BeStent™ 2 with Discrete Technology™ Over-the-Wire and Rapid Exchange Coronary Stent Delivery Systems

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:	BeStent™ 2 with Discrete Technology™ Over-the-Wire and Rapid Exchange Coronary Stent Delivery Systems (BeStent™ 2)
Manufacturer:	Medtronic, Inc.
Address:	800 53rd Avenue Northeast, Minneapolis, Minnesota 55421
Approval Date:	October 16, 2000
Approval Letter:	http://www.fda.gov/cdrh/pdf/p000022a.pdf

What is it? A coronary stent is a mesh-like tubular metal scaffolding implanted in a coronary artery that is threatening to become, or is already, blocked due to the build up of plaque. The stent acts like a scaffold to hold the vessel open so that adequate blood flow can be maintained. The stent is mounted over a deflated balloon, which is attached to a thin flexible tube (a balloon catheter). The tube helps deliver the stent to the diseased area of a coronary artery.

How does it work? The stent is delivered by threading the balloon-catheter through blood vessels to the narrowing, or blockage site in the blood vessel. There, the balloon is inflated to expand the stent and to displace the plaque against the arterial wall. This increases blood flow by holding the artery wall open. Once the stent is fully expanded, the balloon is deflated and the balloon-catheter is removed. The stent stays in place permanently.

When is it used? The BeStent™ 2 is used in patients with symptoms of coronary artery disease (such as, angina, shoulder or jaw pain, lack of ability for sustained exertion, dizziness or light-headedness), who require treatment to increase the flow of blood to the coronary arteries of the heart.

What will it accomplish? Once the stent is in place, the inside lining of the artery will grow over the stent in about 8 weeks. The stent acts as a scaffold for maintaining the inner diameter of the vessel, thereby improving blood flow in the vessel.

When should it not be used? The BeStent ™ 2 should not be used in:

- **Patients who cannot take blood thinning medications, such as antiplatelet and/or anticoagulation drugs.**
- **Patients who have a lesion in their coronary artery that prevents complete inflation of the balloon catheter.**

Additional information: Summary of Safety and Effectiveness and labeling are available at: http://www.fda.gov/cdrh/pdf/p000022.html Other: http://www.americanheart.org