

**Boston
Scientific**

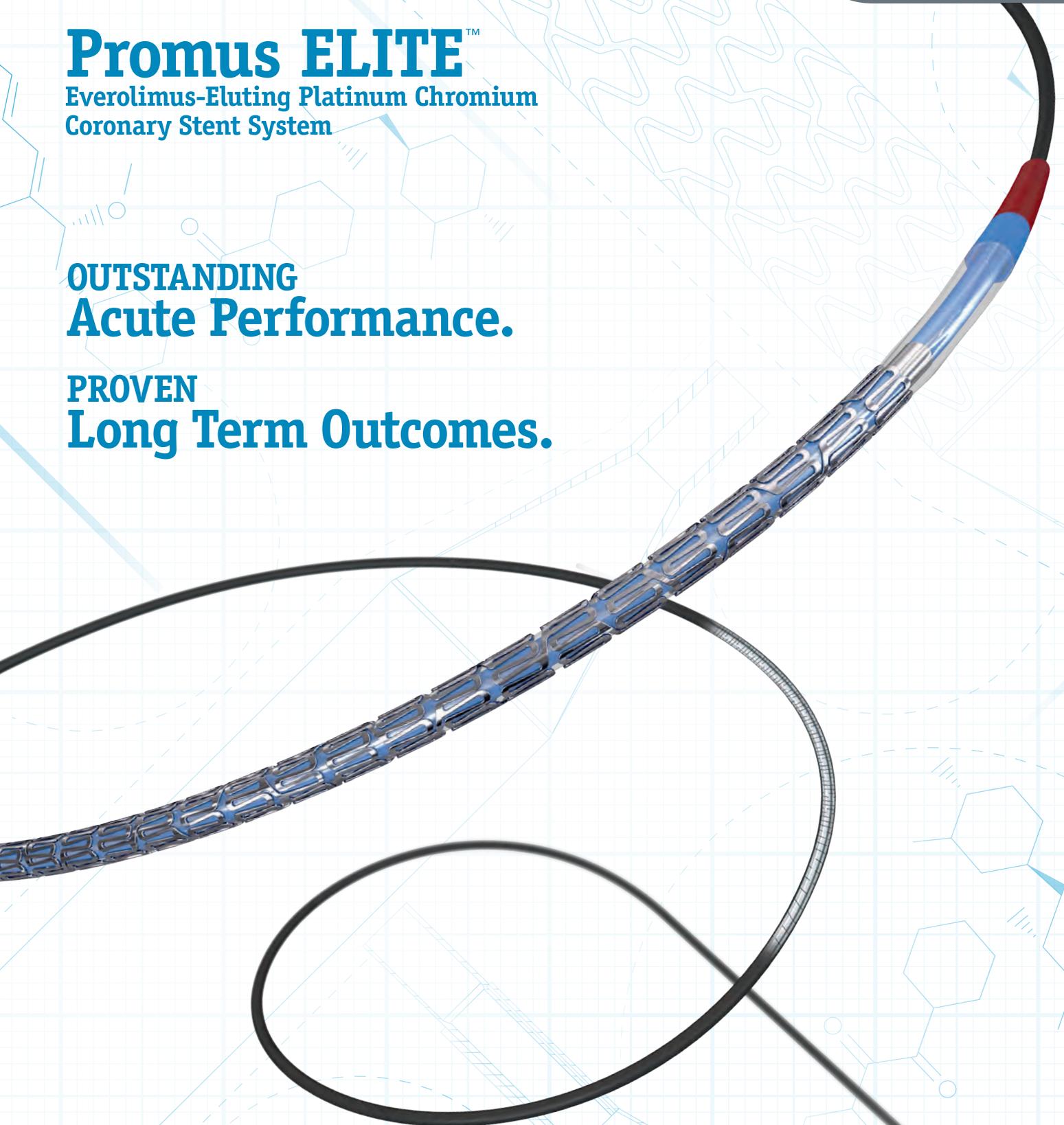
Advancing science for life™

Promus ELITE™

Everolimus-Eluting Platinum Chromium
Coronary Stent System

**OUTSTANDING
Acute Performance.**

**PROVEN
Long Term Outcomes.**

