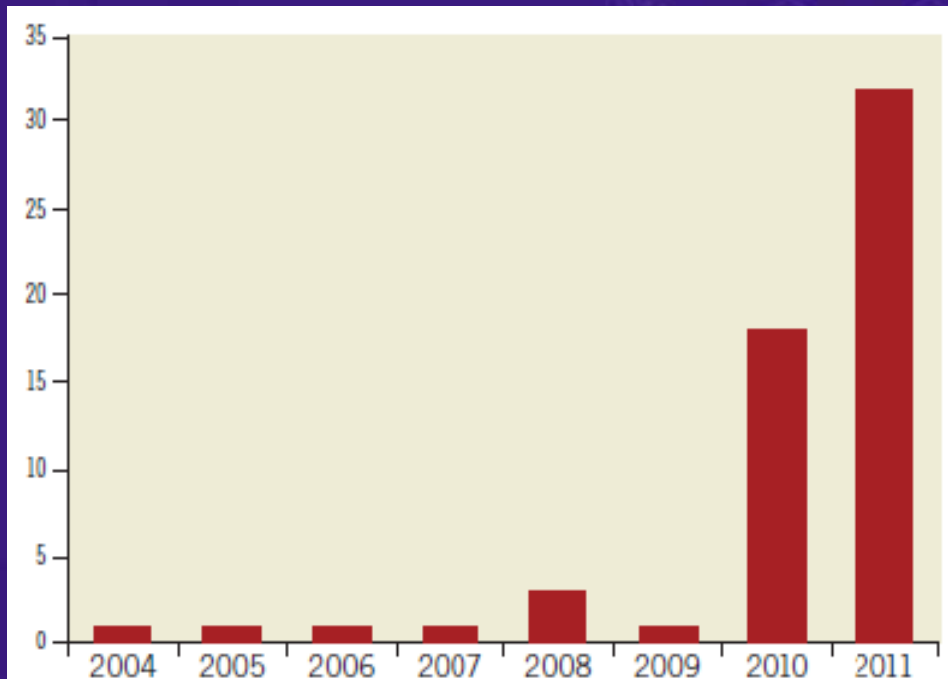


Figure 2. Number of cases of longitudinal stent deformation submitted to MAUDE website according to year.

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

Excellent Deliverability

Without Sacrificing:

