

# Xience PRIME and Bioresorbable Vascular Scaffold (BVS) Update

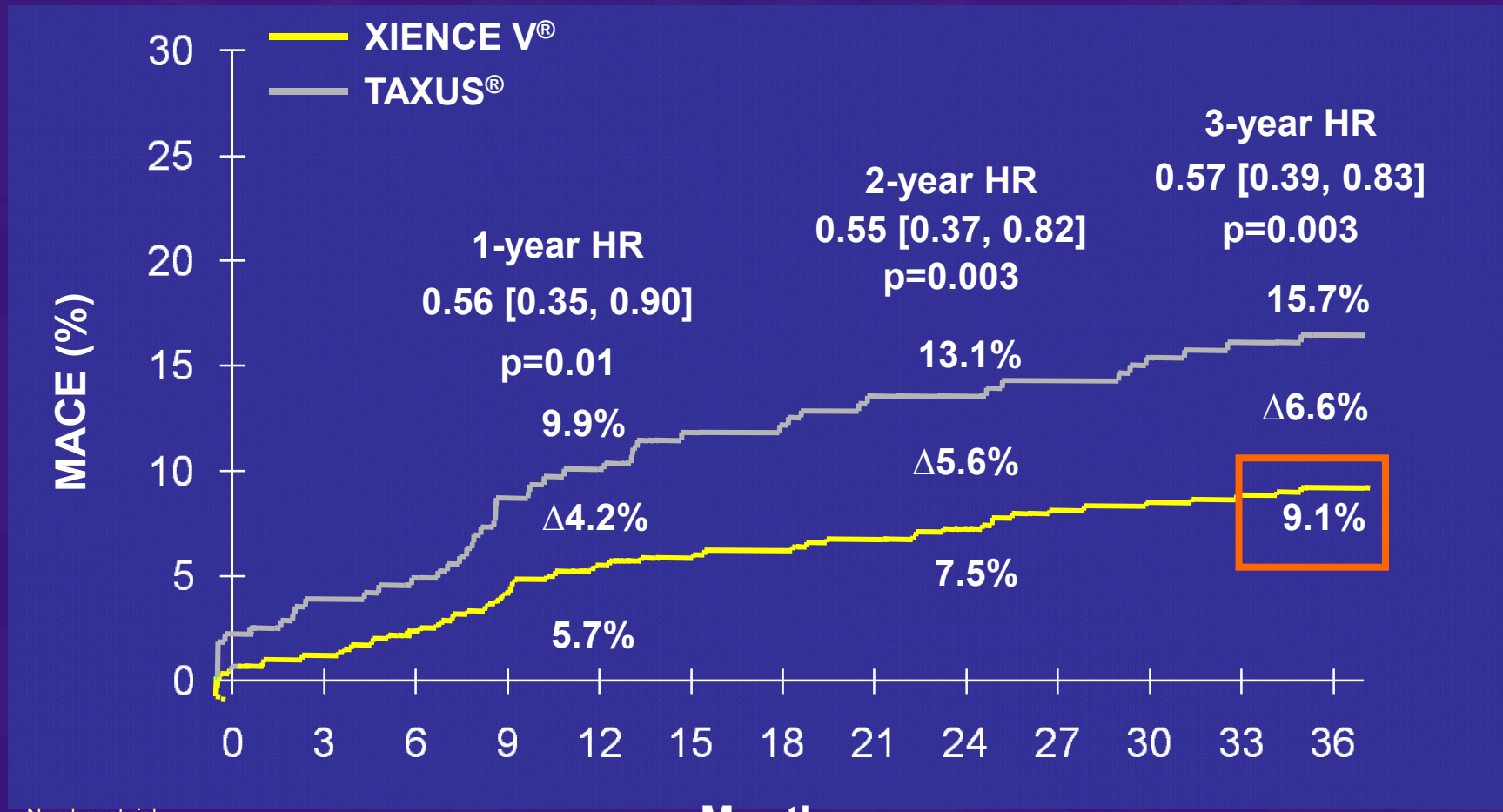
---

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

**Angioplasty Summit**  
**TCTAP 2010**

# SPIRIT III 3-Year

## Major Adverse Cardiac Events

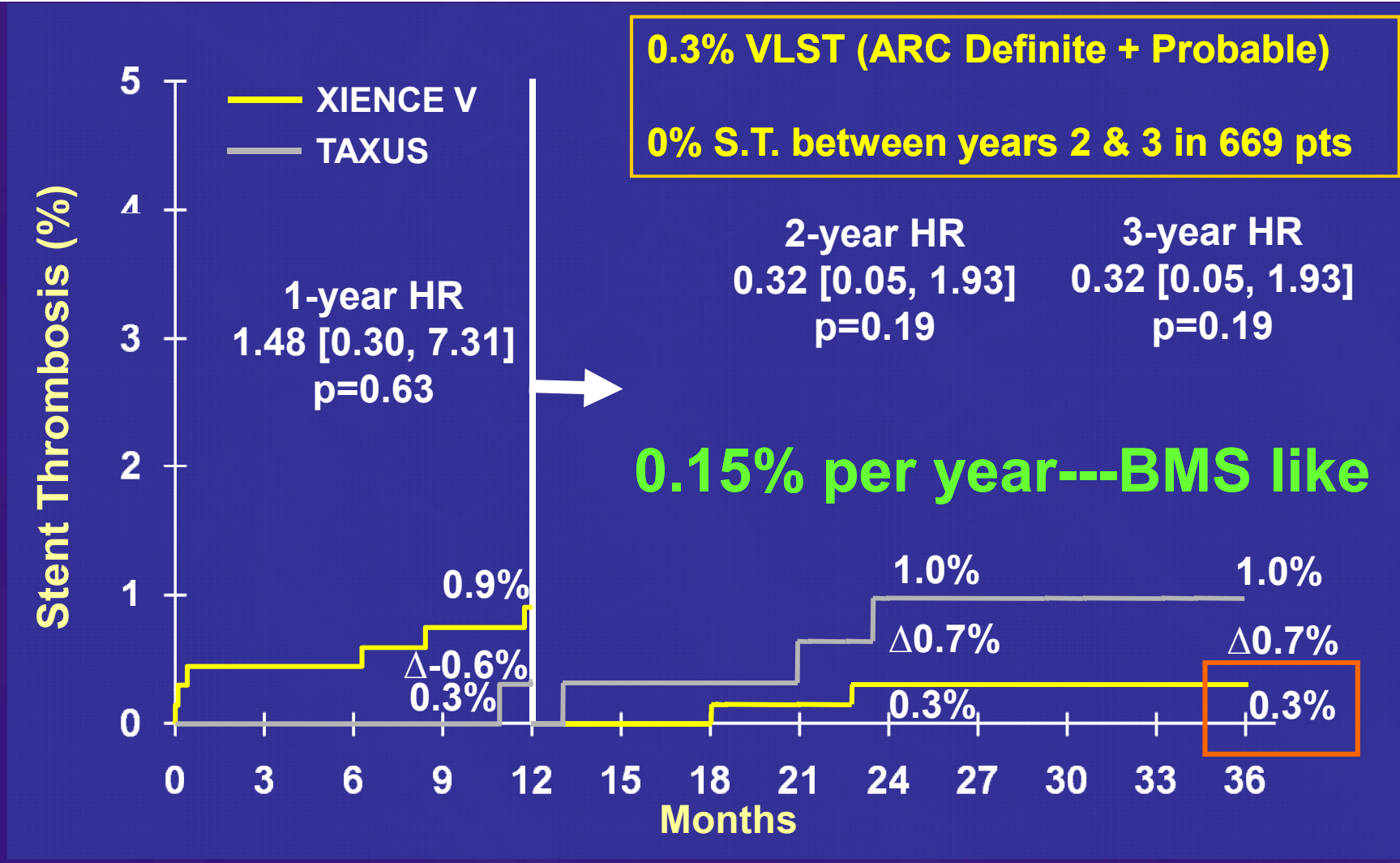


Number at risk

	0	3	6	9	12	15	18	21	24	27	30	33	36
<b>XIENCE V®</b>	669	652	643	628	612	598	597	591	581	576	574	572	569
<b>TAXUS®</b>	332	312	308	291	286	275	272	269	266	264	260	258	255