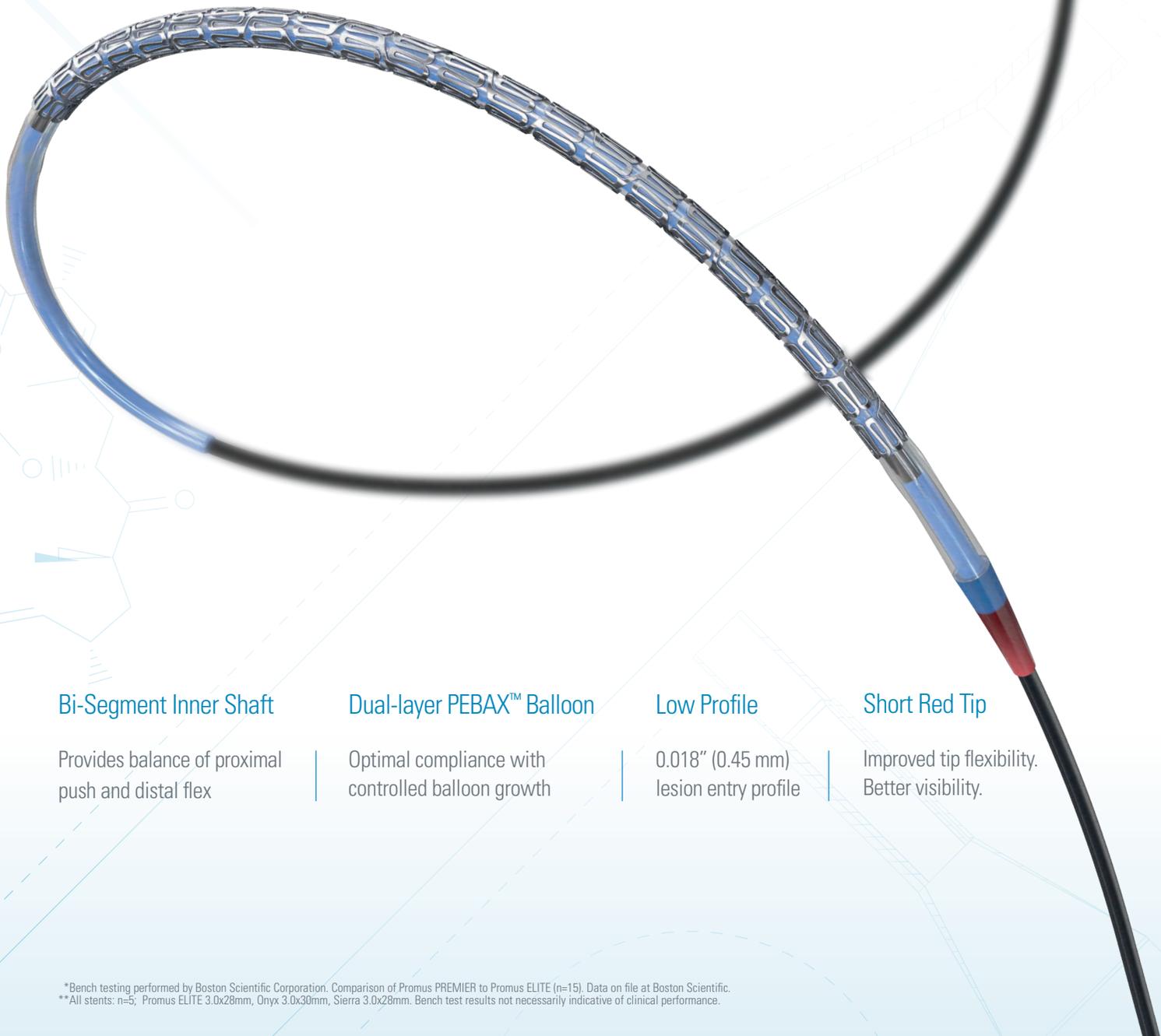


Promus ELITE™

Everolimus-Eluting Platinum Chromium
Coronary Stent System

The Promus ELITE Stent System builds upon the proven performance of the Promus permanent polymer DES family and the platinum chromium (PtCr) platform.

