Incredibly Bright: BVS Will Replace DES in the Majority of Cases

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Incredibly Bright: BVS Will Replace DES in the Majority of Cases

1. Second Gen DES (CoCrEES) are great, but not over the long haul: ***the unmet need***
2. Absorb BVS: Acute Performance
3. Absorb BVS: Longterm Outcomes
4. Absorb BVS: Expanding Real-World Experience in Complex Lesions

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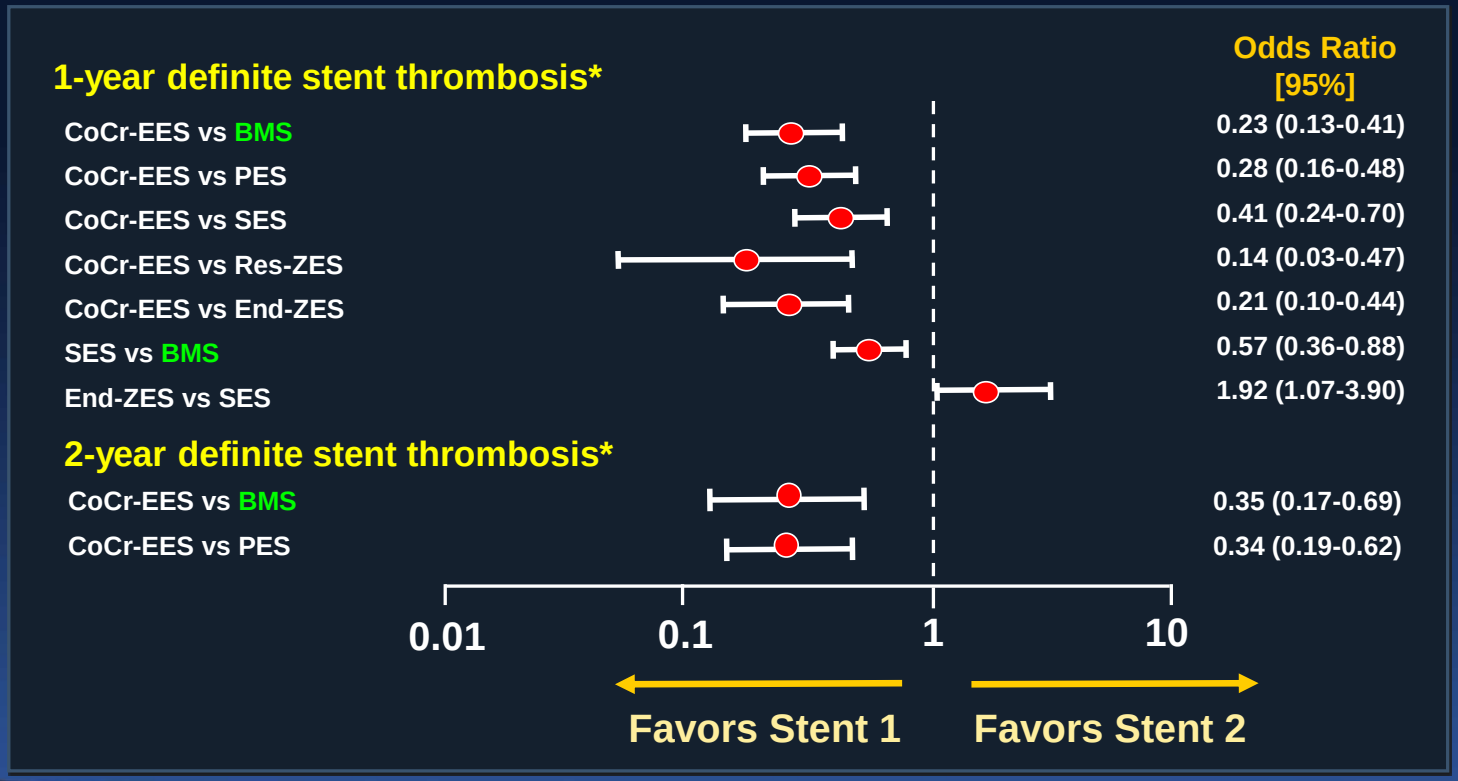
XIENCE (CoCrEES): Independent Safety Analysis

Stent Thrombosis Network Meta-analysis

Primary EP: ARC Definite ST (FU through 2 years)

49 RCTs, 50,844 pts



*Only statistically significant results are shown

Palmerini T et al. *Lancet* 2012:On-line

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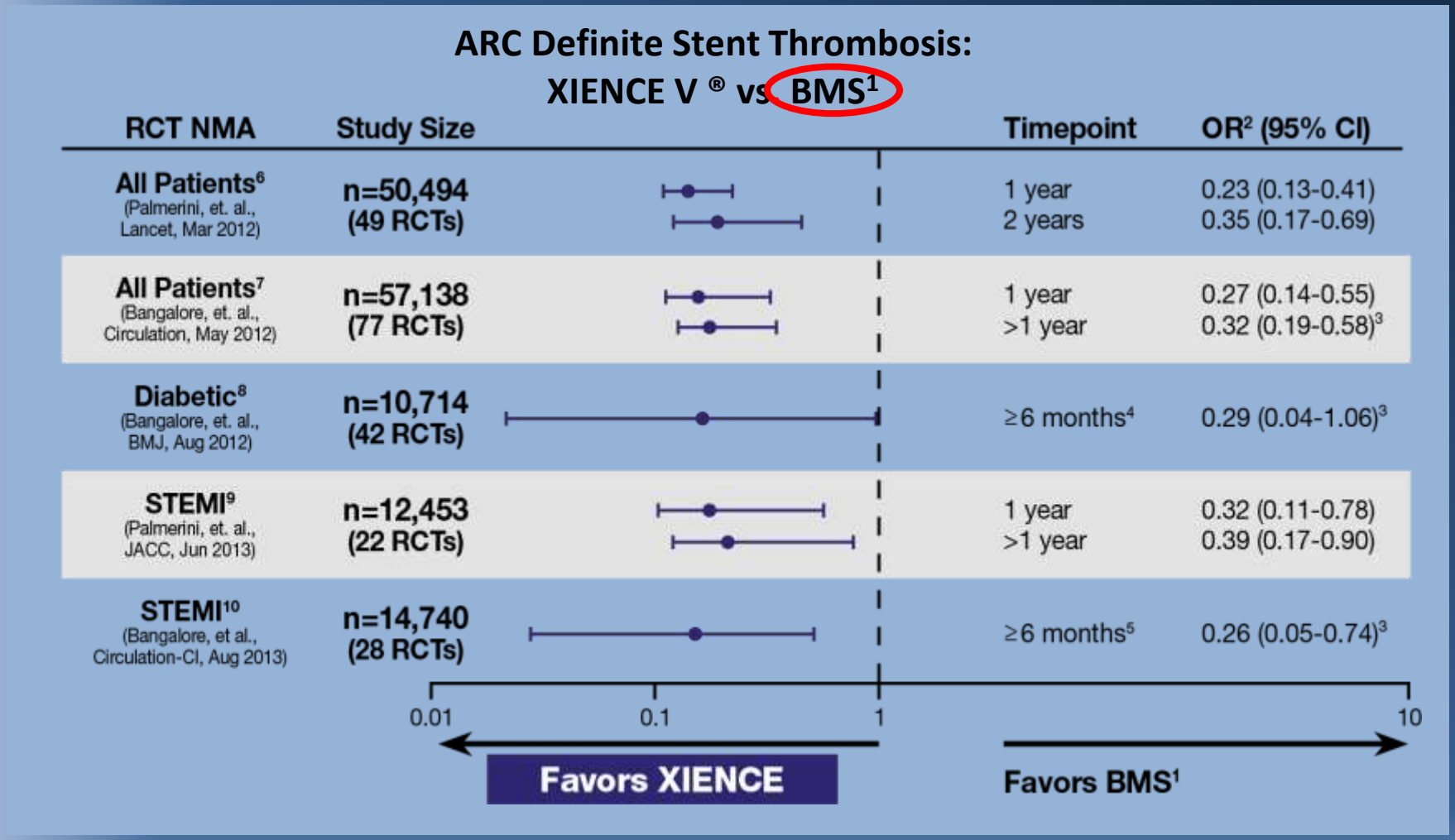
XIENCE CoCrEES Safety Profile Compared to BMS: 5 Major Network Meta-Analyses of RCT's



See slide 5. 1. BMS is a composite of several bare metal stents. 2. An odds ratio is a method of comparing the odds of an event between two groups. 3. A rate ratio was calculated instead of an odds ratio. 4. Median follow-up was 1.9 years in this study. 5. Median follow-up was 2.2 years in this study. 6. Palmerini T, et al. The Lancet. March 23, 2012; 379:1393-1402. 7. Bangalore S, et al. Circulation May 14, 2012;125:2873-2891. 8. Bangalore S, et al. British Medical Journal, Aug 10, 2012. 345:e5170 doi: 10.1136/bmj.e5170. 9. Palmerini T, et al. JACC. June 7, 2013;62:496-504. 10. Bangalore S, et al. Circ Cardiovasc Interv, Aug 6, 2013. doi: 10.1161/circinterventions.113.000415. "Meta-analyses should be regarded as hypothesis-generating and the findings of Palmerini and colleagues suggest that a randomized trial of CoCr EES and BMS is desirable." Ormiston, The Lancet, April 2012.

