BOSTON SCIENTIFIC
Drug Eluting Stent Program:

THE ELEMENT™ STENT SERIES

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FOR INFORMATION PURPOSES ONLY. The TAXUS™ Element™ and PROMUS™ Element™ Stent Systems are pending CE mark, not available for sale in the European Economic Area, Japan or USA.
Element™ Bare Stent System is under development, not available for sale.

1. INTRODUCTION

Development of the breakthrough Platinum Chromium (PtCr) alloy and the Element stent series (or platform) is the result of over 8 years of research and development by Boston Scientific Corporation (BSC) and builds on a pedigree of innovation, design and processing excellence within the field of intra-coronary device manufacturing.

This paper describes the functionality, biocompatibility and vascular compatibility of the PtCr alloy, the unique components of the Element stent design and subsequent rigorous testing and investigation of this new product line. Preclinical and clinical programs for both the TAXUS Element and PROMUS Element Stent Systems iterations are presented which extends the robust investigational data from the TAXUS and PROMUS programs.

The TAXUS Element Stent is the third generation in the BSC TAXUS stent family. The TAXUS Element Stent employs an identical polymer, drug, drug formulation and dose density to both TAXUS™ Liberté™ and TAXUS™ Express™ Stents.

The PROMUS Element Stent is the second generation PROMUS (Xience V) Stent. The PROMUS Element Stent employs an identical polymer, drug, drug formulation and dose density to the currently available PROMUS (Xience V) Stent.

Advances in materials science and stent design achieve the acute deliverability goals expected of a thin strut, low profile and flexible stent. Moreover the important procedural and *in vivo* advantages of increased radiopacity, radial strength, compression resistance and the ability of the Element stent series (or platform) to conform to vessel shape and orientation are illustrated.

The Element stent series (or platform) utilizing a proprietary PtCr alloy has become the chosen durable design for future generations of Boston Scientific drug-eluting stents.

2. ELEMENT STENT PLATFORM

2.1 THE BIOFUNCTIONALITY OF PLATINUM CHROMIUM ALLOY

Stent deliverability was improved with the adoption of cobalt chromium alloys. This enabled a reduction in strut thickness beyond what was possible with stainless steel, while still retaining some degree of radiopacity.[1] But stents produced from cobalt chromium alloys tend to have higher recoil due to the elastic properties of the alloy. With newer generations of stainless steel stents, such as the Liberté™ design, strut thickness was reduced at the expense of radiopacity. Both stainless steel and cobalt chromium were potential alloy choices for the Element stent; however, neither could enable a highly deliverable thin strut stent with optimal radiopacity, while still retaining the low recoil and radial strength characteristic of stainless steel.

The Platinum Chromium (PtCr) alloy is the first alloy created specifically for coronary stenting. Platinum exhibits biocompatibility, chemical stability and corrosion resistance and is therefore a candidate for inclusion in a biomedical alloy. Since the early 1990's, platinum has been successfully incorporated in a variety of implantable medical devices including coronary stents: ProPass™ Stent (Vascular Concepts, Halstead, Essex, UK) and Valecor™ Platinum Stent (CorNova, Inc., Burlington, MA, USA), aortic and intravascular stents, stent markers, and electrodes (neuro-stimulating, intracranial, pacemaker electrodes, vagus nerve stimulators).[2-6]

Platinum added to stainless steel, in a range from 5% to 70%, as a potential coronary stenting alloy was chosen due to the inherent metallurgical viability and the significant impact of platinum on radiopacity.[7] Exhaustive characterization was pursued in an effort to optimise alloy properties including; magnetic susceptibility, radiopacity, microstructure/stability, and mechanical attributes. Numerous metallurgical processing experiments were required to understand furnace charge materials, charge sizes, melting, mixing, cleaning, solidification processes, billet forming/annealing, drilling, tube drawing and final annealing to targeted grain size with this new alloy. A platinum content of 33% homogeneously alloyed into the 316L stainless steel base material was subsequently selected for final product development. A comparison of the composition of the Element PtCr alloy to other stent alloys is included in **Table 1.**

Processing of the PtCr tubes into finished stents required a novel approach in laser cutting, chemical, and electrochemical post processing techniques. Laser cutting was meticulously studied with a systematic characterization of laser parameters and the chemical species present on the multi-faceted and chemically complex surfaces of the cut component. New methods to uniformly strip away specific surface components without damaging the structure or properties of the stent bulk material were developed. In this way, the laser and post chemical processes were specifically matched for efficient removal of laser affected material. A novel electropolishing process was designed using a multi-component chemical bath composition and unique voltage controlled bi-polar waveform which was required to simultaneously strip and polish the platinum chromium alloy. The result was dimensionally uniform, bright, chromium oxide rich, smooth, and rounded surfaces to help optimize biocompatibility.

Prototypes in many different stent geometries were produced in the effort to study the performance characteristics of the finished integrated stent system including; stent radiopacity, mechanical properties, design, profile, recoil, and deliverability, ultimately resulting in the Platinum Chromium Element Stent series (or platform).

Table 1: Comparison of Composition of Stent Alloys

Elemental Composition by Weight (%)				
	316L Stainless Steel	Platinum Chromium Alloy	L605 (Cobalt Chromium Alloy)	MP35N (Cobalt Chromium Alloy)
Iron	**64**	**37**	**3.0 max**	**1.0 max**
Platinum	-	**33**	-	-
Cobalt	-	-	**52**	**34**
Chromium	**18**	**18**	**20**	**20**
Nickel	**14**	**9**	**10**	**35**
Tungsten	-	-	**15**	-
Molybdenum	**2.6**	**2.6**	-	**9.75**
Manganese	**2.0 max**	**0.05 max**	**1.5**	**0.15 max**
Titanium	-	-	-	**1.0 max**

The evolution of the Element stent platform design, over the Liberté and Express™ stent platforms, is intended to improve device deliverability, conformability, and radiopacity without compromising key mechanical properties including recoil and compression resistance. The PtCr alloy was selected for the design of the Element stent to allow for a reduction in stent strut thickness and width without compromising strength, radiopacity, biocompatibility, or vascular compatibility. The addition of 33% platinum, and a corresponding reduction in iron and nickel content compared to 316L stainless steel (**Table 1**), results in an increase in yield strength (PtCr alloy 66 ksi (455MPa) vs. 316L SS 46 ksi (317 MPa)). This allows for

a reduction in stent strut width and thickness in the Element design while maintaining similar levels of strength to previous stent designs.

