Consumer Information on: EverFlex Self-Expanding Peripheral Stent System - P110023

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: EverFlex Self-Expanding Peripheral Stent Systems
Manufacturer: ev3, Inc.
Address: 3033 Campus Drive, Suite #N550
Plymouth, MN 55441
Approval Date: March 7, 2012
Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf11/p110023a.pdf [1]

What is it? The EverFlex Self-Expanding Peripheral Stent System is used to re-open narrowed (stenotic) regions of the superficial femoral and proximal popliteal arteries which supply blood to the legs. It consists of two components, the stent and the delivery system. The stent is an implant constructed of nickel-titanium alloy (nitinol) tubing, laser-cut into a mesh shape. The stent is mounted within the delivery catheter; a long, thin, tube-like device.

How does it work?

- A catheter with a deflated balloon at its tip is inserted into a blood vessel in the groin and advanced within the vessel, to the narrowed section of the superficial femoral or proximal popliteal artery.
- The balloon is inflated within the narrowed artery to open the artery by pushing the plaque against the artery wall (balloon angioplasty).
- The angioplasty balloon and its catheter are removed; then the EverFlex Self-Expanding Peripheral Stent System is advanced through the same vessel and positioned within the expanded artery.
- The stent is then released (deployed) by retracting the outer sheath after it is positioned in the artery and opens automatically over the blockage.
- The stent placement increases blood flow to the legs by holding the artery wall open.
- Once the stent is deployed, the stent delivery catheter is removed.
- The stent remains permanently implanted in the superficial femoral or proximal popliteal artery and acts as a support for the newly opened section of the vessel.

When is it used?
The EverFlex Self-Expanding Peripheral Stents are used to treat patients with narrowing of a superficial femoral or proximal popliteal artery caused by atherosclerosis [2], the collection of fatty substances such as cholesterol that forms "plaque" along the lining of the arteries.

What will it accomplish? The inside lining of the artery will grow over the stent approximately 8 weeks after it is implanted. Once in place, the stent acts as a scaffold to:

- Hold open the narrowed superficial femoral or proximal popliteal artery, and
- Improve blood flow to the legs.

When should it not be used? Use of the EverFlex Self-Expanding Peripheral Stent is contraindicated in the following cases:

- When a patient has a blockage that will not allow complete inflation of the angioplasty balloon or proper placement of the stent.
- When a patient cannot take aspirin or blood-thinning medications, or
- When a patient has an allergy to the metal in the stent.

Additional information: The Summary of Safety and Effectiveness Data and labeling [3] are available online.

Other Resources:

- NIH-MedlinePlus- Angioplasty and Stent Placement – Peripheral Arteries [4]
- Society for Vascular Surgery – Peripheral Artery Disease [5]

SOURCE [6]

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Links:
[1] http://www.accessdata.fda.gov/cdrh_docs/pdf11/p110023a.pdf
[2] http://www.nhlbi.nih.gov/health/dci/Diseases/Atherosclerosis/Atherosclerosis_WhatIs.html
[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p110023
[4] http://www.nlm.nih.gov/medlineplus/ency/article/007393.htm

[5] http://www.vascularweb.org/vascularhealth/Pages/peripheral-artery-disease-(-pad-)-.aspx
[6] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm295961.htm