Scaffolding

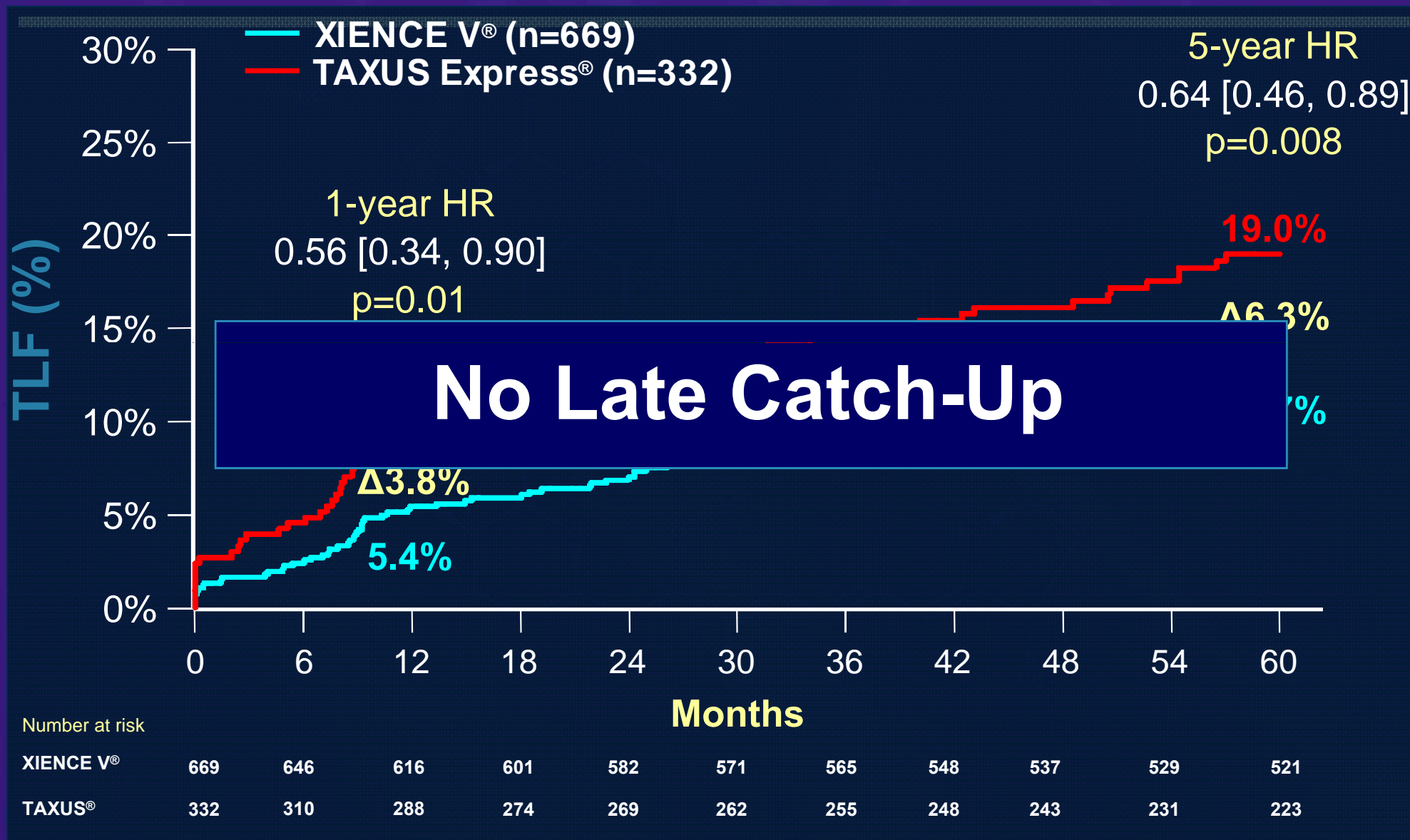
Longitudinal Strength

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				

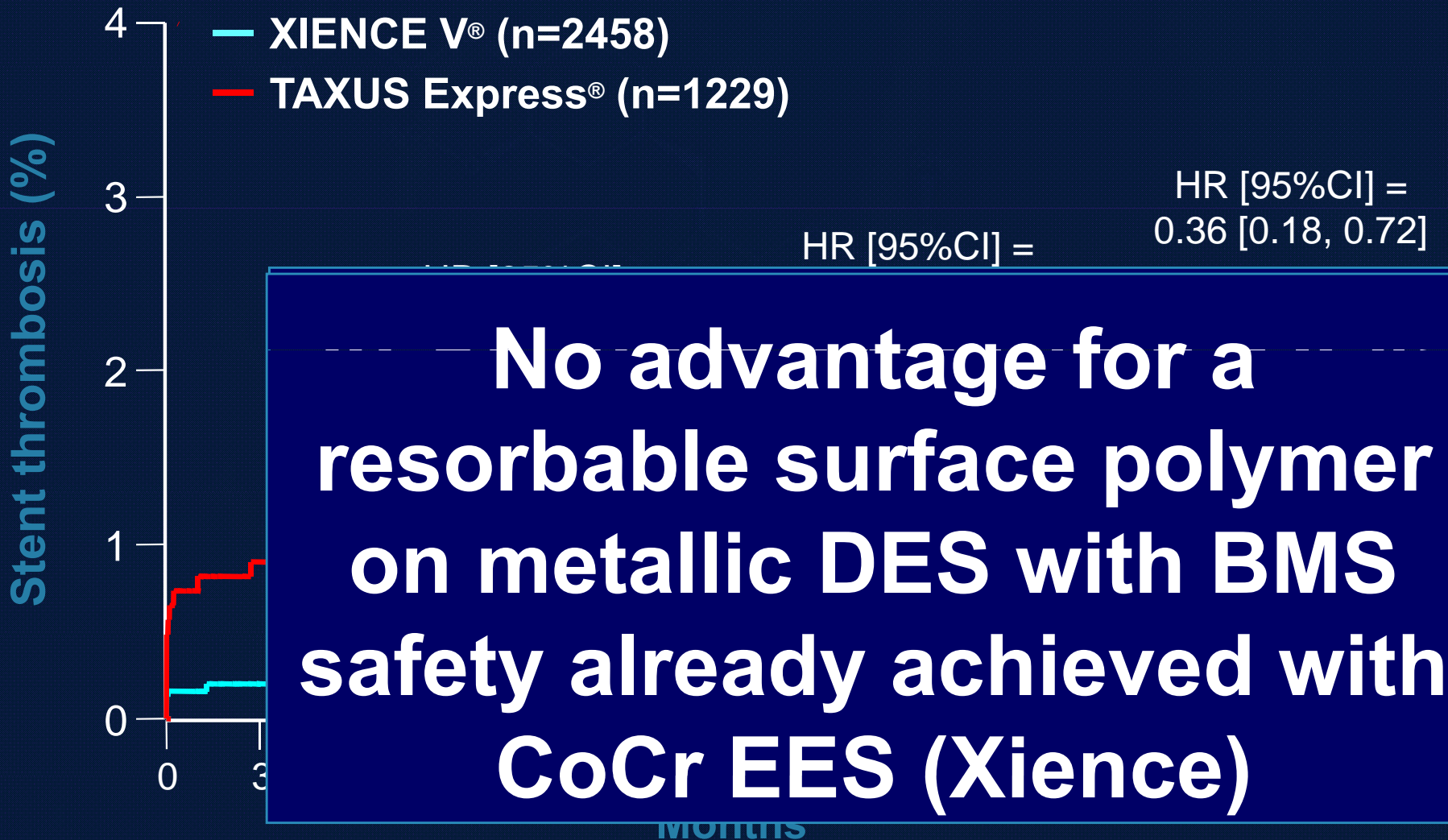
■ New 2011 Data

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

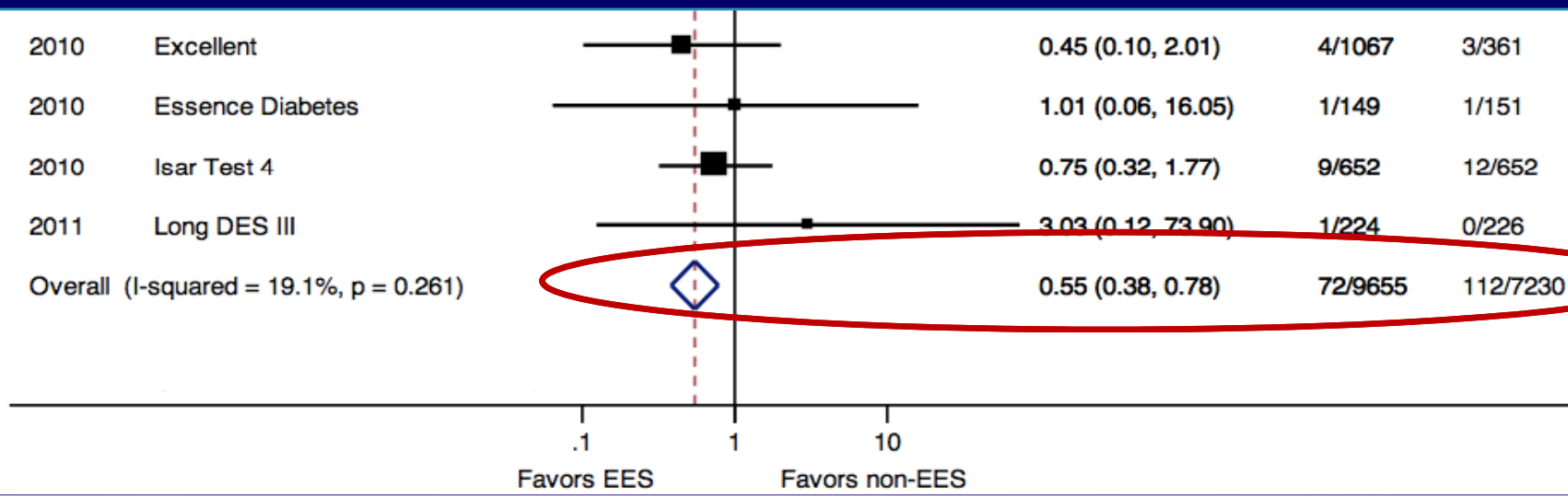
^aMount Sinai Medical Center, New York, NY ^bKaiser Permanente, Pasadena, CA ^cCardiovascular Research Foundation, New York, NY ^dSeoul National University Hospital, Seoul, Korea ^eAsan Medical Center, Seoul, Korea ^fDeutsches Herzzentrum, Technische Universität, Munich, Germany

