



AMS
P930029

Memorandum

Date .FEB 9 1995

From Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Subject Premarket Approval of Medtronic CardioRhythm
Atakr Radio Frequency Catheter Ablation System - ACTION

To The Director, CDRH
ORA _____

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

- (1) a premarket approval order for the above referenced medical device (Tab B); and
- (2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.

Susan Alpert
Susan Alpert, Ph.D., M.D.

Attachments
Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved _____ Disapproved _____ Date _____

Prepared by Mark Massi, CDRH, HFZ-450, February 6, 1995, 443-8609

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

[DOCKET NO. P930029]

MEDTRONIC CARDIORHYTHM; PREMARKET APPROVAL OF ATAKR® RADIO
FREQUENCY CATHETER ABLATION SYSTEM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Medtronic CardioRhythm, San Jose, CA, for premarket approval, under section 515 of the Federal Food, Drug, and Cosmetic Act (the act), of the Atakr® Radio Frequency Catheter Ablation System. After reviewing the recommendation of the Circulatory System Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter on FEB 9 1995, of the approval of the application.

DATE: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER)

ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review, to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1-23, 12420 Parklawn Drive, Rockville, MD

20857.

FOR FURTHER INFORMATION CONTACT:

Mark Massi
Center for Devices and Radiological Health (HFZ-450)
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850
301-443-8609.

SUPPLEMENTARY INFORMATION: On August 26, 1993, Medtronic CardioRhythm, San Jose, CA 95134, submitted to CDRH an application for premarket approval of the Atakr® Radio Frequency Catheter Ablation System. The device is a radio frequency power cardiac catheter ablation system, and is indicated for interruption of accessory atrioventricular (AV) conduction pathways associated with tachycardia, for the treatment of AV nodal re-entrant tachycardia, and for creation of complete AV block in patients with a difficult to control ventricular response to an atrial arrhythmia.

On December 5, 1994, the Circulatory System Devices Panel, an FDA advisory panel, reviewed and recommended approval of the application.

On FEB 9 1995, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch

(address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

OPPORTUNITY FOR ADMINISTRATIVE REVIEW

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. This notice is issued under the Federal Food, Drug, and Cosmetic Act section 520(h), 90 Stat. 554-555, 571 (21 U.S.C. 360e(d), 360j(h)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: _____.

D. Bruce Burlington, M.D.
Director
Center for Devices and
Radiological Health

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. Craig J. Coombs
Director, Regulatory Affairs
Medtronic CardioRhythm
130 Rio Robles
San Jose, California 95134-1806

FEB 9 1995

Re: PMA Number P930029
Atakr® Radio Frequency Catheter Ablation (RFCA) System
RF Ablatr™ Series of RFCA Catheters
RF Mariner® Series of RFCA Catheters

Filed: August 26, 1993

Amended: April 25, June 23, July 18 and 25, August 10,
September 8, October 11, November 10, 15, and 21,
December 5, 14, and 28, 1994, and February 8 and 9, 1995.

Dear Mr. Coombs:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Atakr® RFCA System. This device is indicated for interruption of accessory atrioventricular (AV) conduction pathways associated with tachycardia, for the treatment of AV nodal re-entrant tachycardia, and for creation of complete AV block in patients with a difficult to control ventricular response to an atrial arrhythmia. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

In addition to the postapproval requirements in the enclosure, the postapproval reports must include continued follow-up of:

- a. All patients < 21 years old enrolled at the two pediatric centers, for a total of two years post-ablation, and
- b. Those patients (#'s 6, 70, 131, 203, 255, 310) with the creatine phosphokinase (CPK-MB) increase of > 3 fold over baseline, for a total of five years post-ablation.

The information to be submitted on these patients should include at least telephone contact every six months and a patient history with an emphasis on cardiac events. If a patient presents for an office visit during the follow-up period and a physical examination or twelve-lead electrocardiogram is performed, the data shall be collected and submitted to the FDA. This information should be summarized and submitted as part of your annual reports.

Expiration dating for this device has been established and approved at two (2) years. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of

Page 2 - Mr. Craig J. Coombs

extending the expiration dating as provided by 21 CFR 814.39(a)(8).

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act.

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

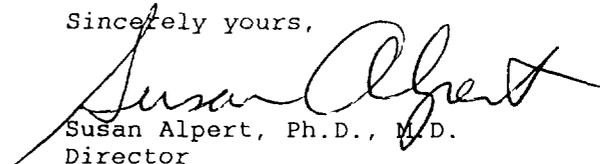
You are reminded that as soon as possible, and before commercial distribution of your device, that you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Mark Massi at (301) 443-8609.

Sincerely yours,


Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Summary of Safety and Effectiveness

PREMARKET APPROVAL APPLICATION (P930029)

Atakr RFCA System

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SUMMARY OF SAFETY AND EFFECTIVENESS

I. GENERAL INFORMATION

Device Generic Name: Radio Frequency-Powered Cardiac Catheter Ablation System.

Device Trade Name: Atakr Radio Frequency Catheter Ablation System

Includes: Atakr RF Power Generator
Steerable Ablation Catheters, models
RF Ablatr, RF Ablatr XL, RF Ablatr XXL
RF Marinr (SC, SCXL, SCXXL, MC, MCXL)
Atakr Rechargeable Battery
Atakr Battery Charger, 110 V
Atakr Battery Charger, 220 V
Atakr Remote Control Foot Pedal
Atakr to RF Catheter Cable
Atakr to ECG Cable
Atakr to Dispersive Electrode Cable
Atakr/ECG Switch Box
Various Accessory Cables

Applicants Name and Address: Medtronic CardioRhythm
130 Rio Robles
San Jose, CA 95134-1806

PMA Number: P930029

Date of Panel Recommendations: December 5, 1994

Date of Notice of Approval to the Applicant: February 9, 1995

II. INDICATIONS FOR USE

The Atakr Ablation System is indicated for use for interruption of accessory atrioventricular (AV) conduction pathways associated with tachycardia, for the treatment of AV nodal re-entrant tachycardia, and for creation of complete AV block in patients with a difficult to control ventricular response to an atrial arrhythmia.

III. DEVICE DESCRIPTION

The Atakr Ablation System is designed to deliver radio frequency (RF) electrical energy to selected sites in the heart. The system includes the Atakr RF Power Generator which provides this electrical energy and two RF Catheters, the RF Ablatr and the RF Marinr.

