New Device Approval

Stinger™ Ablation Catheter and TempLink™ Extension Cable - P000020

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.
[Printer Friendly Version]

Product Name: Stinger™ Ablation Catheter and TempLink™ Extension Cable
Manufacturer: Bard Electrophysiology, C.R. Bard
Address: 55 Technology Drive, Lowell, MA 01851
Approval Date: November 29, 2000
Approval Letter: http://www.fda.gov/cdrh/pdf/p000020a.pdf

What is it? An ablation catheter is a long, thin flexible tube that sends radiofrequency (RF) energy to the inside of the heart to treat cardiac arrhythmias, which are abnormal heartbeats due to loss of rhythm of the heart).

How does it work? The Stinger Ablation Catheter is inserted through a small incision in the skin and advanced through the body's blood vessels into the heart. The end of the catheter is first placed against the inside of the heart to record electrical signals and find the abnormal pathway causing the arrhythmia. Then RF energy is delivered through the tip of the catheter to the inside of the heart. The RF energy destroys ("ablates") the areas of the heart that are causing the arrhythmia.

When is it used?The Stinger Ablation Catheter is used to create focal "lesions" inside the heart to treat cardiac arrhythmias.

What will it accomplish? Cardiac ablation can cure some arrhythmias caused by abnormalities in the heart's ability to conduct electrical signals. In other arrhythmias, cardiac ablation cannot cure the condition, but can reduce the frequency of episodes the patient experiences. In an important clinical study that was the basis for approval of this device, 247 patients were treated. These patients had arrhythmias that can usually be cured by cardiac ablation. Immediately after the treatment, 93% of the patients were considered successfully ablated. After three months, a few of these successfully-treated patients (3%) had a recurrence of their arrhythmias.

Cardiac ablation has some risks. In the clinical study, 11 patients (4.4%) had adverse events related to the ablation procedure. These adverse events were considered typical of an ablation procedure.

When should it not be used? The catheter should not be used under conditions where insertion of the

catheter would be dangerous. For example, the catheter should not be used when it might dislodge a blood clot or other blockage in the blood vessel, or when it might cross an artificial heart valve.

Additional information: Summary of Safety and Effectiveness and labeling will be available at: http://www.fda.gov/cdrh/pdf/p000020.html

Other:

- National Center for Chronic Disease Prevention and Health Promotion: http://www.cdc.gov/nccdphp/cvd/
- American Heart Association: http://www.americanheart.org

(Updated 5/16/2001)