Consumer Information on: PROMUS Element Plus Everolimus-Eluting Platinum Chromium Coronary Stent System (Monorail and Over-The-Wire) - P110010/S001

U.S. Food & Drug Administration

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: PROMUS® Element™ Plus Everolimus-Eluting Platinum Chromium Coronary Stent System (Monorail™ and Over-The-Wire)
PMA Applicant: Boston Scientific Corporation
Address: One Scimed Place, Maple Grove, MN 55311
Approval Date: June 1, 2012
Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf11/p110010s001a.pdf [1]

What is it? The PROMUS Element stent is a metal stent [2] with the drug everolimus contained in a thin coating on the stent's surface. The PROMUS Element stent is mounted on a folded balloon attached to a catheter delivery system for placement into a coronary artery (blood vessel supplying blood to the heart) . The stent is made of a platinum-chromium metal alloy [3]. The PROMUS Element stent uses the identical drug coating formulation and drug dose density as the approved PROMUS / XIENCE V [4] stent. The PROMUS Element uses the identical stent materials, stent design, and balloon materials as the approved ION stent [5].

How does it work?

- A catheter with a small balloon mounted on the end is inserted into a blood vessel in the groin or arm and advanced into a coronary artery.
- The catheter is then positioned at the narrowed portion of the artery and the balloon is inflated. As the balloon inflates, it stretches the coronary artery wall (a procedure known as balloon angioplasty [6]).
- The balloon is then deflated, and the catheter is removed from the artery.
- The PROMUS Element stent delivery catheter is then positioned at the narrowing of the coronary artery. The balloon on the stent delivery catheter is inflated, which expands the stent and presses it against the coronary artery wall. This may be followed by repeat balloon inflations within the stent to achieve the desired stent expansion.
- The stent remains permanently implanted within the coronary artery to help keep the artery open.
- The drug (everolimus) is released over time into the artery wall around the stent to help prevent the vessel from re-narrowing.

When is it used? The PROMUS Element stent is used in patients who have a narrowing in their coronary arteries caused by coronary artery disease [7] – a condition that occurs when the arteries that supply oxygen-rich blood and nutrients to the heart muscle become narrowed or blocked by a gradual build-up of “plaque.” Plaque is made up of fatty deposits (cholesterol [8]), white blood cells, calcium, and scar tissue that collect over time in the coronary artery wall. If these arteries become blocked or narrowed, treatment may be required to improve blood flow and increase the supply of oxygen to the heart. With this approval, longer PROMUS Element stents are now available to treat longer coronary blockages.

The PROMUS Element stent is to be used in patients who have narrowing in coronary arteries with length less than or equal to 34 mm with reference vessel diameters greater than or equal to 2.25 mm and less than or equal to 4.00 mm.

What will it accomplish? A significantly narrowed coronary artery limits blood flow to the heart muscle and can cause chest pain (angina [9]). Placement of the PROMUS Element stent within the narrowed coronary artery improves blood flow. A fter a coronary artery stent is implanted, re-narrowing of the artery may occur. The drug (everolimus) is released over time from the PROMUS Element stent surface into the adjacent artery wall to help prevent re-narrowing of the vessel.

When should it not be used? The PROMUS Element Everolimus Eluting Coronary Stent System should not be used in patients:

- who cannot receive antiplatelet and/or anticoagulant therapy
- who have a coronary blockage that prevents complete angioplasty balloon inflation or proper placement of the stent or stent delivery system, or
- who have known hypersensitivity or contraindication to everolimus or structurally-related compounds, cobalt, chromium, nickel, tungsten, acrylic, and fluoropolymers

Additional information: The Summary of Safety and Effectiveness Data and

labeling [10] are available online.

Other Resources:

- NIH - MedlinePlus - Atherosclerosis [11]
- NIH – MedlinePlus – Heart Attack [12]

SOURCE [13]

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http://www.mdtmag.com/news/2012/06/consumer-information-promus-element-plus-everolimus-eluting-platinum-chromium-coronary-stent-system-monorail-and-over-wire-p110010/s001?qt-recent_content=0

Links:
[1] http://www.accessdata.fda.gov/cdrh_docs/pdf11/p110010s001a.pdf
[2] http://www.nlm.nih.gov/medlineplus/ency/article/002303.htm
[3] http://www.merriam-webster.com/medlineplus/alloy
[4] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm074025.htm
[5] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm255199.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=ucm255199.htm&utm_content=1
[6] http://www.nlm.nih.gov/medlineplus/angioplasty.html
[7] http://www.nlm.nih.gov/medlineplus/coronaryarterydisease.html
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