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

XIENCE V USA

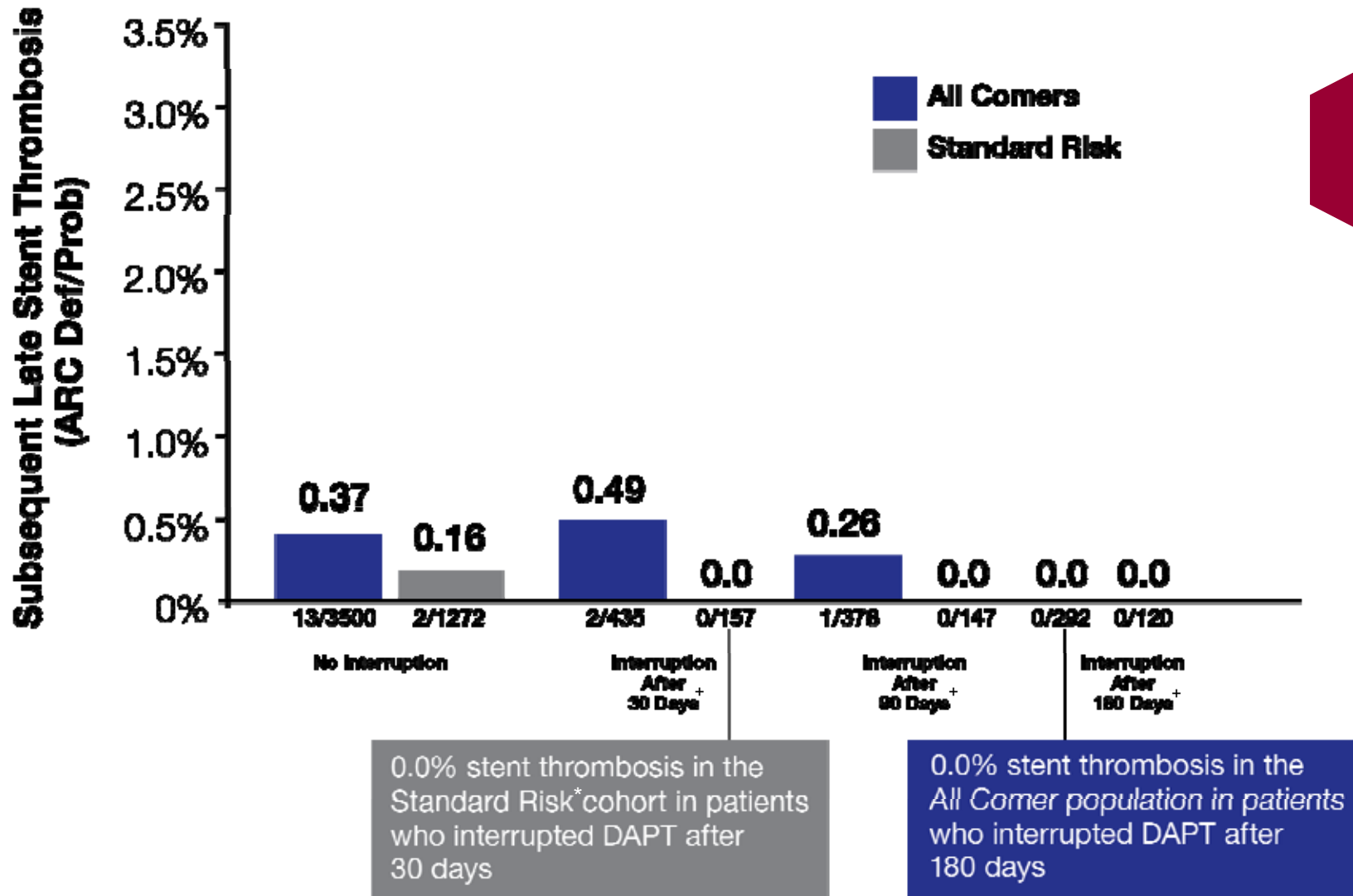
- Single-arm registry of **5,054 real-world patients**
- Primary endpoint of ARC Def/Prob stent thrombosis at 1 year

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.

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

DES Pipeline from Abbott Vascular

Continuing to Innovate

The Next Generations of DES

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

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

XIENCE Xpedition: Most Agile Xience

Designed to DELIVER






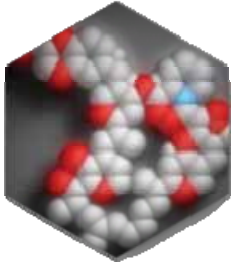

•The most agile XIENCE. Ever.

Coming Soon!
Pending CE Mark

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

XIENCE Xpedition

Designed for improved acute performance

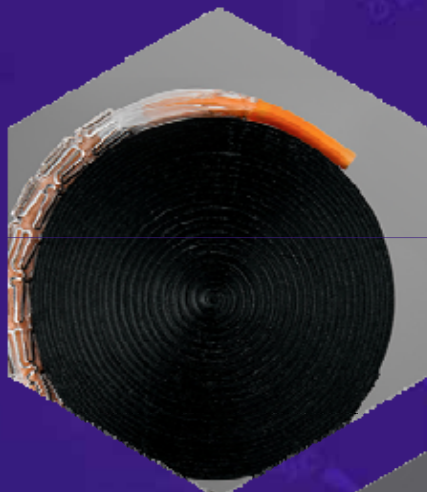
	 Delivery System	 Balloon	 Stent Design and Material	 Drug/Dose	 Polymer
XIENCE PRIME	XIENCE PRIME Delivery System	Single-Layer Balloon	MULTI-LINK 8 Cobalt Chromium	Everolimus 88 µg	Biocompatible Coating Technology
XIENCE Xpedition	NEW! Smooth Transitions Delivery Optimized for Acute Performance	NEW!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

