Consumer Information on: Therapy Cool Path Duo? Ablation Catheter, Safire BLU Duo? Ablation Catheter, and IBI1500T9-CP V1.6 Cardiac Ablation Generator - P110016

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: Therapy Cool Path Duo™ Ablation Catheter, Safire BLU Duo™ Ablation Catheter, and IBI1500T9-CP V1.6 Cardiac Ablation Generato
PMA Applicant: Irvine Biomedical, Inc., A St. Jude Medical Company
Address: 2375 Morse Ave., Irvine, CA 92614
Approval Date: January 25, 2012
Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf11/p110016a.pdf [1]

What is it? The Therapy Cool Path Duo™ Ablation Catheter or the Safire BLU Duo™

Ablation Catheter is a steerable, deflectable, irrigated catheter (a long, thin, flexible tube) used to treat a certain kind of abnormal heart rhythm (arrhythmia [2]) called typical atrial flutter by finding the source of the rhythm disturbance and destroying (ablating) small areas of the heart tissue. The catheters take energy from an external source (the IBI1500T9-CP V1.6 Cardiac Ablation Generator) to a point in the right side of the heart.

How does it work? The Therapy Cool Path Duo™ Ablation Catheter or the Safire BLU Duo™ Ablation Catheter is inserted into a blood vessel (artery or vein), usually though a site in the upper leg or neck. The catheter is manually advanced through the blood vessels until it reaches the correct location inside the heart. The tip of the catheter is moved around by a mechanism on the handle. Inside the heart, electrodes at the tip gather data that pinpoint the location of the faulty tissue in the heart (electrical mapping). Once the site is identified, the device delivers radiofrequency (RF) energy [3] to destroy the small areas of tissue that blocks the heart's internal electrical signals that cause the typical atrial flutter. The catheters are removed after treatment.

When is it used? The Therapy Cool Path Duo™ Ablation Catheter or the Safire BLU Duo™ Ablation Catheter, and the IBI 1500T9-CP V1.6 Cardiac Ablation Generator are used to destroy small areas in the heart that cause an abnormally fast heart beat or abnormal heart rhythm in the upper chambers (the atria) of the heart. The technical name for this kind of abnormal heart beat is typical atrial flutter.

What will it accomplish? Cardiac catheter ablation [4] can cure typical atrial flutter and restore a normal heart rhythm, and in other cases, can reduce the frequency of episodes that a patient experiences. In a clinical study involving 188 patients, the abnormal rhythm (typical atrial flutter) was corrected in 181 patients (96%) for 7 days after treatment; and it remained corrected after 3 months in 174 patients (94.5%).

When should it not be used? The device should not be used in patients:

- who have an active systemic infection.
- with a blood clot attached to the inside of the heart.
- who have had an incision in the atrium or ventricle in the last 4 weeks.

Additional information: Summary of Safety and Effectiveness and labeling [5] are available online.

SOURCE [6]

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http://www.mdtmag.com/news/2012/02/consumer-information-therapy-cool-path-duo-ablation-catheter-safire-blu-duo-ablation-catheter-and-ibi1500t9-cp-v16-cardiac-ablation-generator-p110016

Links:
[1] http://www.accessdata.fda.gov/cdrh_docs/pdf11/p110016a.pdf
[2] http://www.nlm.nih.gov/medlineplus/arrhythmia.html
[3] http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/CellPhones/ucm116338.htm
[4] http://www.nlm.nih.gov/medlineplus/ency/article/007368.htm
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