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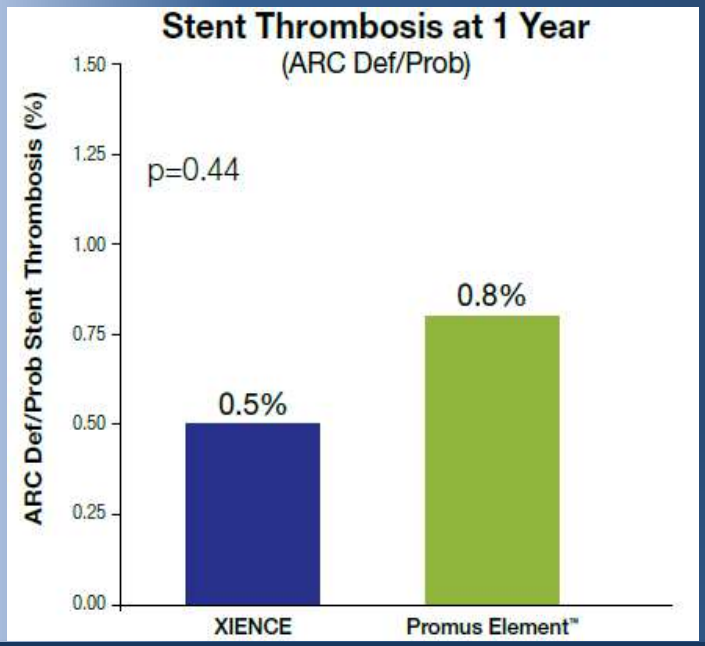
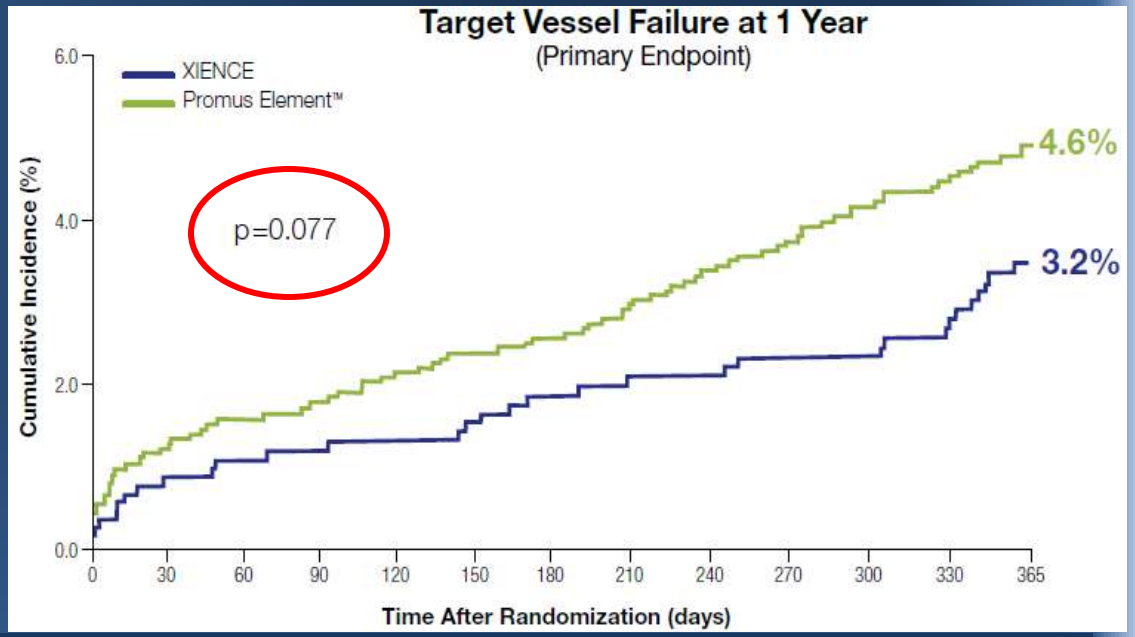
PLATINUM PLUS: XIENCE CoCrEES vs. Promus Element™ PtCrEES

XIENCE Demonstrated Numerically Lower Event Rates vs. Promus Element ™





- At 1 year, XIENCE has numerically lower event rates in several safety and efficacy endpoints compared to Promus Element ™.[1]
- XIENCE showed significantly lower stent thrombosis rates at 30 days as compared to Promus Element ™.[2]
- Premier is Element. With a 99.3% identical stent design, we would expect Premier to have the same clinical performance as Element.

1. Fajadet, J., et al., Results of the Primary Endpoint of the PLATINUM PLUS Trial, TCT 2013. 2. Fajadet J, et al. PLATINUM PLUS 30-day Poster, TCT 2012.

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So, With All this Great Data on CoCrEES Drug-Eluting Stents, What's the Remaining Downside or Unmet Clinical Need for DES??

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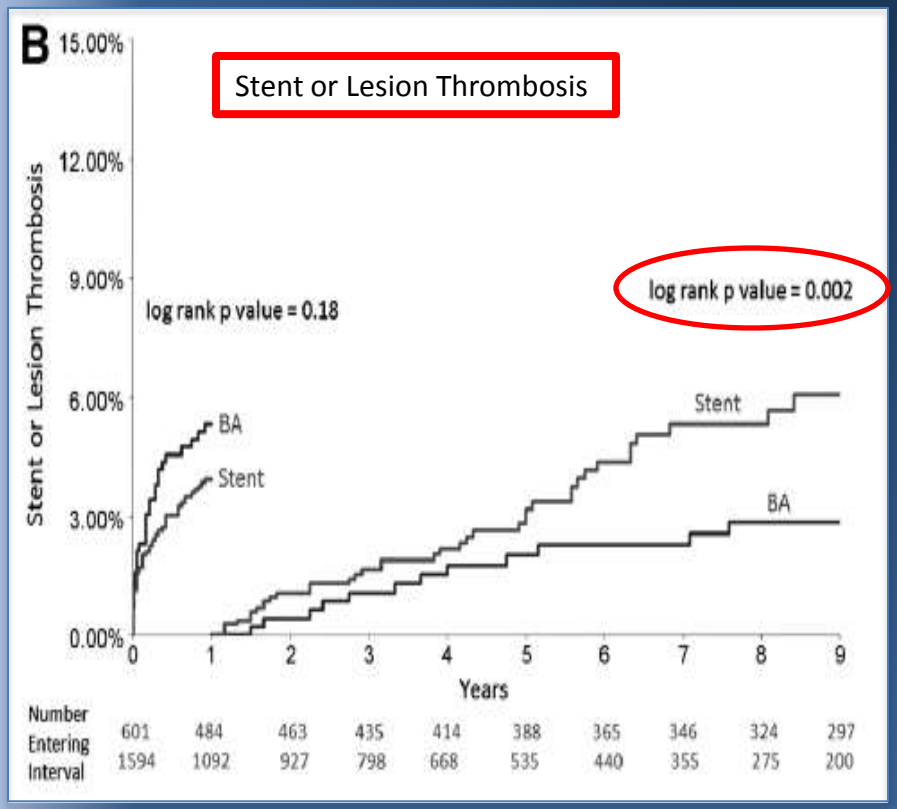
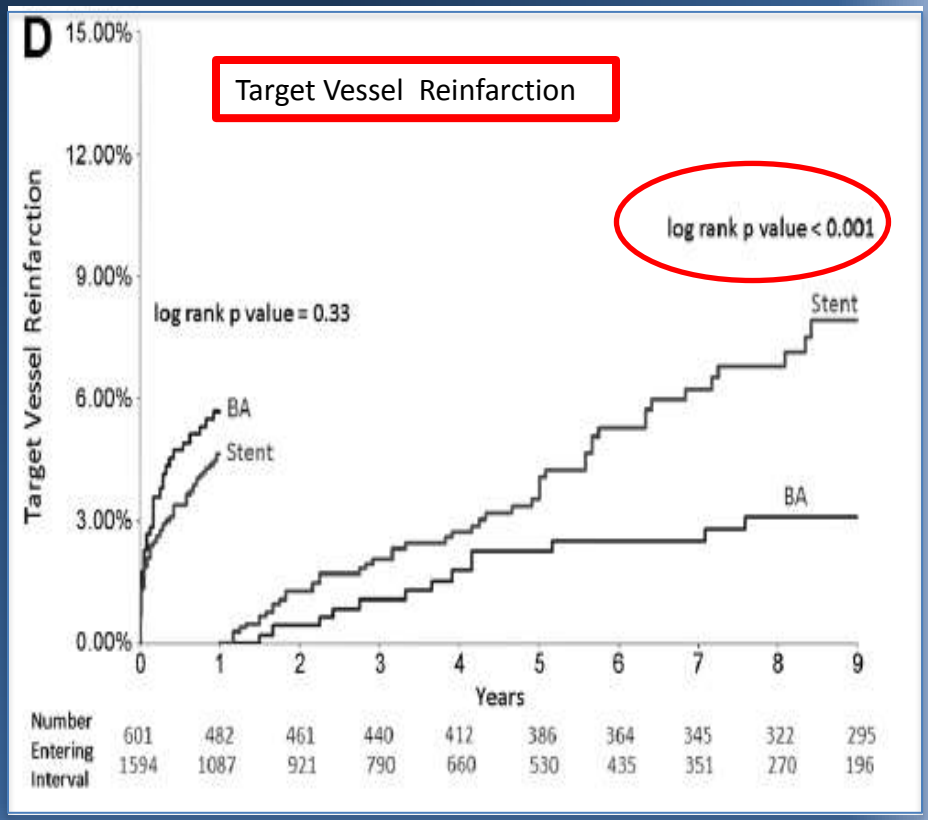
Stents vs. Balloon Angioplasty for STEMI:

Very-Late Events Greater for Metallic Stents (> 1 yr)