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

Coming Soon! Pending CE Mark

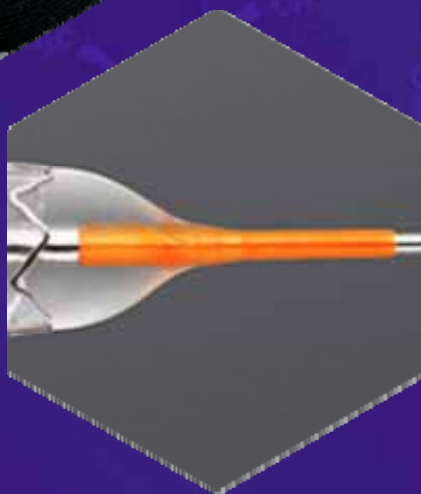
XIENCE Xpedition

Designed to be **TRACKABLE**



Integrated Tip

- Smooth tracking around sharp bends in tortuous anatomy



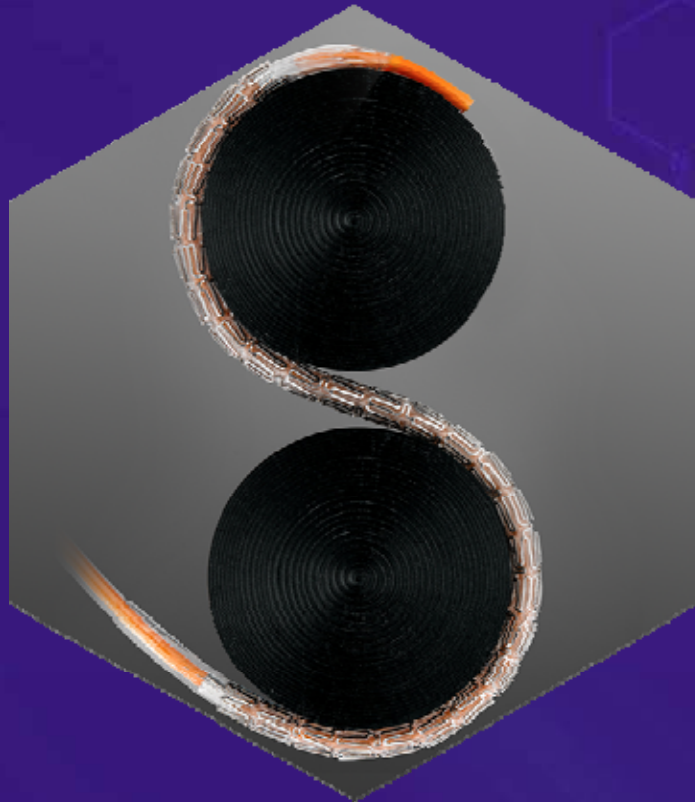
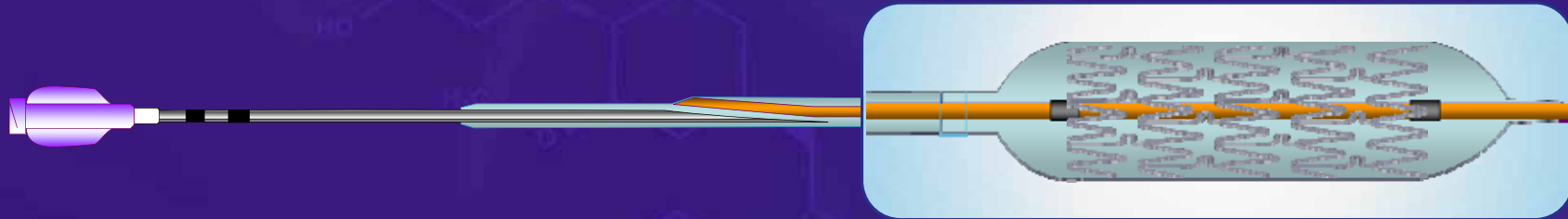
Slim Seal Technology

- 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

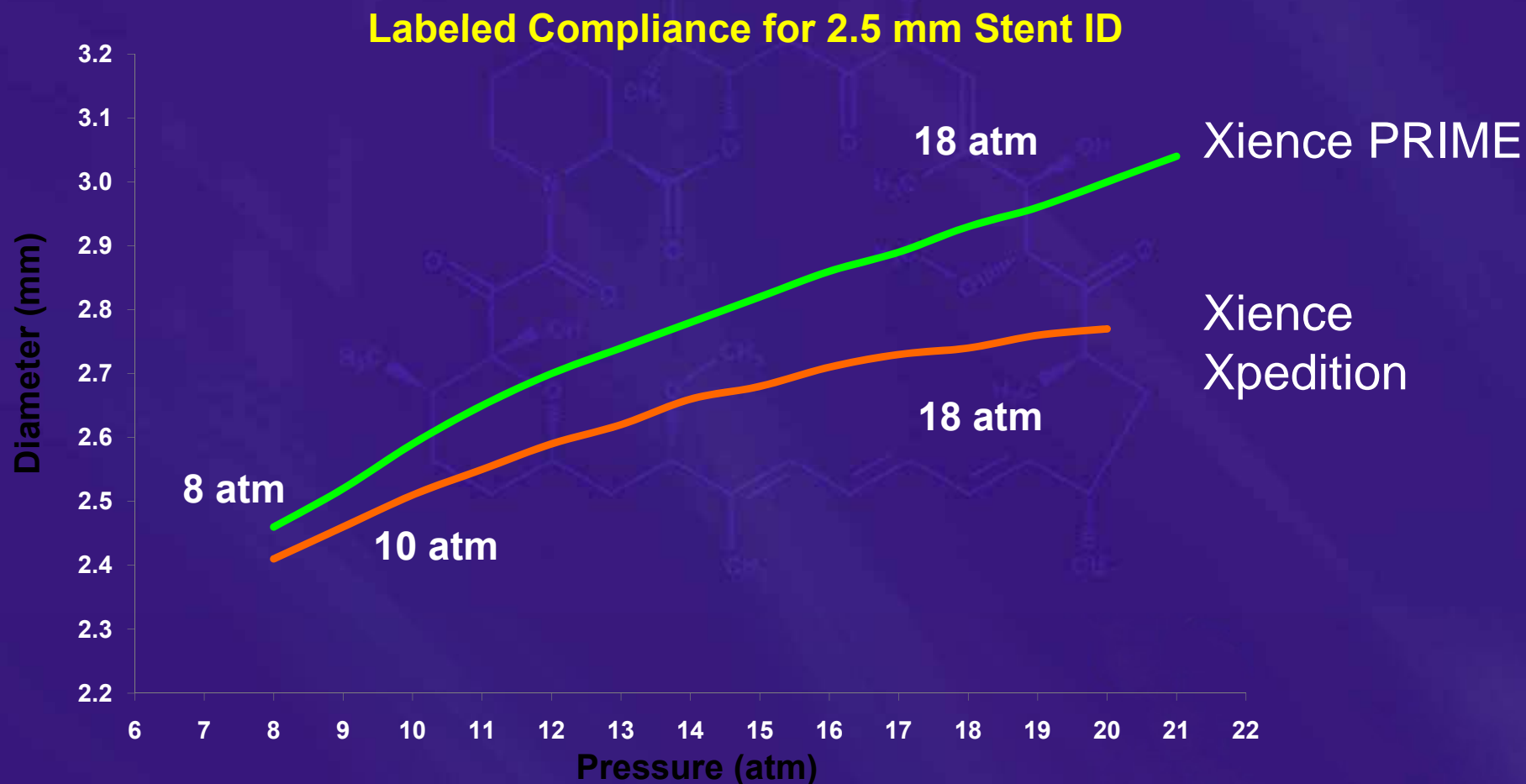
- Thin, multi-layered balloon walls for superb deliverability
- Taper optimized for balloon refold