Atakr RF Power Generator

The Atakr RF Power Generator operates in either temperature or power control mode. In temperature control mode, the Atakr RF Power Generator monitors the temperature of the distal tip of the CardioRhythm RF Catheter and controls the amount of power delivered so that the distal tip temperature approaches, but does not exceed, the temperature set-point. The Atakr RF Power Generator shuts off RF power delivery if factory set minimum or maximum temperature or maximum power limits are exceeded.

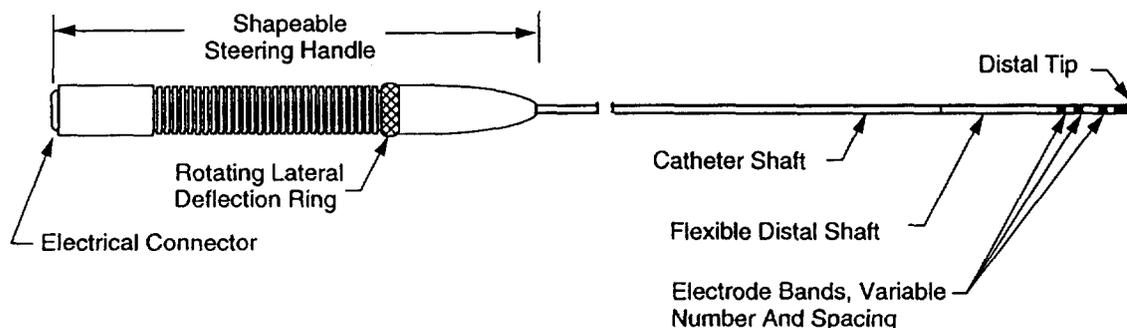
In power control mode, the Atakr RF Power Generator monitors and controls the amount of power delivered to the CardioRhythm RF Catheter at a preset level. The Atakr RF Power Generator shuts off RF power delivery if factory set maximum power or temperature limits are exceeded.

In both temperature and power control modes, the Atakr RF Power Generator monitors the impedance between the CardioRhythm RF Catheter tip and the dispersive electrode during RF ablation. The Atakr RF Power Generator microprocessor shuts off RF power delivery if factory set minimum or maximum impedance limits are exceeded. Redundant detection and shutdown of the RF Power Generator outside of temperature and power limits is provided by the microprocessor control software and separately by the electronic hardware.

The rechargeable battery provides DC power to the Atakr RF Power Generator. The use of a battery instead of an AC power source is intended to minimize the possibility of a an AC current leak into the heart.

Atakr RF Ablatr Catheter

The Medtronic CardioRhythm RF Ablatr steerable ablation catheter is a flexible, radiopaque catheter constructed of extruded nylon over stainless steel braid. The RF Ablatr catheter's shapeable handle allows multiple curve variations of the tip in any direction or plane to facilitate accurate tip placement within the heart. The RF Ablatr catheter is designed for intracardiac radio frequency ablation via the tip electrode and separate dispersive electrode, when connected to the Medtronic CardioRhythm Atakr™ RF Power Generator. The RF Ablatr catheter may also be used for endocardial recording or stimulation.



The RF Ablatr catheter is manufactured in several different configurations. The length of the distal tip in all models is 4 mm. The basic design, materials and construction of these catheters are identical within the ranges shown below:

Usable Length	80 - 125 cm
Number of Electrodes	2, 4, 6, 8, 10
Interelectrode Spacing: Distal Pair Other Adjacent Pairs	2 - 5 mm 1 - 10 mm

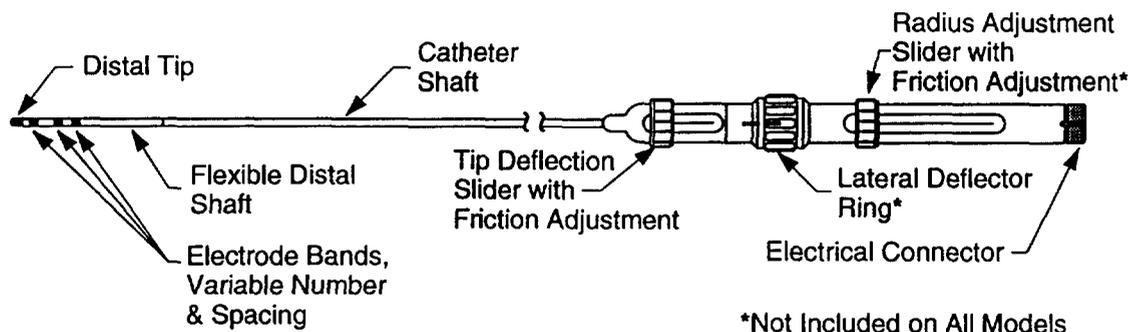
Various RF Ablatr models are available with different steering capabilities as shown in the following table:

RF Ablatr Model	Deflectable Tip?	Lateral Deflection?	Curve Radii*
RF Ablatr	Yes	Yes	50 mm
RF Ablatr XL	Yes	Yes	55 mm
RF Ablatr XXL	Yes	Yes	60 mm

*Curve radius is distance from catheter shaft axis to distal tip, when tip is deflected 90°.

RF Mariner Catheter

The Medtronic CardioRhythm RF Mariner™ steerable ablation catheter is a flexible, radiopaque catheter constructed of extruded polymer over stainless steel braid. The RF Mariner catheter is designed for intracardiac radio frequency ablation via the tip electrode and separate dispersive electrode, when connected to the Medtronic CardioRhythm Atakr™ RF Power Generator. The RF Mariner catheter may also be used for intracardiac recording or stimulation.



The RF Ablatr catheter is manufactured in several different configurations. The length of the distal tip in all models is 4 mm. The basic design, materials and construction of these catheters are identical within the ranges shown below:

Usable Length	80 - 125 cm
Number of Electrodes	2, 4, 6, 8, 10
Interelectrode Spacing: Distal Pair Other Adjacent Pairs	2 - 5 mm 1 - 10 mm

Various RF Maritr models are available with different steering capabilities as shown in the following table:

RF Maritr Model	Deflectable Tip?	Lateral Deflection?	Possible Curve Radii*
RF Maritr SC	Yes	No	45 mm
RF Maritr SCXL	Yes	No	55 mm
RF Maritr SCXXL	Yes	No	65 mm
RF Maritr MC	Yes	Yes	40 - 60 mm
RF Maritr MCXL	Yes	Yes	55 - 75 mm

*Curve radius is distance from catheter shaft axis to distal tip, when tip is deflected 90°.