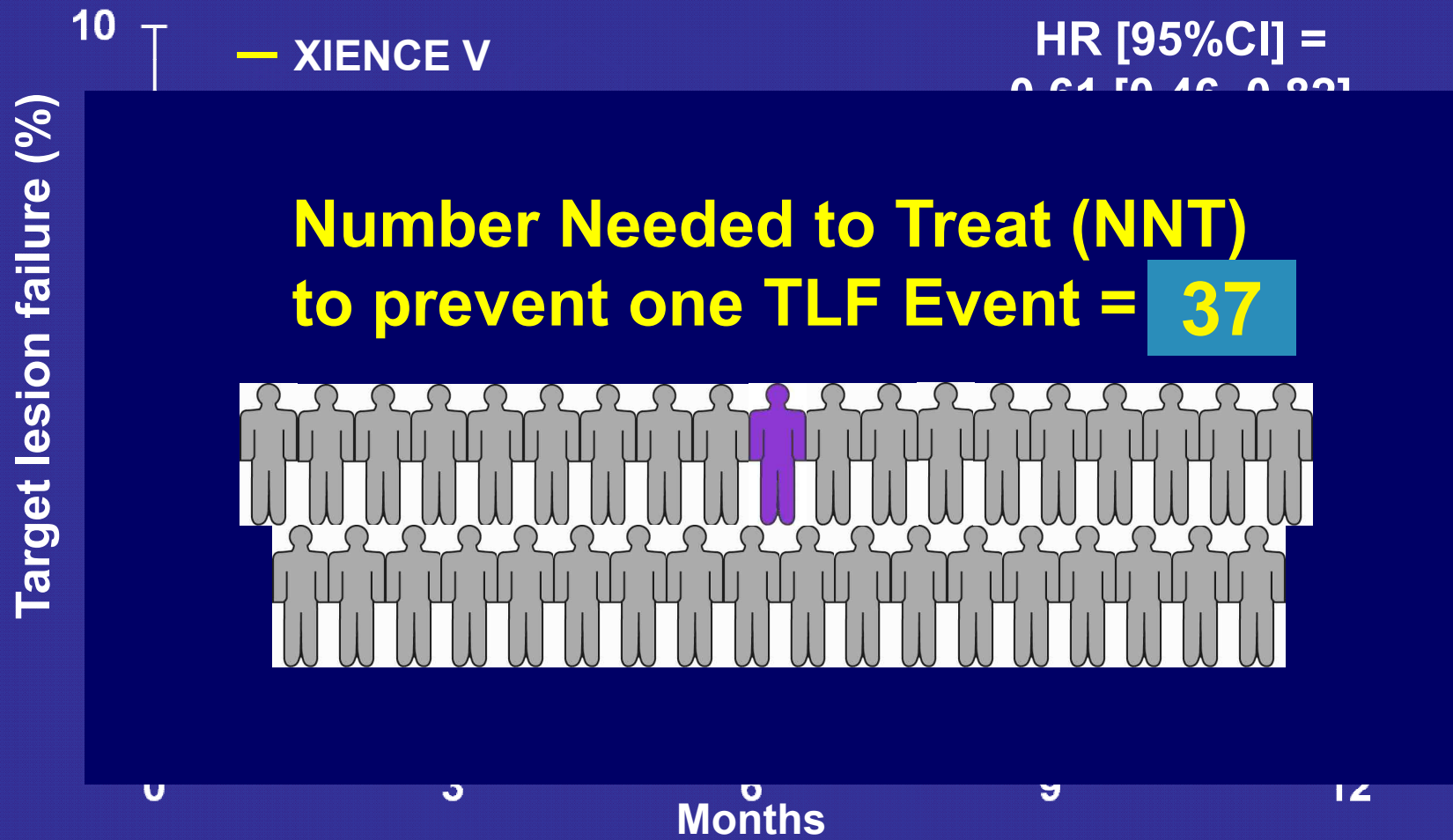
# SPIRIT III 3-Year

## Landmark Analysis Stent Thrombosis (ARC)



# SPIRIT IV: Primary Endpoint (TLF)

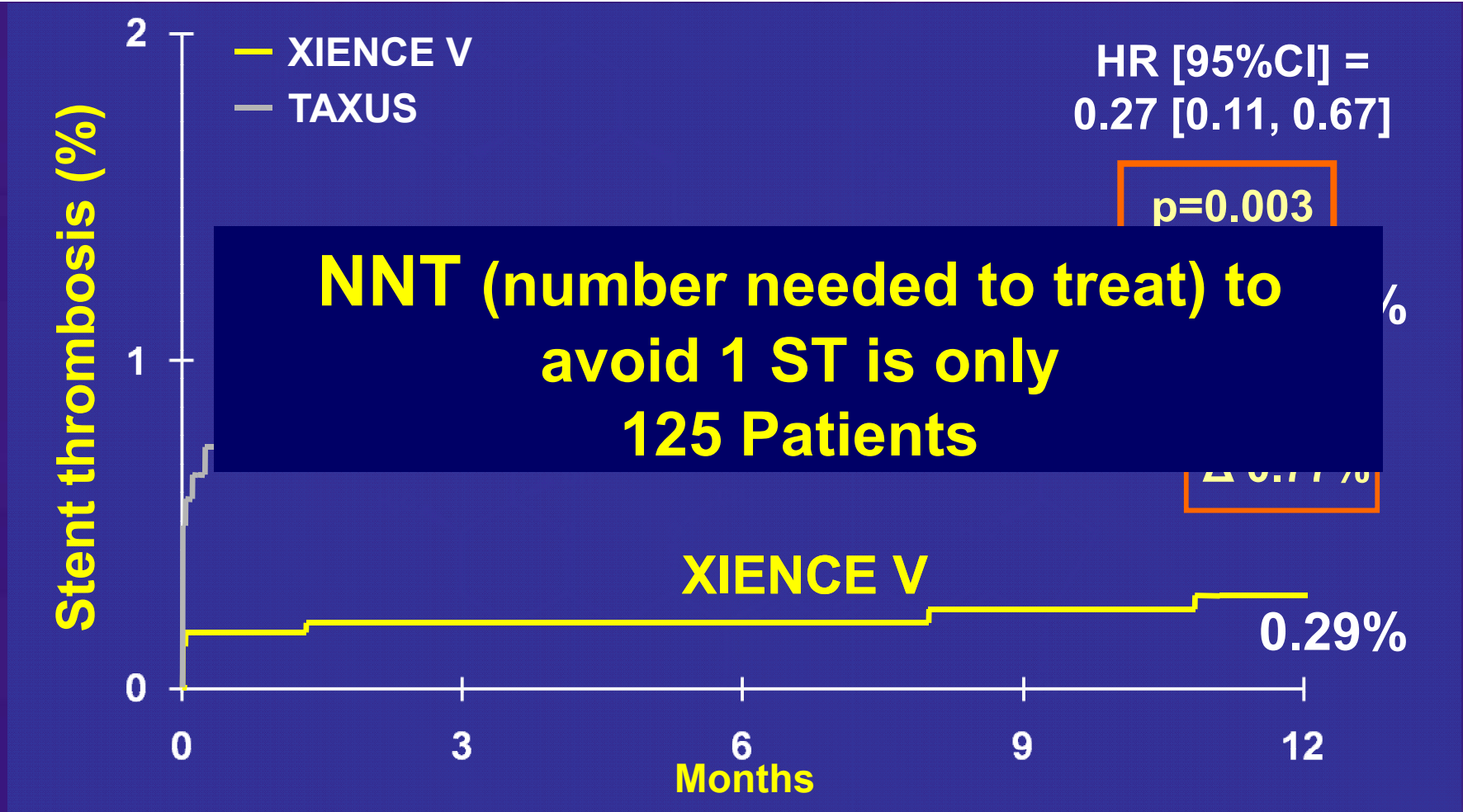
Early & Continuously Divergent Differences



XIENCE V	2458	2390	2362	2323	2298
TAXUS	1229	1165	1137	1119	1104

# SPIRIT IV 1 Year

## Stent Thrombosis: ARC Definite or Probable



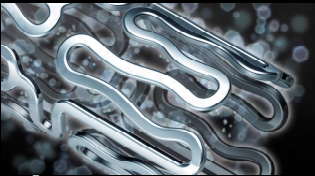
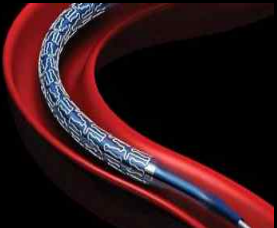
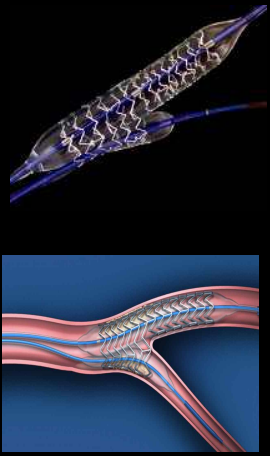
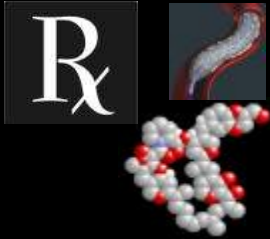
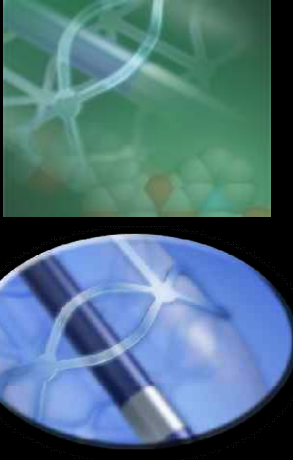
XIENCE V	2458	2426	2412	2388	2376
TAXUS	1229	1195	1184	1174	1166

SE2929250 Rev. A  
Information contained herein for presentation outside of the U.S. and Japan.

# DES Pipeline from Abbott Vascular

Continuing to Innovate Based on the Superiority of XIENCE V

Consistently Exploring the Next Generation DES

Xience™ V	XIENCE PRIME	Xience Side-Branch Access	G3: Ultra-Thin Alloy DES	BVS
 Xience™ V				
E.U. 2006 U.S. 2008	E.U. 2009 U.S. 2012	2012+	2012+	2012+

Pipeline products currently in development. Not available for sale.

# XIENCE PRIME – Key Design Goals

## Enhanced\* Stent & New Delivery System Design

- Increased RBP
- Shorter balloon tapers
- More flexible catheter

## Cobalt Chromium Stent Material

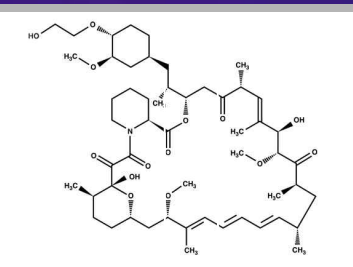
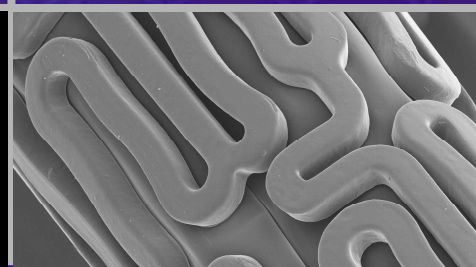
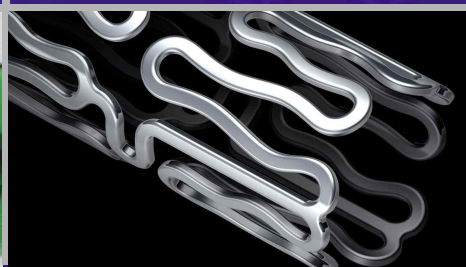
- .0032” struts
- Enhanced flexibility and conformability

## Polymer Coating

- Controlled drug release
- Biocompatible fluorinated copolymer, same as XIENCE V

## Everolimus

- Similar dose and release rate to XIENCE V



\* Compared to Xience V.

Pipeline products currently in development. Not available for sale.

# XIENCE PRIME - Key Design Goals

- **Improve deliverability, especially for longer lengths**
- **Provide a full matrix of lengths and diameters**  
-- 46 commercial sizes vs. 30 for XIENCE V
- **Increase balloon rated burst pressure**
- **Build upon XIENCE V clinical trial history and data**



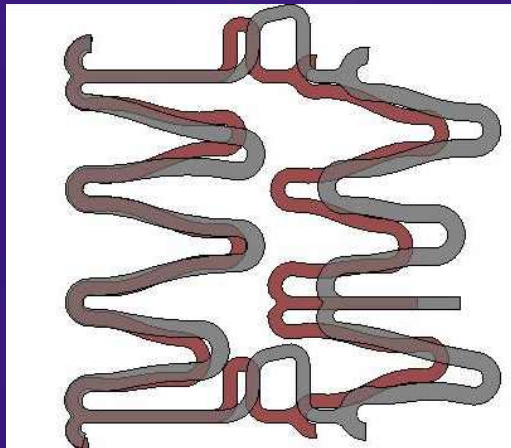
Pipeline products. Currently in development at Abbott Vascular. Not available for sale.



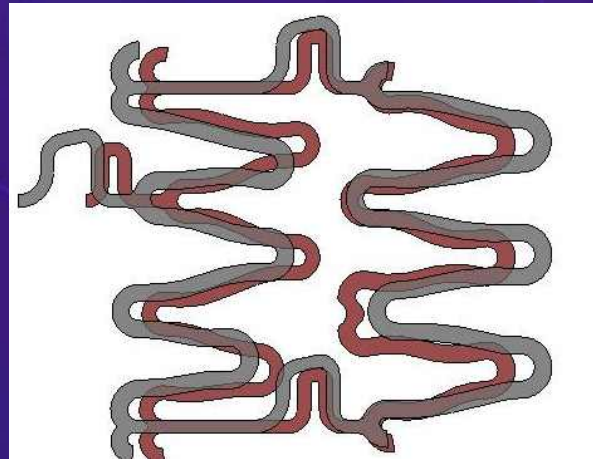
# Enhanced\* Stent Design- Improves Deliverability

Design Feature	Result
Longer Cell Length	Better stent retention
Taller Non-Linear Link	Improved flexibility
Symmetric Proximal End Ring	Better pullback into guide
Designed for Crimping	Reduced strut interference

Body Ring



Proximal End Ring



XIENCE PRIME  
XIENCE V

\* Compared to Xience V.