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

Xience Xpedition

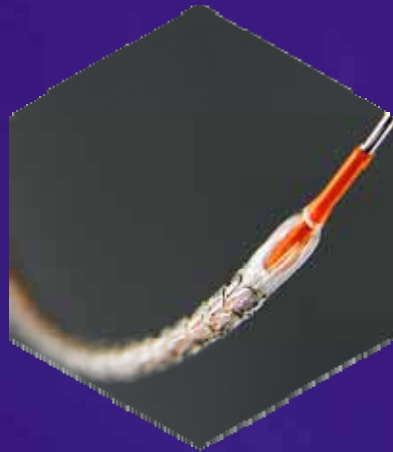
Flatter Balloon Compliance

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

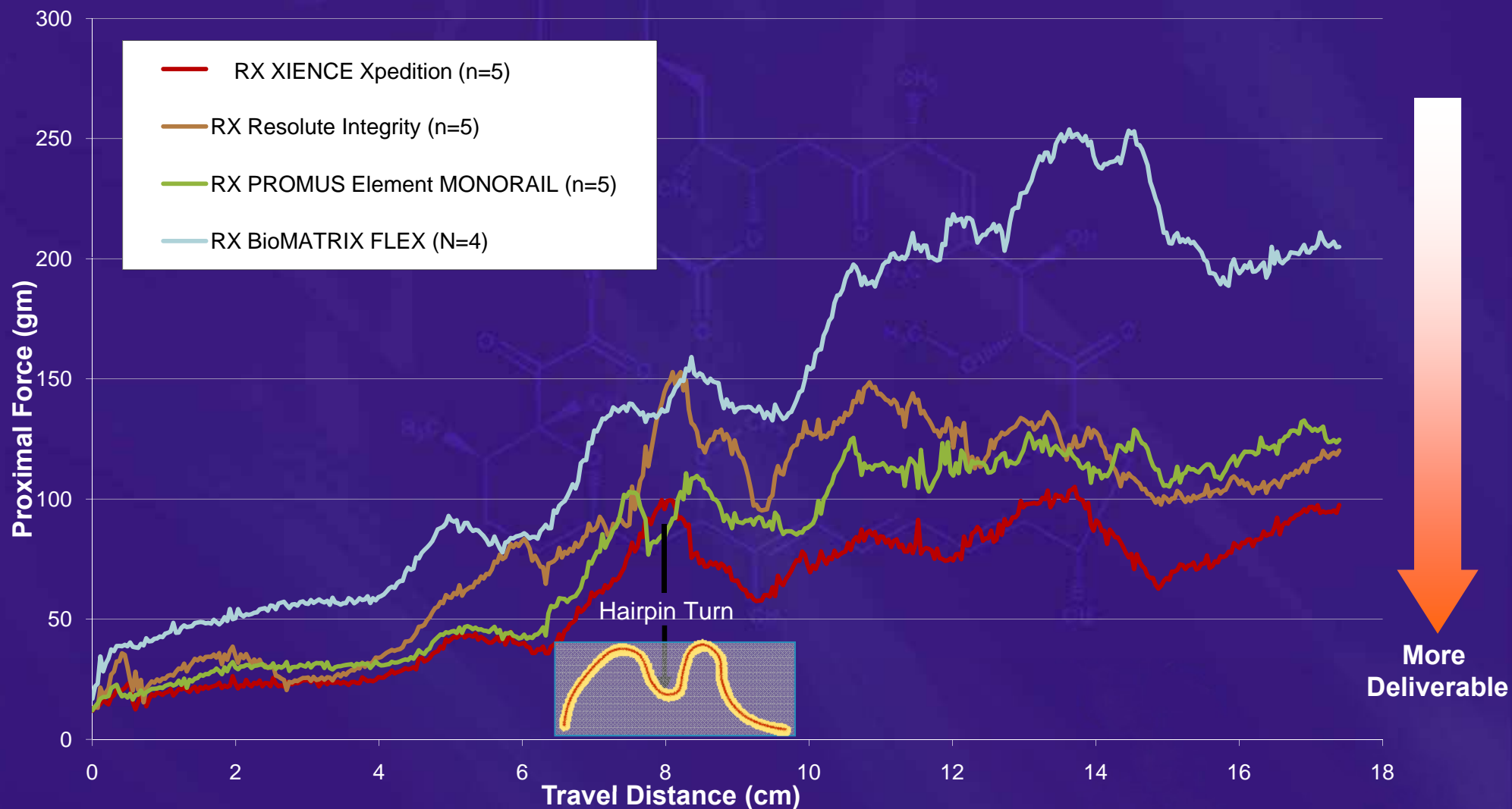
- Smooth transition between hypotube and distal shaft
- Reduced guide wire notch profile

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

Xience Xpedition

Less Work to Track Through Tortuosity

Catheter Performance Test



ABSORB

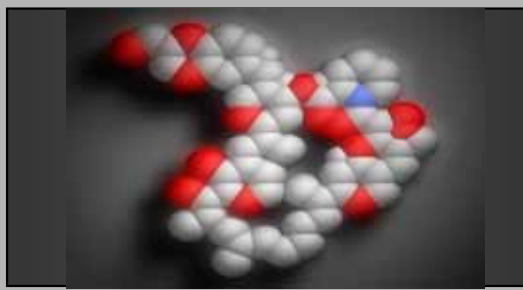
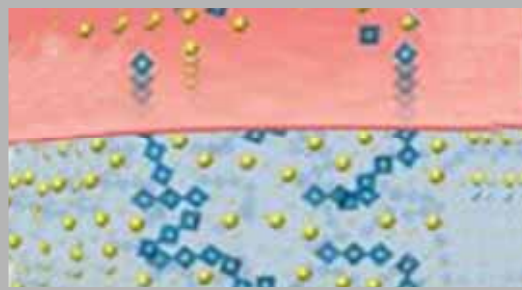
The Fully Bioresorbable Vascular Scaffold

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



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

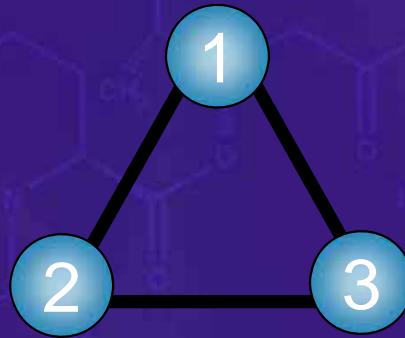
- Biocompatibility
- Thromboresistance or passivation
- Minimal late catch-up after drug is eluted and metabolized
- No fractures that can cause chronic irritation