Brodie et al, J Interven Cardiol 2014:27: 21-28

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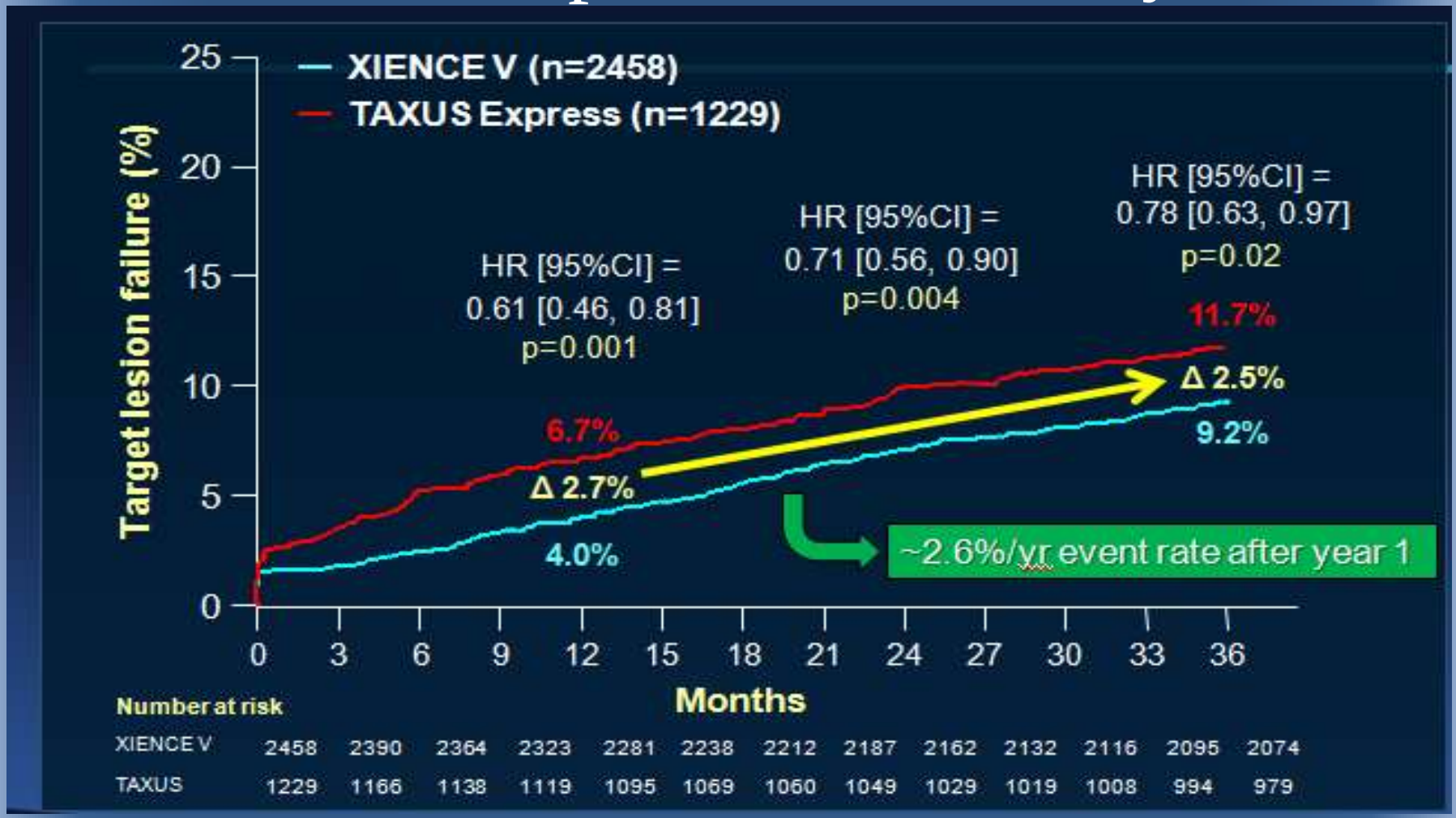
SPIRIT IV: Target Lesion Failure (TLF)

Continued Ramp of TLF out to 3 years



TLF = cardiac death, target vessel MI, or ischemic-driven TLR

Stone, G. – SPIRIT IV 3 year data, TCT 2011

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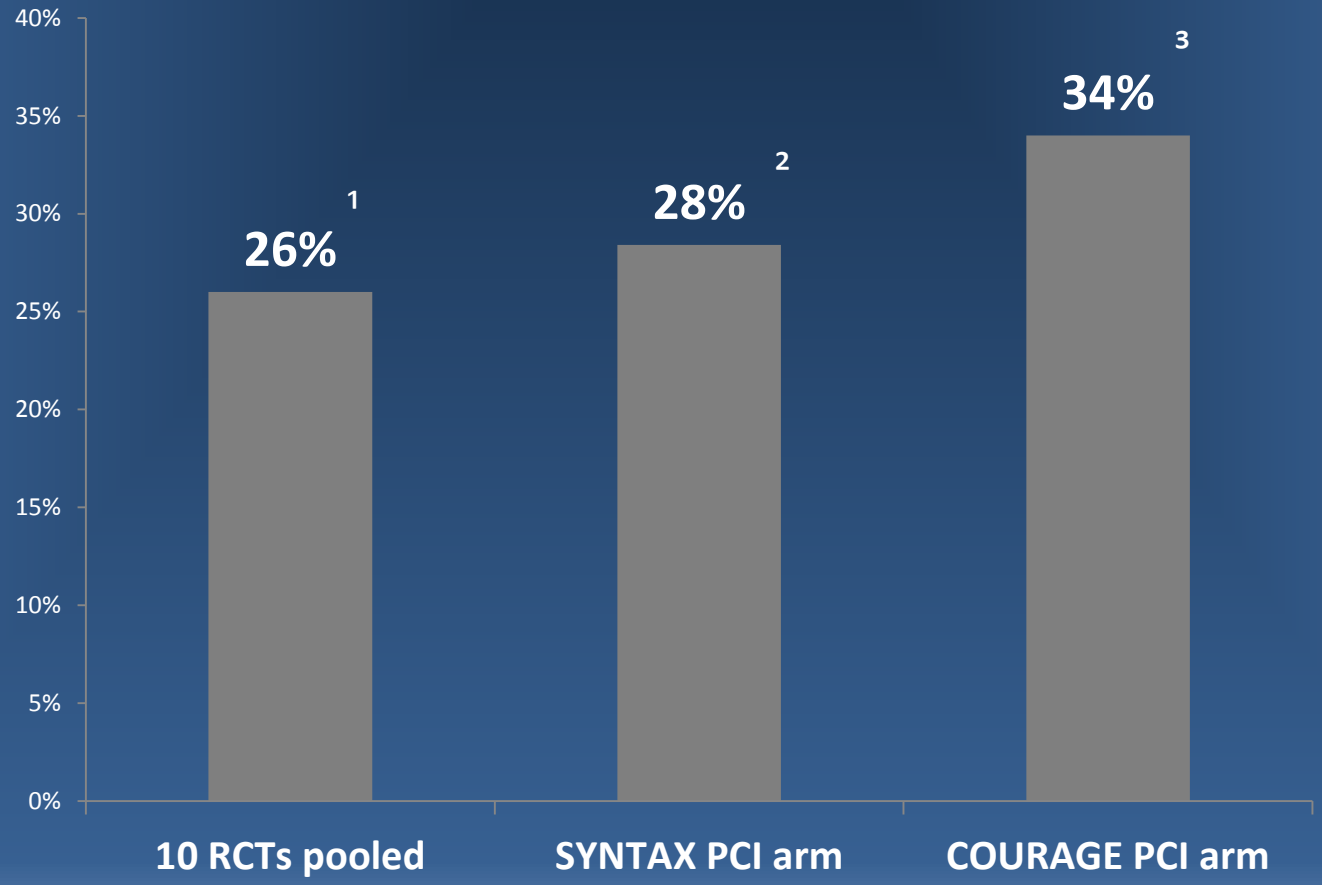
Angina Following PCI: Significant Reports

% of patients with angina at 1 year



[1]Source: Hlatky M. et al; Lancet 2009; 373: 1190 – 97. Angina was site-diagnosed

[2]Source: Cohen D. et al; The New England Journal of Medicine 2011; 364: 1016 – 26. Angina was assessed by Seattle Angina Questionnaire

[3]Source: Boden W. et al; The New England Journal of Medicine 2007; 365: 1503 – 16. Site-diagnosed. Study included only stable angina patients.

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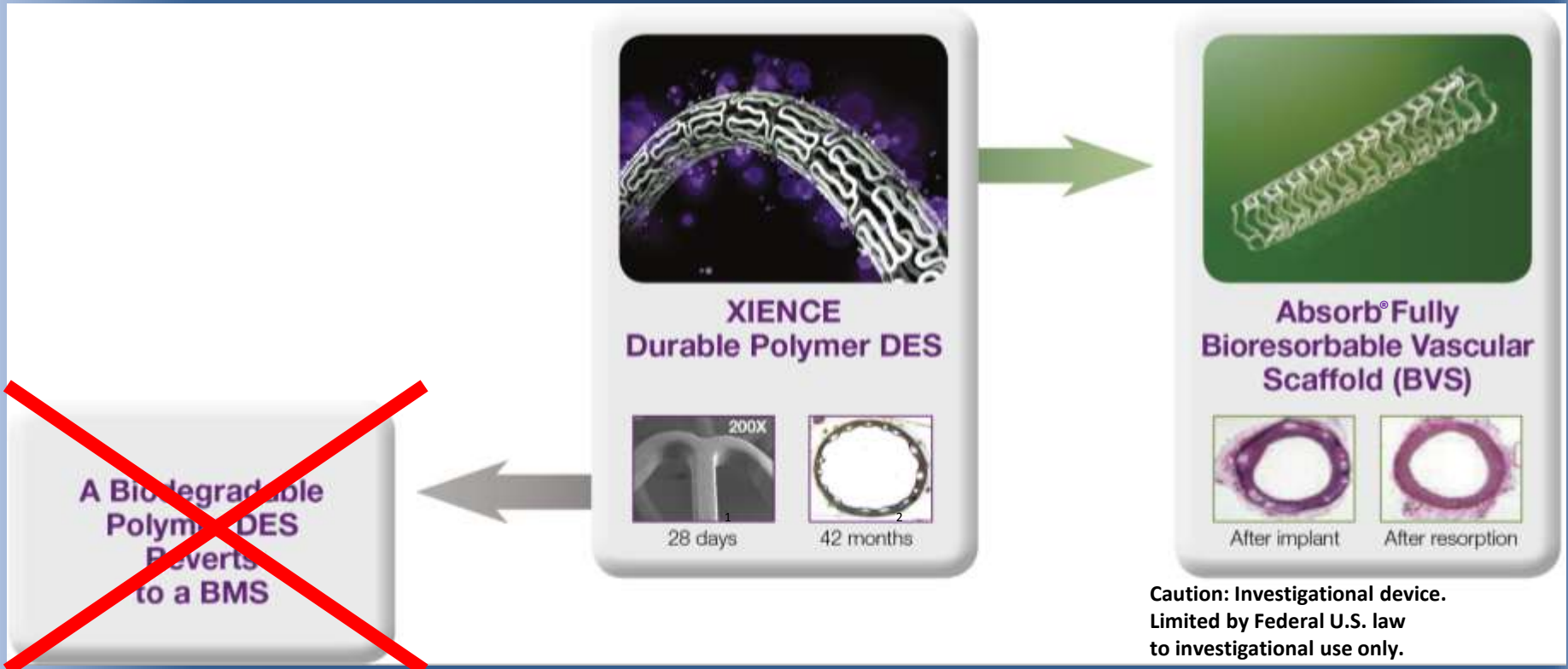
The Future in PCI is to Move Away from Permanent Implants to Fully Resorbable Devices



1. *in vitro* drug elution model.
2. J. Lane, et. al., *Long Term Vascular Safety of an Everolimus-eluting BVS With Benign Positive Remodeling and Late Luminal Gain in Porcine Coronary Arteries as Assessed by OCT , IVUS, and Histology.* Poster, PCR 2013.
Note: Histology images are porcine artery models. Pictures taken by and on file at Abbott Vascular.

