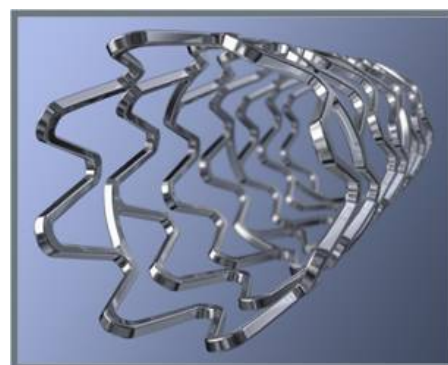


For medical and healthcare media only

Platinum Chromium Element™ Stent Series

The Platinum Chromium Element™ Drug-Eluting Stent Series is the next generation in stent platforms designed specifically for use in coronary stenting to improve the management of patients with coronary artery disease (CAD). To continue the evolution and improve the long-term performance of the coronary stent, the Element Stent Series integrates three components – a breakthrough alloy, an innovative stent design, and a new catheter.



Platinum Chromium Element™ Stent

Element™ Stent Series alloy

Platinum chromium, the alloy used in the Element Stent Series, has been developed and patented for use in coronary stenting to minimise recoil, increase conformability, improve visibility and enhance vascular compatibility. In bench testing* against other leading chromium cobalt stents, the TAXUS™ Element™ Stent was shown to have over 30% less recoil, as measured by the percentage by which the stent diameter decreases after balloon deflation.¹ Clinically this will help to maintain the optimal cross-sectional area of the stent, once the balloon has been deflated, to keep the artery open and prevent reblockage. Currently available stent materials include stainless steel and cobalt chromium. Stainless steel has low recoil and radial strength but an increased strut thickness is needed to maximise radiopacity (which is the ability to detect the stent



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The Element™ Drug-Eluting Stent Series include: the TAXUS™ Element™ and PROMUS™ Element™ Drug-Eluting Stents.


The TAXUS™ Element™ Drug-Eluting Stent is CE mark pending and is not available for sale in the European Economic Area (EEA).

The Element™ Bare Metal Stent (BMS) is under development and is not for sale in the EEA.

** Bench test results may not necessarily be indicative of clinical performance.*

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when it is implanted), while cobalt chromium has a reduced strut thickness but has higher recoil due to its elastic properties. In comparison, platinum chromium is two-times more dense than iron or cobalt providing better radiopacity, it is malleable and corrosion resistant, it has increased strength when alloyed with stainless steel (grade 316L) and it is fully incorporated in the alloy.²

Element™ Stent Series design

The new Element Stent Series design incorporates thinner struts, a new geometry and consistent stent surface to artery ratio to increase strength, improve flexibility and provide uniform drug delivery across the stent matrix. In bench testing* against other leading chromium cobalt stents, the TAXUS™ Element™ Stent was shown to have over 80% more radial strength, as measured by the amount of radial force required to reduce the diameter of a deployed stent.³ Clinically a greater radial strength helps to prevent the stent from collapsing once implanted in the artery. Thinner struts (0.0032" [0.081 mm]) are used to provide a lower system profile while maintaining an appropriate amount of radiopacity, which enables improved visualisation when implanting the stent under fluoroscopy. The new geometry includes a uniform pattern of serpentine segments to optimise drug elution, short segments that can operate almost independently to improve conformability and minimise gaps without contact on a bend, wider peaks to redirect the strain of expansion and minimise recoil, and two offset connectors to improve flexibility. The overall geometry has been designed to provide greater flexibility to enable the stent to be delivered more easily into the artery and to evenly distribute the drug along the vessel wall. There are four stent models across the range of diameters to optimise the surface to artery ratio providing more uniform scaffolding to reduce the risk of vessel prolapse.

