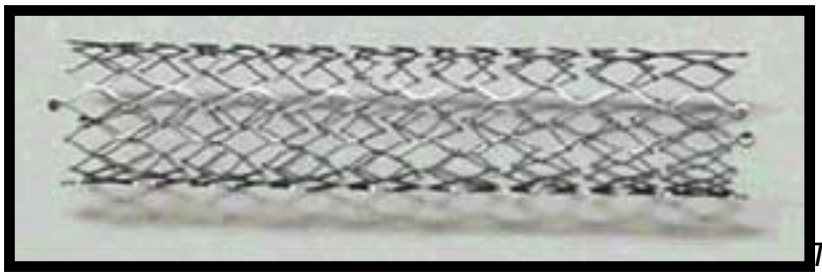
Consumer Information on: Complete & #xae; SE Vascular Stent System (20-100mm lengths) - P090006

FDA (The Center for Devices and Radiological Health)

Medtronic Vascular Complete® SE Vascular Stent System - P090006



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: Complete® SE Vascular Stent System (20-100mm lengths)
Manufacturer: Medtronic Vascular
Address: 3576 Unocal Place, Santa Rosa, CA 95403
Approval Date: March 17, 2010
Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf9/P090006a.pdf [1]

What is it? The Complete SE Vascular Stent is a thin, flexible metal mesh tube that can be implanted in the large arteries that supply blood to the pelvis and legs (iliac arteries). It consists of two parts, the stent and the delivery system. The stent is an implant constructed of a nickel-titanium alloy (nitinol) tubing and laser-cut into a mesh shape. The stent is mounted within a long, thin, tube-like device called the delivery catheter.

When is it used?
The Complete SE Stent is used to treat patients with narrowing of an iliac artery caused by atherosclerosis [2], the collection of fatty substances such as cholesterol that forms â??plaqueâ?□ along the lining of the arteries.

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 iliac artery.
- The balloon is inflated within the narrowed artery to open it by pushing the plaque against the artery wall (balloon angioplasty).
- The angioplasty balloon and its catheter are removed; then the Complete SE Stent system is advanced through the same vessel and positioned within the expanded artery.
- The stent is then 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 iliac artery and acts as a support for the newly opened section of the vessel.

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 a narrowed iliac artery, and
- improve 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 Complete SE Stent 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 receive blood thinners.
- have known allergies to nickel.
- had a treatment site that is within or adjacent to a weakening of the wall of an artery (aneurysm).
- 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: Summary of Safety and Effectiveness and labeling will be available
at:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=P090006 [3]

Other:

- **Angioplasty and Stent Placement - Peripheral Arteries** [4]

SOURCE [5]

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http://www.ecnmag.com/news/2010/03/consumer-information-complete-xae-se-vascular-stent-system-20-100mm-lengths-p090006?qt-video_of_the_day=0

Links:
[1] http://www.accessdata.fda.gov/cdrh_docs/pdf9/P090006a.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=P090006
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