The Promus ELITE system combines a unique customized stent architecture and the market-leading Everolimus and PVDF-HFP polymer combination with an enhanced delivery system for better pushability and trackability – offering outstanding deliverability and acute performance.



Bi-Segment Inner Shaft

Provides balance of proximal push and distal flex

Dual-layer PEBAX™ Balloon

Optimal compliance with controlled balloon growth

Low Profile

0.018" (0.45 mm) lesion entry profile

Short Red Tip

Improved tip flexibility. Better visibility.

*Bench testing performed by Boston Scientific Corporation. Comparison of Promus PREMIER to Promus ELITE (n=15). Data on file at Boston Scientific.
**All stents: n=5; Promus ELITE 3.0x28mm, Onyx 3.0x30mm, Sierra 3.0x28mm. Bench test results not necessarily indicative of clinical performance.

OUTSTANDING DELIVERABILITY

Enhanced delivery system for optimal balance of pushability, flexibility, and trackability



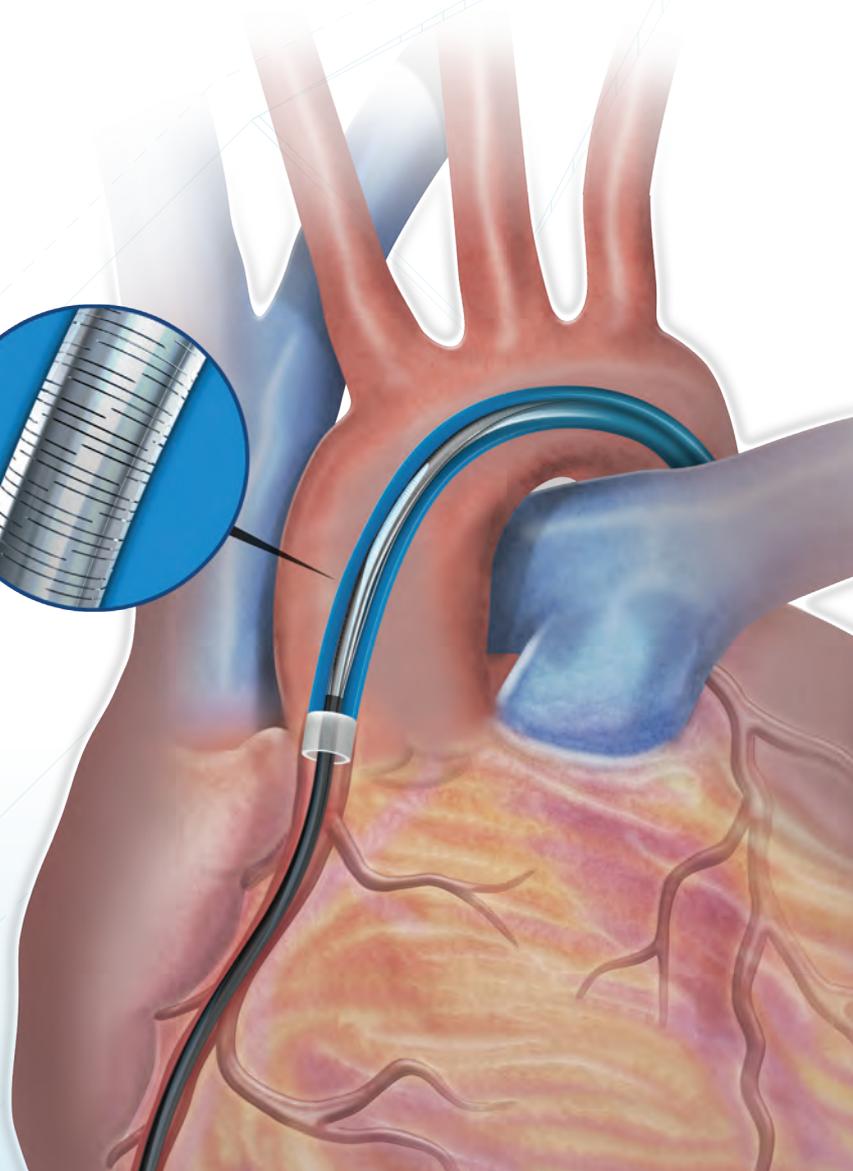
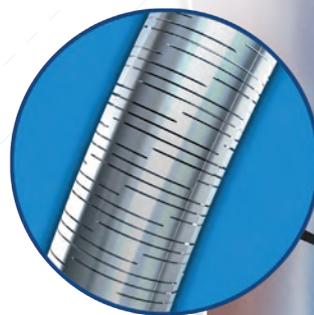
Proprietary Laser-Cut Hypotube Technology