The impact of stent design on clinical outcomes has been studied in numerous clinical trials, supporting the hypothesis that thinner struts are associated with less restenosis. [8-13]

2.1.1. VASCULAR COMPATIBILITY OF PLATINUM CHROMIUM ALLOY

The PtCr alloy consists of 33% Platinum homogeneously alloyed into the 316L stainless steel base material, which is in contrast to surface coating as was used in earlier stents such as the NIROYAL™ gold plated stent (Medinol Ltd, Jerusalem). The Element stent is laser cut from a tube of PtCr alloy, electro-polished and then dipped in an acid solution. This process, referred to as passivation, draws chromium to the surface of the stent and yields a chromium oxide rich surface. The surface of the Element stent that is exposed to the vessel is a passive, corrosion resistant oxide surface comparable to that of stainless steel stents which undergo the same passivation process.[14]

The bio- and vascular-compatibility of the platinum chromium alloy has been demonstrated through an extensive battery of testing. Preclinical evaluation of the TAXUS Element and PROMUS Element Stent Systems has included evaluations of safety, vascular compatibility, *in vivo* drug release characterization, and acute device performance.

Vessels implanted with bare platinum chromium alloy stents, bare 316L stainless steel stents and bare L605 cobalt chromium alloy stents were comparable for all clinical safety parameters and were histologically indistinguishable at 30, 90, and 180 days in a non-diseased swine model.

2.2. THE ELEMENT STENT DESIGN

The Element stent is mounted on a customised stent delivery system based on the APEX™ dilatation balloon catheter to maximize pushability, trackability, stent securement and stent deployment. The Element Stent design incorporates several improved stent performance features with 4 stent models across the range of diameters. A dimensionally uniform pattern of serpentine segments each with two offset connectors that reverse direction for alternate rows maintains a balance of forces along the stent. This also allows each segment to operate almost independently of the other, improving deliverability and conformability. **Figure 1** illustrates an unexpanded Element stent platform.

Figure 1. Element Stent Platform

The peaks are widened at the crown to redirect the strain of expansion to the longitudinal portion. This, along with the properties of the alloy, reduces the recoil of the expanded stent and helps to maintain radial strength. The peaks are offset and nested which reduces potential strut to strut contact when delivering and deploying the stent on a bend.

The thinner struts incorporated in the Element design, compared to Express™ and Liberté™ Stents platform (or design), and equal to that of the Vision Stent, provide a lower system profile while still maintaining an appropriate amount of radiopacity. This enables improved visualization of the implanted stent under fluoroscopy.

Stent designs such as Express, Vision™ (Abbott Vascular Corporation), BX Velocity™ (Cordis Corporation) and Driver™ (Medtronic Corporation) Stents have only 2 stent models to cover the range of diameters. That is, an identical stent is used for a 2.25 mm up to a 3.0 mm labeled device, but is mounted on a different sized stent delivery balloon. Increasing the number of models optimizes the surface to artery ratio over the range of diameters, and provides more uniform drug distribution and scaffolding which may reduce the risk of plaque prolapse. The Element stent has 4 stent models across the range of diameters. Most importantly, the Element stent has a specific model for the 2.25 diameter which has a lower system profile and shorter segments (and therefore more) per stent than the larger diameter models, thus improving the deliverability and conformability of the stent in more tortuous, complex and small vessels.

The thinner strut thickness in Element (0.081-0.086 mm) is comparable to the 0.081 mm struts in the PROMUS (Xience V) stent (**Table 2**). The higher density of platinum compared to iron or cobalt, enhances the radiopacity of the PtCr alloy compared to 316L SS, L605 CoCr or MP35N Co Cr. Thus the thinner stent strut design of the Element stent does not come at the expense of a reduction in stent visibility.

The PROMUS Element and TAXUS Element stents demonstrate comparable or superior performance to the predicate PROMUS (Xience V), TAXUS™ Express™ and

Liberté™ stent designs on conformability, compression resistance, recoil and stent-to-artery ratio (**Table 2**). These performance measures, when taken as a whole, are a surrogate for the ability of the stent to perform its mechanical functions of maintaining the vessel lumen and curvature, therefore optimizing stent strut to vessel wall apposition.

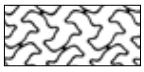
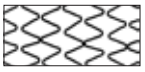
Compression resistance, a measure of radial strength, relates to the ability of a stent to maintain the vessel lumen. The compression resistance for the PROMUS Element and TAXUS Element stent (0.26 N/mm) falls within the range for the TAXUS™ Liberté™ stent (0.24 N/mm). It also compares favorably to PROMUS (Xience V) (0.11 N/mm), Cypher™ (0.17 N/mm), and Endeavor™ Stents (0.14 N/mm).

Recoil is a measure of the ability of a stent to maintain its initial expansion diameter and minimize the risk of malapposition to the vessel. Post-deployment recoil for PROMUS Element and TAXUS Element stent ranges from 1.74-3.64% across all stent diameters. These values fall within the range of commercially available stents as demonstrated by a comparison of recoil: PROMUS Element and TAXUS Element (3.0%), PROMUS (Xience V) (4.6%), TAXUS Liberté (2.8%), Cypher (3.4%), and Endeavor Stents (5.1%).

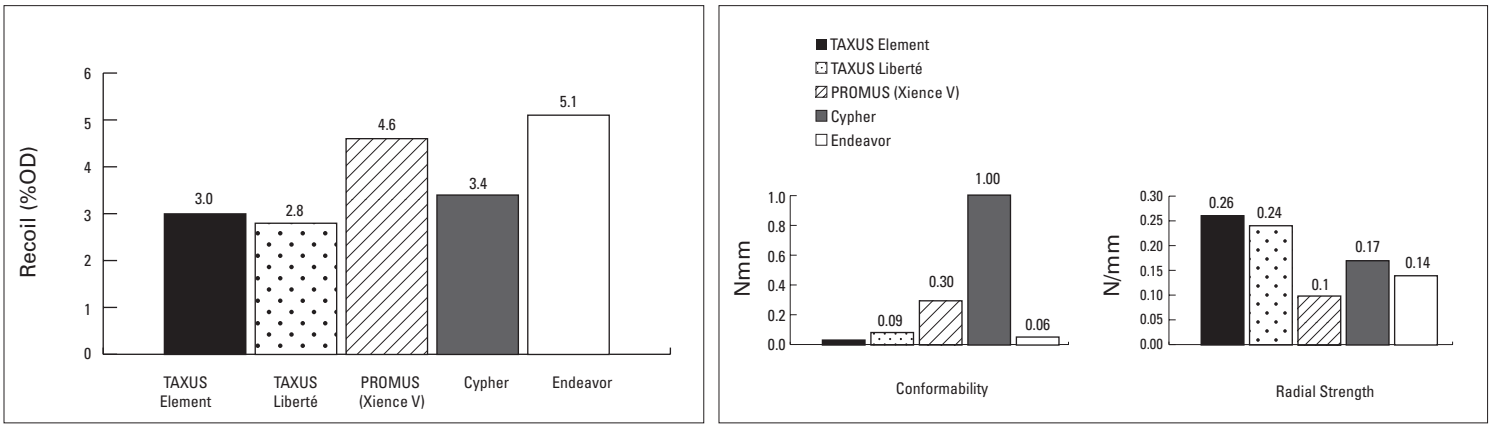
Conformability relates to the ability of a stent to support tortuous vessels without inducing vessel straightening and may be an important predictor of the potential to induce vessel damage. Increased stent rigidity limits the use of stents in both tortuous segments and at bends which may result in a hinge effect that has been associated with an increase in restenosis.[15] The PROMUS Element and TAXUS Element stents have improved conformability (0.04 Nmm) compared to other platforms (TAXUS Liberté 0.09 Nmm, Cypher 1.0 Nmm, PROMUS (Xience V) 0.30 Nmm and Endeavor Stents 0.06 Nmm).