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



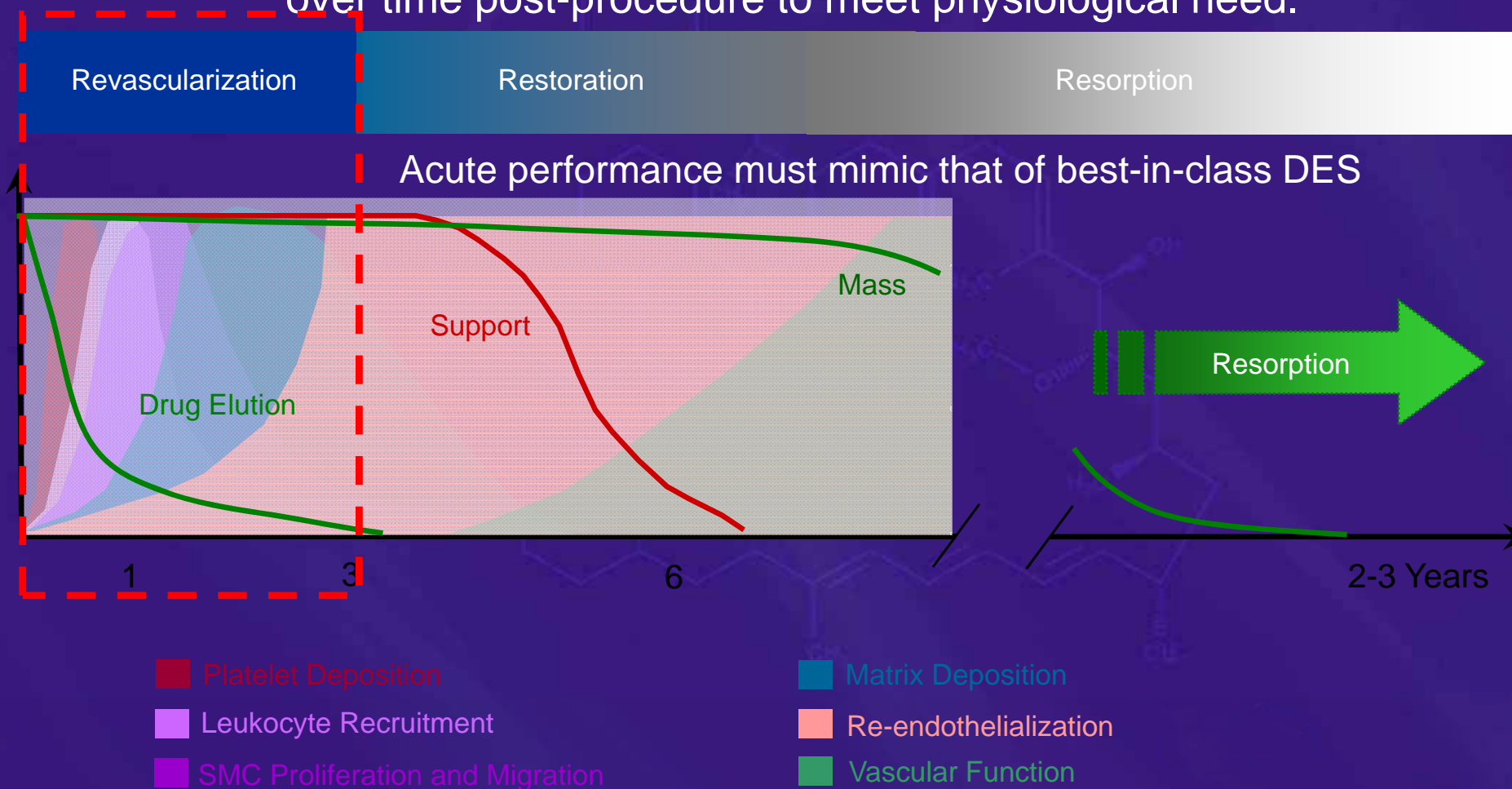
Restoration of
Physiological Environment
(shear stress, multidirectional
motion, morphology)

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.

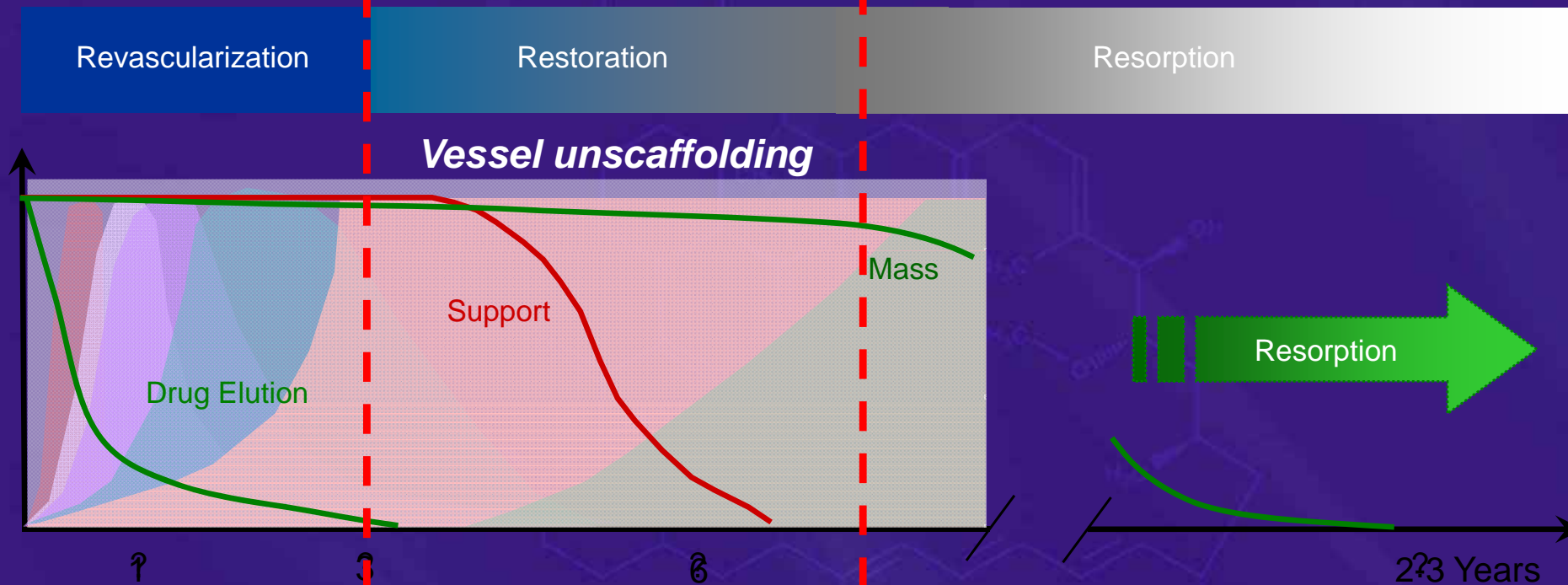


Forrester JS, *et al.*, *J. Am. Coll. Cardiol.* 1991; 17: 758.

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?