All illustrations are artist's renditions

# Xience PRIME - Expanded Size Matrix

## XIENCE V

		Stent Length (mm)							
		8	12	15	18	23	28	33	38
Stent Diameter (mm)	2.25								
	2.50								
	2.75								
	3.00								
	3.50								
	4.00								

- Continuous Sizes:  
2.25 – 4.0 mm diameter  
8 – 28 mm lengths

## XIENCE PRIME

		Stent Length (mm)							
		8	12	15	18	23	28	33	38
Stent Diameter (mm)	2.25								
	2.50								
	2.75								
	3.00								
	3.50								
	4.00								

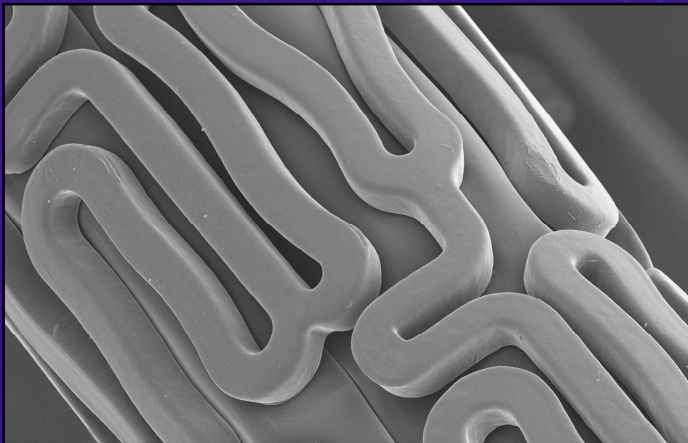
- Differences:  
Longer lengths with XIENCE PRIME (33, 38)

Pipeline products. Currently in development at Abbott Vascular. Not available for sale.

# Xience PRIME: Leveraging XIENCE Fluoro-Copolymer Technology

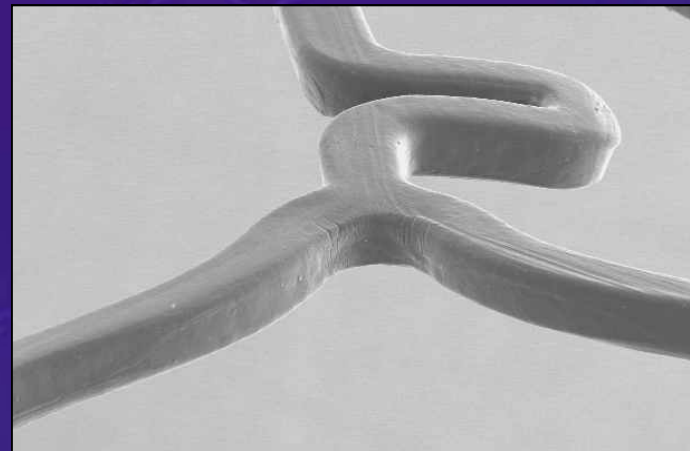
Hardness

Polymer must withstand crimping onto the delivery system and delivery to the lesion



Elasticity

Polymer must be flexible and elastic to withstand stent deployment and post-dilation



Thrombo-Resistance by  
Fluoropassivation

# The Fourth Revolution

---

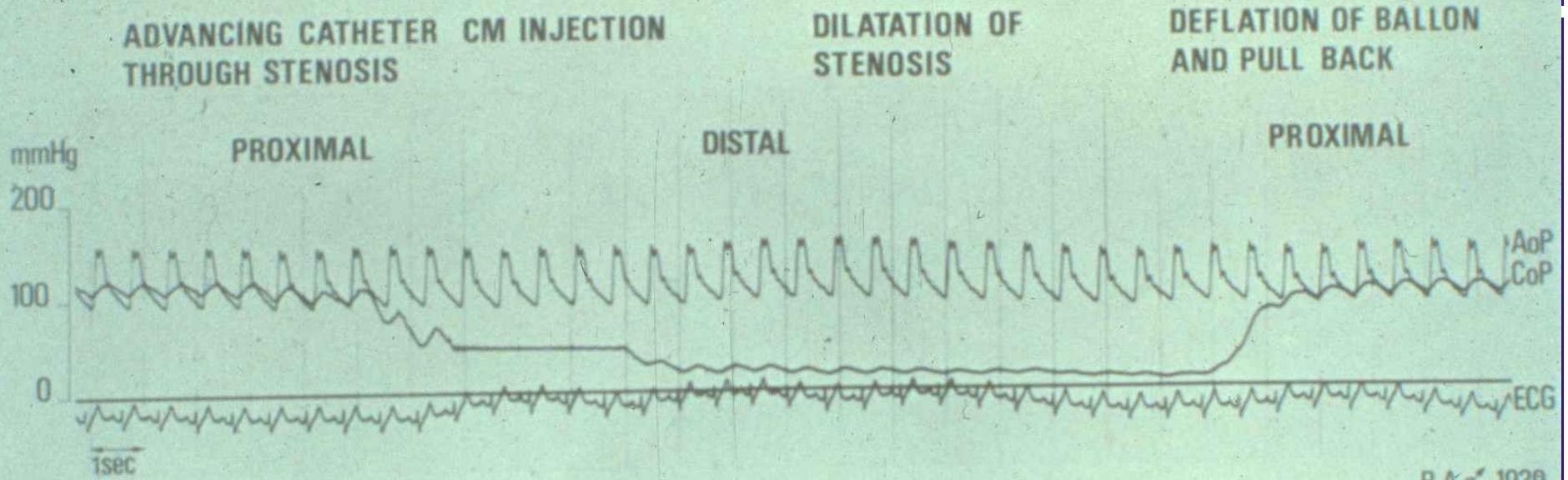
## Fully Bioresorbable Devices The Abbott Vascular BVS Program

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

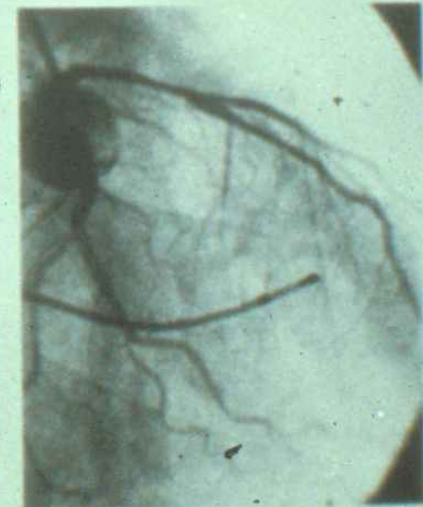
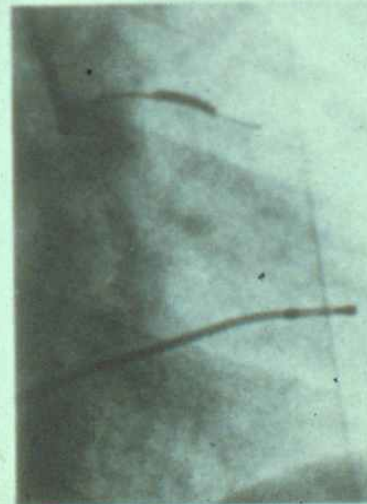
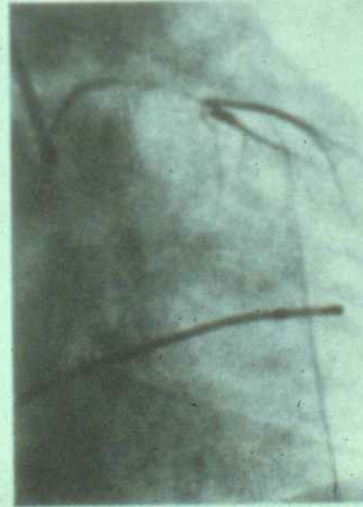
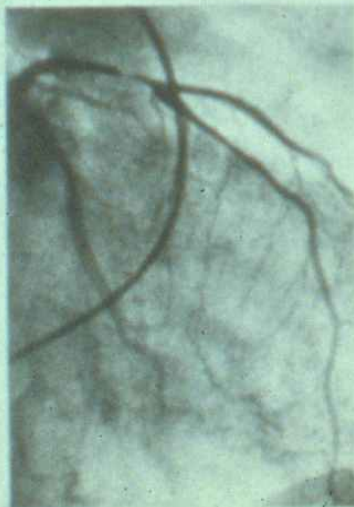


CRT 2010

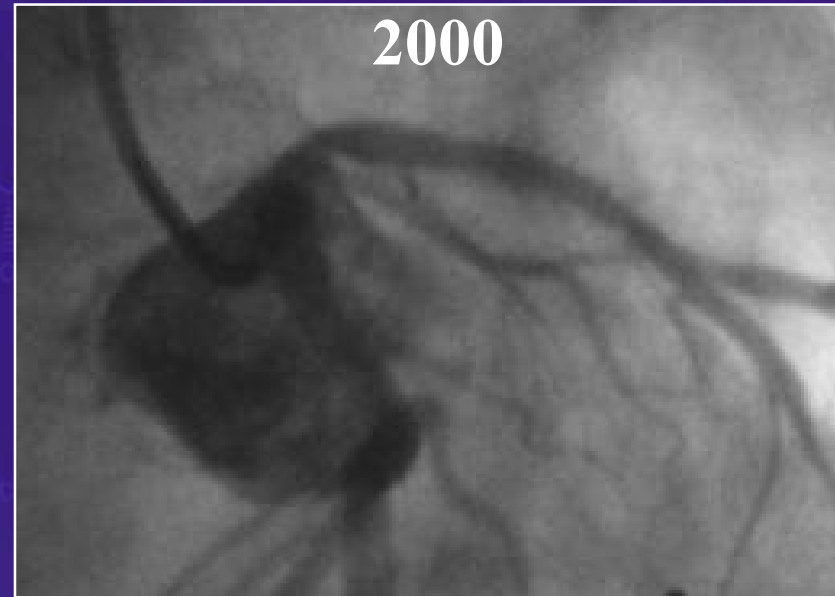
# First PTCA, Zurich September 16, 1977



B.A. 1939

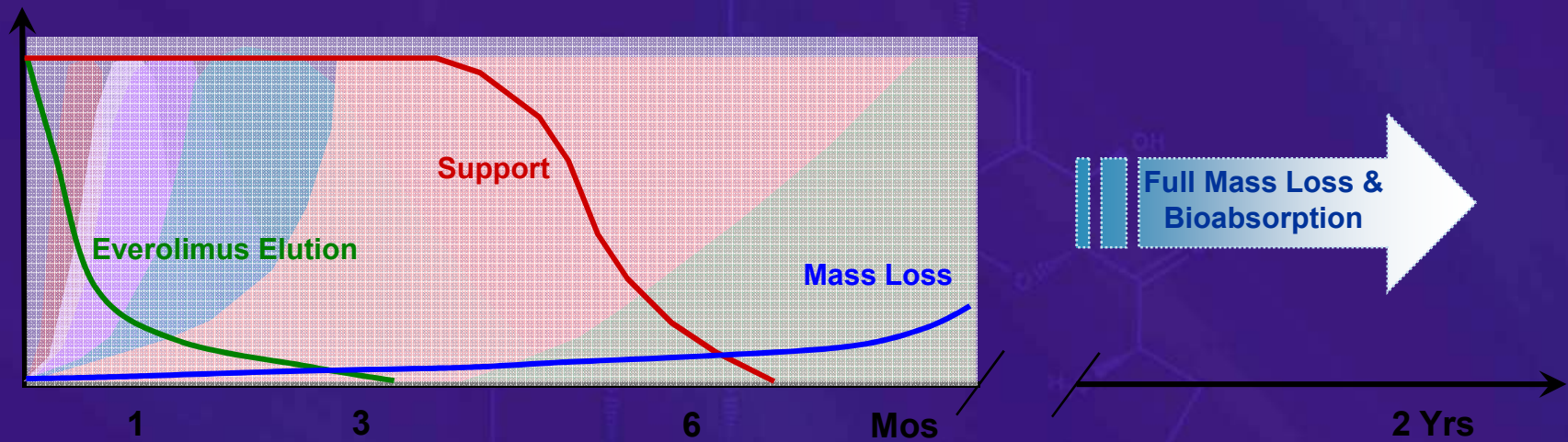


# First PTCA and Follow-Up (A. B.)



**A.B. ,the 1<sup>st</sup> PTCA by Andreas Gruentzig on September 29, 1977, attended and spoke at the 30<sup>th</sup> Anniversary on September 30, 2007 in Zurich, an incredible tribute to the breakthrough made by Andreas 30 years ago**