15% increase
in pushability*

19% more trackable
than competitive DES**

Variable cut pattern specifically
designed for coronary anatomy

More than 300 cuts
over 100 mm length

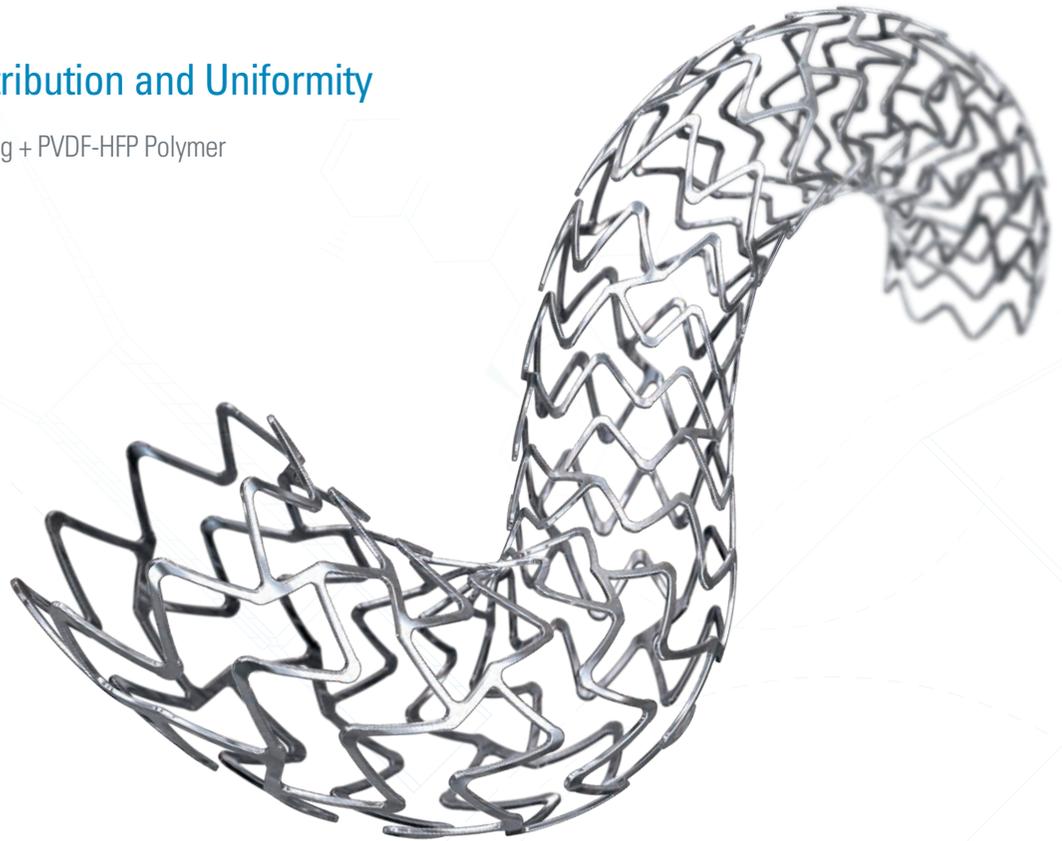


TRUSTED STENT PLATFORM

Customized stent architecture design offers the ideal balance of strength and flexibility

