Consumer Information on: AtriCure Synergy Ablation System - P100046

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: AtriCure Synergy Ablation System
PMA Applicant: AtriCure, Inc.
Address: 6217 Centre Park Drive, West Chester, OH 45069
Approval Date: December 15, 2011
Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100046a.pdf [1]

What is it? The AtriCure Synergy Ablation System is used to destroy (ablate) heart tissue that is beating abnormally. It includes the Synergy Ablation Clamp, a handheld surgical device that destroys the heart tissue that is grasped between the clamp's jaws during open-heart surgery. The clamp is also connected to a generator that delivers radiofrequency (RF) energy [2] to the clamp during ablation.

How does it work? The Synergy Ablation Clamp is used to destroy heart tissue to create scars in a specific pattern on the upper chambers of the heart. This is accomplished while the surgeon is looking directly at the heart. When the clamp is placed in a desired location on the heart, the surgeon begins delivering RF energy by pressing a footswitch. The RF energy flows through the electrodes in the clamp, heating the heart tissue held by the clamp, and creating a scar on the heart tissue that is the shape of the clamp.

When is it used? The device is used in patients who have persistent or longstanding persistent atrial fibrillation [3] and are also undergoing surgery for coronary artery bypass grafting [4] or valve repair or replacement [5].

What will it accomplish? The creation of scars in the specific pattern on the upper chambers of the heart will block the abnormal electrical conduction in the heart that causes the atrial fibrillation. In a clinical study, the procedure was shown to be effective in treating atrial fibrillation for 6 months in 37 out of 50 patients.

When should it not be used? The AtriCure Synergy Ablation System should not be used for sealing blood vessels during contraceptive surgery of the fallopian tubes. The device is not designed for safe and effective use for this purpose.

Additional information : Summary of Safety and Effectiveness and labeling [6] are available online.

SOURCE [7]

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http://www.mdtmag.com/news/2011/12/consumer-information-atricure-synergy-ablation-system-p100046

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