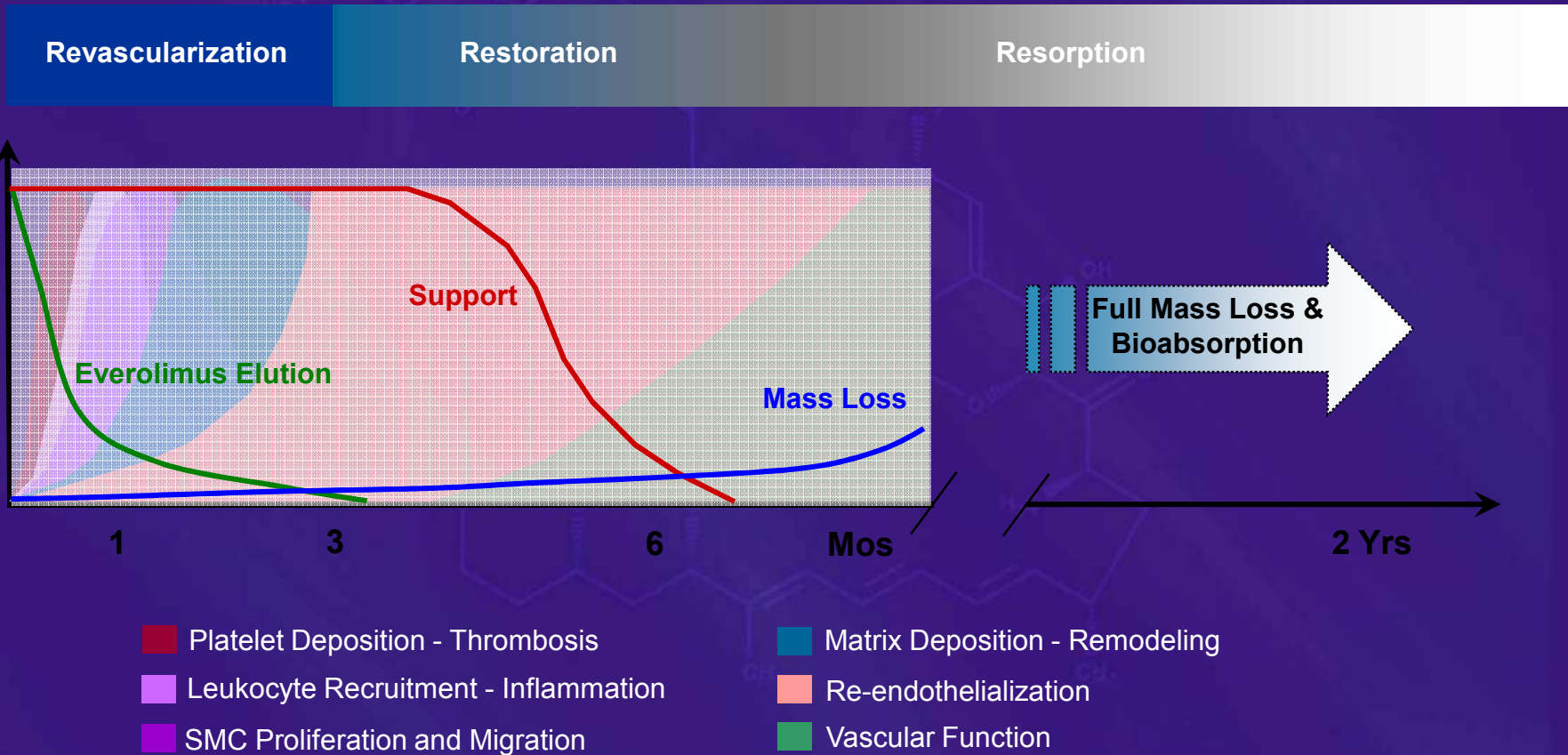
# Performance Criteria for a Fully Bioabsorbable Device



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

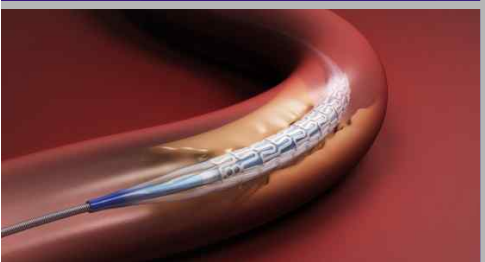
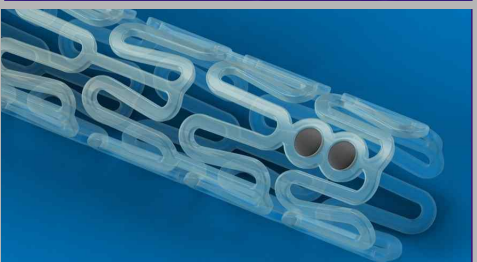
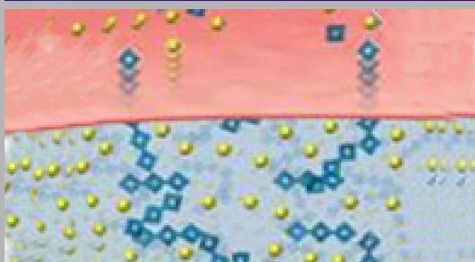
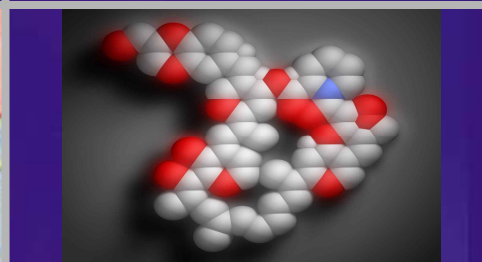
Data on file at Abbott Vascular  
 Forrester JS, et al. *J Am Coll Cardiol* 1991, 17(3): 758-69.

# Phases of Functionality





# Bioresorbable Vascular Scaffold (BVS)

MULTI-LINK VISION Stent Delivery System	Bioresorbable Device Platform	Bioresorbable Coating	Everolimus
<ul style="list-style-type: none"> <li>Seven generations of MULTI-LINK success</li> </ul>	<ul style="list-style-type: none"> <li>Poly (Lactic Acid) (PLLA)</li> <li>Resorbed, fully metabolized (2 years)</li> </ul>	<ul style="list-style-type: none"> <li>PDLA coating</li> <li>Fully bioresorbable (3 months)</li> </ul>	<ul style="list-style-type: none"> <li>Similar dose and release rate to XIENCE V</li> </ul>
			

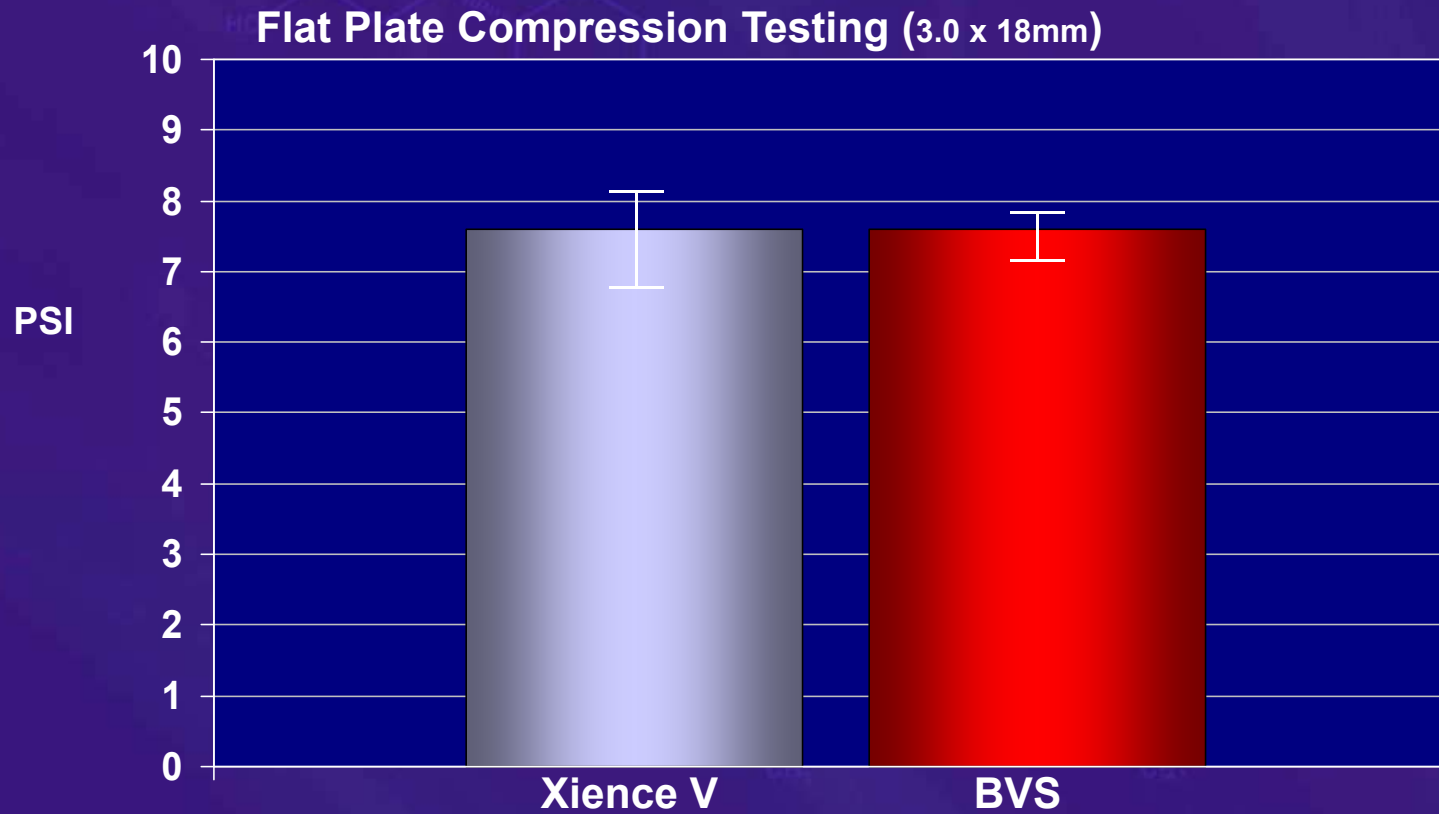
All illustrations are artists' renditions

SE2929250 Rev. A  
Information contained herein for presentation outside of the U.S. and Japan.

Pipeline product. Currently in development at Abbott Vascular. Not available for sale.  
Information contained herein for presentation at Singapore Great Minds Meeting. Not to be reproduced, distributed or excerpted.

© 2010 Abbott Laboratories

# Radial Strength



**Radial strength comparable to metal stent at T=0**

Data on file at Abbott Vascular.

