

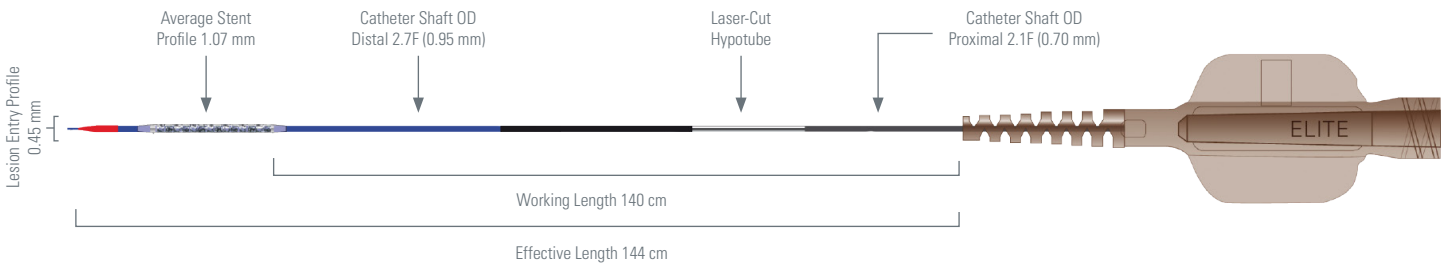
Promus ELITE™

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 coronary luminal diameter in patients with symptomatic ischemic heart disease, including patients with acute myocardial infarction and patients with concomitant diabetes mellitus due to discrete de novo native coronary artery lesions. The Promus ELITE Stent is also indicated for treatment of patients presenting with: Coronary bifurcation lesions • Coronary artery ostial lesions • Unprotected left main coronary artery lesions • Coronary artery total occlusion lesions • In-stent restenosis in coronary artery lesions
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)
Average Stent Profile	1.07 mm
Lesion Entry Profile	0.45 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 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 26 cm from tip. Designed for guidewire ≤36 mm (0.014")
Stent Delivery Balloon	Dual-layer PEBAX™ Balloon with two radiopaque markerbands, nominally placed 0.4 mm (0.016") beyond the stent at each end.
Guide Catheter Inner Diameter	≥1.42 mm (0.056")
Guide Catheter Compatibility	5 F ≥ 1.42 mm (0.056")
Catheter Shaft Outer Diameter	2.1 F (0.70 mm) proximal and 2.7 F (≤ 0.95 mm) distal
Stent Strut Thickness	2.25 – 3.50 mm = 0.081 mm (0.0032") 4.00 mm = 0.086 mm (0.0034")
Shelf Life	24 months
Sterilization	Ethylene Oxide
Marker Band Material and Length	Platinum Iridium; 1 mm
Maximum Balloon Inflation Pressure	Nominal Inflation Pressure: 11 ATM – 1117 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)

Ordering Information



(mm)	8	12	16	20	24	28	32	38
2.25	H749 394130822 0	H749 394131222 0	H749 394131622 0	H749 394132022 0	H749 394132422 0	H749 394132822 0	H749 394133222 0	n/a
2.5	H749 394130825 0	H749 394131225 0	H749 394131625 0	H749 394132025 0	H749 394132425 0	H749 394132825 0	H749 394133225 0	H749 394133825 0
2.75	H749 394130827 0	H749 394131227 0	H749 394131627 0	H749 394132027 0	H749 394132427 0	H749 394132827 0	H749 394133227 0	H749 394133827 0
3.0	H749 394130830 0	H749 394131230 0	H749 394131630 0	H749 394132030 0	H749 394132430 0	H749 394132830 0	H749 394133230 0	H749 394133830 0
3.5	H749 394130835 0	H749 394131235 0	H749 394131635 0	H749 394132035 0	H749 394132435 0	H749 394132835 0	H749 394133235 0	H749 394133835 0
4.0	H749 394130840 0	H749 394131240 0	H749 394131640 0	H749 394132040 0	H749 394132440 0	H749 394132840 0	H749 394133240 0	H749 394133840 0

Caution: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations. Information contained herein is for use or distribution outside the US, France, and Japan only.

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