The following components are included with the Atakr RFCA System:

- **Atakr Rechargeable Battery:** The Battery supplies 12 Volt DC power to the Atakr RF Power Generator. The Battery is rechargeable.
- **Atakr Battery Charger:** The Battery Charger recharges the Battery fully within eight hours.
- **Remote Control Foot Pedal:** The Foot Pedal activates the delivery of RF Power when it is pressed and held. The control of RF energy can also be achieved via the control panel on the Atakr RF Power Generator
- **Atakr to RF Catheter Cable:** The Atakr to RF Catheter Cable connects the Atakr RF Power Generator to the CardioRhythm RF Catheter.
- **Atakr to Dispersive Electrode Cable:** The Atakr to Dispersive Electrode Cable connects the Atakr RF Power Generator to the dispersive electrode which is affixed to the patient.
- **Atakr to ECG Cable:** The Atakr to ECG Cable connects the electrodes of the attached CardioRhythm RF Catheter to the physician's stimulating/recording equipment via the Atakr RF Power Generator.

Accessories

The following accessories may be connected to the Atakr RF Power Generator, but their use is not necessary for the proper operation of the Atakr RFCA System. They may be obtained separately from the rest of the System.

- **Atakr to Data Recorder Cable:** The Atakr to Data Recorder Cable connects the Atakr RF Power Generator to the physician's analog data recorder.
- **Atakr to Computer Cable:** The Atakr to Computer Cable connects the Atakr RF Power Generator to the physician's computer.
- **Atakr/ECG Switch Box:** The Atakr/ECG Switch Box is designed to prevent RF energy from being delivered into older ECG equipment. In "ECG" mode, all ECG signals go through the Atakr/ECG Switch Box rather than through the Atakr RF Power Generator. In "Ablate" mode the distal electrode pair of the RF Ablatr Catheter is disconnected from the physician's ECG equipment. Switching between modes, "ECG" and "ABLATE", is manual.

IV. CONTRAINDICATIONS

The use of this device is contraindicated in patients with active systemic infection.

The transseptal approach is contraindicated in patients with left atrial thrombus or myxoma, or interatrial baffle or patch.

The retrograde transaortic approach is contraindicated in patients with aortic valve replacement.

V. WARNINGS

Catheter ablation procedures present the **potential for significant x-ray exposure**, which can result in acute radiation injury as well as increased risk for somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps taken to minimize this exposure. Careful consideration must therefore be given to the use of the device in pregnant women.

During the transaortic approach, adequate **fluoroscopic visualization** is necessary to avoid placement of the ablation catheter in the coronary vasculature. Catheter placement and RF power application **within a coronary artery** have been associated with myocardial infarction and death.

Catheter materials are **not compatible with magnetic resonance imaging (MRI)**.

Perforation of the vasculature is an inherent risk of any catheter placement. A number of serious adverse events have been documented for catheter ablation procedures including pulmonary embolism, myocardial infarction, stroke, cardiac tamponade, and death. See Section 6.0, ADVERSE EVENTS, for additional potential complications.

Patients undergoing **left-sided ablation procedures** should be closely monitored during the post-ablation period for clinical manifestations of infarction.

Implantable pacemakers and implantable cardioverter/defibrillators (ICDs) may be adversely affected by radio frequency (RF) current. It is important to: have temporary external sources of pacing and defibrillation available during ablation; exercise extreme caution during ablation when in close proximity to atrial or ventricular permanent leads; and, perform complete implantable device analysis for all patients after ablation.

Implantable cardioverter/defibrillators should be deactivated during delivery of RF power.

Catheters with distal pair electrode spacing greater than 2 mm should not be used in the ablation of septal accessory pathways or in the treatment of AV nodal re-entrant tachycardia because of the potential for creating inadvertent complete AV block.

Patients undergoing AV node modification or septal accessory pathway ablation are at risk for complete AV block. Permanent pacing was required in 1.6% (2/128) of septal accessory pathway, 3.1% (1/32) of left posterior pathways, and 1.7% (4/238) of AV nodal modification patients who experienced inadvertent partial or complete AV block during the study. Closely monitor AV conduction during RF energy delivery. Immediately terminate energy delivery if partial or complete AV block is noted.

The Atakr RF Power Generator is capable of delivering significant RF power. **Do not touch the distal tip** of the CardioRhythm RF catheter and the dispersive electrode at the same time - especially while operating the Atakr RF Power Generator - or operator injury may occur.

Use only isolated amplifiers, pacing equipment, and ECG equipment or patient injury or death may occur. Leakage current from any connected device to the patient must not exceed 10 microAmps (μ A) under any circumstances.

The CardioRhythm RF Catheters are **disposable and intended for single use only**. Do not resterilize or reuse. This may result in loss of proper electrical and mechanical function and could cause patient injury.

VI. PRECAUTIONS



Do not attempt to operate the Atakr Ablation System or connect the catheter to the Atakr RF Power Generator prior to completely reading and understanding the Atakr Ablation System Technical Manual and the CardioRhythm RF Catheter Instructions For Use.

Precautions During Use (see Section 9.0)

Cardiac ablation procedures should be performed only by **appropriately trained personnel** in a fully-equipped electrophysiology laboratory.

This catheter should be used only by or under the supervision of physicians well trained in electrophysiology, including the placement and use of intracardiac electrode catheters and experienced in performing radio frequency catheter ablation procedures.

The **long-term risks of protracted fluoroscopy** have not been established. Careful consideration must therefore be given for the use of the device in **prepubescent children**.

The **long-term risks of lesions created by RF ablation have not been established**. In particular, any long-term effects of lesions in proximity to the specialized conduction system or coronary vasculature are unknown. Furthermore, the risk/benefit in asymptomatic patients has not been studied. .

The Atakr RF Power Generator is intended for **use only with CardioRhythm RF Catheters** and accessories. The safety of use with other electrophysiology catheters or accessories has not been assessed. Use only Medtronic CardioRhythm cables supplied with the Atakr Ablation System.

Regularly inspect and test reusable cables and accessories, including inspection for possible damage to insulation. Replace damaged cables and accessories.

During Use of the Atakr RF Power Generator (see Section 9.4)

Do not mount the Atakr RF Power Generator over 36 inches high on a portable IV standard. Higher mounting could cause the pole to tip over.

Do not allow any fluid or moisture into the Atakr RF Power Generator or any connector or cables. Do not hang fluids above the Atakr RF Power Generator. The device may not function correctly if the electronic circuitry or the connectors are wet. Do not soak cables.