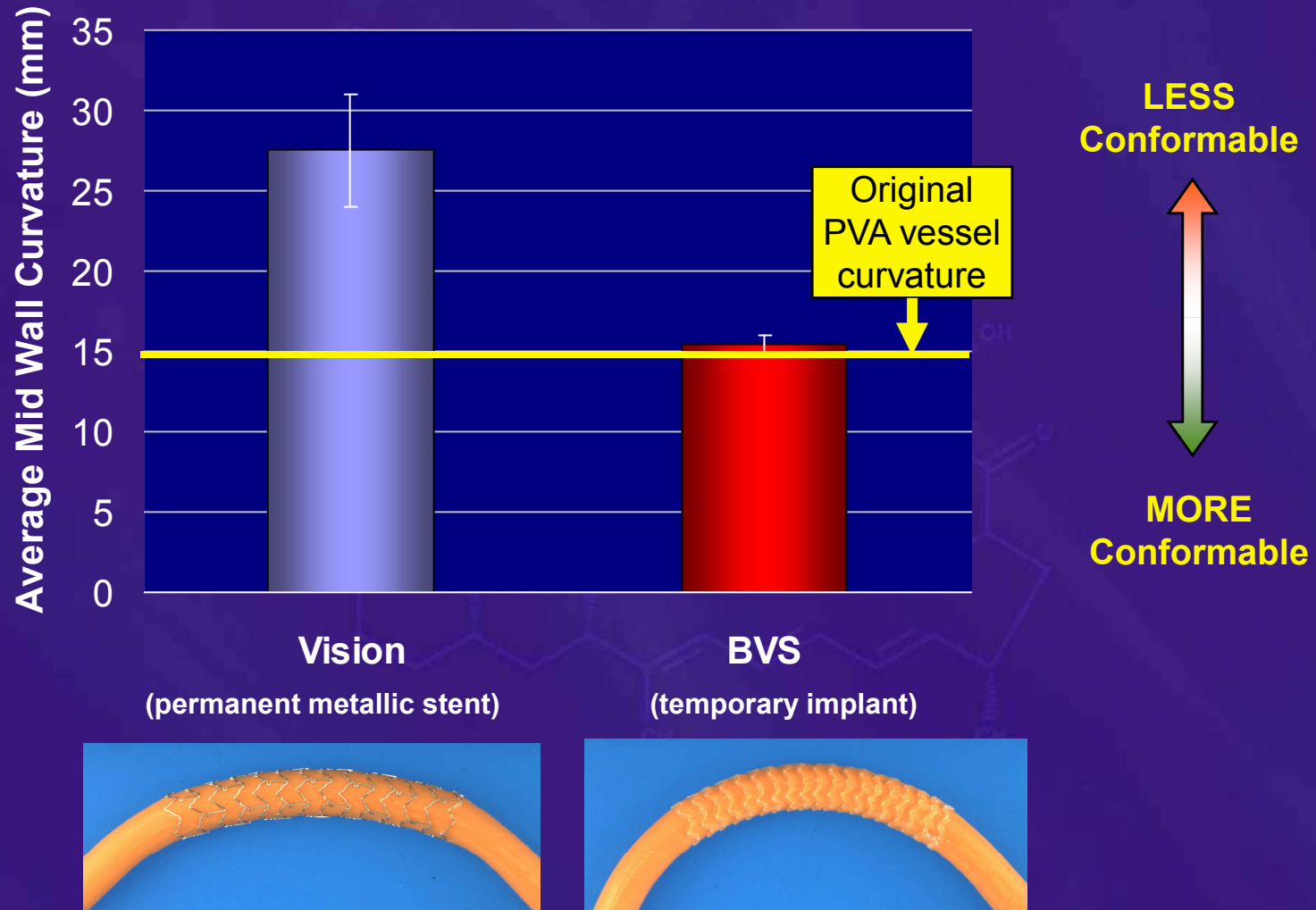
SE2929250 Rev. A  
Information contained herein for presentation  
outside of the U.S. and Japan.

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

Information contained herein for presentation at Singapore Great Minds Meeting. Not to be reproduced, distributed or excerpted.

© 2010 Abbott Laboratories

# Addressing Vessel / Implant Compliance Mismatch



Data on file at Abbott Vascular.

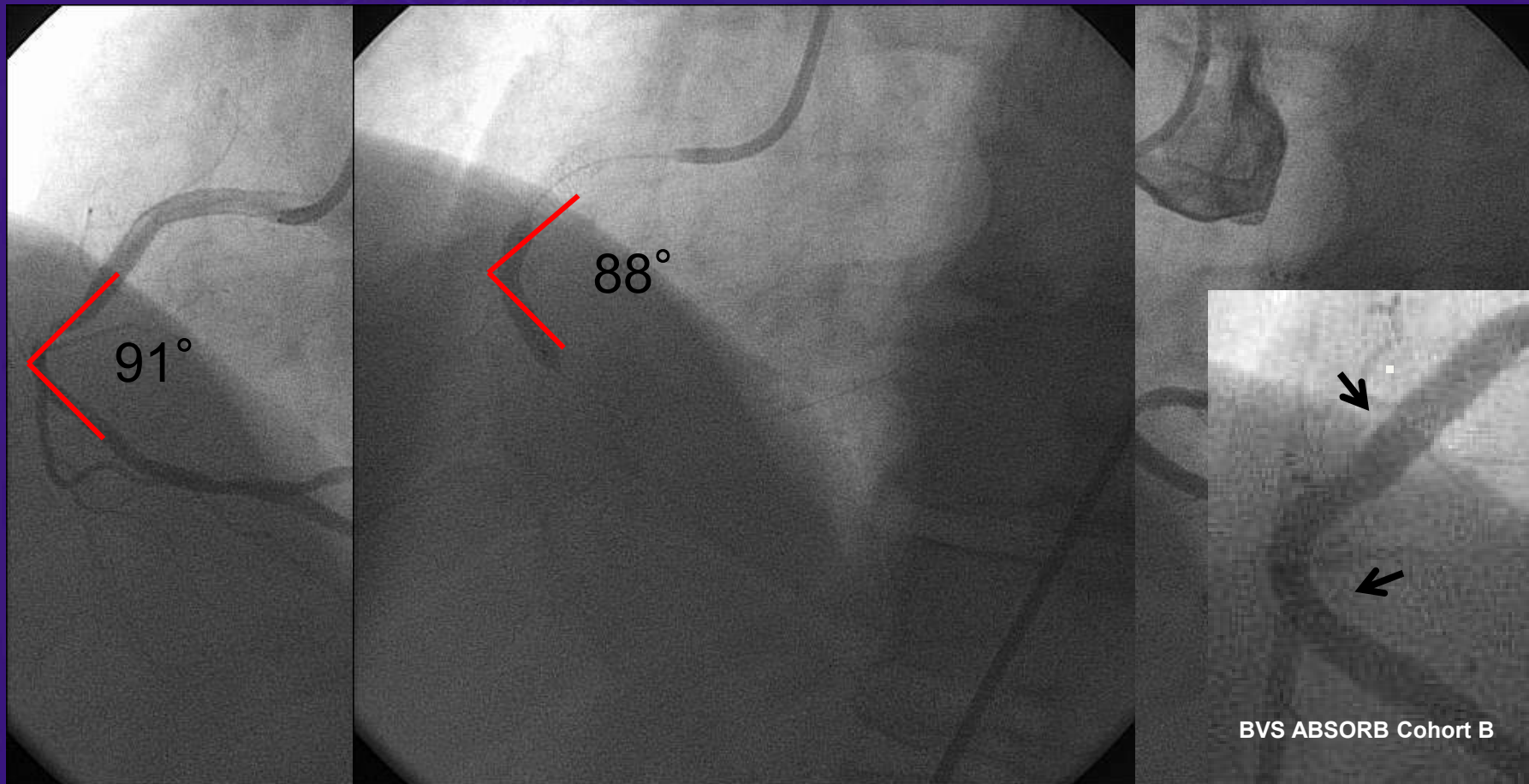
SE2929250 Rev. A  
Information contained herein for presentation  
outside of the U.S. and Japan.

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

Information contained herein for presentation at Singapore Great Minds Meeting. Not to be reproduced, distributed or excerpted.

© 2010 Abbott Laboratories

# Addressing Vessel / Implant Compliance Mismatch



Serruys, P. , TCT 2009

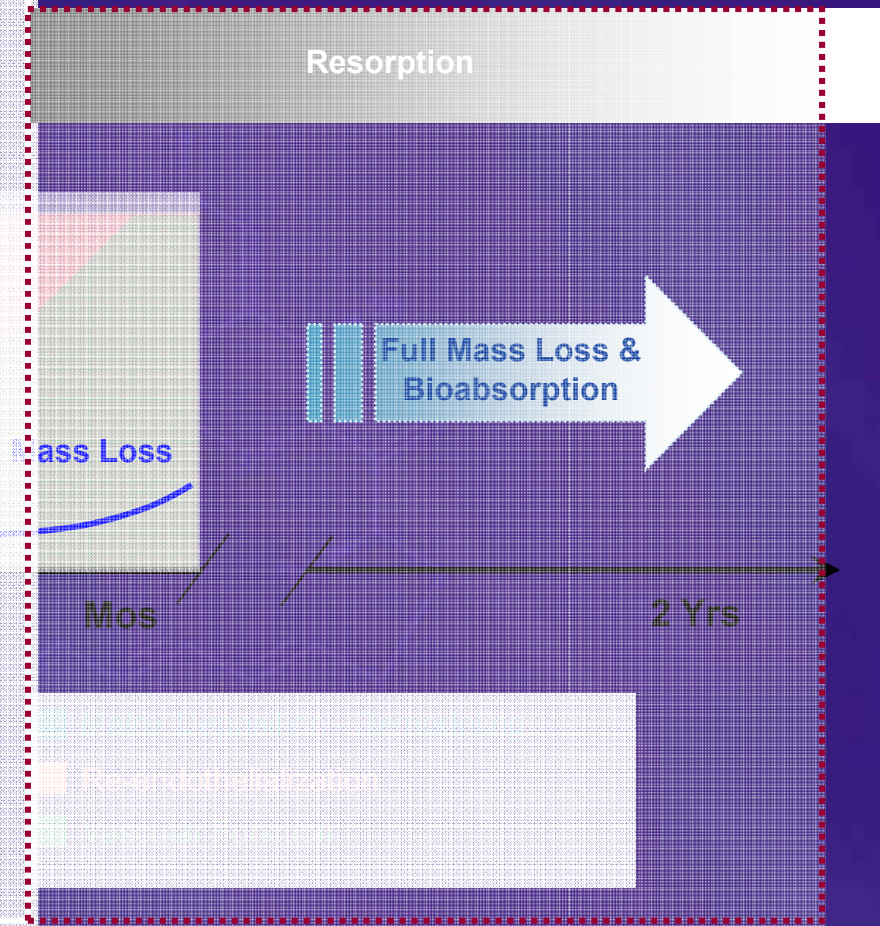
SE2929250 Rev. A  
Information contained herein for presentation  
outside of the U.S. and Japan.