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The Abbott Vascular Bioresorbable Vascular Scaffold

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Data and images on file at Abbott Vascular.

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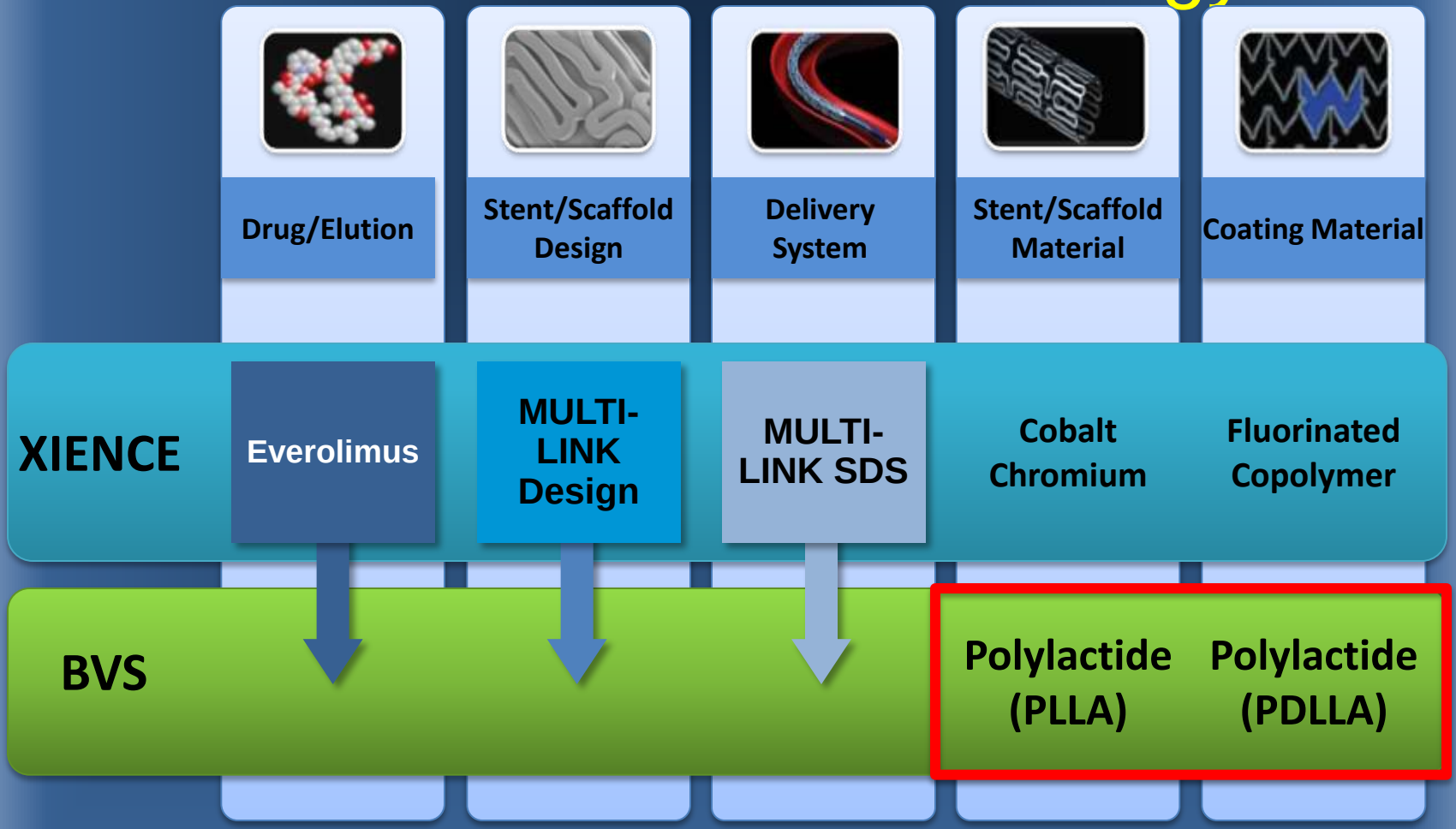
BVS Design Elements

Built on XIENCE Technology



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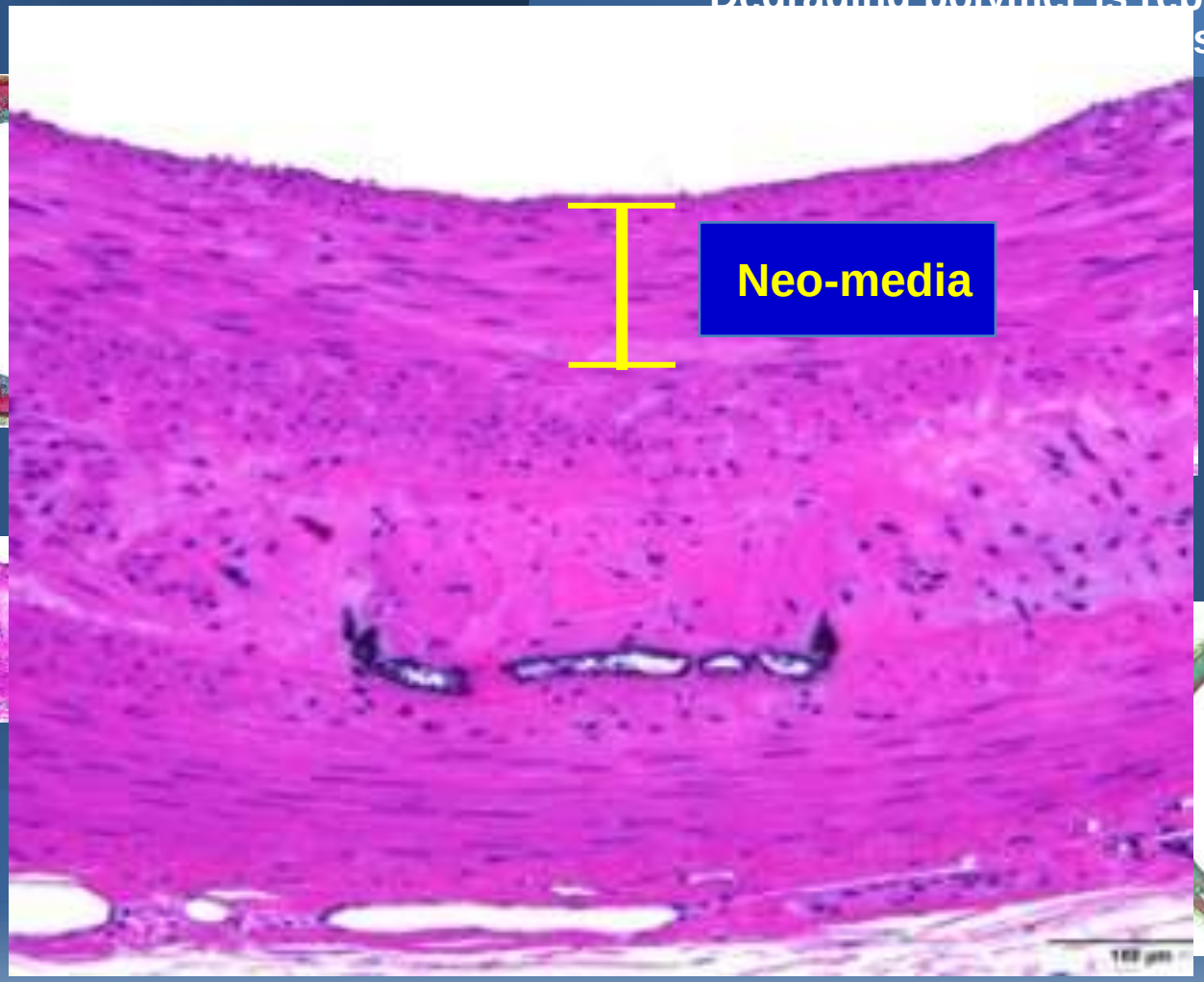
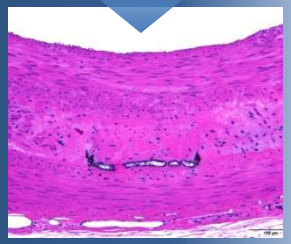
Restoration of Vascular Integrity

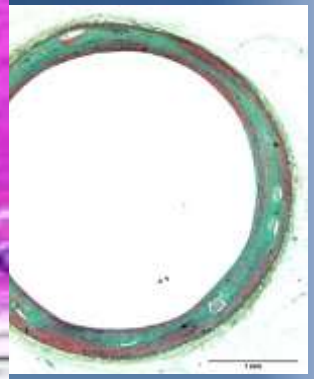
Degrading polymer is replaced by
sional matrix





42 months

6 months



Based on preclinical histology evidence. Data and images on file at Abbott Vascular.