Allow the device to reach room temperature (at least 30 min) before using if the Atakr Ablation System has been stored at temperatures higher than 30°C or less than 15°C.

Excessive **bending or kinking of catheter** may damage internal electrode wires and/or distal tip shaping capabilities.

During Placement of EP Diagnostic and CardioRhythm RF Catheters (see Section 9.7)

The sterile packaging and catheter should be inspected prior to use. If damaged, do not use; contact your local Medtronic representative.

Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation or tamponade. Catheter advancement should be performed under **fluoroscopic guidance**. Do not use excessive force to advance or withdraw the catheter when resistance is encountered.

During Delivery of RF Energy (see Section 9.8)

The risk of igniting flammable gases or other materials is inherent in electrosurgery and cannot be eliminated by device design. Precautions must be taken to **restrict flammable materials** and substances from the electrosurgical site, whether they are present in the form of an anesthetic or skin preparation agent, are produced by natural processes within body cavities, or originate in surgical drapes or other materials.



Electromagnetic interference (EMI) produced by the Atakr RF Power Generator during normal operation may adversely affect the performance of other equipment. If RF interference is apparent during the application of RF power, EMI may be reduced by repositioning the Atakr RF Power Generator or other equipment.

If RF interference occurs in electrogram or ECG recording equipment during RF power delivery after re-adjusting tip electrode, **disconnect the distal electrode and pin #2** from the recording equipment. If the noise persists, unplug all electrodes.

Do not deliver DC energy through the Atakr Ablation System or the CardioRhythm RF Catheter. Neither the Atakr Ablation System nor the CardioRhythm RF Catheter were designed to deliver DC energy and no testing has been performed.

Apparent **low power output** or failure of the equipment to function correctly at normal settings may indicate faulty application (or a faulty connection) of the dispersive electrode or failure of an electrode lead. **Do not increase power before checking for obvious defects or misapplication.** Effective contact between the patient and the dispersive electrode must be verified whenever the patient is repositioned after the initial application of the dispersive electrode. Some otherwise normal patients may have an abnormally low impedance between the catheter and dispersive electrode precluding the normal RF power due to the low impedance shutdown. If necessary, the dispersive electrode may be moved to a location on the body that is further from the catheter if the physician feels that this is desirable.

The **catheter impedance display should be monitored** during energy delivery. If a sudden impedance rise is observed during the ablation procedure, energy delivery should be discontinued and the catheter tip examined for coagulum, and coagulum removed if present.

Do not begin an ablation procedure if the LOW BATTERY display is illuminated on the Atakr RF Power Generator. Replace battery. When the LOW BATTERY legend lights, record procedure data prior to replacing the battery as procedure data is lost when the Atakr RF Power Generator is turned off. Follow instructions in Section 11.0, BATTERY REPLACEMENT & CHARGING, for details on replacing the battery.

Patients undergoing **left sided catheter insertions** should be anticoagulated. See Section 8.5, CLINICAL BACKGROUND - Recommended Anticoagulation Guidelines for typical anticoagulation during the clinical study.

Bench testing of the CardioRhythm RF Catheters demonstrated that they could withstand twenty-five RF energy deliveries without any reduction in performance. During the clinical trial as many as 73 energy deliveries were made with a single catheter, although the average number was about seven.

VII. ALTERNATIVE PRACTICES AND PROCEDURES

The principal alternative forms of therapy for the management of supraventricular tachyarrhythmias (SVT) are antiarrhythmic drugs, surgical ablation, and other commercially available catheter ablation systems. Antiarrhythmic drugs, although they are effective in many patients, may be associated with significant side[1,2]. Surgical ablation is curative, but may be associated with higher morbidity than catheter ablation [3,4].

VIII. MARKETING HISTORY

The Atakr RFCA System has been marketed since April 15, 1993 in the following countries: Argentina, Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Hong Kong, Israel, Italy, Jordan, Mexico, The Netherlands, Norway, Oman, Russia, Singapore, South Africa, Spain, Sweden, Switzerland, Turkey, Uruguay and the United Kingdom.

The device has not been withdrawn from marketing in any country for any reason related to safety and effectiveness.

IX. POTENTIAL ADVERSE EFFECT OF THE DEVICE ON HEALTH

One or more adverse events was reported in 67 of the 683 patients (a total of 88 adverse events) during the clinical study of the Atakr Ablation System. The following adverse events are listed in descending order according to their clinical significance as determined by their severity and frequency (<1% unless otherwise indicated).

- Death
- Cardiac Tamponade
- Cerebrovascular Accident
- Myocardial Infarction
- Unintended AV or Bundle Branch Block
 Requiring new pacemaker (1.0 %)
- Coronary Sinus Perforation
- Bacterial Endocarditis
- Ventricular Fibrillation
- Coronary Artery Spasm
- Valvular Insufficiency
- Femoral Artery Laceration
- Thrombus/Embolic Event
- Bowel Obstruction
- Brachial Plexus Injury
- Pneumonia
- Inferior Vena Cava Clot
- Deep Vein Thrombosis
- Pericardial Effusion (2.2 %)
- Pericarditis
- Pleural Effusion
- Respiratory Depression
- Atrial Lead Dislodgment
- Infected IV Site
- Hypotension
- Bradycardia
- Vasovagal Reaction
- Thrombophlebitis
- Temperature Elevation
- Puncture Site Hematoma (1.6%)
- Phlebothrombosis
- High CPK

Other complications of catheter ablation procedures which have been reported include:

- Pulmonary Embolism
- Thromboembolism
- Nerve or Blood Vessel Injury
- Transient Ischemic Attack
- Infection

There were 18 deaths reported among the 683 patients enrolled in the study. None of the 18 deaths were judged by the investigators as definitely related to use of the Atakr RFCA System, but two deaths were judged possibly device related and a third as possibly procedure related.

Device-related complications were reported in 30 of the 683 of patients (4%) including unintentional AV block in 13 patients (1.9%), pericardial effusion in 8 patients (1.2%), and cardiac tamponade in 3 patients (0.4 %).

X. SUMMARY OF STUDIES

Nonclinical Studies

Electrical and mechanical studies carried out on the RF Power Generator, the RF catheters, and system components and other preclinical studies are summarized below.