Excellent Drug Distribution and Uniformity

Market-leading Everolimus drug + PVDF-HFP Polymer



Superior Conformability

Up to 8x more conformable*

Unmatched Radial Strength

Up to 24% higher radial strength*

Low Recoil

50% less recoil than competitive DES*

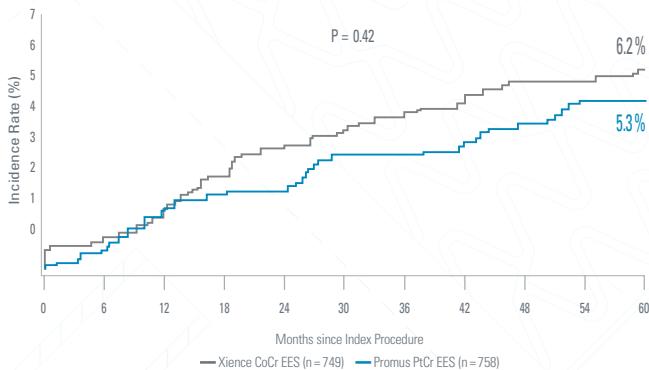
Best-in-Class Visibility

Unique PtCr stent platform

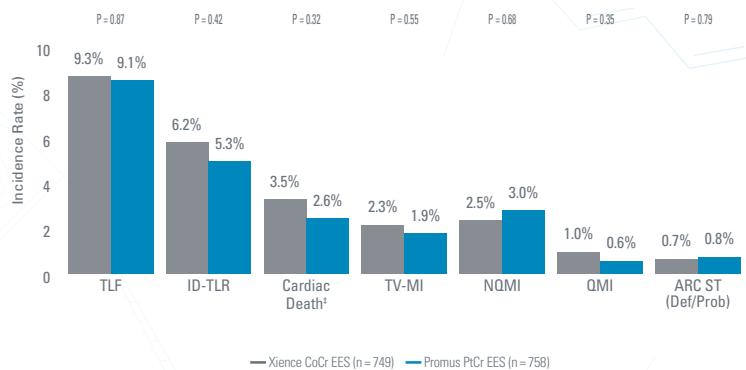
PROVEN CLINICAL OUTCOMES

The PLATINUM Family of trials demonstrate outstanding clinical outcomes in 11 studies of almost 10,000 patients.

Numerically Lower Ischemia-Driven TLR through 5-Years¹



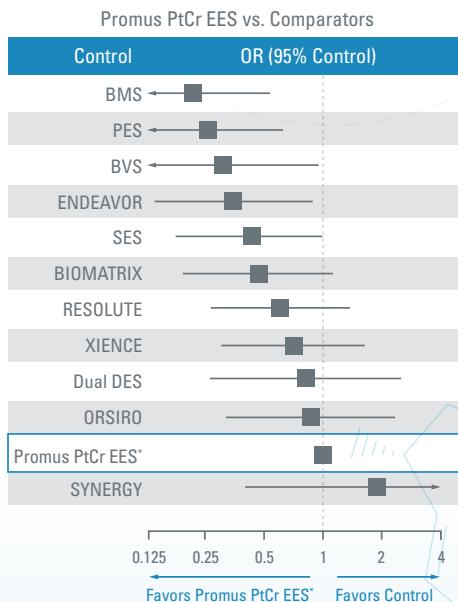
Numerically Lower Event Rates through 5-years¹



Outstanding safety shown in real-world use

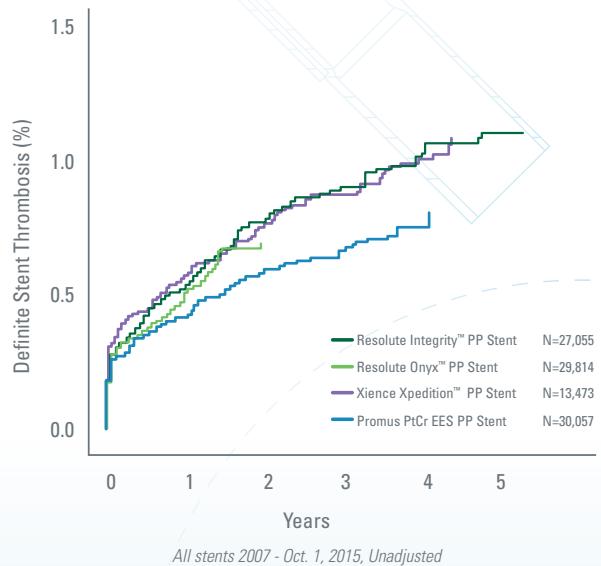
Kang Network Meta-Analysis²

Promus PtCr EES ranked #2 for the lowest relative risk of Def/Prob Stent Thrombosis