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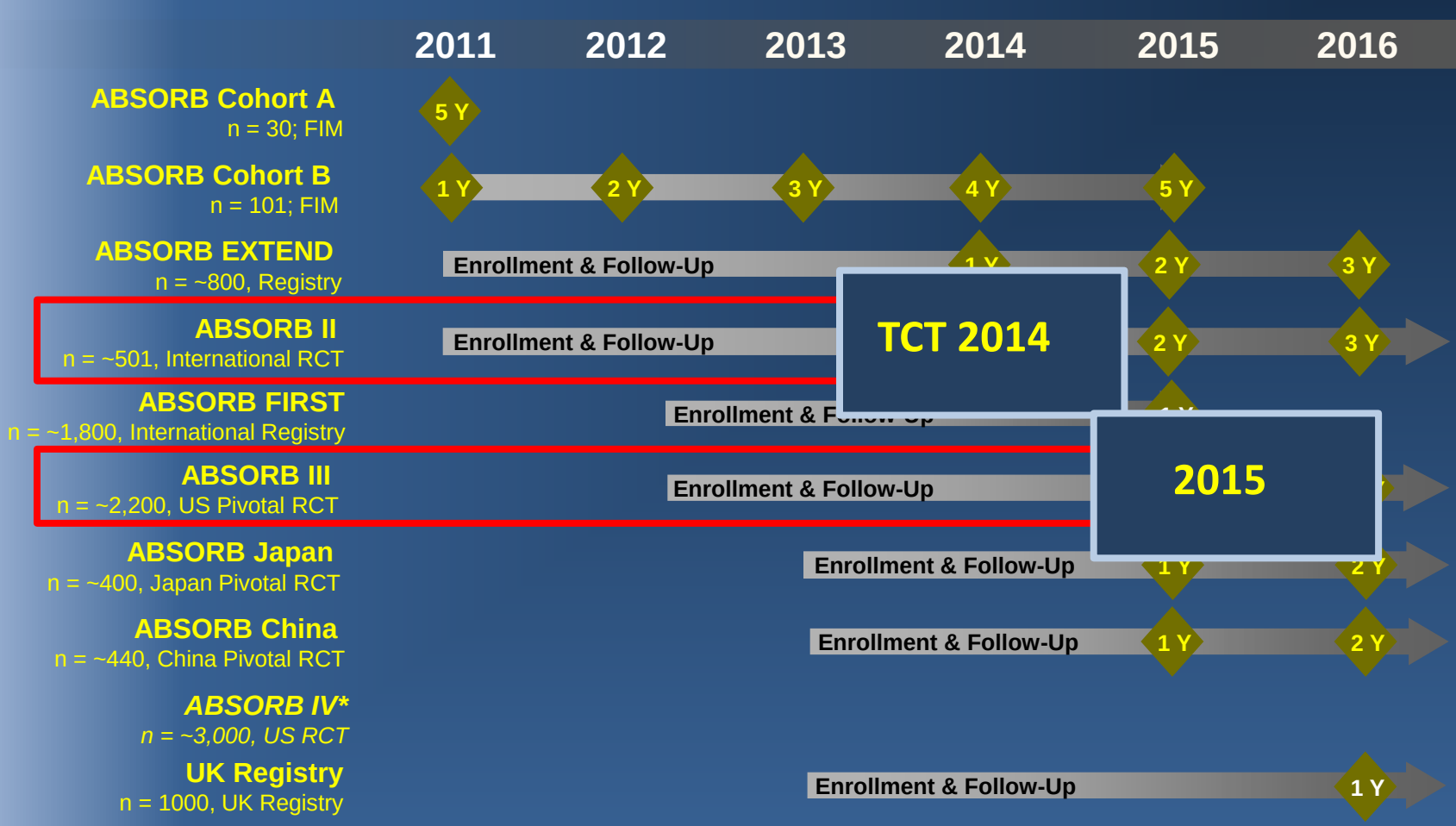
ABSORB: Comprehensive Abbott Vascular - Sponsored Clinical Trial Program



Each trial n reflects total patients. Data effective September 2013
*ABSORB IV trial is in the planning stage and subject to change.

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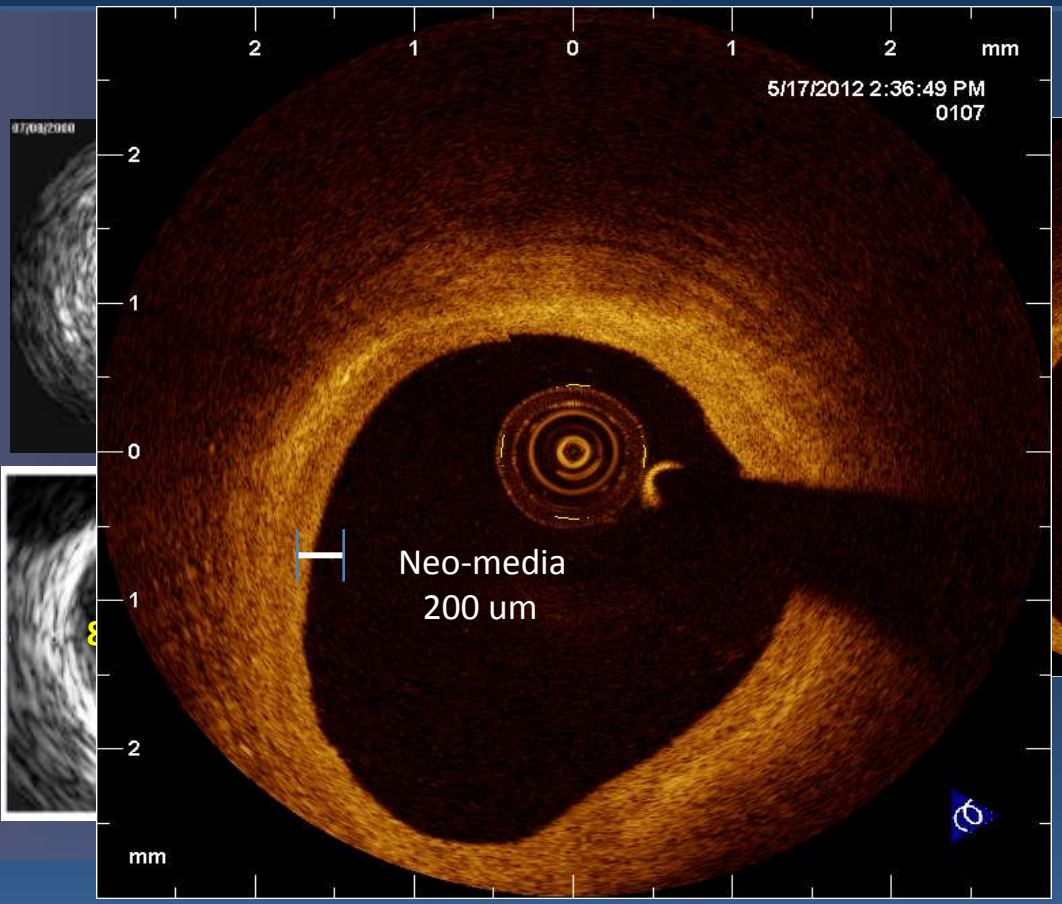
ABSORB Cohort A Intravascular Imaging at 5 years

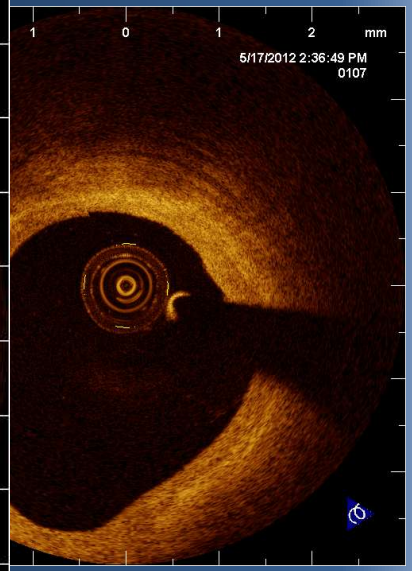
Late lumen gain on OCT

ABSORB Cohort A

6 month follow up

5 year follow up





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R.J. van Geuns, PCR 2012. Images courtesy of Thoraxcenter, Erasmus MC, Rotterdam, The Netherlands

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First Report of the Three Year Clinical and Multi-Modality Imaging Results of the ABSORB Trial Evaluating the Absorb™ Everolimus Eluting Bioresorbable Vascular Scaffold in the Treatment of Patients with De Novo Native Coronary Artery Lesions

P. W. Serruys

Y Onuma

H Garcia-Garcia

On behalf of the ABSORB cohort B investigators

No conflict of interest to declare

The ABSORB Cohort B trial was sponsored and funded by Abbott Vascular, Santa Clara, California

Serruys, PW., 3 Year Clinical and Multi-modality Imaging Results of the ABSORB Trial, ACC 2013.

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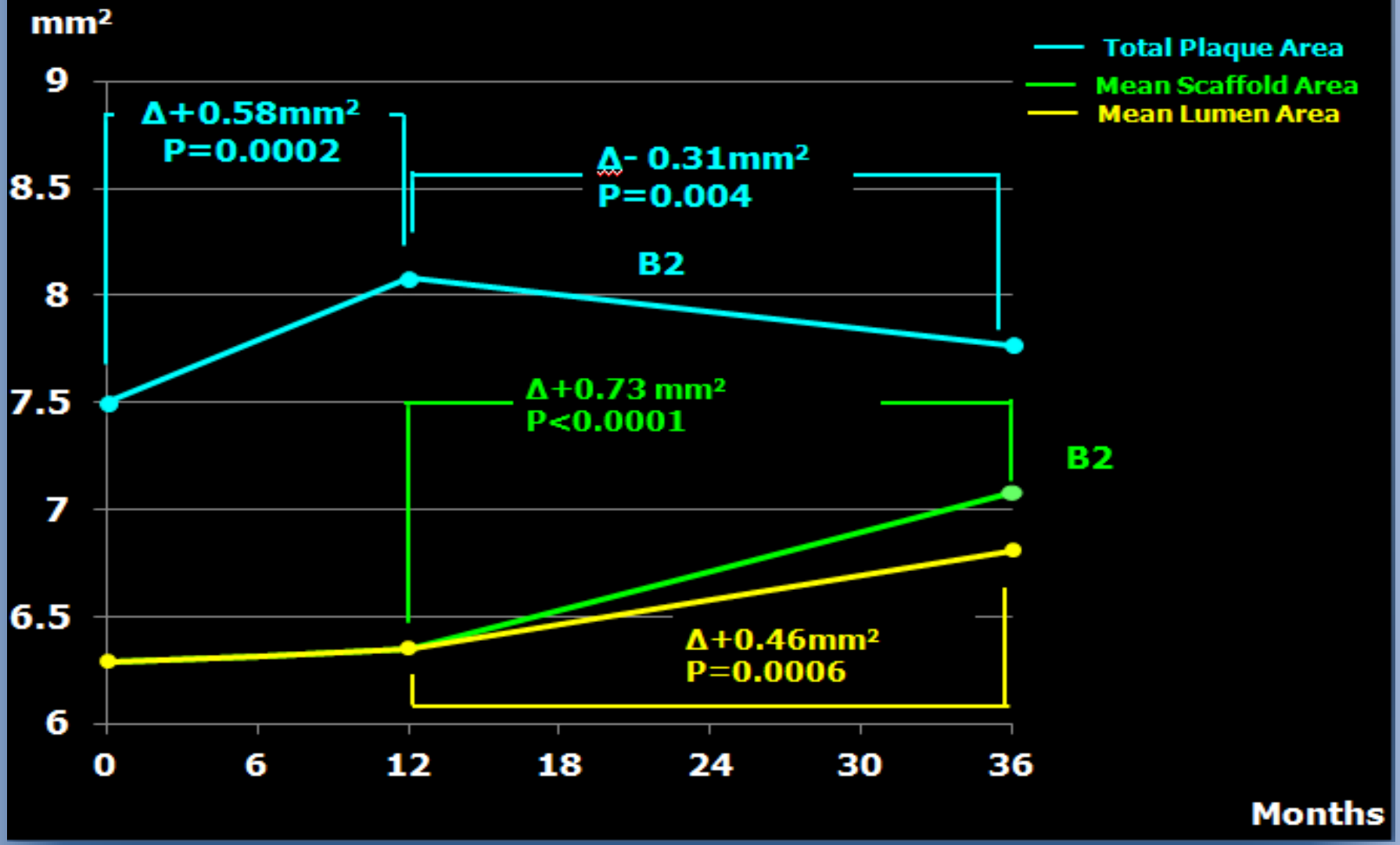
Results of Serial Quantitative IVUS Analysis (n=45)



Serruys, PW., 3 Year Clinical and Multi-modality Imaging Results of the ABSORB Trial, ACC 2013.