The PROMUS Element and TAXUS Element stent maintains the mechanical support of the vessel wall as the other stent designs, and aims to improve acute performance with new design features. In addition, the key design and performance criteria impacting clinical safety and performance of the PROMUS Element and TAXUS Element stents i.e. conformability, compression resistance, surface-to-artery ratio and recoil are comparable or improved to that of the PROMUS™ (Xience V), TAXUS™ Liberté™ and TAXUS™ Express™ stents. Each of these predicate devices are supported by the TAXUS and SPIRIT Clinical programs respectively, which have cumulatively established clinical safety and performance in over 45,000 patients with more than 100,000 patient-years of follow-up.

Table 2:
*Comparison of Stent Platform Specifications for Drug Eluting Stents**

	Specification	PROMUS Element/ TAXUS Element Stent Platform	TAXUS Liberté Stent Platform	TAXUS Express Stent Platform	PROMUS (Xience V) Stent Platform	CYPHER Stent Platform	ENDEAVOR Stent Platform
Design Elements	Pattern						
	Material	PtCr	316L SS	316 L SS	L605 CoCr	316 L SS	MP35N CoCr
	Range of Strut Width Nominal (mm/in)	0.061 / 0.0024 (SV) 0.089 / 0.0035 (LV)	Min: 0.076 / 0.0030 Max: 0.094 / 0.0037	Min: 0.071 / 0.0028 Max: 0.091 / 0.0036	0.076 / 0.0030	0.081 / 0.00321 0.132 / 0.0052	0.090 / 0.0036
	Strut Wall Thickness (mm/in)	0.081 / 0.0032[a] 0.086 / 0.0034[b]	0.097/ 0.0038	0.132 / 0.0052	0.081 / 0.0032	0.140 / 0.0055	0.090 / 0.0036
Bench testing	Surface Artery Ratio (SAR) (%)	2.5mm: 17.6 3.0mm: 16.4	2.5mm: 15.5 3.0mm: 17.6	Data not available	2.5mm: 16.8 3.0mm: 14.1	2.5mm: 18.3 3.0mm: 14.3	2.5mm: 18.1 3.0mm: 21.4
	Additional testing available in Figure 2 below.						
Stent Integrity	Fatigue Strength	Passed 400 mil cycles	Passed 400 mil cycles	Passed 400 mil cycles	Data not available for comparison	Data not available for comparison	Data not available for comparison
	Focal Bending	All designs demonstrated acceptable bending fatigue performance					
	Corrosion Resistance	All designs passed potentiodynamic, galvanic, crevice, fretting testing					
	Overexpansion	All designs passed to overexpansion diameter					

[a] Data represent the following stent sizes : 2.25 – 3.50mm
[b] Data represent the following stent sizes : 4.00 – 5.00 mm
Note: PROMUS (Xience V) uses the Vision stent platform, Cypher uses the Bx Velocity stent platform. Endeavor uses the Driver Stent platform.
*Data on File. Testing completed by Boston Scientific. 2.5mm Stent Products tested: TAXUS Element n=15, Xience V n=10, Endeavor n=3, TAXUS Liberté n=8, Cypher n=3. Bench test results may not necessarily be indicative of clinical performance.



Note: Data represent 2.5 mm diameter comparison; Data on File. Testing completed by Boston Scientific.TAXUS Element n=15, TAXUS Liberté n=8, Xience V n=10, Cypher n=3 and Endeavor n=3. Bench test results may not necessarily be indicative of clinical performance. Abbreviations: N/mm=Newtons per millimeter; Nmm=Newton millimeters; %OD=percent observed decrease.

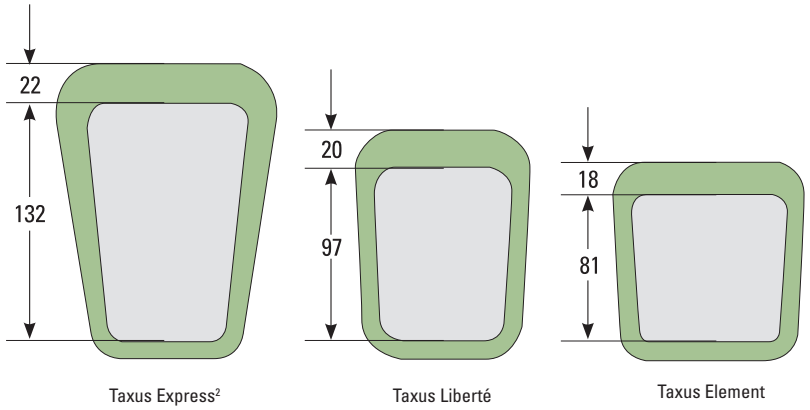
Figure 2:
Recoil, Radial Strength, and Conformability Comparisons among DES Platforms

2.3. TAXUS ELEMENT STENT

2.3.1. TAXUS Element Stent coating

The coating on the TAXUS Element stent consists of a polymer matrix material, poly (styrene-isobutylene-styrene) referred to as SIBS (Translute™) and an active pharmaceutical ingredient, Paclitaxel. Paclitaxel is a white powder, isolated from a spectrum of Taxus species and hybrids. It binds to β-tubulin, a structural component of microtubules, and thus disrupts many microtubular-dependent cell processes such as cell proliferation, cell migration, cellular activation, secretory processes and signal transduction.[16] [17] Paclitaxel targets a number of cell types in a dose-dependent manner including inflammatory cells, endothelial cells, smooth muscle cells, and platelets. In human smooth muscle cells, low doses as eluted from TAXUS stents, inhibit cell proliferation (cytostatic effect).[18] Each TAXUS Element stent is coated with 1.0 µg Paclitaxel per mm^2 of stent surface area in an 8.8% formulation (weight percent Paclitaxel in the polymer coating). This is the identical polymer matrix, dose density and formulation as used on TAXUS Express Stent and TAXUS Liberté Stent. The 8.8% Paclitaxel slow-release (SR) formulation provides controlled drug delivery to the stented vessel segment. To date, Boston Scientific has successfully transferred this drug/polymer combination across 3 different platforms: NIR™ Stent (Medinol Ltd. Jerusalem), Express Stent, Liberté™ Stent, and now to the Element Stent. **Figure 3** demonstrates the strut and polymer thickness for the various iterations of TAXUS stents.