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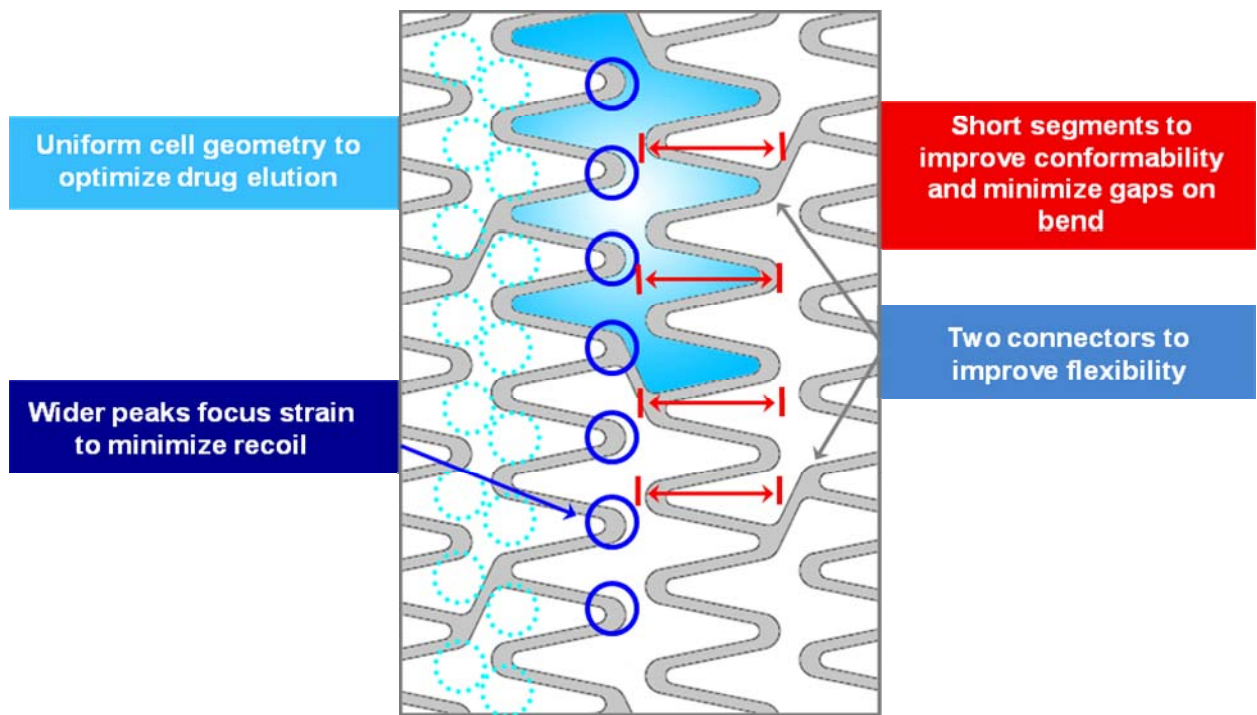
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The geometry of the Element™ Stent Series platform

Element™ Stent Series catheter

The Element Stent Series catheter includes a new balloon system, robust shaft and low profile to improve deliverability, improve flexibility, enhance pushability and improve withdrawal. In bench-testing* against other leading drug-eluting stents, both the TAXUS™ Element™ Stent and PROMUS™ Element™ Stent have the smallest tip profile (0.017" [0.432 mm]) and lowest stent crossing profile (0.042" [1.067 mm]).⁴ Clinically this provides clinicians with an easier to use catheter and may also allow tighter and/or more complex lesions to be treated. The new bi-segment inner lumen has a flexible distal segment and pushable proximal segment to improve

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trackability and pushability. In addition, a new DuoLeap™ balloon material is included to improve the distal segment flexibility and balloon withdrawal.

Element™ Stent Series platform

The Platinum Chromium Element Stent Series will be used as the platform in the third generation of the TAXUS™ Stent Systems** and in the second generation of the PROMUS™ Stent Systems**.

The TAXUS™ Element™ Stent System

The clinical trial programme for the TAXUS stents (TAXUS™ Express™, TAXUS™ Express²™ and TAXUS™ Liberté™) has provided extensive clinical evidence that has established the safety and efficacy of these stents for the treatment of patients with CAD, including progressively more complex patient populations, lesions and procedures based on clinical, angiographic and intravascular ultrasound (IVUS) outcomes. Over 5 million paclitaxel-eluting stents have been implanted worldwide to date⁵ and follow-up data are available from more than 50,000 patients in clinical trials⁶, with outcomes data available for over at least 5 years.*** Many more patients who received TAXUS stents have been evaluated in large, international registries.

The new TAXUS Element Stent uses the proven drug (paclitaxel), polymer (Translute™ [poly(styrene-b-isobutylene-b-styrene)] polymer), drug formulation (8.8%, slow release) and dose density (1.0 µg/mm²) of the TAXUS Liberté and two TAXUS Express Stents. The slow-release paclitaxel provides controlled drug delivery to the stented vessel segment and its unique mechanism of action helps to inhibit cell migration and proliferation regardless of the cellular signalling process or pathway.⁷

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Comprehensive analytical bench testing has been conducted comparing the TAXUS Element Stent with TAXUS Liberté and two TAXUS Express Stents.⁸ In addition, preclinical animal studies have demonstrated that the TAXUS Element Stent has equivalent vascular compatibility, early and late healing, safety and drug release profiles to the other TAXUS stents.⁹