SCAAR Registry³

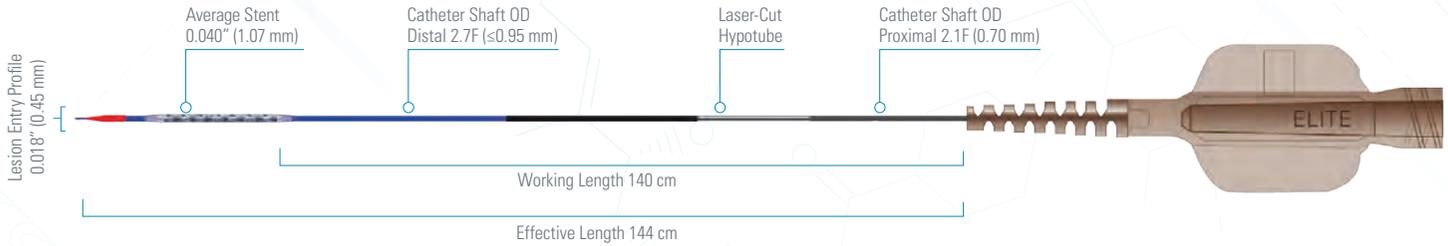
Promus PtCr EES reported numerically lowest Permanent Polymer ST rates in real-world SCAAR Registry



Nearly 9 Million Promus PtCr DES implanted worldwide[§]

Caution should be taken in interpreting study results, as some stents had limited numbers of comparisons, and some of the studies had a potential risk of bias. *All Promus PtCr-EES stents, also includes PROMUS Element, PROMUS Element Plus, and Promus PREMIER. Def/prob ST was available in 110 studies with 111,088 patients. † Deaths due to unknown causes were adjudicated as cardiac death. § Implants based on Promus DES units sold through March 2018. Includes (Promus, Promus Element, Promus Element Plus, Promus PREMIER). 1. Stone, GW. PLATINUM Workhorse Trial. ACC 2015. PLATINUM Clinical Trial Program studied the PROMUS Element™ Stent (Promus PtCr EES) and the Xience V™ Stent (Xience CoCr EES). 2. Kang, S. et al. J Am Coll Cardiol Interv. doi:10.1016/j.jcin.2016.03.038 3. Adapted from Presentation by Stefan James, MD at TCT 2017 (Swedish SCAAR database, real-world outcomes of latest DES generations).

Ordering Information



(mm)	8	12	16	20	24	28	32	38
2.25	H749 394120822 0	H749 394121222 0	H749 394121622 0	H749 394122022 0	H749 394122422 0	H749 394122822 0	H749 394123222 0	n/a
2.50	H749 394120825 0	H749 394121225 0	H749 394121625 0	H749 394122025 0	H749 394122425 0	H749 394122825 0	H749 394123225 0	H749 394123825 0
2.75	H749 394120827 0	H749 394121227 0	H749 394121627 0	H749 394122027 0	H749 394122427 0	H749 394122827 0	H749 394123227 0	H749 394123827 0
3.00	H749 394120830 0	H749 394121230 0	H749 394121630 0	H749 394122030 0	H749 394122430 0	H749 394122830 0	H749 394123230 0	H749 394123830 0
3.50	H749 394120835 0	H749 394121235 0	H749 394121635 0	H749 394122035 0	H749 394122435 0	H749 394122835 0	H749 394123235 0	H749 394123835 0
4.00	H749 394120840 0	H749 394121240 0	H749 394121640 0	H749 394122040 0	H749 394122440 0	H749 394122840 0	H749 394123240 0	H749 394123840 0