A. Electrical and Systems Tests - Atakr RF Power Generator

A series of tests were performed on the Atakr Ablation System to assess the performance of the system for the intended use of cardiac catheter ablation. Specific electrical and systems tests conducted included the following:

1. Accuracy of Performance Specifications, Power Display, and Power Control

Testing by CardioRhythm and independent laboratories verified that the hardware and software of the Atakr RF Power Generator correctly measured DC and RF Voltage, current, power, impedance, and temperature, and correctly controlled power at the desired set-point. All safety shutdown functions (impedance, temperature and power), power delivery and accuracy, front panel display and controls were functionally verified.

2. Resistance to Extraneous Electrical Shocks

Testing by CardioRhythm and independent laboratories verified that the Atakr RF Power Generator withstood spurious applications of line (120 VAC), RF, and DC currents including electrostatic discharge. Additionally the Atakr was shown to be protected from damage by pulses from external defibrillation devices (2000 Volts) as defined by IEC 601-2-2.

3. Resistance to Extreme Environmental Conditions

The Atakr RF Power Generator was subjected to an external spraying of water, dropping from a height of 5 cm (per IEC 601) and thermal cycling (per ANSI/AAMI HF-18 and

MIL-STD-810D) to evaluate the performance of the Generator following extreme environmental conditions.

4. Reliability Test

Reliability information was provided to Medtronic CardioRhythm for components with moving parts. Specifically, the RF power control switch, the foot switch, and catheter connectors are specified with a minimum mechanical life of at least 1 million operations.

Additional reliability tests were performed on the Atakr RF Power Generator. Three Generators were each tested by delivering the number and power of RF cycles that could be expected during five years of use (4000 RF cycles). The three generators performed within specifications following the 4000 cycles.

5. Electromagnetic Compatibility (EMC) Test

The Atakr Ablation System was tested for immunity to radiated electromagnetic emissions and for electrostatic discharge. Results of the testing demonstrated that the System passed the requirements of FDA voluntary standard MDS-201-004 as well as IEC 601-2-2 and IEC 801-2. A precaution is included in the labeling concerning the potential for the Atakr to adversely affect the performance of other equipment due to radiated electromagnetic interference.

6. Battery Performance

Testing verified that the Atakr Rechargeable Batteries were capable of delivering at least twenty cycles of RF energy, even after being used in "Standby" mode for four hours.

7. Shipping Tests

Shipping tests were conducted by an outside contractor to validate that the Atakr Ablation System withstands vibration, drop and compression conditions established in accordance with ASTM D 4169. These conditions simulate most extreme conditions expected during shipping. After subjecting the test sample to the physical stresses, the Atakr Ablation System met all functional and electrical safety specifications.

B. RF Catheters - Mechanical and Electrical Testing

The mechanical tests of the catheters were evaluated according to the performance attribute's impact on the safety of the device. For non-safety related tests (e.g., lateral deflection force, handle joint strength) the sample was required to demonstrate, with 95% confidence, that 95% of the entire RF Catheter population (i.e., RF Ablatr and RF Marinr) met the specification. For safety related tests (e.g., tip flexibility, tip joint strength, thermocouple responsiveness) the sample was required to demonstrate, with 95% confidence, that 99.9% of the entire RF Catheter population met the specification.

1. Extent of Tip Deflection

The RF Ablatr catheters met the product specification for tip deflection in multiple planes; the RF Marindr catheters met the product specification for tip deflection in a single plane. Both catheters met their respective product specifications for electrical and mechanical performance following multiple (approximately 100) tip deflections, torquing, and push/pulls.

2. Tip and Shaft Flexibility

The flexibility of the distal tubing (i.e., tip) and catheter shafts were evaluated. The stiffness of the catheter shafts was demonstrated to be equivalent or less than commercially available electrophysiology catheters. The distal tubing was found to meet the sponsor's validated performance specification in a porcine model.

3. Lateral Deflection Force and Steerability

The range of models of RF Catheters were evaluated to determine if they could exert an adequate amount of lateral force (i.e., torque transmission) to remain in position in a beating heart. The specification for the lateral force was derived from validation studies conducted with each model. All catheter models exhibited adequate lateral deflection as defined by the sponsor.

Steerability testing determined whether the tip of the RF Catheters could be adequately positioned by rotating the catheter handle. Measurements of expected rotation of the tip versus actual were made for every 90° rotation of the catheter handle. The results demonstrated that the handle-to-tip steering ratio met the sponsor's performance specifications.

4. Mechanical Strength of RF Catheters

The joints of all RF Catheters were evaluated to verify that the construction of the catheters minimizes the potential of separation in the patients body. The tip joint (i.e., tip electrode to flexible distal section), shaft butt joint (i.e., flexible distal tubing to catheter shaft) and the catheter shaft/handle joints were all shown to possess strengths in adequate excess of the minimum product specification.

The RF Catheters demonstrated physical integrity after five rotations of the catheter (maximum of two rotations expected) with respect to a fixed tip electrode.

5. Electrical Reliability of RF Catheters

Various electrical tests derived from IEC 601-1, IEC 601-2-2 and HF-18 demonstrated the dielectric withstand strengths of the catheter handle and shaft, the RF leakage current of the shaft (after soaking in saline) and of the RF leakage current between the tip electrode and ring electrodes.

The electrical performance of the RF Catheters was also evaluated following twenty-five applications of RF energy through the catheter. The catheters met the relevant product specifications following the RF cycling.

6. Accuracy of Tip Electrode Temperature and Responsiveness to Changing Temperatures

RF catheters connected to an Atakr RF Power Generator were transferred between water baths at 20°C and 80°C. The accuracy of the displayed tip temperature and the speed at which the tip temperature changed was recorded. The tip temperature displayed was found to be within +/- 3°C of the water bath temperature and responded to the change in temperature fast enough to meet the sponsor's criteria. This testing was repeated after twenty-five applications of RF energy through the catheter. None of the catheters demonstrated a degradation of thermocouple accuracy or response time after twenty-five RF thermal cycles. The mean number of RF cycles used during the human clinical trial was seven.

7. Diagnostic Capabilities of RF Catheters

A bench study was conducted to determine the mapping resolution capabilities of the RF Catheters. Using this model of a cardiac signal source, the sponsor claimed to demonstrate adequate signal resolution for location and subsequent ablation of cardiac arrhythmia pathways.

A test was also conducted to determine if the RF Catheters permit accurate recording of intracardiac signals from 10 to 500 Hz. It is generally accepted that the fastest cardiac signals, accessory pathway potentials, are about 100 Hz. Measurements of signal attenuation verify that the RF Catheters can provide adequate recording of cardiac electrograms.

