



New Device Approvals

Stockert 70 RF Generator - P990071

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: STOCKERT 70 RF Generator
Manufacturer: STOCKERT GmbH
Address: Botzinger StraBe 72, D-79111 Freiburg, Germany
Distributed By: Biosense Webster, Inc., 3333 Diamond Canyon Road, Diamond Bar, CA 91765
Approval Date: May 31, 2000
Approval Letter: <http://www.fda.gov/cdrh/pdf/p990071a.pdf>

What is it? The STOCKERT 70 RF Generator system consists of a high energy generator and other equipment used to destroy areas of heart tissue that cause abnormal heart rhythms. The generator is used with a thin hollow tube called a catheter. The generator controls the temperature at the tip of the catheter, and monitors electrical signals from the heart.

How does it work? Along with a catheter, the STOCKERT 70 RF Generator allows the physician to locate the sites in the heart that give rise to, or support, abnormal heart rhythms. The abnormal sites are found by mapping the electrical signals of the heart. A type of energy called radiofrequency (RF) is delivered to the heart muscle to destroy tissue that creates abnormal heart rhythms. The generator delivers up to 50 watts of electrical power for 60-90 seconds through the catheter tube to the location in the heart that requires treatment. This energy heats the targeted heart tissue and causes a burn (ablation) that will prevent erroneous heart rhythms.

When is it used? The STOCKERT 70 RF Generator is used for cardiac ablation procedures. Cardiac ablation is frequently used as an alternative to chronic drug treatment of abnormal heart rhythms.

What will it accomplish? Help stop abnormal heart rhythms that may be causing palpitations, lightheadedness, or chest pain.

When should it not be used? The STOCKERT 70 Generator system should not be used for patients with an active infection. In addition, if a patient has a pacemaker, there is some risk of the STOCKERT 70 Generator interfering with the pacemaker and this risk should be discussed with your physician.

Additional information: Summary of Safety and Effectiveness is available at:
<http://www.fda.gov/cdrh/pdf/p990071.html>

Other: <http://www.americanheart.org>