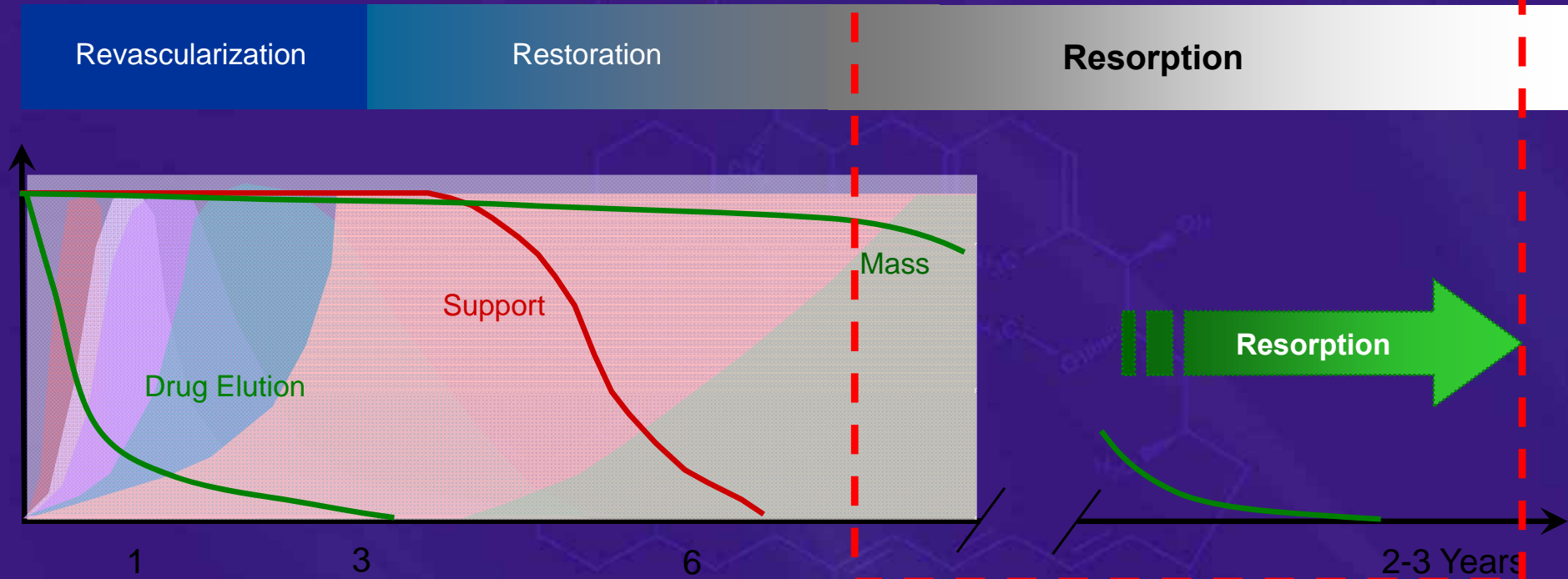
- Platelet Deposition
- Matrix Deposition
- Leukocyte Recruitment
- Re-endothelialization
- SMC Proliferation and Migration
- Vascular Function

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.

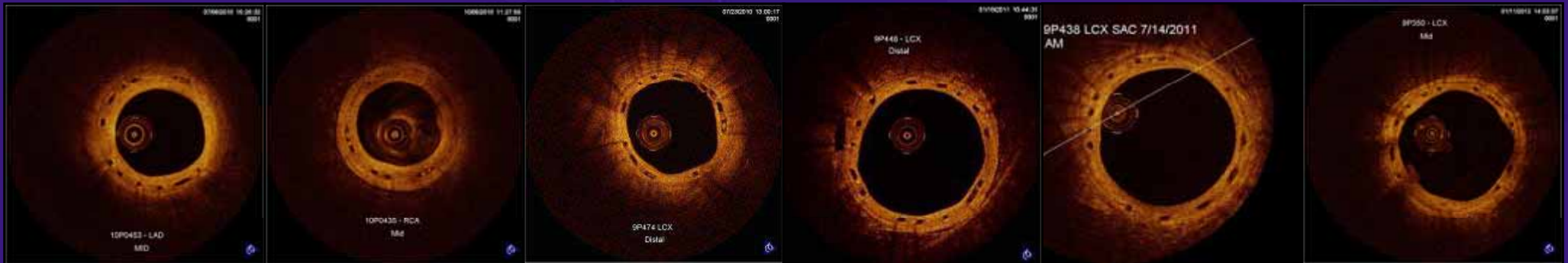
- Platelet Deposition
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Forrester JS, *et al.*, *J. Am. Coll. Cardiol.* 1991; 17: 758.