Figure 3:
DES strut and polymer thickness (µm) for BSC TAXUS™ stents



2.3.2. TAXUS Element Clinical Program

Comprehensive analytical bench testing has been conducted on the TAXUS Element Stent and the results have been compared to those of TAXUS™ Liberté™ and TAXUS™ Express™ Stents. Preclinical animal studies demonstrate equivalent vascular compatibility, early and late healing, safety and similar drug release profiles for the TAXUS Element, TAXUS Liberté, and TAXUS Express Stents. **Figure 4** shows comparable healing of TAXUS Element stent compared to TAXUS Liberté and TAXUS Express stents in an overlapping porcine coronary artery model.

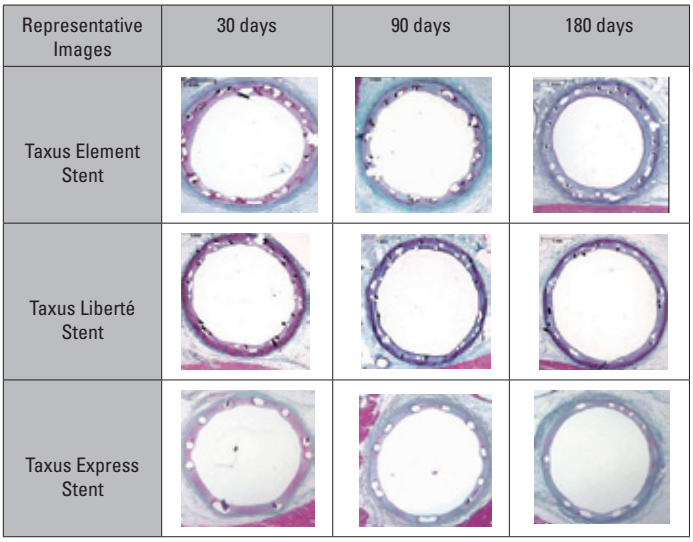


Figure 4
Healing in an overlapping porcine coronary artery model

The BSC TAXUS clinical program provides a large body of clinical evidence establishing the safety and efficacy of the TAXUS stents used in the treatment of coronary artery disease. Progressively more complex patient populations, lesions and procedures were evaluated by clinical, angiographic and IVUS outcomes. Historic trial designs and key clinical results from the TAXUS clinical program are summarized in **Appendix 1, Appendix 2, and Appendix 3**.

Taken together, these studies demonstrate the safety and effectiveness of paclitaxel delivered from the polymer carrier on different stent platforms, the TAXUS™ NIR™ stent (TAXUS I, II and III trials), the TAXUS Express stent (TAXUS IV, V-*de novo*, V-ISR, VI, SYNTAX trials and ARRIVE registry) and the TAXUS™ Liberté stent (TAXUS ATLAS trials and OLYMPIA registry) in diseased coronary arteries.

Clinical data directly supporting the TAXUS Element Stent is through the PERSEUS Workhorse and Small Vessel trials. The PERSEUS Workhorse trial is a randomized clinical trial comparing the TAXUS Element stent to the TAXUS Express^2 stent. The PERSEUS Small Vessel study is a single arm study evaluating use of the TAXUS Element stent for the treatment of lesions in vessels with a reference vessel diameter between 2.25 and 2.75 mm. Enrollment was completed for the PERSEUS trials in Oct 2008. These randomized, controlled trials are pivotal for regulatory approval in USA and Japan. All safety events are adjudicated and fully monitored by an independent monitoring committee. These trials will remain blinded, but ongoing safety reviews have indicated no safety concerns to date, consistent with prior iterations of the TAXUS stent (**Table 3**). The PERSEUS trial primary endpoint results are planned to be presented at ACC 2010.

Table 3:
PERSEUS WH (Work Horse) and SV (Small Vessel) Studies

Parameter	PERSEUS WH (N=1264)	PERSEUS SV (N=224)
Study design	Prospective, multicenter, randomized, single-blind, non-inferiority	Prospective, multicenter, single-arm, superiority with historical control
No. of sites	98 US, Australia, NZ, Singapore	35 US sites
Lesion criteria	De novo, ≤28 mm length, RVD of 2.75 mm to 4.00 mm	De novo, ≤20 mm length, RVD of ≥2.25 mm to <2.75 mm
Study Stent platform	TAXUS Element Stent (N=948)	TAXUS Element Stent (N=224)
Control Stent Platform	TAXUS Express^2 Stent (N=316)	Historical (ITT patients, RVD ≥2.25mm - <2.75mm, lesion length ≤20 mm randomized to receive an Express^2 BMS in TAXUS V)
Primary endpoint	12-mo TLF	9-mo in-stent late loss (by QCA)
Follow-up	9-mo: clinical, angiographic; 30 days, 1, 2, 3, 4, and 5 years: clinical - ONGOING	9-mo: clinical, angiographic; 30 days, 1, 2, 3, 4, and 5 years: clinical – ONGOING

2.4. PROMUS ELEMENT STENT

2.4.1. PROMUS Element Stent Coating

The coating on a PROMUS Element stent is composed of 2 layers, a primer layer, and an active drug matrix layer blended with the anti-proliferative drug Everolimus. Everolimus is a novel semisynthetic macrolide immunosuppressant, obtained through chemical modification of rapamycin.[19] On a cellular level, Everolimus reversibly inhibits growth factor-stimulated cell proliferation and subsequently inhibiting activation of the regulatory kinase mammalian target of rapamycin (mTOR).[20] This inhibition interferes with functions that govern cell metabolism, growth, and proliferation by arresting the cell cycle at the late G1 phase.[21] Animal studies have shown everolimus to have similar immunosuppressive and toxicological properties as sirolimus[19]. Under the trade name Certican® (Novartis Pharmaceuticals Inc, East Hanover, NJ, USA), Everolimus has been studied in preclinical and clinical studies as

an anti-rejection therapy.[19] The drug to polymer formulation ratio is identical to PROMUS™ (Xience V) stent. The resulting drug loading density (total weight of drug per unit of stent surface area) on the coated stent is 1.0 µg of everolimus/mm². **Figure 5** shows the strut and polymer thickness for the PROMUS Element and PROMUS (Xience V) stents.