Promus ELITE Coronary Stent System Brief Summary – eDFU 50493043

INTENDED USE/INDICATIONS FOR USE: The Promus ELITE Everolimus-Eluting Platinum Chromium Coronary Stent System is indicated for improving luminal diameter in patients, including those with diabetes mellitus, with symptomatic heart disease or documented silent ischemia due to de novo lesions in native coronary arteries ≥ 2.25 mm to ≤ 4.00 mm in diameter in lesions ≤ 34 mm in length. **CONTRAINDICATIONS:** Use of the Promus ELITE Everolimus-Eluting Platinum Chromium Coronary Stent System is contraindicated in patients with known hypersensitivity to: • 316L stainless steel, platinum, chromium, iron, nickel or molybdenum • Everolimus or structurally-related compounds • The polymers or their individual components. Coronary Artery Stenting is contraindicated for use in: • Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or delivery device. • Patients with uncorrected bleeding disorders or patients who cannot receive anticoagulation or antiplatelet aggregation therapy. **WARNINGS:** • The use of this product carries the risks associated with coronary artery stenting, including stent thrombosis, vascular complications, and/or bleeding events. • This product should not be used in patients who are not likely to comply with recommended antiplatelet therapy. **PRECAUTIONS:** • Only physicians who have received adequate training should perform implantation of the stent. • Subsequent stent blockage may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized stents is not well characterized. • Consideration should be given to the risks and benefits of use in patients with history of severe reaction to contrast agents. • Stent thrombosis is a low-frequency event that current drug-eluting stent (DES) clinical trials are not adequately powered to fully characterize. Stent thrombosis is frequently associated with myocardial infarction (MI) or death. In the clinical trials analyzed to date, differences in the incidence of stent thrombosis have not been associated with an increased risk of cardiac death, MI, or all-cause mortality. Additional data from longer-term follow-up of the PLATINUM clinical trials and analyses of stent thrombosis related to DES are expected and should be considered in making treatment decisions as data become available. • When DES are used outside the specified Indications for Use, patient outcomes may differ from the results observed in the NG PROMUS and PLATINUM pivotal clinical 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 triglyceride levels. **Pre- and Post-Procedure Antiplatelet Regimen** The optimal duration of antiplatelet therapy, specifically P2Y12 inhibitor therapy, is unknown and DES thrombosis may still occur despite continued therapy. **Oral Antiplatelet Therapy** Continuation of combination treatment with aspirin and a P2Y12 inhibitor after PCI appears to reduce major adverse cardiac events. On the basis of randomized clinical trials and the 2016 ACC/AHA guidelines, aspirin 81 mg daily should be given indefinitely after PCI. In patients who are not at high risk of bleeding, a P2Y12 inhibitor should be given daily for at least 6 months in stable ischemic heart disease patients and for at least 12 months in acute coronary syndrome (ACS) patients. Full guidelines are provided at the following website: <http://content.onlinejacc.org/cgi/content/full/j.jacc.2011.08.007v1>. It is very important that the patient is compliant with the post-procedural antiplatelet recommendations. Premature discontinuation of prescribed antiplatelet medication could result in a higher risk of thrombosis, MI or death. Prior to PCI, if a surgical or dental procedure is anticipated that requires early discontinuation of antiplatelet therapy, the interventional cardiologist and patient should carefully consider whether a DES and its associated recommended antiplatelet therapy is the appropriate PCI choice. **Pediatric Use** The safety and effectiveness of the Promus ELITE stent in pediatric patients have not been established. **Lesion/Vessel Characteristics** The safety and effectiveness of the Promus ELITE Stent have not been established in the cerebral, carotid, or peripheral vasculature or in the following patient populations: • Patients with vessel thrombus at the lesion site. • Patients with coronary artery reference vessel diameters < 2.25 or > 4.00 mm. • Patients with coronary artery lesions longer than 34 mm or requiring more than one Promus ELITE Stent. • Patients with lesions located in the saphenous vein grafts, in the left main coronary artery, ostial lesions, or lesions