TAXUS™ Element™ Stent clinical trial programme

Two trials of the TAXUS Element Stent in comparison to the TAXUS Express² stent are being carried out:

PERSEUS WH (Work Horse):

- Clinical data from 1244 patients in US, Australia, New Zealand and Singapore to support marketing applications to the FDA in US and PMA in Japan (enrolment was completed in October 2008)

PERSEUS SV (Small Vessel):

- Clinical data involving 219 patients with small vessel lesions in US (enrolment was completed in October 2008)

Preliminary results from the ongoing safety monitoring in these blinded trials indicate no safety concerns, with consistent safety observations to those of previous TAXUS Stent Systems.

Data from the PERSEUS trials are expected to be presented in early 2010.

The PROMUS™ Element™ Stent System

The clinical trial programme (SPIRIT studies) for the PROMUS™ Stent has demonstrated the safety and efficacy of this stent system for the treatment of patients with symptomatic ischaemic

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disease due to *de novo* native coronary artery lesion(s). To date, over 1 million everolimus-eluting stents have been implanted worldwide¹⁰ and follow-up data are available from more than 5,000 patients in clinical trials.¹¹

The PROMUS Element Stent uses the same polymer (fluorinated copolymer [polyvinylidene fluoride-hexafluoropropylene]), anti-proliferative drug (everolimus) and drug loading (1.0 µg/mm²) to the PROMUS/Xience V™ Stent. The PROMUS Stent uses a thin, durable polymer matrix that results in the controlled release of everolimus which provides powerful neointimal suppression.^{12,13}

Preclinical studies demonstrated that the PROMUS Element Stent has a comparable drug release profile, similar everolimus arterial tissue levels and blood drug levels, equivalent vascular compatibility and safety to the PROMUS/Xience V Stent.¹⁴

The PROMUS Element Drug Eluting Stent received CE Mark in October 2009.

PROMUS™ Element™ Stent clinical trial programme

A programme of trials of the PROMUS Element stent is being carried out:

PLATINUM WH (Work Horse):

- Clinical data from 1532 patients in more than 140 sites in US, Europe, Asia Pacific and Japan to support submissions to the FDA in USA and PMA in Japan. The enrolment was completed in September 2009.

PLATINUM SV (Small Vessel):

- Non-randomised subtrial examining 94 patients with small vessel lesions in US and Japan (enrolment ongoing)

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PLATINUM LL (Long Lesion):

- Non-randomised subtrial involving 102 patients with long lesions in US and Japan (enrolment ongoing)

PLATINUM QCA (Quantitative Coronary Angiography):

- Observational study of 100 patients in Asia Pacific (enrolment was completed in July 2009)

In each of these trials, patients will be followed for up to 5 years to provide long-term efficacy and safety data on the PROMUS Element Stent.

Data from the PLATINUM trials are expected to be presented in late 2011.

Boston Scientific cardiovascular stent portfolio

The Platinum Chromium Element™ Stent Series will form the backbone for future generations of Boston Scientific's drug-eluting stent pipeline.

The Platinum Chromium TAXUS™ Element™ and PROMUS™ Element™ Stent Systems are complementary technologies that enable Boston Scientific to offer interventional cardiologists the choice of the most appropriate drug-eluting stent options available for their patients.

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References (available upon request)

¹ Data on file at Boston Scientific

² Data on file at Boston Scientific

³ Data on file at Boston Scientific

⁴ Data on file at Boston Scientific

⁵ Data on file at Boston Scientific

⁶ Data on file at Boston Scientific

⁷ Kamath KR, Barry JJ, Miller KM. The Taxus drug-eluting stent: a new paradigm in controlled drug delivery. *Adv Drug Deliv Rev* 2006;58:412–436

⁸ Data on file at Boston Scientific

⁹ Data on file at Boston Scientific

¹⁰ Data on file at Boston Scientific

¹¹ Data on file at Boston Scientific

¹² Crowe A, Bruelisauer A, Duerr L, et al. Absorption and intestinal metabolism of SDZ-RAD and rapamycin in rats. *Drug Metab Disp* 1999;27:627–632

¹³ Crowe A, Lemaire M. In vitro and in situ absorption of SDZ-RAD using a human intestinal cell line (Caco-2) and a single pass perfusion model in rats: comparison with rapamycin. *Pharm Res* 1998;15:1666–1672

¹⁴ Data on file at Boston Scientific

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