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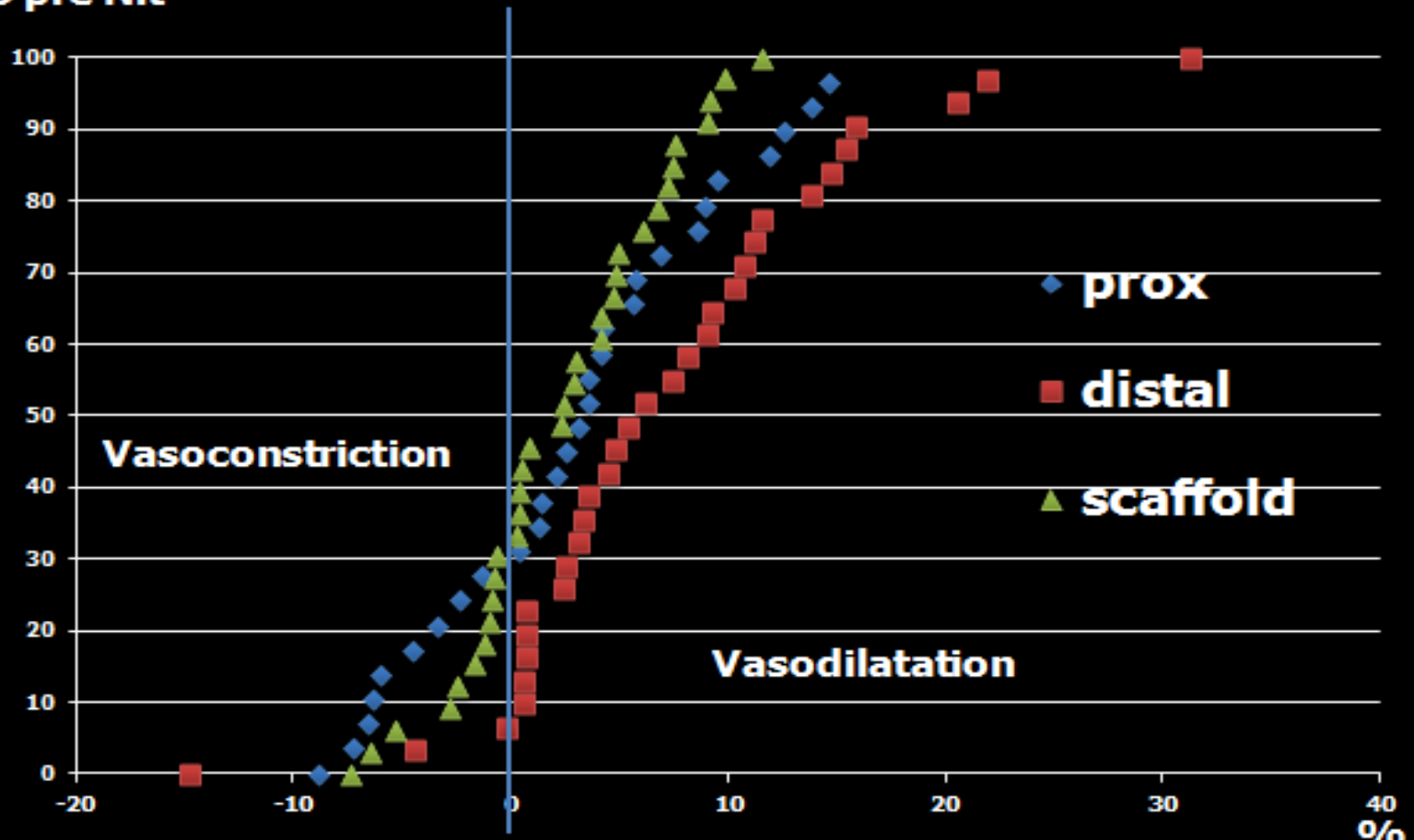
Relative changes (%) of Mean LD before and after Nitrate in proximal, distal and scaffolded segment

Relative change = 100 x (mean LD post Nit – Mean LD pre Nit) / Mean LD pre Nit



Serruys, PW., 3 Year Clinical and Multi-modality Imaging Results of the ABSORB Trial, ACC 2013.

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ABSORB EXTEND

Non-Randomized, Single-Arm, Continued Access Trial

Up to 1,000 subjects.
Up to 100 global sites (non-US)

Study Objective	**Continued Access trial. FPI: Jan 11, 2010. LPI on Oct 2, 2013. 812 enrolled**
Endpoints	**Typical PCI clinical endpoints**
Treatment	**Up to 2 *de novo* lesions in different epicardial vessels** **Planned overlapping allowed in lesions >22 and ≤ 28 mm**
Device Sizes	**Scaffold diameters: 2.5, 3.0, 3.5 mm** **Scaffold lengths: 12*, 18, 28 mm**

Bartorelli, A, An Interim Report on the 12-Month Clinical Outcomes from the First 250 Patients Registered, and An Interim Report on the 6-Month Clinical Outcomes from the First 500 Patients Registered, TCT 2012

•12 mm lengths in 3.0 and 2.5 mm diameters will be introduced into trial when available

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ABSORB EXTEND
Final Enrollment Numbers

ENROLLMENT COMPLETE
812 Subjects Enrolled
From 58 International Sites

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ABSORB EXTEND: Clinical Outcomes on First 450 Patients Through 2 years

Non-Hierarchical % (n)	30 Days* (N = 450)	6 Months* (N = 450)	12 Months* (N = 450)	24 Months* (N = 448)
Cardiac Death %	**0 (0)**	**0.2 (1)**	**0.2 (1)**	**0.7 (3)**
Myocardial Infarction % **	**2.2 (10)**	**2.7 (12)**	**2.9 (13)**	**4.0 (18)**
Q-wave MI	0.7 (3)	0.7 (3)	0.9 (4)	0.9 (4)
Non Q-wave MI	1.6 (7)	2.0 (9)	2.0 (9)	3.1 (14)
Ischemia driven TLR %	**0.2 (1)**	**0.4 (2)**	**1.8 (8)**	**3.8 (17)**
CABG	0 (0)	0 (0)	0.2 (1)	0.4 (2)
PCI	0.2 (1)	0.4 (2)	1.6 (7)	3.6 (16)
Hierarchical MACE %	**2.2 (10)**	**2.9 (13)**	**4.2 (19)**	**6.7 (30)**
Hierarchical TVF %	**2.2 (10)**	**3.1 (14)**	**4.7 (21)**	**7.4 (33)**
Hierarchical TLF %	**2.2 (10)**	**2.9 (13)**	**4.2 (19)**	**6.5 (29)**

* Reflects an interim snapshot of patients with 24 month FU as of the cut-off date of 31 January 2014

** Per Protocol Definition

MACE: Cardiac Death, Protocol-defined MI, Ischemia Driven-TLR

TVF: Cardiac Death, Protocol-defined MI, Ischemia Driven-TLR, Ischemia Driven-Non-TLR TVR

TLF: Cardiac Death, Protocol-defined Target Vessel-MI, Ischemia Driven-TLR

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Investigator Sponsored Studies (ISS) Ongoing (not sponsored by Abbott)

Study Title	Design	Number of Patients	Primary Endpoint	Patient FU (Years)
Randomized Controlled Trials (2704 Pts)				
AIDA	All – comers RCT vs XIENCE	2194	2-Yr TVF	5
TROFI II	STEMI RCT vs XIENCE	190	6-Mo neo-intimal healing score	3
PROSPECT II ABSORB	RCT vs OMT in unstable asymptomatic pts	300	2-Yr IVUS MLA	3
PROACTIVE	RCT vs XIENCE	20	Peri-Proc Platelet Reactivity	1
Registries (8030 Pts)				
BVS EXPAND	All – comers Registry (excl STEMI)	300	1 – Yr MACE	5
ASSURE	All – comers Registry	180	Safety and Efficacy	3
ABSORB CTO	Feasibility in CTO	20	Safety and Performance	2
PABLOS	Feasibililty in Bifurcations	30	Device, Procedural, Main and Side Branch Success	2
IT-DISSAPEARS	MVD and Long Lesion Registry	1000	Safety and Efficacy	5
GABI-R	All – comers Registry	5000	Safety and Efficacy	5
REPARA	All – comers Registry	1500	1- Yr MACE	1