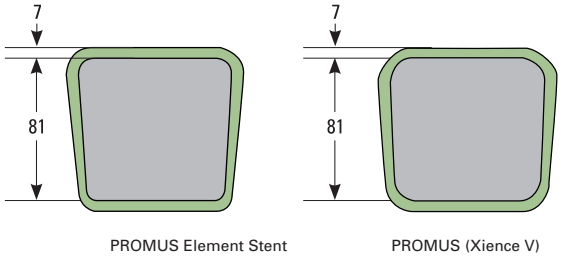


Figure 5:
DES strut and polymer thickness (µm) for PROMUS™ stents

Preclinical testing with the PROMUS Element Stent demonstrated comparable drug release profiles, Everolimus arterial tissue levels and blood drug levels to PROMUS (Xience V) Stent. **Figure 6** shows the *in vivo* everolimus percent release profiles for PROMUS (Xience V) and PROMUS Element stent in coronary arteries, with consistent release achieved within the first 24 hours (23-36%).

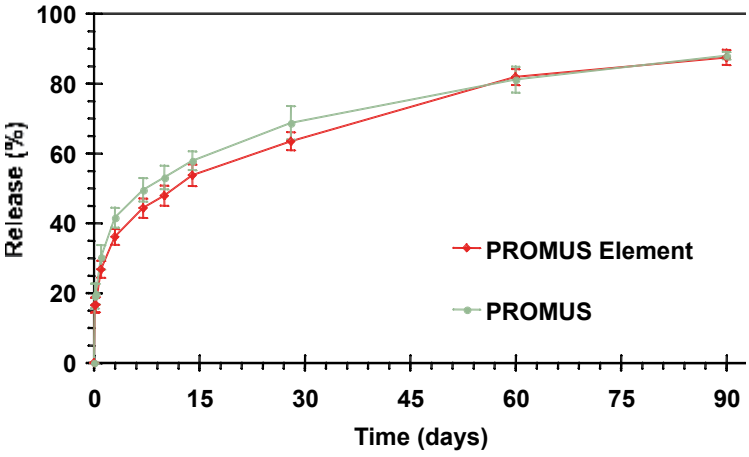


Figure 6:
Everolimus release for PROMUS Element and PROMUS (Xience V) stents in coronary arteries

The majority of the drug was released from the stent by 60 days following implant (75-85%), with nearly complete release by 90 days (85-90%).
The safety of the PROMUS Element Stent was demonstrated in extensive porcine artery preclinical testing out to 180 days against the PROMUS (Xience V) Stent, Bare Metal Element and polymer only coated Bare Metal Element stent. Results showed no stent related mortality or myocardial infarction and no stent thrombosis. The vascular compatibility was demonstrated out to 180 days with the absence of micro and luminal thrombus, early (30 day) strut and endothelial cell coverage, stable at 90 days, safe tissue response with limited inflammation, comparable for all device types and maintenance of vascular architecture.

2.4.2. PROMUS Stent Clinical Program

Preclinical studies demonstrate equivalent vascular compatibility and safety for the PROMUS Element, PROMUS and Bare Element stents, and equivalent drug release profiles for PROMUS Element and PROMUS Stents. Additionally, *in vivo* bioequivalence of PROMUS Element and PROMUS Stents has also been established.

The PROMUS (Xience V) stent has been studied in patients with symptomatic ischemic heart disease due to *de novo* lesions in native coronary arteries in the SPIRIT First, SPIRIT II and SPIRIT III clinical trials, all of which have achieved their primary endpoint. Long-term outcome studies of PROMUS continue to support safety and performance in the treatment of de novo lesions. The SPIRIT IV and V trials are ongoing. The SPIRIT trials demonstrate the efficacy of everolimus in the treatment of coronary artery disease and that everolimus is safe when delivered on a coronary stent platform.

The safety and performance of the PROMUS (Xience V) Stent in patients with *de novo* native coronary artery lesions were first demonstrated in the SPIRIT First clinical trial. SPIRIT II was a further assessment of safety and performance of the PROMUS™ (Xience V) stent in more complex anatomy including patients with a maximum of two *de novo* native coronary artery lesions located in two different epicardial vessels. SPIRIT III was the pivotal clinical trial designed to demonstrate the non-inferiority of the PROMUS stent to the TAXUS™ Express™[2] stent. Finally, the SPIRIT III 4.0 mm study was a prospective clinical trial in the United States evaluating the 4.0 mm diameter PROMUS stent, with the goal to demonstrate the non-inferiority compared to the TAXUS Express[2] Stent arm of the SPIRIT III trial. Historic trial designs and key clinical results from the SPIRIT clinical program are summarized in **Appendix 4**.

Clinical data directly supporting the PROMUS Element Stent is through the PLATINUM clinical trial (**Table 4**). The PLATINUM trial is a randomized clinical trial initiated in January 2009 comparing the PROMUS Element stent to the PROMUS (Xience V) stent in a 1:1 fashion in a total of 1,532 patients. Enrollment commenced in January 2009 in the US, Europe, Asia Pacific and Japan and completed enrollment early September, 2009 in the randomized study. The PLATINUM study will support the regulatory

submissions for USA and Japan. There are also concurrent small vessel and long lesion subtrials with historical controls ongoing in the US, Japan and Europe. The primary endpoint is twelve-month target lesion failure (TLF) rate, defined as any ischemia-driven revascularization of the target lesion (TLR), myocardial infarction (MI, Q-wave and non-Q-wave) related to the target vessel, or cardiac death related to the target vessel. Clinical endpoints will be measured in hospital and at 30 days, 6 months, 12 months, 18 months, 2 years, 3 years, 4 years, and 5 years in the randomized clinical trial and non-randomized small vessel and long lesion subtrials. Finally, the non-randomized QCA study has completed enrollment of 100 patients receiving the PROMUS Element stent at sites in the Asia Pacific region.

Table 4:
PLATINUM Studies

Parameter	PLATINUM WH (N=1532)	PLATINUM SV Subtrial (N=94)	PLATINUM LL Subtrial (N=102)	PLATINUM QCA (N=100)
Study design	Prospective, multicenter, randomized, single-blind, non-inferiority	Prospective, multicenter, single-blind, non-randomized non inferiority subtrial	Prospective, multicenter, single-blind, non-randomized non inferiority subtrial	Prospective, multicenter, single arm, observational study
No. of sites	Up to 160 sites (US, Europe, Asia Pacific and Japan)	Up to 30 sites (US, Europe and Japan)	Up to 30 sites (US Europe and Japan)	Up to 20 sites (Asia Pacific region)
Lesion criteria	Up to 2 *de novo* lesions, single stent per lesion, ≤24 mm length, RVD of 2.75 mm to 4.25 mm	SV subtrial, <28 mm length, RVD ≥2.25 mm to <2.50 mm	LL subtrial, >24 mm and ≤34 mm in length, RVD ≥2.50 mm to ≤4.25 mm	One *de novo* lesion in a major coronary artery or branch with visually estimated stenosis ≥50% and <100% and TIMI flow >1
Study Stent Platform	PROMUS Element Stent (N=766)	PROMUS Element Stent (N=94)	PROMUS Element Stent (N=102)	PROMUS Element Stent (N=100)
Control Stent Platform	PROMUS Stent (N=766)	Historical PROMUS data from SPIRIT trials	Historical PROMUS data from SPIRIT trials	Not applicable
Primary endpoint	12-m TLF	12-m TLF	12-m TLF	30 day cardiac events and 9 m in-stent late loss and post-procedure IA
Clinical Follow-up	1m, 6m, 12m, 18m, 2, 3, 4, and 5 years: ONGOING	1m, 6m, 12m, 18m, 2, 3, 4, and 5 years: ONGOING	1m, 6m, 12m, 18m, 2, 3, 4, and 5 years: ONGOING	1m, 9m, 12m: ONGOING