located at a bifurcation. • Patients with diffuse disease or poor flow distal to the identified lesions. • Patients with tortuous vessels (> 60 degrees) in the region of the obstruction or proximal to the lesion. • Patients with a recent acute myocardial infarction where there is evidence of thrombus or poor flow. • Patients with in-stent restenosis. • Patients with moderate or severe calcification in the lesion or a chronic total occlusion. • Patients with 3 vessel disease. **Magnetic Resonance Imaging (MRI) Safety Information:** Non-clinical testing has demonstrated that the Promus ELITE Stent is MR Conditional for single and overlapped conditions up to 74 mm. A patient with this device can be safely scanned in a Magnetic Resonance system meeting the following conditions: • Static magnetic field of 3.0 and 1.5 Tesla only • Maximum spatial gradient magnetic field of 2200 gauss/cm (22 T/m) • Maximum Magnetic Resonance system reported, whole body averaged specific absorption rate (SAR) of < 2 W/kg (Normal Operating Mode) Under the scan conditions defined above, the Promus ELITE Stent is expected to produce a maximum temperature rise of 2.6°C after 15 minutes of continuous scanning. Non-clinical testing has demonstrated that the image artifact caused by the device extends approximately 8 mm from the Stent when imaged with a spin echo pulse sequence and a 3.0 Tesla MRI system. The artifact does not obscure the device lumen. **Potential Adverse Events** Potential adverse events (in alphabetical order) which may be associated with the use of a coronary stent in native coronary arteries include but are not limited to: • Abrupt stent closure • Acute myocardial infarction • Allergic reaction to anti-coagulant and/or antiplatelet therapy, contrast medium, or stent materials • Angina • Arrhythmias, including ventricular fibrillation and ventricular tachycardia • Arteriovenous fistula • Bleeding • Cardiac tamponade • Cardiogenic shock/pulmonary edema • Coronary aneurysm • Death • Dissection • Emboli, distal (air, tissue or thrombotic material or material from device(s) used in the procedure) • Heart failure • Hematoma • Hemorrhage, which may require transfusion • Hypotension/hypertension • Infection, local or systemic • Ischemia, myocardial • Pain, access site • Perforation or rupture of coronary artery • Pericardial effusion • Pseudoaneurysm, femoral • Renal insufficiency or failure • Respiratory failure • Restenosis of stented segment • Stent embolization or migration • Stent deformation, collapse, or fracture • Stent thrombosis/occlusion • Stroke/cerebrovascular accident/transient ischemic attack • Total occlusion of coronary artery • Vessel spasm • Vessel trauma requiring surgical repair or reintervention. Zortress™, the oral formulation of everolimus developed by Novartis Pharmaceuticals Corporation, has been evaluated in clinical trials and is approved in the United States for the prevention of organ rejection in adult kidney transplant recipients at the dose of 1.5 mg/day. Everolimus is also approved in the United States under the name of Afinitor™ for patients with advanced renal cell carcinoma (cancer), after failure of treatment with sunitinib or sorafenib, at doses of 5 to 20 mg/day when taken by mouth. The following list includes the known risks of everolimus at the oral doses listed above. The amount of drug that circulates in the bloodstream following implantation of a Promus ELITE™ Stent is several folds lower than that obtained with oral doses (1.5 mg to 20 mg/day, • Abdominal pain (including upper abdominal pain) • Anemia • Angioedema • Anorexia • Asthenia • Constipation • Cough • Delayed wound healing/fluid accumulation • Diarrhea • Dyslipidemia (including hyperlipidemia and hypercholesterolemia) • Dysgeusia • Dyspepsia • Dyspnea • Dysuria • Dry skin • Edema (peripheral) • Epistaxis • Fatigue • Headache • Hematuria • Hyperglycemia (may include new onset of diabetes) • Hyperkalemia • Hyperlipidemia • 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 CYP3A4 • 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, back, chest, musculoskeletal • Proteinuria • Pruritus • Pyrexia • Rash • Stomatitis • Thrombocytopenia • Thrombotic microangiopathy (TMA)/Thrombotic thrombocytopenic purpura (TTP)/Hemolytic uremic syndrome (HUS) • Tremor • Upper respiratory tract infection • Urinary tract infection • Vomiting 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. **CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please refer to the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

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