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

OCT Imaging: Absorb BVS

ABSORB BVS



3 months

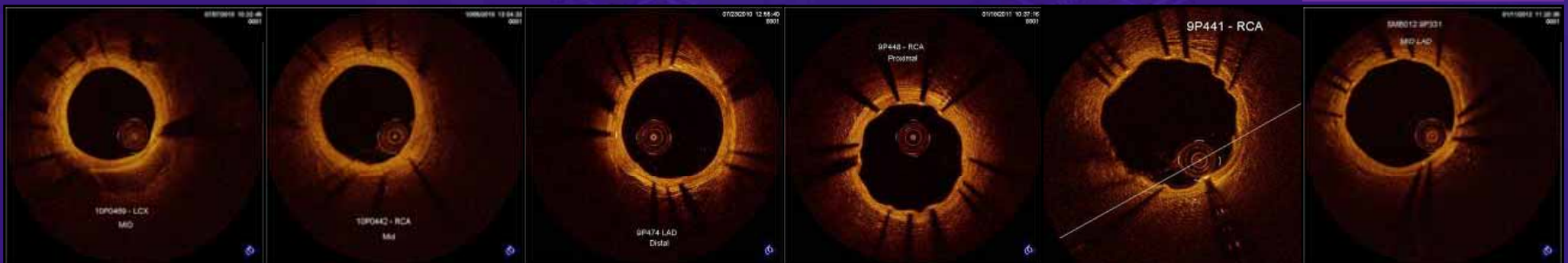
6 months

12 months

18 months

24 months

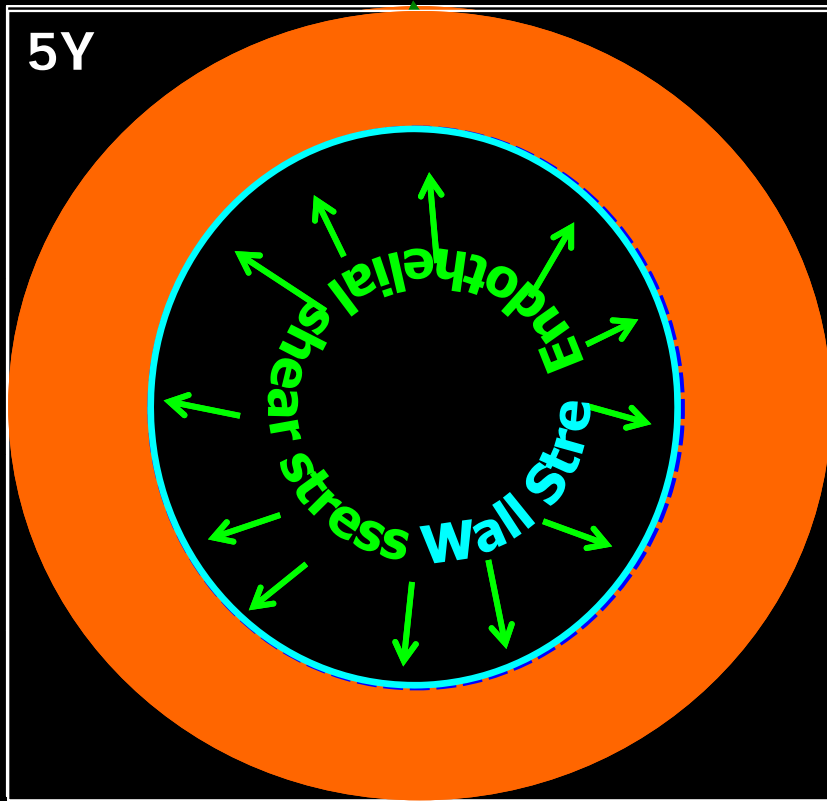
30 months



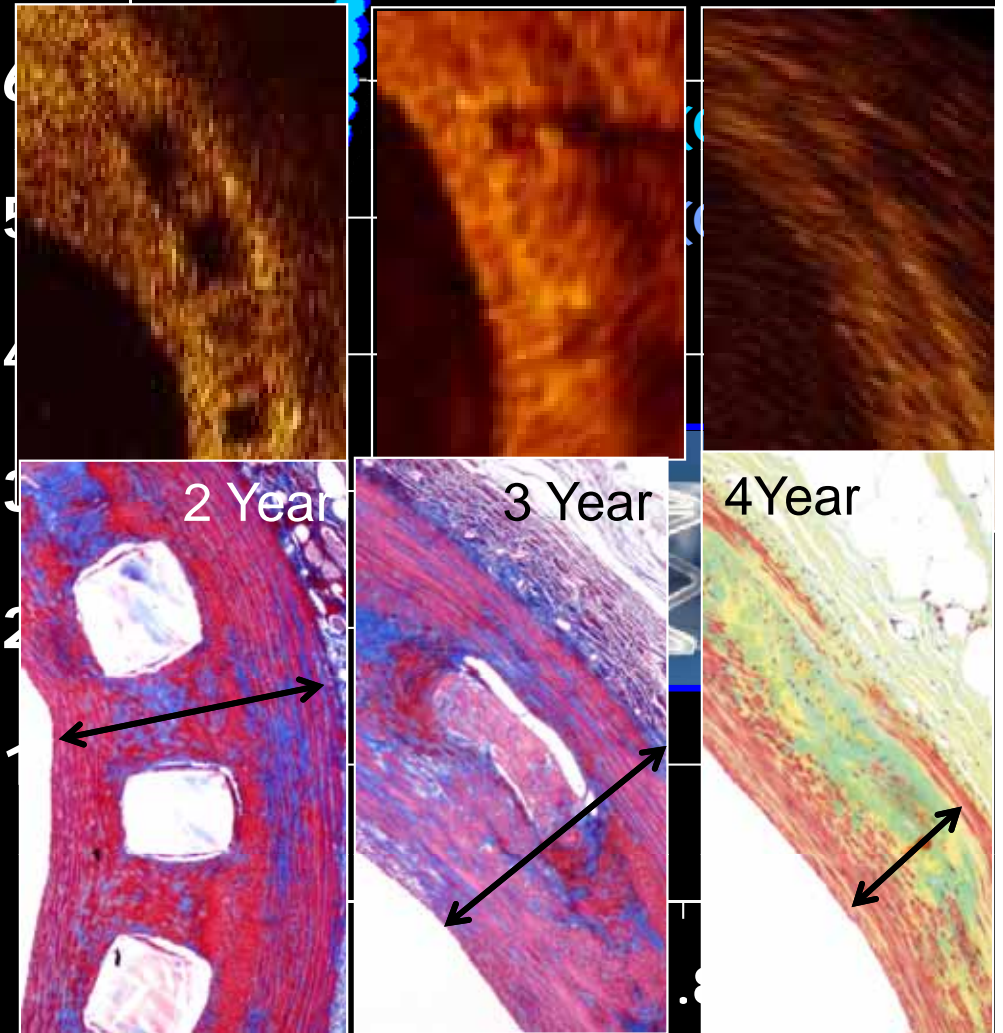
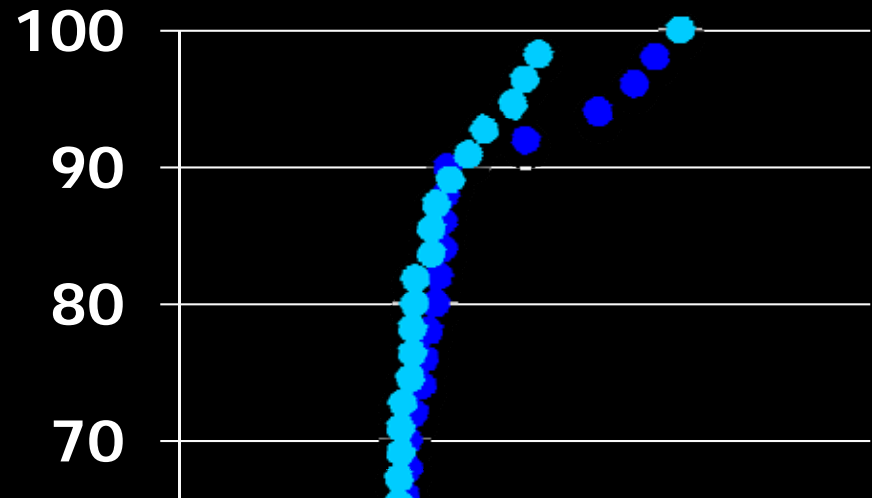
XIENCE V

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

Representative optical coherence tomography images of porcine coronary arteries



At 5 years, the vessel wall thinning (plaque media reduction?) will result in late lumen enlargement.



Summary

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 4th Revolution of PCI, achieving revascularization and vessel restoration due to the return of more normal vessel biology and defenses against atherosclerosis