Consumer Information on: Presillion plus CoCr Coronary Stent on RX System - P110004

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: Presillion *plus* CoCr Coronary Stent on RX System
PMA Applicant: Medinol Ltd
Address: Kiryat Atidirn Bldg 7, Entrance A, Tel Aviv, Israel 61581
Approval Date: April 12, 2012
Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf11/p110004a.pdf [1]

What is it? The Presillion *plus* CoCr Coronary Stent on RX System is a metal stent [2] that is mounted on a folded balloon attached to a catheter delivery system for placement into a blood vessel supplying blood to the heart (coronary artery). The stent is made of a cobalt-chromium metal alloy [3] [4].

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 [5]).
- The balloon is then deflated, and the catheter is removed from the artery.
- The Presillion *plus* CoCr Coronary 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.

When is it used? The Presillion *plus* CoCr Coronary Stent on RX System is used in patients who have a narrowing in their coronary arteries caused by coronary artery disease [6] – 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 [7]), 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.

The Presillion *plus* CoCr Coronary Stent on RX System is to be used in patients who have narrowing in coronary arteries with a length less than or equal to 30 mm with reference vessel diameters of 2.5 mm to 4.0 mm.

What will it accomplish? A significantly narrowed coronary artery limits blood flow to the heart muscle and can cause chest pain (angina). Placement of the Presillion *plus* CoCr Coronary stent within the narrowed coronary artery improves blood flow.

When should it not be used? The Presillion *plus* CoCr Coronary Stent on RX System should not be used in patients:

- who cannot receive antiplatelet and/or anticoagulant therapy, or
- who have a lesion that prevents complete angioplasty balloon inflation or proper placement of the stent or stent delivery system.

Additional information: The Summary of Safety and Effectiveness Data and labeling [8] are available online.

Other Resources:

- NIH - MedlinePlus - Atherosclerosis [9]
- NIH-MedlinePlus – Heart Attack [10]

SOURCE [11]

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http://www.mdtmag.com/news/2012/05/consumer-information-presillion-plus-cocr-coronary-stent-rx-system-p110004

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[11] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm302534.htm