Catheter impedances at 500 and 5000 Hz were determined. Results demonstrated no significant inductive resistance to electrogram signals.

8. Shelf Life of RF Catheters and Packaging

The tests evaluated the shelf life performance of the packaging materials and the RF Catheters. Microbial barrier testing was performed on the packaging materials and performance testing was conducted on RF Catheters that had undergone accelerated aging. Based on the results of these tests (i.e. microbial barrier protection and product testing following aging), the data support expiration date labeling of two years for the catheters.

C. Foot switch - Mechanical Performance

The strength of the pneumatic foot switch cabling along with the activating forces necessary to engage the foot switch were tested and found to be in compliance with ANSI/AAMI HF-18.

D. Accessory Cables - Mechanical & Electrical Performance

The reliability of all accessory cables was tested following 100 deflections and connections and following repetitive cleaning and sterilizations. The cables met all functional and electrical safety requirements following this testing. Electrical testing documented the dielectric withstand, propensity for High frequency leakage current between wires and the adherence to sink current limits as defined by ANSI/AAMI HF-18 and AAMI ECGC. The cable strain relief demonstrated the resistance to damage following a static load of 40 Newtons, and a dynamic load of 0.64 Joules. The cabling was demonstrated to not create electrical noise in excess of the limits described in AAMI ECGC when moved.

E. Biocompatibility Testing

All blood and tissue contact materials of the catheter were tested in accordance with relevant sections of the US Pharmacopoeia and Tripartite Biocompatibility Guidance for Medical Devices. The biocompatibility of the catheter materials was established for the intended use.

The thrombogenicity of the RF catheters was evaluated in non-heparinized anesthetized dogs. This study demonstrated that the RF Catheters present no more thrombogenic potential than commonly used diagnostic EP catheters. This data, along with the medical practice of heparinizing patients during left sided procedures, suggest that the thrombogenic potential of the RF Catheters is not clinically significant.

Additional biocompatibility testing was conducted to determine whether RF cycling affected the chemical constituents of the RF Catheters in a way that could change its biocompatibility profile. Twenty-five cycles of 40 W RF current, at 30 seconds per cycle, were passed through the RF Catheter. Thereafter the biocompatibility (hemolysis and cytotoxicity) of the cycled catheters was evaluated. It was concluded that the RF Catheters do not undergo clinically significant physicochemical changes following the application of 25 cycles of RF energy. The mean number of applications of RF energy during the human clinical trial was seven.

F. Animal Testing

The Atakr Ablation System was evaluated using separate animal test protocols for: 1) general performance and safety of the system, and 2) diagnostic capabilities of the RF catheters.

1. General System Evaluation in a Porcine Model

The performance and animal safety of the therapeutic operation of the Atakr Ablation System was evaluated in a long term porcine model. In anesthetized animals, the first lesion was created in the region of the His bundle with the aim of creating complete AV block. Two additional lesions were created in the left heart: the first, in the region of the mitral valve annulus, simulating the location of most accessory pathways; the second, in the region of the left ventricular apex, simulated a common site of origin for ventricular tachycardia. Ventricular pacemakers were installed in each animal to facilitate normal cardiac contraction. Cardiac function was monitored during the ablation procedure and at intervals post ablation to evaluate the stability of the electrophysiologic effects and to monitor the occurrence of adverse events.

Complete heart block was successfully achieved in 6/6 animals during the initial procedure. All animals remained in complete heart block (CHB) and survived in good health until 6 weeks post-ablation, at which time each was sacrificed.

No impedance rises were seen despite average power delivery in excess of 40 Watts at durations of 30-60 seconds.

There were 13 episodes of ventricular tachycardia (VT) during catheterization; 10 occurred when RF power was switched off and 3 occurred during RF current application (3/63 or 4.8%). Eight VT episodes occurred shortly (<10 seconds) after cessation of RF current

delivery and two VT episodes were associated with catheter manipulation alone. All VT episodes were successfully terminated by cardioversion at 200-400J. Each animal experienced at least one episode of VT (range 1-4) for a mean of 2.2 episodes per animal.

No recurrence of atrioventricular conduction, arrhythmias or other untoward events were noted during the follow-up period. Ventricular pacemakers functioned without incident in all animals during the study period.

Echocardiogram data demonstrated no valvular or wall motion changes post ablation. Examination during necropsy determined that lesion sizes were well defined and typical in size.

Based on these results the Atakr Ablation System was considered reasonably safe for creation of cardiac lesions in human subjects.

2. Determination of Pacing Thresholds in a Canine Model

This test assessed the activation energy necessary to initiate pacing in a dog heart. The ability of the catheter to pace at energy levels near other diagnostic electrophysiology catheters is a performance requirement.

The catheter tip was advanced into the right atrium of an anesthetized dog. The minimum pacing protocol necessary to entrain the heart was determined. This procedure was repeated after advancing the tip of the catheter to the right ventricular apex.

This procedure was also conducted with four marketed EP catheters: the Mansfield Polaris and Explorer catheters, the CardioRhythm Torqr, and the Bard Dynamic Tip catheter.

Results for the RF Ablatr were consistent with those of other diagnostic EP catheters. Since the RF Ablatr and RF Marinr are electrically identical, the results may be applied to both catheters.

Clinical Studies

Clinical Trial of the Atakr Radiofrequency Catheter Ablation (RFCA) System in the Treatment of Supraventricular Tachyarrhythmias (SVT)

The Atakr RFCA System was evaluated in a study of 683 consecutive patients treated for accessory pathways (AP), AV node reentrant tachycardia (AVNRT), or intractable atrial arrhythmias requiring ablation of the AV junction (AVJ). The closed-loop temperature control mode of operation was compared to the open-loop (power control) mode.

Description of Patients

The prospective, multicenter (11 US sites), open study enrolled consecutive patients (683) with disabling symptoms due to SVT, unresponsiveness to drug therapy, and/or significant risk of malignant arrhythmia.

Approximately equal numbers of males (328) and females (355) were included. This selection ratio of men vs. women in the study is reflective of the underlying distribution of the disease in this age group. The mean age was 37 yr, 98% were symptomatic pre-ablation, 26% had concomitant heart disease and 76% were on antiarrhythmic drugs.

Ablation targets in most patients were AP only, AVNRT only, or AVJ only; but multiple targets were ablated in some patients.

