Novoste™ Beta-Cath™ System

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 and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: Novoste™ Beta-Cath™ System
Manufacturer: Novoste Corporation
Address: 3890 Steve Reynolds Boulevard, Norcross, GA 30093
Approval Date: November 3, 2000
Approval Letter: http://www.fda.gov/cdrh/pdf/p000018a.pdf

What is it? The Novoste Beta-Cath™ System consists of the following components: a closed end delivery catheter (hollow tube), a source train that contains several, individual, radioactive seeds, and a transfer device that is used to store and deliver the source train. The radioactive seeds use a type of radiation called beta radiation.

How does it work? Using an X-ray machine in a cardiac catheterization laboratory, the physician places the delivery catheter in the coronary artery at the site of the in-stent restenosis (re-blockage in the artery). The transfer device is connected to the delivery catheter, and is used to deliver the radioactive seeds to the location. The radioactive seeds are positioned at the location for an appropriate length of time to administer radiation to the artery. At the completion of the radiation treatment, the radioactive seeds are returned to the transfer device.

When is it used? The Beta-Cath™ System is used in patients who have in-stent restenosis. In-stent restenosis is a re-blockage inside a coronary artery at the site of previous stent placement. A stent is an expandable metal tube that is placed inside an artery to keep an artery open at a site of narrowing.

What will it accomplish? In-stent restenosis (re-blockage) may occur after placement of a stent in a coronary artery. This type of restenosis may be caused by an increased amount of scar tissue in the artery at the site of stent placement. The radiation treatment delivered by the radioactive seeds is intended to interrupt scar tissue growth and thus reduce the occurrence of in-stent restenosis of the coronary artery at the site of previous stent placement.

When should it not be used? The Beta-Cath™ System should not be used in patients with unprotected left main coronary artery disease (50% narrowing of the coronary artery) or in patients who are not candidates for blood-thinning drugs or antiplatelet therapy.

Additional information: Summary of Safety and Effectiveness is available at:
http://www.fda.gov/cdrh/pdf/p000018.html
Other: http://www.americanheart.org , http://jama.ama-assn.org/issues/v285n1/ffull/jfd00011-1.html