

Metal Composition

Promus ELITE™ Everolimus-Eluting Platinum Chromium Coronary Stent System

The Promus ELITE™ Stent is made from Platinum Chromium alloy and nominally consists of the following elements (with additional trace elements):

Promus ELITE Stent	Elemental Composition by Weight
Iron	37%
Platinum	33%
Chromium	18%
Nickel	9%
Molybdenum	3%
Manganese	Trace

Directions for Use (DFU):

Section 4.0 CONTRAINDICATIONS

Use of the Promus ELITE Stent System is contraindicated in patients with the following:

- Known hypersensitivity to platinum, the platinum chromium alloy (or similar alloy types such as stainless steel).
- Known hypersensitivity or contraindication to everolimus or structurally related compounds.
- Known hypersensitivity to the polymer or its individual components (see details in Section 2.2.2, Primer polymer and drug matrix copolymer carrier).
- Known severe reaction to contrast agents that cannot be adequately pre-medicated prior to the Promus ELITE Stent placement procedure.

Coronary artery stenting is contraindicated for use in the following:

- Patients who cannot receive recommended anti-platelet and/or anticoagulant therapy.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or delivery device.

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.

For more information, contact your local sales representative.