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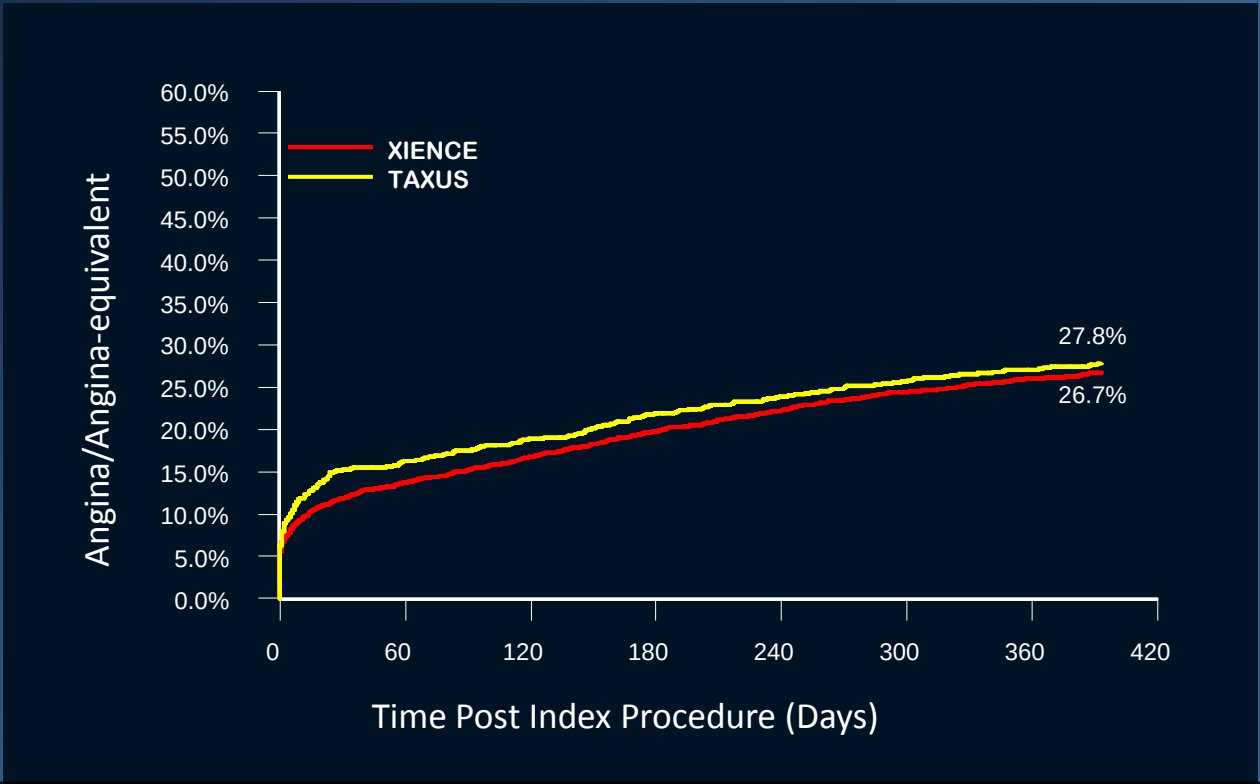
Angina Following Metallic DES: SPIRIT IV Trial

Reported Angina Rates through One Year



Time post-Index Procedure (days)	0	37	194	393
XIENCE Subjects At Risk:	2051	1784	1600	1438
# Events	114	256	415	542
TAXUS Subjects At Risk:	1032	859	782	711
# Events	65	160	228	283

Source: Data on file at Abbott Vascular

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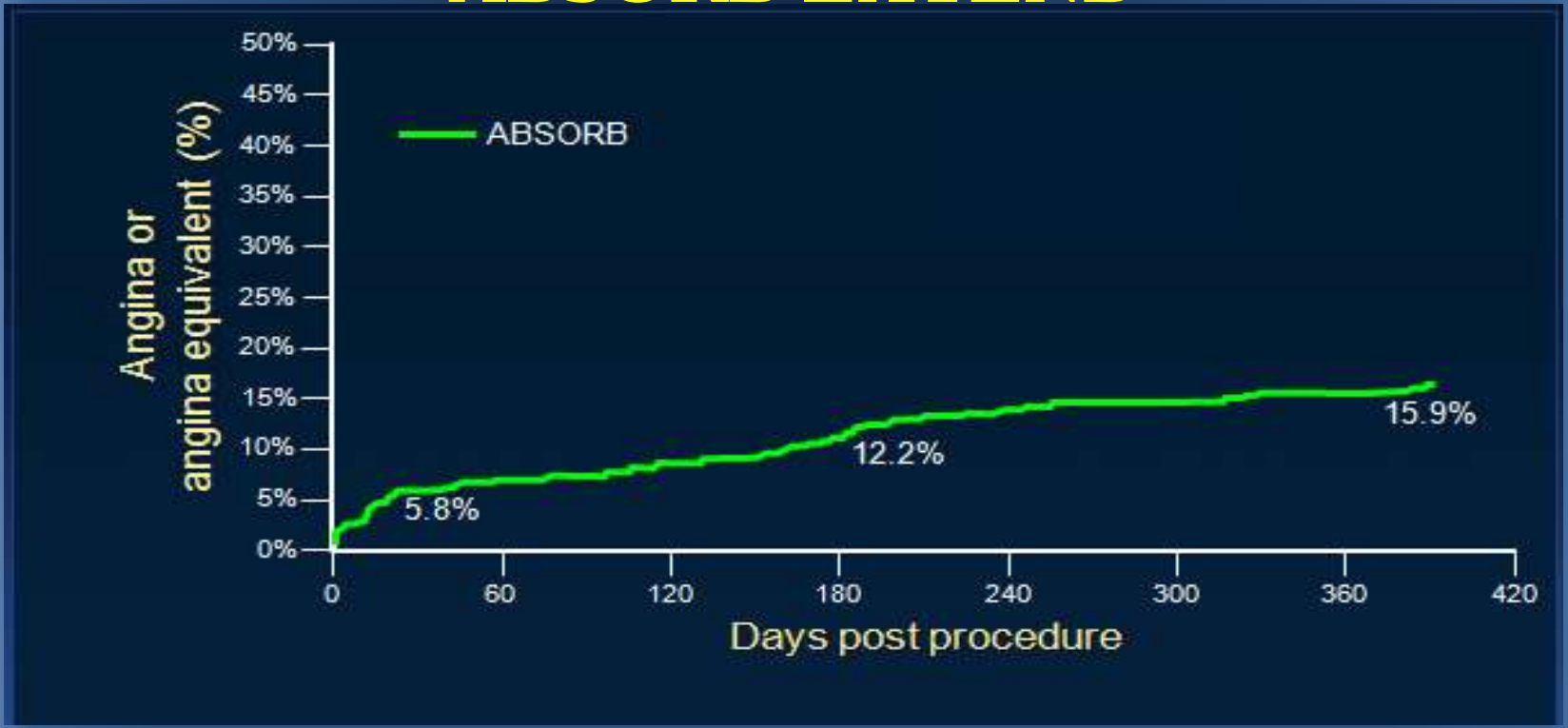
Angina KM Curve Through 1 Year
ABSORB EXTEND



Time post-index procedure	0	37	194	393
Absorb Subjects At Risk:	378	355	330	314
# Events	5	22	46	60

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EXTEND Pop Excludes Non-Japanese Asians

Source: ABSORB EXTEND\11June2013\Sasprog\ABSEXT_KM_Fail_Multi_Curves.sas (September 26, 2013 (17:27))

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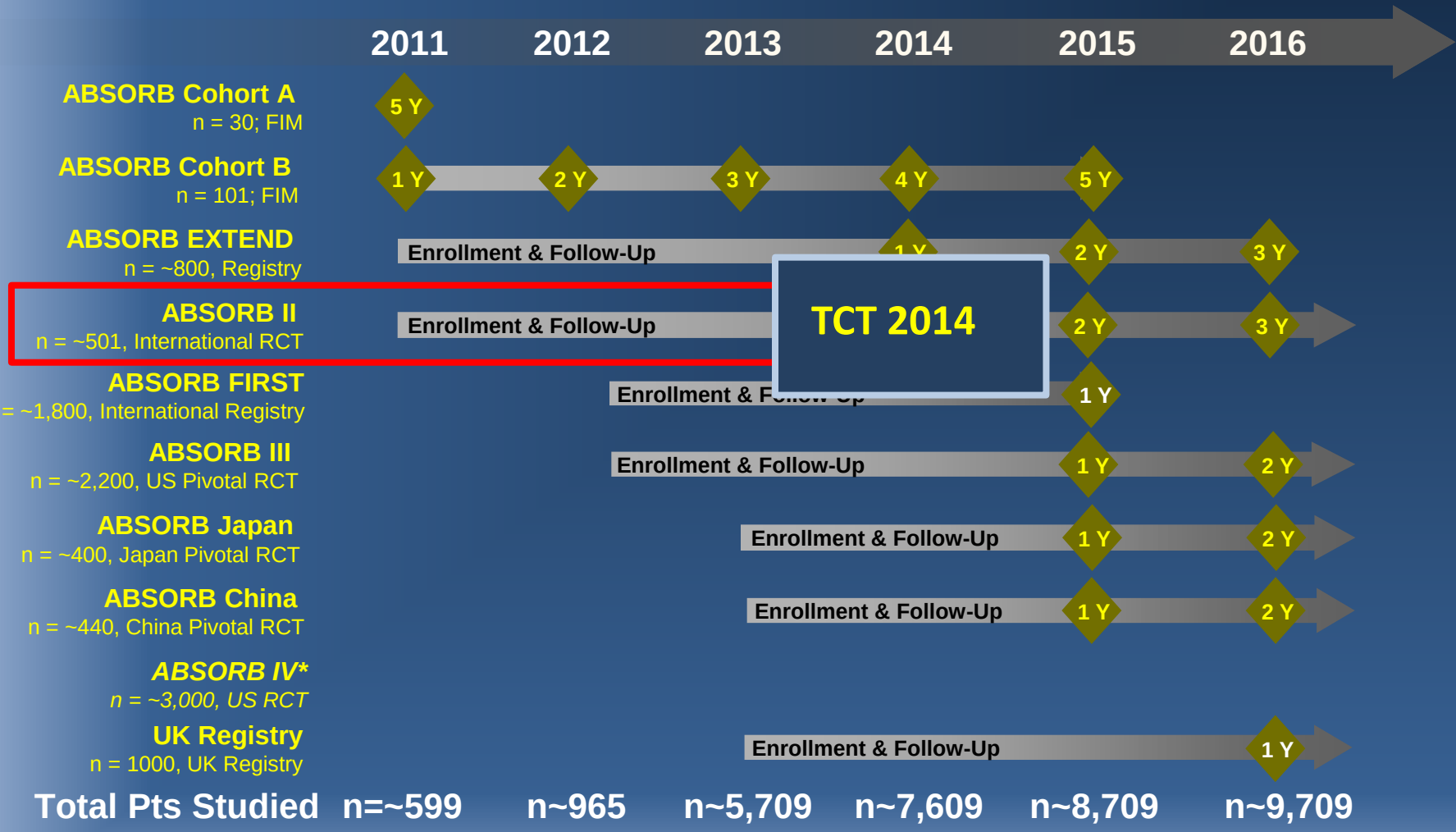

Each trial n reflects total patients. Data effective September 2013
*ABSORB IV trial is in the planning stage and subject to change.