Abbreviations: IA=Incomplete apposition; LL=long lesion; WH=work horse; SV=small vessel; m=month; QCA=quantitative coronary angiography; RVD=reference vessel diameter; TIMI=thrombolysis in myocardial infarction; TLF=target lesion failure defined as any ischemia-driven revascularization of the target lesion (TLR), myocardial infarction or cardiac death related to the target vessel; US = United States.

3. SUMMARY

TAXUS stents have demonstrated favorable outcomes throughout their clinical program and demonstrate highly reproducible safety and efficacy based on clinical, angiographic and IVUS outcomes. The consistent results of the proven drug/polymer combination used on three different stent platforms (NIR™, Express™ and Liberté™ Stents) support the transferability of this stable drug/polymer combination from one stent platform to another.

Similarly, clinical outcomes of the SPIRIT First, SPIRIT II, and pivotal SPIRIT III trials demonstrate that the Everolimus drug and polymer combination utilized in PROMUS (Xience V) Stent is safe and effective in treating *de novo* coronary lesions.

Boston Scientific has an established history of successfully transferring proven drug/polymer combinations to improved stent platforms. The PtCr Element stent is the next design iteration for both the TAXUS and PROMUS Stent programs.

Extensive investigation and analysis of both TAXUS Element and PROMUS Element Stent Systems has been undertaken to support regulatory approvals and further corroborating data from the PERSEUS and PLATINUM clinical studies will define the promise of these new stent systems.

On behalf of Keith D. Dawkins, MD, Mary V. Jacoski, MS, Barbara Huibregste, DVM, Tim Mickley, BSME, and Donald S. Baim, MD

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Appendix 1:
Summary of TAXUS™ Express™ Randomized Clinical Studies

Parameter	TAXUS I		TAXUS II		TAXUS III	TAXUS IV		TAXUS V de novo		TAXUS V ISR		TAXUS VI	
Study design	Prospective, multicenter, randomized, double-blind		Prospective, multicenter, randomized, double-blind with 2 consecutive cohorts		Prospective, multicenter, single-arm (non-randomized)	Prospective, multicenter, randomized, double-blind		Prospective, multicenter, randomized, double-blind		Prospective, multicenter, randomized, open-label (comparison with brachytherapy)		Prospective, multicenter, randomized, double-blind	
No. of sites	3 Germany		38 EU and CA		2 EU	76 US		66 US		37 US and CA		44 WW	
Lesion criteria	*de novo*, single lesion, single vessel, ≤12 mm length, RVD of 3.0 to 3.5 mm		*de novo*, single lesion, single vessel, ≤12 mm length, RVD of 3.0 to 3.5 mm		In-stent restenosis, single lesion, single vessel, ≤30 mm length, RVD of 3.0 to 3.5 mm	*de novo*, multiple lesion, multiple vessel, ≥10 to ≤28 mm length, RVD of 2.5 to 3.75 mm		*de novott*, multiple lesion, multiple vessel, ≥10 to ≤46 mm length, RVD of 2.25 to 4.0 mm		In-stent restenosis, multiple lesion, multiple vessel, ≤46 mm length, RVD of 2.5 to 3.75 mm		De novo, multiple lesion, multiple vessel, ≥18 to ≤40 mm length, RVD of 2.5 to 3.75 mm	
Study Stent	NIRx™		NIRx		NIRx	TAXUS Express		TAXUS Express²		TAXUS Express²		TAXUS Express	
PTx release formulation	SR		SR and MR		SR	SR		SR		SR		MR	
No. of stents	Single		Single		1 or 2 Contiguous	Single		Multiple Overlapping		Multiple Overlapping		Multiple Overlapping	
Antiplatelet therapy	Aspirin indefinitely and clopidogrel or ticlopidine for 6 months.												
Primary endpoint	30-d MACE		6-mo %net VO (IVUS)		30-d MACE	9-mo ischemia-driven TVR		9-mo ischemia-driven TVR		9-mo ischemia-driven TVR		9-mo ischemia-driven TVR	
Patient numbers #	**TAXUS n=31**	**NIR n=30**	**TAXUS* n=131 (SR)**	**BMS n=270**	**TAXUS n=28**	**TAXUS n=651**	**BMS n=643**	**TAXUS n=575**	**BMS n=571**	**TAXUS n=217**	**Brachy n=193**	**TAXUS n=217**	**BMS n=223**
	0.0%	0.0%	**7.9±9.9**	**21.9±17.5**	3.6%	**4.7%**	**12.1%**	**12.1%**	**17.3%**	**9.7%**	**17.5%**	**9.1%**	**19.4%**
Follow-up	30-d: clinical; 6- 9- and 24-mo: clinical, angiographic; 1, 3, 4, and 5 years: clinical		30-d: clinical; 6- and 24-mo: clinical, angiographic, IVUS; 1, 3, 4, and 5 years: clinical		30-d: clinical; 6-mo: clinical, angiographic, IVUS; 1, 2, 3, 4, and 5 years: clinical	30-d and 4-mo: clinical; 9-mo: clinical, angiographic, IVUS; 1, 2, 3, 4, and 5 years: clinical		30-d and 4-mo: clinical; 9-mo: clinical, angiographic, IVUS; 1, 2, 3, 4, and 5 years: clinical		30-d and 4-mo: clinical; 9-mo: clinical, angiographic, IVUS; 1, 2, 3, 4, and 5 years: clinical		1-, 3-, 6-mo: clinical; 9-mo: clinical, angiographic, IVUS; 1, 2, 3, 4, and 5 years: clinical	
Latest Follow-up	Complete - 5 years		Complete - 5 years*		4 years	Complete - 5 years		Complete - 5 years		Ongoing - 3 years		Complete - 5 years	
TLR	0.0%	10.0%	**10.3%**	**18.4%**	25.0%	**9.3%**	**21.9%**	**17.0%**	**23.2%**	**10.7%**	**26.4%**	15.4%	22.1.%
TVR	10.7%	13.3%	16.6%	22.5%	28.6%	**17.5%**	**29.2%**	24.9%	29.2%	**20.5%**	**33.7%**	23.1%	24.4%
MACE	10.7%	13.3%	20.4%	27.6%	35.7%	**25.2%**	**35.3%**	30.6%	33.6%	**23.9%**	**36.0%**	32.7%	28.6%
Cardiac death	0.0%	0.0%	2.4%	1.5%	3.6%	4.5%	4.8%	5.3%	3.6%	2.4%	2.2%	2.9%	3.3%
ST	0.0%	0.0%	2.3%	0.8%	0.0%	1.6%	1.1%	2.4%	1.5%	2.0%	NA	1.0%	1.0%

