Boston Scientific
Advancing science for life™

Promus ELITE™

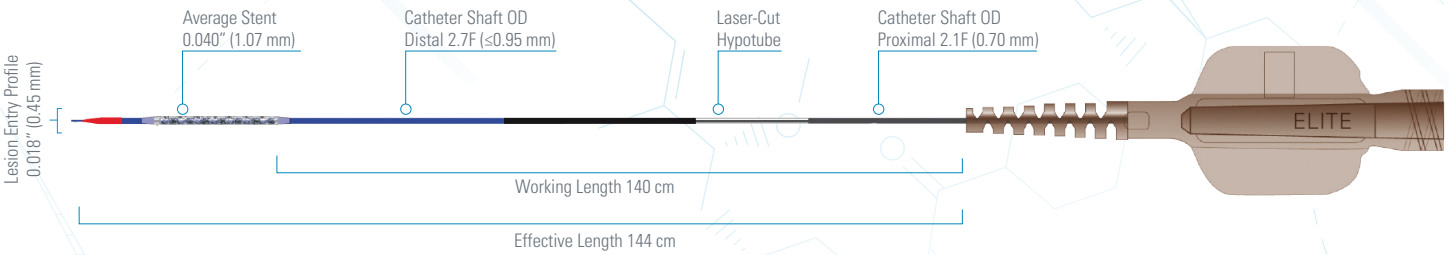
Everolimus-Eluting Platinum Chromium Coronary Stent System

General Specifications

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.
Drug and Polymer	The drug-polymer coating consists of a PVDF-HFP polymer and the active pharmaceutical ingredient Everolimus.
Stent Material	Platinum Chromium (PtCr) Alloy
Available Stent Lengths	8, 12, 16, 20, 24, 28, 32, 38* (mm)
Available Stent Diameters	2.25*, 2.50, 2.75, 3.00, 3.50, 4.00 (mm)
Drug Product	A conformal coating of a polymer carrier loaded with 100 µg/cm² Everolimus applied to the stent with a maximum nominal drug content of 243.0 µg on the largest stent (4.00 mm x 38 mm).
Drug Release	100% released by 120-days
Delivery System Effective Length	144 cm
Delivery System Ports	Single access port to inflation lumen. Guidewire exit port is located approximately 25 cm from tip. Designed for guidewire ≤ 0.014 in (0.36 mm).
Stent Delivery Balloon	Dual-layer PEBAX™ Balloon with two radiopaque markerbands, nominally placed 0.4 mm (0.016 in) beyond the stent at each end.
Guide Catheter Inner Diameter	≥ 0.056 in (1.42 mm)
Guide Catheter Compatibility	5F ≥ 0.056 in (1.42 mm)
Catheter Shaft Outer Diameter	2.1F (0.70 mm) proximal and 2.7F (≤ 0.95 mm) distal
Stent Strut Thickness	0.0032 in (0.081 mm) for diameters 2.25 mm to 3.50 mm 0.0034 in (0.086 mm) for diameter 4.00 mm
Shelf Life	18 months
Sterilization	Ethylene Oxide
Markerband Material and Length	Platinum Iridium; 1 mm
Maximum Balloon Inflation Pressure	Nominal Inflation Pressure: 11 ATM – 1,117 kPa Rated Burst Pressure: 18 ATM – 1,827 kPa (stent diameters 2.25 – 2.75 mm) 16 ATM – 1,620 kPa (stent diameters 3.00 – 4.00 mm)

*38 mm length is not available in 2.25 mm diameter size.

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 see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

92305414 Rev A

Boston Scientific
Advancing science for life™

Interventional Cardiology
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

To order product or for more information contact customer service at 1.888.272.1001.

IC-555505-AA US