Follow-up Schedule

All patients were followed regardless of acute outcome. Patients were to return at 1, 3, and 6 months for physical examination and 12-lead electrocardiogram (ECG) recording. At 12 months, patients underwent an interview, either in person or via telephone. Patients who had successful ablation with the Atakr RFCA System for either APs or AVNRT were required to undergo an electrophysiology study (EPS) one to three months post-ablation. The protocol schedule is summarized in Table 1.

Table 1. Summary of Protocol Schedule

Evaluation	Pre-ablation	Post-ablation	1, 3, & 6 mo	12 Mo
EPS*	X	X	see note below	
CPK-MB**	X	X		
Echocardiogram	X	X		
12-lead ECG	X	X	X	
Physical Exam	X	X	X	
Patient Interview	X	X	X	X

* Long-term EPS was limited to those patients who had successful ablation for AVRT or AVNRT with the Atakr RFCA System. The EPS was to be performed from one to three months post-ablation.

** The measurement of CPK-MB was discontinued on July 23, 1993.

Comparison Study Population

No matched concurrent control population was developed in the study. When the study began, no FDA-approved RFCA systems were available and RFCA was considered the treatment of choice for these patients. It was, therefore, not considered possible to conduct a randomized controlled study.

The primary outcome measures were acute and chronic success of the procedures. Acute Success was defined as decrease in inducibility for patients with AP and AVNRT or creation of complete heart block (CHB) in patients with AVJ. Long Term Success was defined as continuing absence of: inducibility in the 1-3 Month EPS (AV or AVNRT only), documented SVT, and symptoms suggestive of SVT.

Statistical Analysis

The study design used the patient as their own control. The patient's pre-ablation condition, including inducibility of the target SVT, cardiac function, symptoms, antiarrhythmic (AA) drug use, and hospitalization rates, were compared to those observed post-ablation.

Descriptive statistics included the mean, standard deviation, and range.

Inferential statistics were used to estimate the probability of the occurrence of the observed outcome under the null hypothesis (H_0). For the determination of significance, p-values less than or equal to 0.05 were considered to be statistically significant and resulted in rejection of the null hypothesis. Unless otherwise stated, all hypotheses were two-tailed.

Kaplan-Meier survival curves were used to analyze patient survival, time to first SVT recurrence, time to symptom recurrence, and time to resumption of antiarrhythmic drug use. The log-rank (Mantel-Cox) test was used to compare subgroups.

Effectiveness Results

The results of the Atakr RFCA System Clinical Study, when matching the patient's post-ablation condition to that observed pre-ablation, demonstrated the following:

- Acute Success was defined as decrease in inducibility (AP and AVNRT) or creation of CHB (AVJ). Most (84%) of patients enrolled had acutely successful procedures when using the Atakr RFCA System.
- Long Term Success was defined as continuing absence of: inducibility in the 1-3 Month EPS (AV or AVNRT only), documented SVT, and symptoms suggestive of SVT. Kaplan-Meier estimate of one year freedom from SVT was 92%; post-ablation EPS confirmed that 99% of patients' arrhythmias were non-inducible.
- Cardiac Function - Paired echocardiograms showed no significant change in cardiac function. There was no net change in valve function, wall motion abnormalities, thrombus formation, or ejection fraction. Although the of pericardial effusion occurred in 5% of patients (McNemar's p-value < 0.001), it was typically minor and required no treatment in most (28/32, 88%) occurrences.
- Clinical Utility - Long term follow-up confirmed that patients exhibited statistically significantly fewer symptoms and fewer hospitalizations associated with those symptoms in the year following than in the year preceding ablation. Patients also had statistically significant decreases in antiarrhythmic drug use.
- Temperature vs. Power - The Temperature Control Mode was associated with significantly fewer shutdowns, coagulum formations and clinical complications when compared to those observed in the Power Control Mode. While the Power Mode was found to be an appropriate energy delivery mode in certain circumstances, the Temperature Mode was considered a more appropriate mode of RF energy delivery in most cases.
- RF Ablatr vs. RF Marinr - The acute success rate was found to be comparable for the RF Marinr and the RF Ablatr. There was no difference in device related complication rates.

Patients treated with the Atakr RFCA System showed an acute success rate of 84%. Time to recurrence (evidenced by SVT inducibility, documentation of spontaneous SVT, return of SVT-related symptoms, and/or documented ECG changes) of those treated successfully were estimated by the Kaplan-Meier method.

Table 2. Principal Effectiveness Results.
N=683, all patients treated

Treatment	Acute Success	Non-recurrence (%) in those Initially Successfully Treated (n = patients at risk)		
		60 days	6 months	12 months
Atakr RFCA (N=683)	84% 571/683	94% (n=396)	93% (n=248)	91% (n=194)

Acute Success by Gender

No statistically significant differences in success rate were detected for males and females in this patient population.

Acute Success by Age Group

Two of the study centers enrolled predominately pediatric patients. Of the 683 patients, 215 (31%) were juveniles. A comparison of Atakr success on the basis of age is shown in Table 3. There were no statistically significant differences in the acute success rates.

Table 3. Acute Success Rate - Adult vs. Juvenile
All Patients (N=683), Success Rate (%)

Procedure	Adult Patients (n=512)	Juvenile Patients (n=171)
AP (n=364)	75%	82%
AVNRT (n=226)	94%	85%
AVJ (n=78)	87%	100%
More than one of the above (n=15)	44%	83%
All RFCA	84%	83%

RF Ablatr vs. RF Mariner Catheters

The RF Mariner catheter differs from the RF Ablatr in the addition of a tip deflection radius adjustment control to the handle. Fifty-seven of the 683 patients from five investigational sites were treated using the RF Mariner catheter. The study group consisted of 31 males (54%) and 26 females (46%) with a mean (\pm SD) age of 29 ± 19 years. Table 4 shows the acute success by catheter.

Table 4. Acute Success Based on RF Catheter Type
All Patients N=683, Acute Success Rate (%)

Procedure	RF Ablatr (n=626)	RF Maritr (n=57)
AP (n=364)	77%	83%
AVNRT (n=226)	91% ¹	100%
AVJ (n=78)	87%	50%
More than one of above (n=15)	57%	100%
All RFCA	83%	88%*

* Three of these failures were later successfully treated with an RF Ablatr in the same procedure.

All but two patients were successfully treated with the RF Maritr 38/40 (95%). These two patients both had single accessory pathways. A single complication, transient AV block, was observed among the 57 patients.