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ABSORB IV

Primary and Secondary Endpoints

Primary Endpoint	**TLF between 1 and 5 years, tested first for non-inferiority of Absorb BVS to XIENCE with reflex testing to superiority.** • **This analysis will consist of ~5000 subjects (2000 primary analysis subjects of ABSORB III and 3000 subjects of ABSORB IV).**
Powered Secondary EP 1	**The percent of patients who experienced angina within 1 year, tested first for non-inferiority of Absorb BVS to XIENCE with reflex testing to superiority.** **Angina is defined as any angina or angina equivalent symptoms determined by the physician after interview of the patient, and as adjudicated by a clinical events committee (CEC).** • **This analysis will consist of ~3000 subjects in ABSORB IV.**
Powered Secondary EP 2	**TLF through 1 year, tested for non-inferiority of Absorb BVS to XIENCE.** • **This analysis will consist of ~3000 subjects in ABSORB IV.**

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Final Conclusions: Bright Future of BVS

1. Metallic DES have solved the revascularization problem with BMS, and now safety is restored with 2nd Gen DES
2. However, longterm follow-up of DES shows an *unrelenting increase in TLF* at a minimum of 2.6%/year after the first year, and within the first year at least 25% of patients will have recurrent or persistent angina
3. Absorb BVS early clinical trial data shows excellent acute procedural success, safety and longterm outcomes, as well as late lumen preservation and reduction in plaque volume and a signal for reduced angina
4. Real-world use of Absorb is expanding quickly into more complex lesions with excellent early results

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Important Safety Information

Rx ONLY

The XIENCE V®, XIENCE nano®, XIENCE PRIME®, XIENCE PRIME® LL, XIENCE Xpedition™, XIENCE Xpedition™ SV and XIENCE Xpedition™ LL (XIENCE Family) of Everolimus Eluting Coronary Stents on the MULTI-LINK VISION® or MULTI-LINK MINI VISION® Delivery Systems

The XIENCE V®, XIENCE nano®, XIENCE PRIME®, XIENCE PRIME® LL, XIENCE Xpedition™, XIENCE Xpedition™ SV and XIENCE Xpedition™ LL (XIENCE Family) of Everolimus Eluting Coronary Stents on the MULTI-LINK VISION® or MULTI-LINK MINI VISION® Delivery Systems

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, XIENCE NANO AND XIENCE XPEDITION SV LENGTH ≤ 28 MM AND XIENCE PRIME, XIENCE PRIME LL, XIENCE XPEDITION AND XIENCE XPEDITION LL LENGTH ≤ 32 MM) WITH REFERENCE VESSEL DIAMETERS OF 2.25 MM TO 4.25 MM.

CONTRAINDICATIONS

The XIENCE Family of stents is contraindicated for use in patients:

- Who cannot receive antiplatelet and/or anti-coagulant therapy
- With lesions that prevent complete angioplasty balloon inflation or proper placement of the stent or stent delivery system
- With hypersensitivity or contraindication to everolimus or structurally-related compounds, cobalt, chromium, nickel, tungsten, acrylic, and/or fluoropolymers.

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WARNINGS

Ensure that the inner package sterile barrier has not been opened or damaged prior to use.

Judicious patient selection is necessary because device use has been associated with stent thrombosis, vascular complications, and/or bleeding events.

This product should not be used in patients who are not likely to comply with the recommended antiplatelet therapy.

PRECAUTIONS

Stent implantation should only be performed by physicians who have received appropriate training.

Stent placement should be performed at hospitals where emergency coronary artery bypass graft surgery is accessible.

Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. Long-term outcomes following repeat dilatation of the stent are presently unknown.

Risks and benefits should be considered in patients with severe contrast agent allergies.

Care should be taken to control the guiding catheter tip during stent delivery, deployment and balloon withdrawal. Before withdrawing the stent delivery system, visually confirm complete balloon deflation by fluoroscopy to avoid guiding catheter movement into the vessel and subsequent arterial damage.

Stent thrombosis is a low-frequency event that is frequently associated with myocardial infarction (MI) or death.

When DES are used outside the specified Indications for Use, patient outcomes may differ from the results observed in the SPIRIT family of trials.

Compared to use within the specified Indications for Use, the use of DES in patients and lesions outside of the labeled indications may have an increased risk of adverse events, including stent thrombosis, stent embolization, MI, or death.

Orally administered everolimus combined with cyclosporine is associated with increased serum cholesterol and triglycerides levels.

A patient's exposure to drug and polymer is proportional to the number and total length of implanted stents. See *Instructions for Use* for current data on multiple stent implantation.

Safety and effectiveness of the XIENCE Family of stents have not been established for subject populations with the following clinical settings:

Patients with prior target lesion or in-stent restenosis related brachytherapy, patients in whom mechanical atherectomy devices or laser angioplasty devices are used simultaneously, women who are pregnant or lactating, men intending to father children, pediatric patients, unresolved vessel thrombus at the lesion site, coronary artery reference vessel diameters < 2.25 mm or > 4.25 mm or lesion length > 32 mm, lesions located in saphenous vein grafts, unprotected left main coronary artery, ostial lesions, chronic total occlusions, lesions located at a bifurcation or previously stented lesions, diffuse disease or poor flow (TIMI < 1) distal to the identified lesions, excessive tortuosity .proximal to or within the lesion, recent acute myocardial infarction (AMI) or evidence of thrombus in target vessel, moderate or severe lesion calcification, multivessel disease, and in-stent restenosis

Everolimus has been shown to reduce the clearance of some prescription medications when it was administered orally along with cyclosporine (CsA). Formal drug interaction studies have not been performed with the XIENCE Family of stents because of limited systemic exposure to everolimus eluted from the stent.

Everolimus is an immunosuppressive agent. Consideration should be given to patients taking other immunosuppressive agents or who are at risk for immune suppression.

Oral everolimus use in renal transplant patients and advanced renal cell carcinoma patients was associated with increased serum cholesterol and triglycerides, which in some cases required treatment.

Non-clinical testing has demonstrated that the XIENCE Family of stents, in single and in overlapped configurations up to 68 mm in length for XIENCE V and XIENCE nano and up to 71 mm in length for XIENCE PRIME, XIENCE PRIME LL, XIENCE Xpedition, XIENCE Xpedition SV and XIENCE Xpedition LL are MR Conditional. It can be scanned safely under the conditions in the *Instructions for Use*.

The XIENCE Family of stents should be handled, placed, implanted, and removed according to the *Instructions for Use*.

POTENTIAL ADVERSE EVENTS

Adverse events (in alphabetical order) which may be associated with coronary stent use in native coronary arteries include but are not limited to:

Abrupt closure, Access site pain, hematoma, or hemorrhage, Acute myocardial infarction, Allergic reaction or hypersensitivity to contrast agent or cobalt, chromium, nickel, tungsten, acrylic and fluoropolymers; and drug reactions to antiplatelet drugs or contrast agent, Aneurysm, Arterial perforation and injury to the coronary artery, Arterial rupture, Arteriovenous fistula, Arrhythmias, atrial and ventricular, Bleeding complications, which may require transfusion, Cardiac tamponade, Coronary artery spasm, Coronary or stent embolism, Coronary or stent thrombosis, Death, Dissection of the coronary artery, Distal emboli (air, tissue or thrombotic), Emergent or non-emergent coronary artery bypass graft surgery, Fever, Hypotension and / or hypertension, Infection and pain at insertion site, Injury to the coronary artery, Ischemia (myocardial), Myocardial infarction (MI), Nausea and vomiting, Palpitations, Peripheral ischemia (due to vascular injury), Pseudoaneurysm, Renal Failure, Restenosis of the stented segment of the artery, Shock/pulmonary edema, Stroke / cerebrovascular accident (CVA), Total occlusion of coronary artery, Unstable or stable angina pectoris, Vascular complications including at the entry site which may require vessel repair, Vessel dissection

Adverse events associated with daily oral administration of everolimus to organ transplant patients include but are not limited to:Abdominal pain (including upper abdominal pain); Anemia; Angioedema; Anorexia; Asthenia; Constipation; Cough; Delayed wound healing/fluid accumulation; Diarrhea; Dyslipidemia (including hyperlipidemia and hypercholesterolemia); Dyspnea; Dysgeusia; Dyspepsia; Dysuria; Dry skin; Edema (peripheral); Epistaxis; Fatigue; Headache; Hematuria; Hyperglycemia (may include new onset of diabetes); Hyperlipidemia; Hyperkalemia; Hypertension; Hypokalemia; Hypomagnesemia; Hypophosphatemia; Increased serum creatinine; Infections and serious infections: bacterial, viral, fungal, and protozoal infections (may include herpes virus infection, polyoma virus infection which may be associated with BK virus associated nephropathy, and/or other opportunistic infections); Insomnia; Interaction with strong inhibitors and inducers of CY3PA4; Leukopenia; Lymphoma and other malignancies (including skin cancer); Male infertility (azospermia and/or oligospermia); Mucosal inflammation (including oral ulceration and oral mucositis); Nausea; Neutropenia; Non-infectious pneumonitis; Pain: extremity, incision site and procedural, and back; Proteinuria; Pruritus; Pyrexia; Rash; Stomatitis; Thrombocytopenia; Thrombotic microangiopathy (TMA)/Thrombotic thrombocytopenic purpura (TTP)/ Hemolytic uremic syndrome (HUS); Tremor; Urinary tract infection; Upper respiratory tract infection; Vomitin Live vaccines should be avoided and close contact with those that have had live vaccines should be avoided. Fetal harm can occur when administered to a pregnant woman. There may be other potential adverse events that are unforeseen at this time.

Prior to use, please reference the *Instructions for Use* at www.abbottvascular.com/ifu for more information on indications, contraindications, warnings, precautions, and adverse events.

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