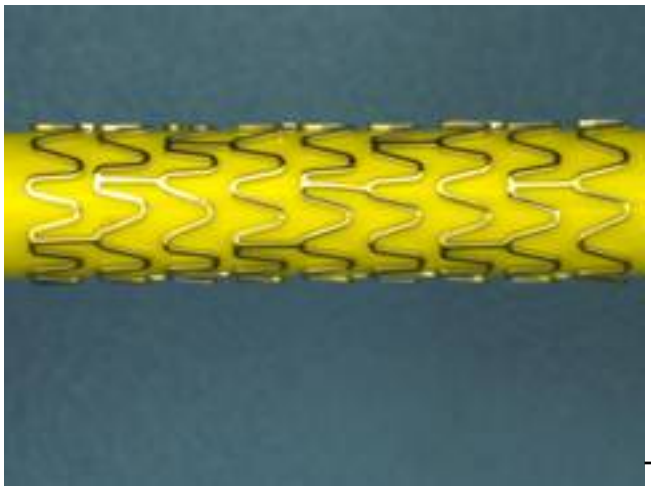
Consumer Information on: Omnilink Elite Vascular Balloon-Expandable Stent System - P110043

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: Omnilink Elite Vascular Balloon-Expandable Stent System
Manufacturer: Abbott Vascular
Address: 3200 Lakeside Drive, Santa Clara, CA 95054
Approval Date: July 31, 2012
Approval Letter: http://www.accessdata.fda.gov/ cdrh_docs/pdf11/p110043a.pdf [1]

What is it? The Omnilink Elite Vascular Balloon-Expandable Stent System is a thin, flexible, metal mesh tube that is implanted in the large arteries that supply blood to the pelvis and legs (iliac arteries).

How does it work?

- The Omnilink Elite Vascular Balloon-Expandable Stent System is mounted onto a stent delivery catheter and held in place by an outer cover until it is positioned in the artery.
- After the catheter is positioned in the narrowed area of the artery, the stent is then inserted into the artery by inflating the nylon balloon that is attached to the end of the catheter.
- The stent holds open the arteries to increase blood flow.
- Once the stent is inserted, the balloon is deflated and stent delivery catheter is removed.
- The stent remains permanently implanted in the iliac artery and acts as a

support for the newly-opened section of the artery.

When is it used? The Omnilink Elite Vascular Balloon-Expandable Stent System is used to treat patients with narrowing of an iliac artery caused by atherosclerosis [2], the collection of plaque, a sticky substance made up of fat, cholesterol, calcium and other substances found in the blood, along the lining of the arteries.

What will it accomplish? The inside lining of the artery will grow over the stent in approximately eight weeks after it is implanted. Once in place, the stent holds open a narrowed iliac artery and improves blood flow to the legs.

When should it not be used? Generally, patients who are not suitable candidates for balloon angioplasty are also not suitable candidates for stent placement. The Omnilink Elite Vascular Balloon-Expandable Stent System should also not be used in patients who:

- exhibit persistent blood clots in the blood vessels near the treatment site, following use of drugs that dissolve clots.
- have uncorrected bleeding disorders or patients who cannot take blood thinners.
- have known allergies to cobalt or chromium.
- had a treatment site that is within or adjacent to a weakening of the wall of an artery (aneurysm [3]).
- experienced a puncture of an artery or the formation of a weakened sac-shaped or widened artery wall during the procedure, preceding possible stent implantation.
- have excessive blood vessel twisting or bending.
- have punctured blood vessels evidenced by contrast media exiting the vessel into the surrounding tissue.

Additional Information: The Summary of Safety and Effectiveness Data and labeling [4] are available online.

Other Resources:

- NIH - National Library of Medicine – Angioplasty and Stent Placement – Peripheral Arteries [5]
- Society for Vascular Surgery – Peripheral Artery Disease [6]

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Links:
[1] http://www.accessdata.fda.gov/cdrh_docs/pdf11/p110043a.pdf
[2] http://www.nlm.nih.gov/medlineplus/atherosclerosis.html
[3] http://www.nlm.nih.gov/medlineplus/aneurysms.html
[4] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p110043
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