Note: Statistically significant comparisons presented in **bold** type. Abbreviations: BMS=bare metal stent; CA=Canada; d=day; EU=Europe; ISR=in-stent restenosis; IVUS=intravascular ultrasound; MACE=major adverse cardiac event (includes cardiac death, Q-wave and non-Q-wave MI, and TVR); MI=myocardial infarction; mo=month; MR=moderate release; PCI=percutaneous intervention; PTx=paclitaxel; RVD=reference vessel diameter; SR=slow release; ST=stent thrombosis; TVR=target vessel revascularization; US=United States; %net VO=percent net volume obstruction; WW=worldwide; yr=year; 3VD=3-vessel disease. * only SR (commercialized stent) data presented. # Numbers represent data from the safety population, and data represent the binary event rates. NIRx is a trademark of Medinol Ltd, Jerusalem.

Appendix 2:
Summary of TAXUS™ Express™ Studies

Parameter	WISDOM	MILESTONE II	ARRIVE 1	ARRIVE 2	SYNTAX
Study design	Prospective, web-based; multicenter, observational, transitional registry	Web-based, multicenter, observational, postapproval registry	Web-based, multicenter, observational, FDA-mandated periapproval registry	Web-based, multicenter, observational, BSC-initiated postapproval registry	Prospective, multicenter, randomized, all-comers design with nested PCI-only and CABG-only registries
No. of subjects	778	3,688	2,487	4820	903 (RCT PCI arm)
No. of sites	22 WW	164 WW	50 US[d]	53 US[d]	85 EU and US
Lesion criteria	De novo, <20 mm length, RVD 2.5 – 3.5 mm	Unspecified[e]	Unspecified[e]	Unspecified[e]	*de novo* 3VD** and/or LM* disease (isolated or associated with 1, 2, 3VD)
Stent platform	Express[2]	Express[2]	Express[2]	Express[2]	Express[2]
PTx formulation	SR	SR	SR	SR	SR
No. of stents	Single or Multiple	Single or Multiple	Single or Multiple	Single or Multiple	Multiple
Primary endpoint	1-yr physician reported target lesion reintervention rate	1-yr usage pattern analysis of TAXUS™ Express by lesion type and patient subset	1-yr TAXUS™-related CE rateb		12-mo MACCE
	2.0%		6.5%		17.8%
Follow-up	3-, 6-, 9-, 12-mo: clinical[b] (site visit or phone contact)	6- and 12-mo: clinical (site visit or phone contact)	1 and 6-mo and 1 and 2 years: clinicalc (site visit or phone contact)	1 and 6-mo and 1 and 2 years: clinicalc (site visit or phone contact)	1- and 6-mo and 1, 2, 3, 4, and 5 years: clinical
Latest follow-up	**Complete - 1 year**	**Complete - 1 year**	**Complete, 2 year - Pooled data (n=7,274)**		**Ongoing - 1 year**
TLR	2.0%	NA	7.7%		-
TVR	NA	5.5%	10.2%		13.7%[a]
MACE	5.2%	7.5%	9.3%[a]		-
Cardiac Death	2.2%	1.5%	1.2%		3.7%
ST	0.6%	1.7%	2.5%		4.4%

Abbreviations: BSC: Boston Scientific Corporation; CE=cardiac event; CEC=Clinical Events Committee; EU=Europe; FDA: Food and Drug Administration; MACE=majoradverce cardiac event; MACCE=major adverse cardiac and cerebrovascular event; MI=myocardial infarction; mo=month; PCI=percutaneous coronary intervention; PTx=paclitaxel; RCT=randomized clinical trial; RVD=reference vessel diameter; SR=slow release; TVR=target vessel revascularization; US=United States; WW=worldwide; yr=year.

a. TVR in SYNTAX is equal to any revascularization.
b. TAXUS™ stent-related major cardiac events (MCE), defined as cardiac death, MI, and TVR, were adjudicated by the CEC and were included in the primary endpoint. The CEC also adjudicated stent thromboses.
c. Additionally, patients requiring target vessel reintervention >365 days following stent implantation were to be followed for 1 year postreintervention.
d. Two (2) sites were excluded from study analysis due to site GCP non-compliance.
e. All patients admitted to the cardiac catheterization laboratory for a coronary angioplasty procedure and eligible for use of a TAXUS™ Express[2] stent could have been enrolled in the registry.

* Isolated or in conjunction with 1, 2, 3VD and ** revascularization for all 3 vascular territories