Conclusions: Clinical evaluation of the Atakr Cardiac Ablation System demonstrated it to be effective for interruption of accessory atrioventricular AV conduction pathways associated with tachycardia, treatment of AV nodal re-entrant tachycardia, and for creation of complete AV block in patients with a rapid ventricular response to an atrial arrhythmia. Success rates with this system were comparable to those reported in the literature and with other ablation systems.

Safety Results

Complications were reported in 88 (13%) of the 683 patients studied. Twenty patients had more than one complication. Complications were stratified into their categories as shown in Table 5. Severe complications were defined as myocardial infarction MI, cerebrovascular accident CVA and tamponade.

Table 5. Atakr Clinical Trial Reported Clinical Complications Summary

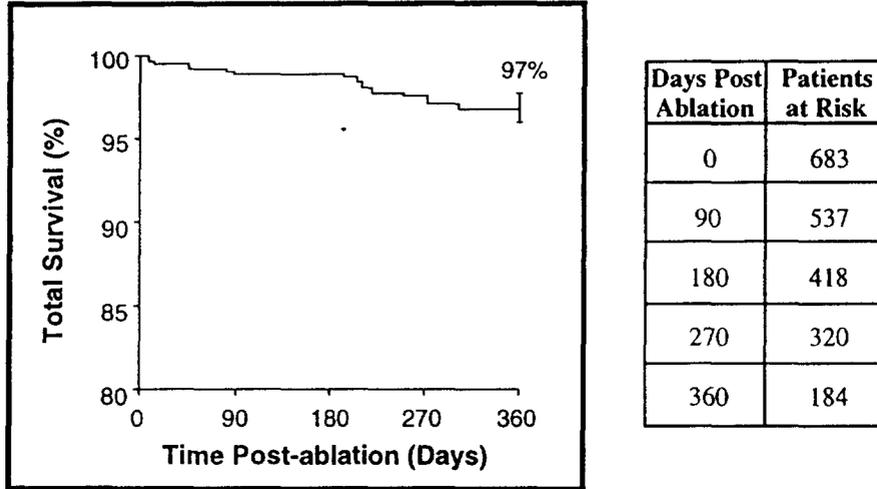
Complications- # of patients N=683	Total	Device Related	Procedure Related
Any reported complication	88 13%	30 4%	37 5%
Severe MI, CVA, tamponade	11 2%	6 <1%	4 <1%
Death	18 3%	2 <1%	1 <1%

Patient Survival

Total Mortality;

A Kaplan-Meier curve was used to estimate total survival for all patients treated and enrolled in the study. This curve is depicted in Figure 1.

Figure 1. Total Survival, All Patients N=683



Operative Mortality: Operative mortality was defined as death from all causes within 30 days from the date of ablation. There was one operative death in the Atakr population undergoing AP ablation.

Conclusions: The Atakr Cardiac Ablation System was demonstrated in this study to be reasonably safe for the treatment of supraventricular tachycardia. Fewer than 1% of patients in the clinical series had a serious complication that appeared to be related to the investigational device. The Kaplan-Meier estimate of one-year survival for the patients enrolled in the Atakr Clinical Study was 97%.

XI. CONCLUSIONS DRAWN FROM THE STUDIES

The Atakr Cardiac Ablation System is determined to be reasonably safe and effective for the treatment of supraventricular tachycardia. Non-clinical testing demonstrated that the system meets or exceeds safety, reliability and performance specifications established by FDA and Medtronic CardioRhythm. Clinical evaluation of the Atakr Cardiac Ablation System demonstrated it to be effective for interruption of accessory atrioventricular AV conduction pathways associated with tachycardia, treatment of AV nodal re-entrant tachycardia, and for creation of complete AV block in patients with a rapid ventricular response to an atrial arrhythmia. Success rates with this system are comparable to those reported in the literature. Fewer than 1% of patients in the clinical series had a serious complication that appeared to be related to the investigational device.

XII. PANEL RECOMMENDATIONS

The Circulatory System Devices Advisory Panel met on December 5, 1994 and unanimously recommended approval of the Atakr Cardiac Ablation System with the following conditions on the product labeling:

1. The label reflect the range in the number of energy applications provided with a single catheter.
2. The label provide some guidance on temperature such as: "The electrode temperature may underestimate the tissue temperature attained. Therefore, although permanent tissue damage is associated with the tissue temperature greater than 50 degrees centigrade, this may be attained with an electrode temperature of less than 50 degrees centigrade. Also, although coagulum formation is associated with a tissue temperature of greater than 100 degrees centigrade, coagulum formation may occur with an electrode temperature of less than 100 degrees centigrade 80 to 94 degrees centigrade in the clinical studies here."
3. Catheter distal tip length be limited to the 4 mm device studied in the PMA.
4. The label include "Therapy Guidance in Asymptomatic Patients" with: frequent episodes of prolonged tachycardia; occupation such as airline pilot or operation of industrial machinery, where untimely recurrence of an arrhythmia may pose a significant hazard; a risk of sudden cardiac death via rapid conduction of atrial fibrillation; and heart disease requiring pre-surgical ablation to minimize the post-operative morbidity.

XIII. FDA DECISIONS

The FDA concurred with the approval and with recommendations 1 through 3 of the Circulatory System Devices Panel. While the proposed "Therapy Guidance in Asymptomatic Patients" represents reasonable clinical guidance, it was not supported by the clinical experience in this application (12 asymptomatic patients studied). Thus a precaution -- "The risk/benefit in asymptomatic patients has not been studied" was included.

The following additional conditions were recommended by the agency::

The PMA must be amended to include the sponsor's concurrence with, or suggested revision of, the "Conditions of Approval," and the following conditions:

1. The sponsor continue to follow all patients < 21 years old enrolled at the two pediatric centers until they complete the 2-year follow-up, and the 5 patients with the greatest creatine phosphokinase CPK-MB increase for a total of five years post-ablation. The information to be submitted on these patients should include at least telephone contact every six months and a patient history with an emphasis on cardiac events. Follow-up office visits should also include documentation of a physical examination and a twelve-lead electrocardiogram if they are performed. This information should be summarized and submitted as part of the sponsor's annual reports.
2. That the sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520e of the Federal Food, Drug, and Cosmetic Act the act under the authority of section 515d1Bii of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520e under the authority of section 515d1Bii insofar as the sale, distribution, and use must not violate sections 502q and r of the act.

XIV. APPROVAL SPECIFICATIONS

The approval specifications are described in Sections XII and XIII.

XV. REFERENCES

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