Pipeline product. Currently in development at Abbott Vascular. Not available for sale.  
Information contained herein for presentation at Singapore Great Minds Meeting. Not to be reproduced, distributed or excerpted.  
© 2010 Abbott Laboratories

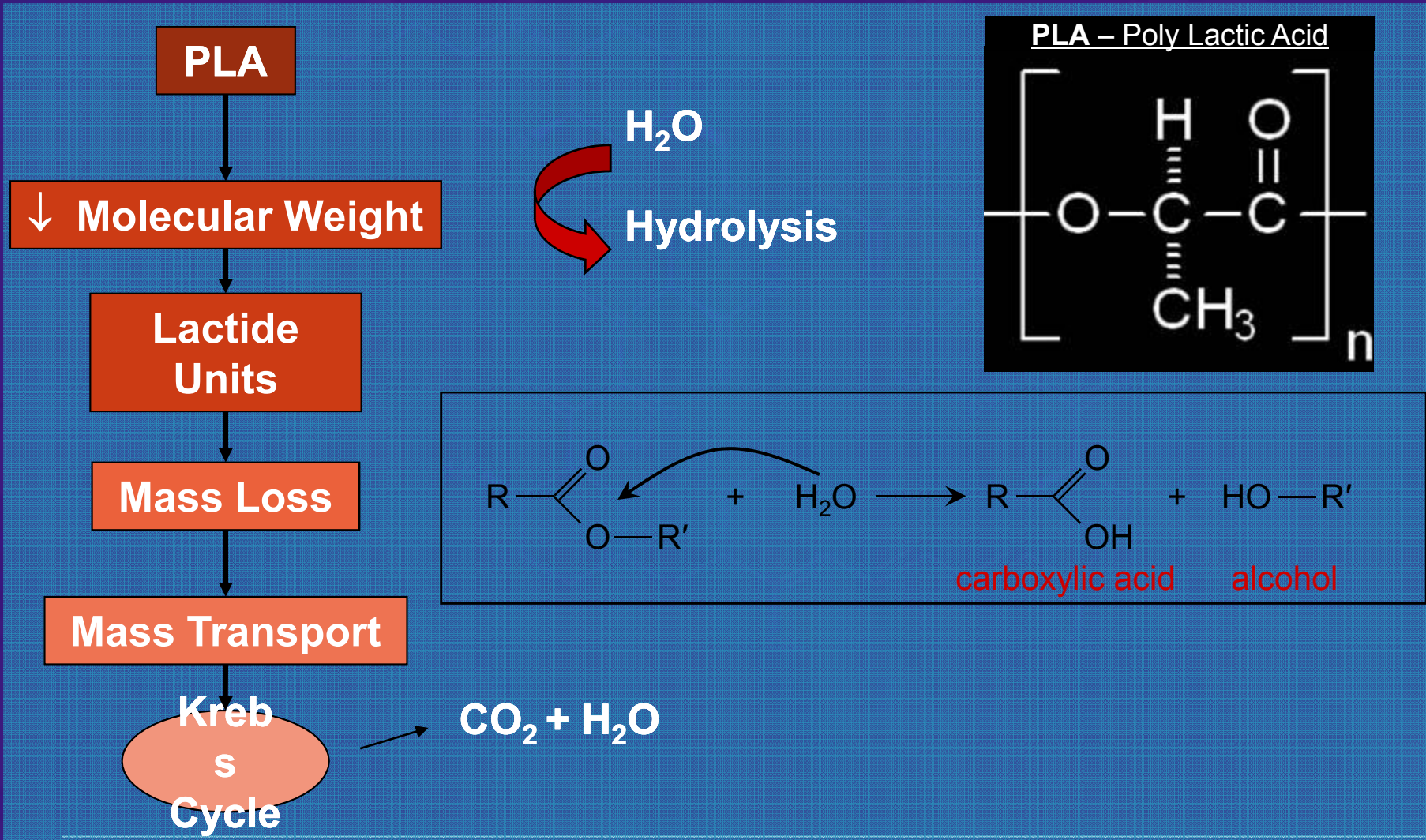
# Resorption

What if a fully bioabsorbable device could completely disappear, leaving behind a more natural vessel?

- Benign Bioabsorption
- Return of Vascular Function
- Address Current DES Concerns
- Expansive Remodeling



# BIORESORPTION: Poly Lactide Acid - Hydrolysis

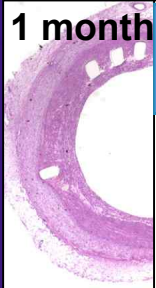


# Porcine Coronary Safety Study: Representative Photomicrographs (2x)

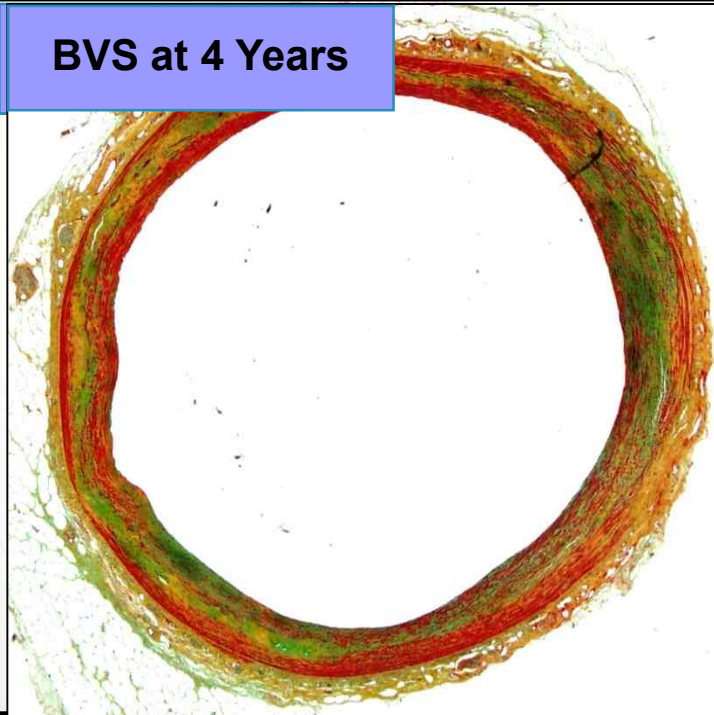
## Porcine Coronary Artery Model.

**BVS**

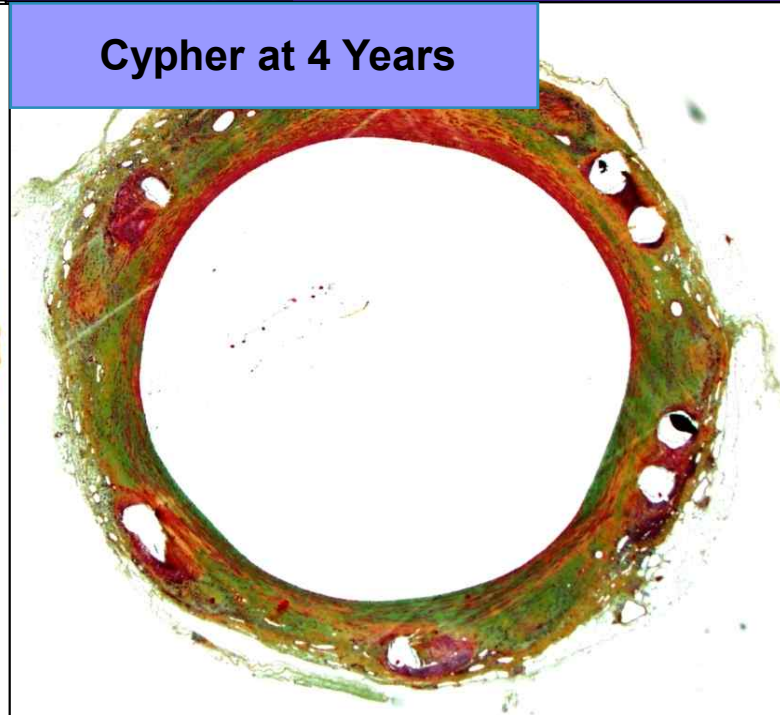
1 month



**BVS at 4 Years**



**Cypher at 4 Years**



**CYPH**

1 month



**Representative photomicrographs 2X.**

Photos taken by and on file at Abbott Vascular.

SE2929250 Rev. A  
Information contained herein for presentation  
outside of the U.S. and Japan.

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

Information contained herein for presentation at Singapore Great Minds Meeting. Not to be reproduced, distributed or excerpted.

© 2010 Abbott Laboratories

# ABSORB Serial IVUS Results – Per Treatment

	Post-PCI n=16	6-month F/U n=16	2-year F/U n=16	% Diff (6M to 2Y)	p- value
Vessel (EEM) area (mm <sup>2</sup> )	13.17*	13.11*	12.56*	-4.89	0.055
Lumen area (mm <sup>2</sup> )	5.99	4.92	5.60	<b>+11.53</b>	<b>0.034</b>
Plaque area (mm <sup>2</sup> )	7.44*	8.60*	7.10*	<b>-17.44</b>	<b>&lt;0.001</b>
Minimal Lumen area (mm <sup>2</sup> )	5.05	3.76	4.54	<b>+18.32</b>	<b>0.005</b>

\*n=24

\*n=15

Serruys, P, et al. *Lancet* 2009; 373: 897-910.

P-values per Wilcoxon's signed rank test



# ABSORB: 3 Year Clinical Results

Hierarchical	6 Months 30 Patients	12 Months 29 Patients**	2 Years 28 Patients**	3 Years 28 Patients**
Ischemia Driven MACE (%)	3.3% (1)*	3.4% (1)*	3.6% (1)*	3.6% (1)*
Cardiac Death (%)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
MI (%)	3.3% (1)*	3.4% (1)*	3.6% (1)*	3.6% (1)*
Q-wave MI (%)				(0)
Non-Q-wave MI (%)				(1)*
Ischemia Driven TLR (%)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
by PCI	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
by CABG	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)

**No Stent Thrombosis Up to 3 Years**

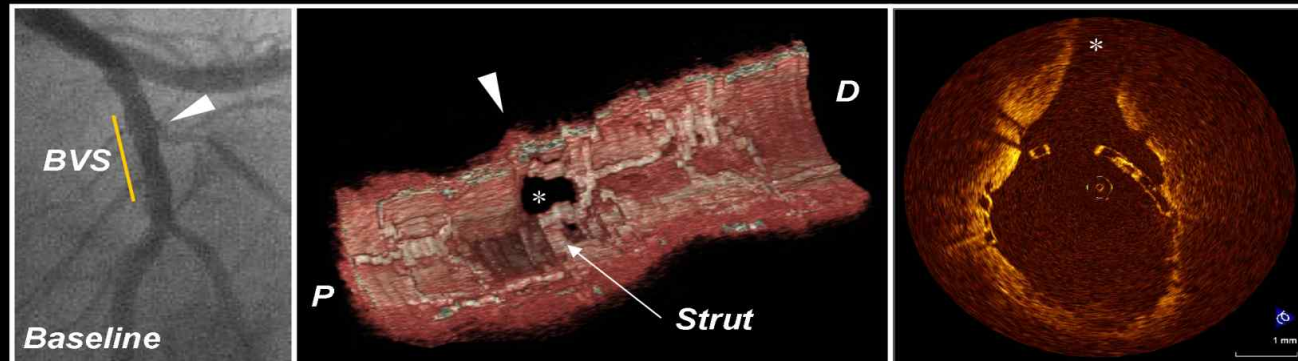
## No new MACE events from 6 months and 3 years

\*Same patient – this patient also underwent a TLR, not qualified as ID-TLR (DS = 42%) and died from a non-cardiac cause 888 days post-procedure.