Appendix 3: Summary of TAXUS™ Liberté™ Clinical Studies

Parameter	TAXUS™ ATLAS Workhorse		TAXUS™ ATLAS Direct Stent		TAXUS™ ATLAS Small Vessel		TAXUS™ ATLAS Long Lesion		OLYMPIA Phase I	OLYMPIA Phases II & III
Study design	Prospective, multicenter, single-arm, historically-controlled		Prospective, multicenter, single-arm, historically-controlled		Prospective, multicenter, single-arm, historically-controlled		Prospective, multicenter, single-arm, historically-controlled		Prospective, web-based; multicenter, observational, global transitional registry	Web-based, multicenter, observational, global post approval registry
No. of sites	61 (North America and Asia Pacific)		24 (US, Singapore, and New Zealand)		23 (US, Singapore, and New Zealand)		24 (US, Singapore, and New Zealand)		16 WW	381 WW
Lesion criteria	*de novo*, multiple lesions, ≥10 and ≤28 mm length total, RVD of 2.5 – 4.0 mm		*de novo*, multiple lesions, ≥10 and ≤28 mm length total, RVD of 2.5 – 4.0 mm		*de novo*, multiple lesions, ≥10 and ≤28 mm length total, RVD of 2.2 – 2.5 mm		*de novo*, multiple lesions, ≥26 and ≤34 mm length total, RVD of 2.7 – 4.0 mm		All-comers, unspecified.	All-comers, unspecified.
Stent platform	Liberté									
No. of stents	Single		Single		Single		Single		Single or Multiple	Single or Multiple
Antiplatelet therapy	Aspirin recommended indefinitely and clopidogrel or ticlopidine for 6 months.									
Primary endpoint	9-mo TVR		9-mo %DS, analysis segment (mm)		9-mo %DS, analysis segment (mm)		9-mo %DS, analysis segment (mm)		30-d TAXUS™ Liberté stent related cardiac events a as adjudicated by CEC	12-mo TAXUS Liberté stent related cardiac events as classified by an IMR
	TAXUS™ n=871	**Control* n=991**	**TAXUS™ n=241**	**Control* n=538**	**TAXUS™ n=254**	**Control* n=73**	**TAXUS™ n=150**	**Control* n=145**	**N=529**	**N = 21,905**
	8.0%	7.1%	**26.4 ± 14.1**	**29.2 ± 19.1**	**32.1 ± 18.4**	**38.4 ± 23.6**	31.7 +/- 17.2		1.3%	4.4%
Follow-up	30-d, 4-mo: clinical; 9-mo: clinical (all), angiographic and IVUS (subset); and 1, 2, 3, 4, and 5 years: clinical		30-d, 4-mo: clinical; 9-mo: clinical, angiographic, and IVUS (all); and 1, 2, 3, 4, and 5 years: clinical		30-d, 4-mo: clinical; 9-mo: clinical and angiographic (all); 1, 2, 3, 4, and 5 years: clinical		30-d and 4-mo: clinical; 9-mo: clinical and angiographic (all), IVUS (subset); and 1, 2, 3, 4, and 5 years: clinical		30-d, 6 mon and 1 year clinical (site visit or phone contact)	6 mon and1 year clinical (site visit or phone contact)
Latest Follow-up	**3 years**		**3 years**		**3 years**		**3 years**		**Complete - 1 year**	**Complete - 1 year**
TLR	8.6%	8.7%	**3.3%**	**10.2%**	**10.0%**	**22.1%**	12.4%	11.9%	1.9%	2.5%
TVR	13.7%	15.7%	**7.0%**	**17.1%**	**15.2%**	**27.9%**	17.5%	16.3%	NA	3.1%
MACE	19.0%	20.2%	**13.5%**	**23.7%**	**19.5%**	**32.4%**	21.2%	25.2%	3.7%	3.8%
Cardiac death	3.3%	2.3%	2.4%	4.8%	2.6%	4.4%	**1.5%**	**6.7%**	1.5%	1.4%
ST	1.8%	1.9%	0.3%	2.4%	1.4%	1.5%	**0.0%**	**3.9%**	1.7%	0.8%

Note: Statistically significant comparisons presented in **bold** type.
Abbreviations: d=day; IMR=independent medical reviewer; IVUS=intravascular ultrasound; MACE=major adverse cardiac event (includes cardiac death, Q-wave and non-Q-wave MI, and TVR); MI=myocardial infarction; mo=month; PCI=percutaneous intervention; PTx=paclitaxel; QCA=quantitative coronary angiography; RVD=reference vessel diameter; rec. indef.=recommended indefinitely; ST=stent thrombosis (ARC definite/probable); TVR=target vessel revascularization; US=United States; %net VO=percent net volume obstruction; WW=worldwide.
* TAXUS Express historical control.

Appendix 4:
Summary of SPIRIT Clinical Trials

Parameter	SPIRIT First		SPIRIT II		SPIRIT III RCT		SPIRIT III Registry 4.0mm
Study design	Prospective, multicenter, randomized, single-blind, first human use		Prospective, multicenter, randomized, single-blind		Pivotal, US, Prospective, multicenter, randomized, single-blind		Prospective, multicenter, single-arm registry to study larger (4.0 mm) vessels
No. of sites	9 sites in Europe		28 sites in Europe, India, and NZ		65 sites in US		4.0 mm = 12 sites
Lesion criteria	*de novo*, single lesion, single vessel, ≤12 mm length, RVD of 3.0 mm		Up to 2 de novo lesions in different vessels, ≤28 mm length, RVD of ≥2.5 to ≤4.25 mm		Up to 2 *de novo* lesions in different vessels, ≤28 mm length, RVD of ≥2.5 to ≤3.75 mm		Up to 2 *de novo* lesions in different vessels, ≤28 mm length, RVD of ≥3.75 mm to ≤4.25 mm
Study Stent Platform	**XIENCE V™ Stent (N = 27)**		**XIENCE V (N = 223)**		**XIENCE V (N = 669)**		**XIENCE V (N = 69)**
Control Stent Platform	**Vision Stent (N = 29)**		**TAXUS™ Express™² Stent (N = 77)**		**TAXUS Express² stent (N = 333)**		**Not applicable**
No. of stents	Single		Single		1 or 2 Contiguous		Single
Postprocedure antiplatelet therapy	ASA: 12 mo; Clopidogrel / ticlopidine: 3 mo minimum		ASA: 12 mo; Clopidogrel / ticlopidine: 6 mo minimum		ASA: 5 yr; Clopidogrel / ticlopidine: 6 mo minimum		ASA: 12 mo; Clopidogrel / ticlopidine: 6 mo minimum
Primary Endpoint	In-stent late loss at 180 days (mm)		In-stent late loss at 180 days (mm)		9 month Target Vessel Failure[#]		In-segment late loss at 240 days (mm)
	XIENCE™	**Vision™**	**XIENCE™**	**TAXUS**	**XIENCE™**	**TAXUS**	**XIENCE V**
	0.10±0.23	**0.85±0.36**	**0.11±0.27**	**0.36±0.39**	7.6%	9.7%	0.17 ± 0.38
Follow-up	30, 180, 270 days, 1 to 5 yrs		30, 180, 270 days, 1 to 5 yrs: clinical; 180 days and 2 yrs: angiographic and IVUS		30-d: clinical; 6-mo: clinical, angiographic, IVUS; 1, 2, 3, 4, and 5 yrs: clinical		30-d and 4-mo: clinical; 9-mo: clinical, angiographic, IVUS; 1, 2, 3, 4, and 5 yrs: clinical
Latest Follow-up	Complete - 5 years		3 years		3 years		2 years
TLR	8.3%	28.0%	**4.6%**	**10.1%**	**5.4%**	**8.9%**	1.5%
MACE	16.7%	28.0%	**7.2%**	**15.9%**	**9.7%**	**16.4%**	7.7%
Cardiac death	0.0%	0.0%	0.5%	4.3%	1.4%	1.6%	3.0%
ST	0.0%	0.0%	0.9%	1.4%	1.2%	1.6%	0.0%

Note: Statistically significant comparisons presented in **bold** type.
Abbreviations: d=day; ITT=intent-to-treat; IVUS=intravascular ultrasound; MACE=major adverse cardiac events; mo=month; NZ=New Zealand; RVD=reference vessel diameter; rec. indef.=recommended indefinitely; ST=stent thrombosis (ARC definite-probable); TVR=target vessel revascularization; US=United States; yr=year.
[#] TVF is defined as hierarchical composite of cardiac death, MI, ischemic-driven TLR and ischemic-driven non-TLR TVR. *P*-value for superiority was not pre-specified. *P*-value was met (statistically significant) for non-inferiority.

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