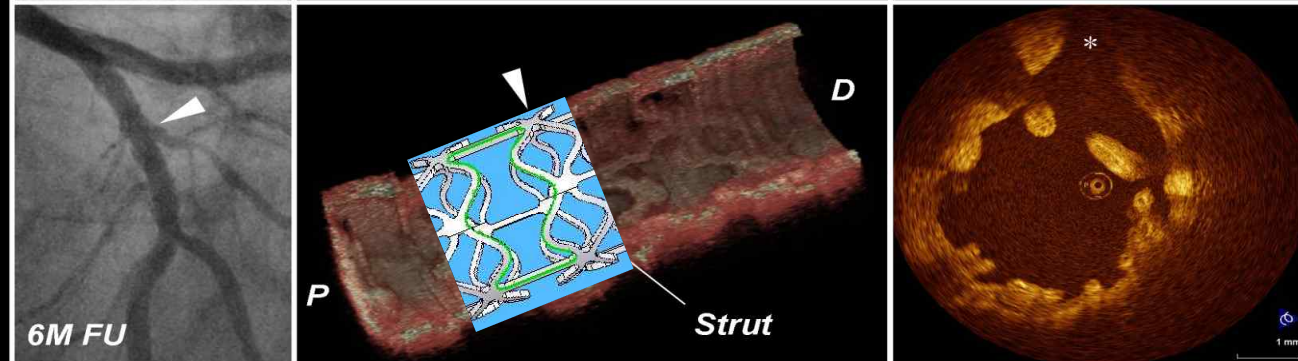
\*\*One patient missed the 9, 12, 18 month and 2 and 3 year visits. One patient died from a non-cardiac cause 706 days post-procedure

# 3-Year Follow-Up: 3-D OCT Example of Strut Resorption and Side-Branch Preservation by OCT

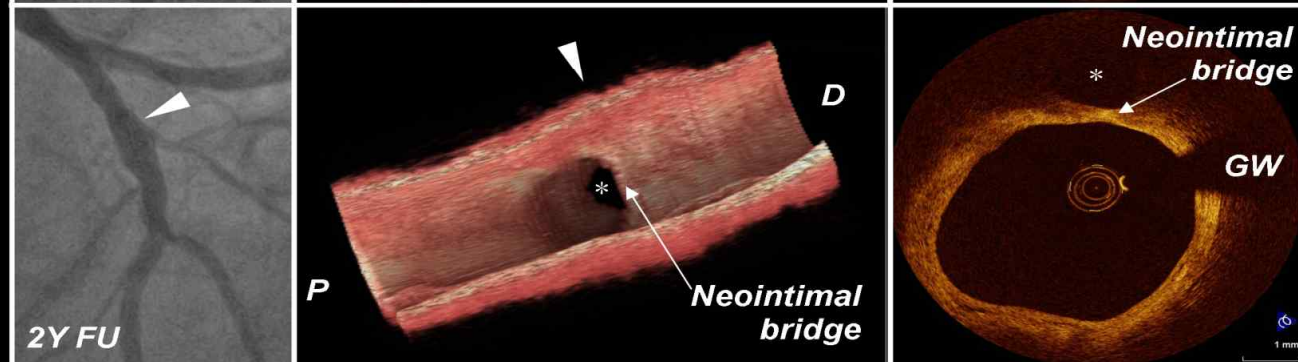
2006  
M2 1.0 mm/s



2007  
M3 1.0 mm/s



2009  
C7 20 mm/s



Serruys, ICI 2009

SE2929250 Rev. A  
Information contained herein for presen  
outside of the U.S. and Japan.

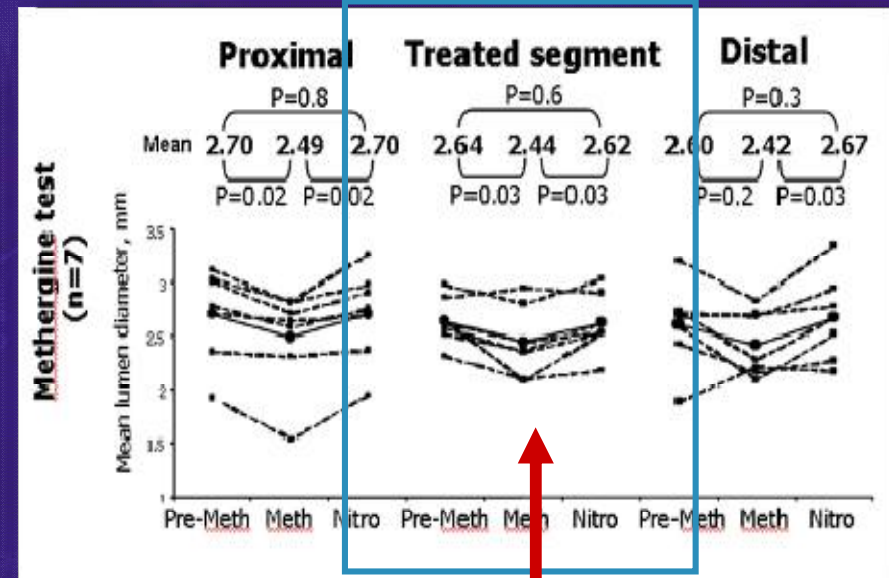
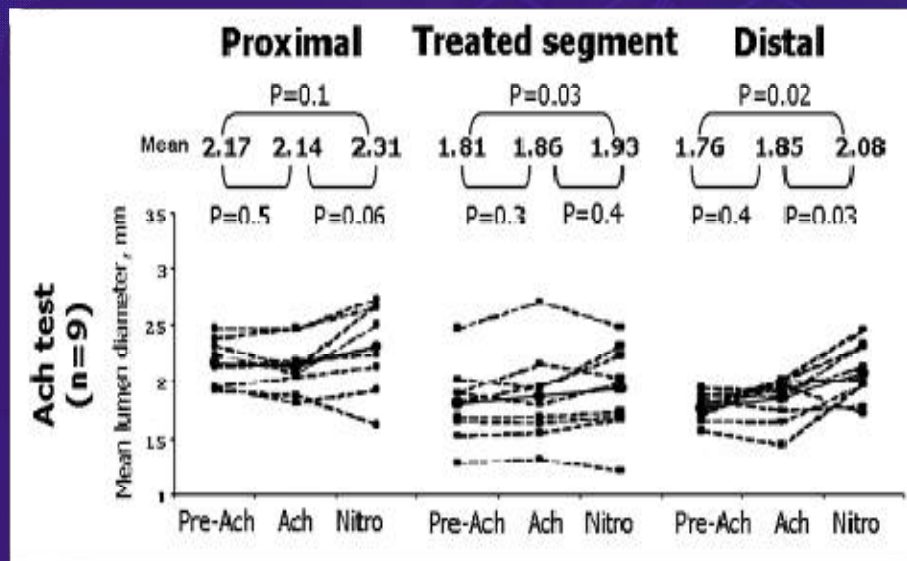
A

B

C

ted.

# ABSORB: Vasomotor Function Testing at 24 Months



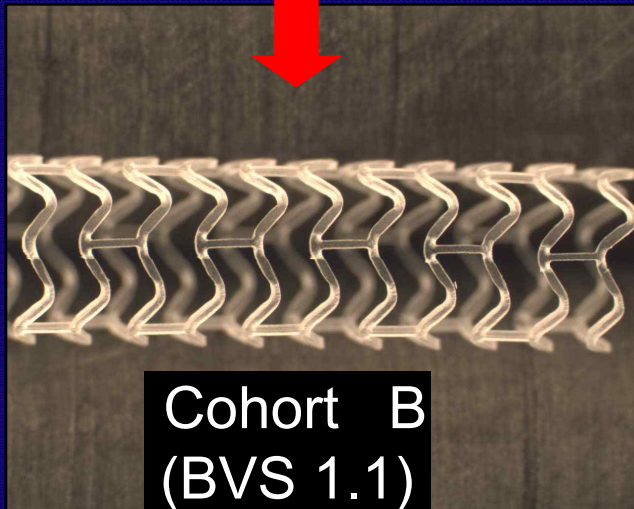
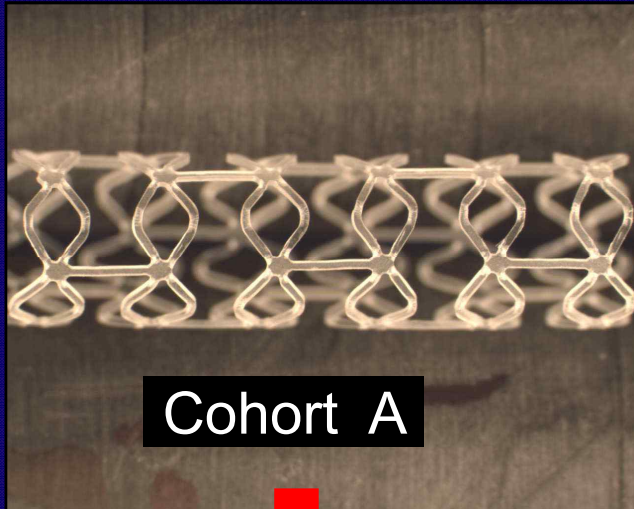
**Stented Segment !**

## Potential clinical significance:

- Intact, functional endothelium → reduced thrombosis risk?
- Improved coronary reserve → improved perfusion/less angina?
- Glagov's phenomenon, accommodative remodeling → fewer TLRs?
- Reduction in other MACE?

Serruys, P, et al. *Lancet* 2009; 373: 897-910.

# Next Generation BVS Device: Objectives



- More uniform strut distribution
- More even support of arterial wall
- Higher radial strength
- Lower late 'stent' area loss
- Storage at room temperature
- Improved device retention
- Unchanged:
  - Material, coating and backbone
  - Strut thickness
  - Drug release profile
  - Total degradation Time

# ABSORB Cohort B (BVS 1.1)

- N = 101 pts; 12 sites (Europe, Australia, New Zealand)
- Clinical follow-up schedule:
  - 30 days, 6 months, 12 months, annually to 5 years
- Imaging schedule:

## Group B1 (n = 45)

QCA, IVUS, OCT, IVUS VH

Baseline

6  
Months

12  
Months

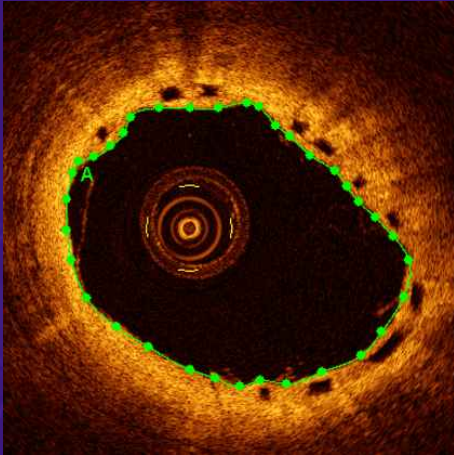
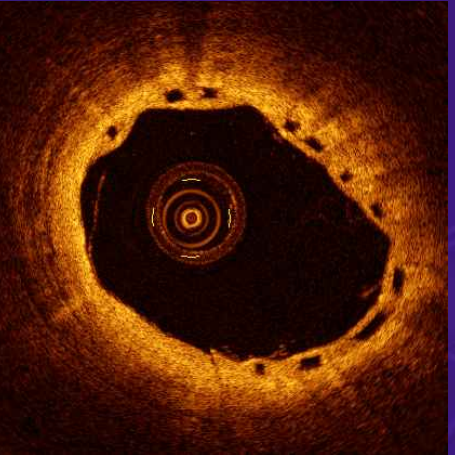
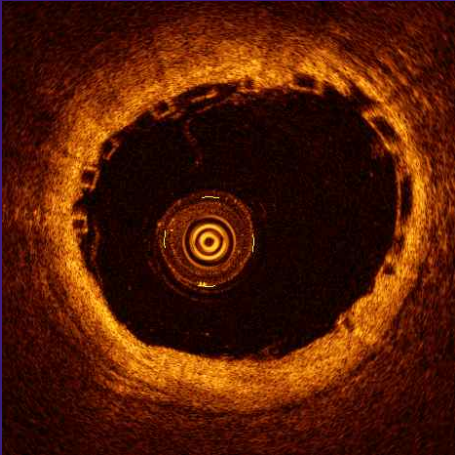
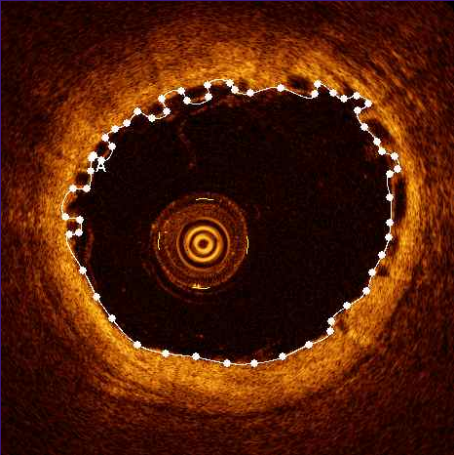
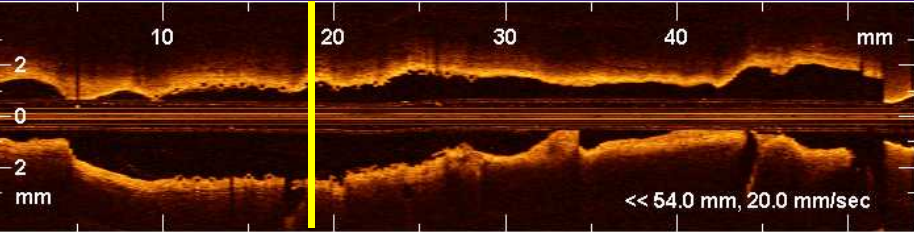
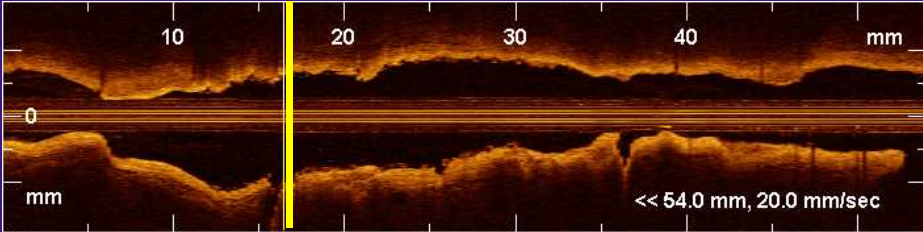
24  
Months

## Group B2 (n = 56)

# ABSORB Cohort B

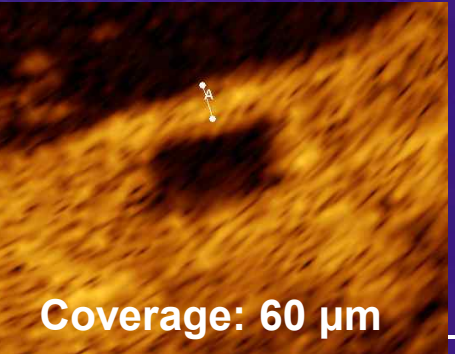
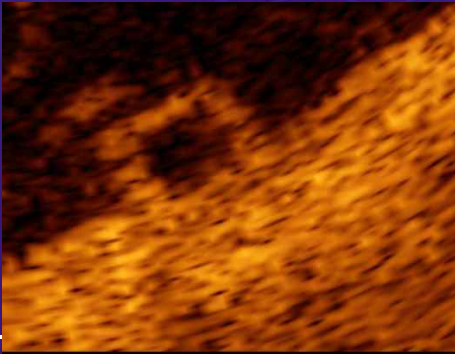
Baseline

6 month follow up



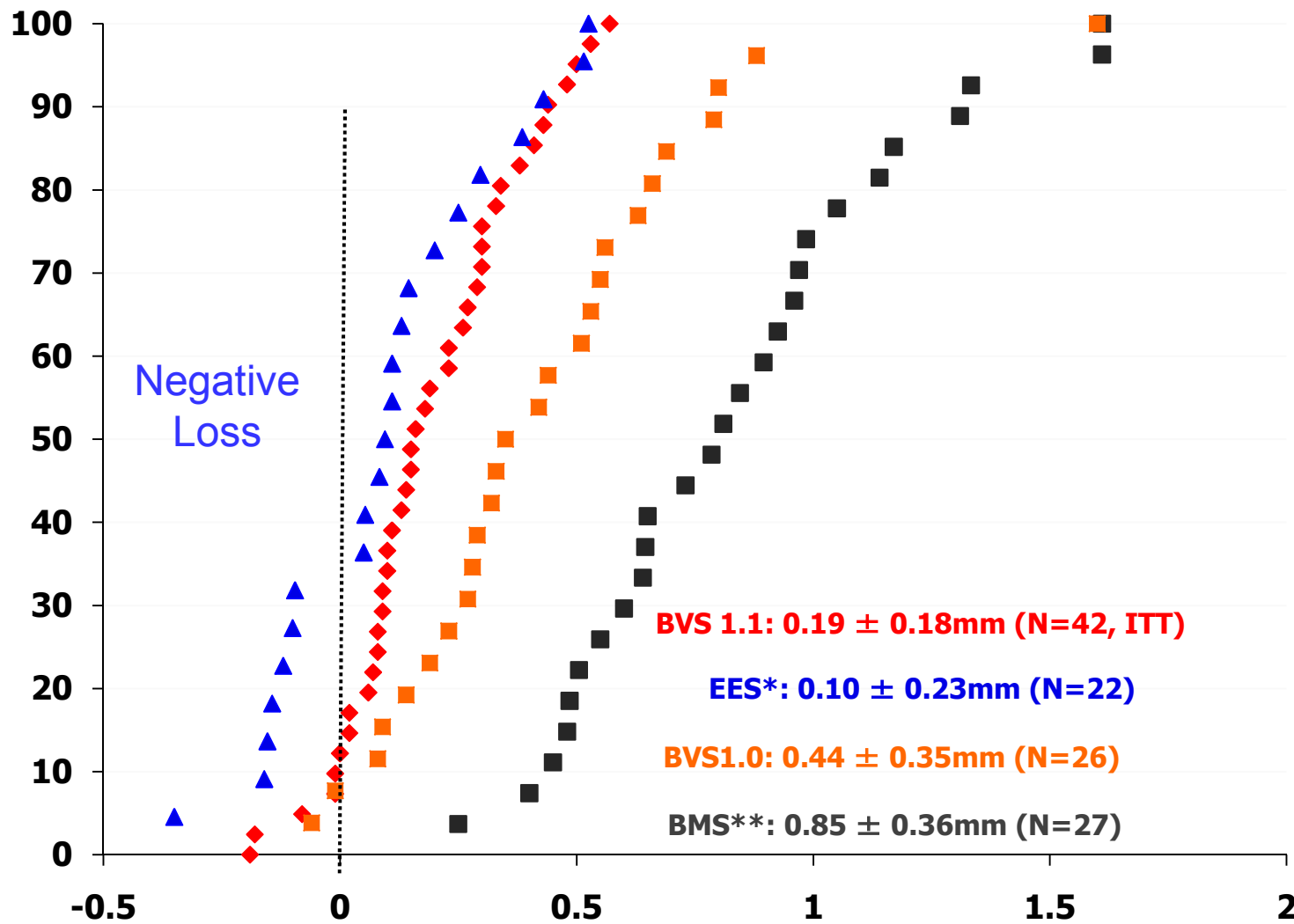
Baseline  
MLA: 7.39 mm<sup>2</sup>

Follow up  
MLA: 8.18 mm<sup>2</sup>



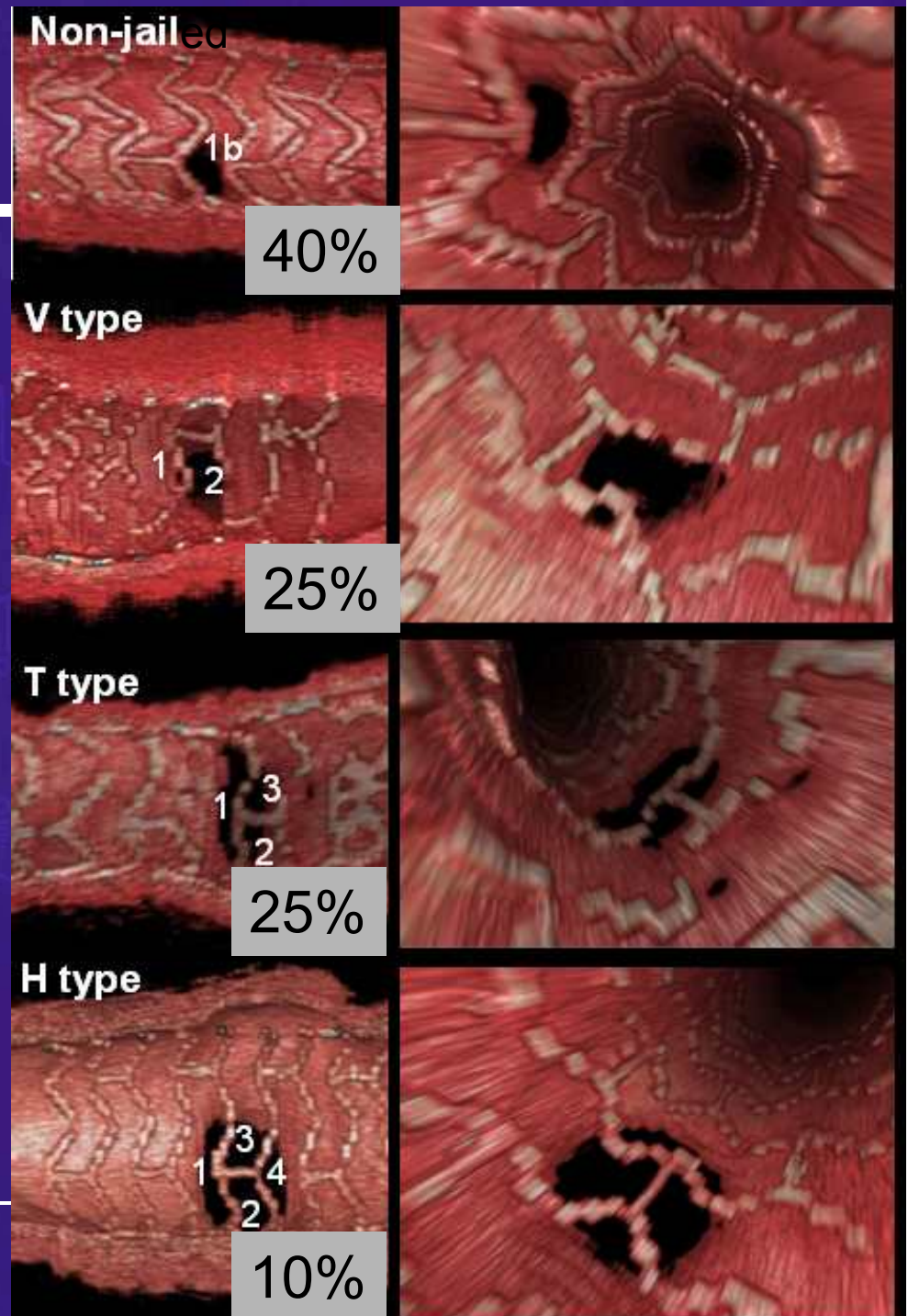
Coverage: 60 μm

# Cohort B (BVS 1.1) Late Loss – 6 months



# The analysis of side-branch jailed with the polymeric BVS struts with 3-D reconstruction by OFDI

Jailed sidebranch ostium can be classified according to number of compartment created by the overhanging struts with different configuration (e.g. V, T and H type)





# ABSORB EXTEND Study

---

- Continued enrollment in ABSORB with expanded lesion complexity
- *1000 patients in up to 100 sites internationally outside the U.S. (P.I. = Alexander Abizaid MD)*
- **Objective:** Continue expanding experience with the COHORT B BVS device with the aim of substantiating confidence in the acute performance and late clinical outcomes with an expanded matrix of sizes in more complex patients