



[Handwritten signature]

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Jon Brumbaugh
Manager, Regulatory Affairs
Biotronik, Inc.
6024 Jean Road
Lake Oswego, OR 97035-5369

OCT 27 1998

Re: P980023
Phylax Implantable Cardioverter Defibrillator (ICD) System
Filed: June 8, 1998
Amended: August 24 and September 18, and 22 1998

Dear Mr. Brumbaugh:

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 Phylax Implantable Cardioverter Defibrillator (ICD) System: (a) ICD Pulse Generator - Phylax XM ICD, model number 121491; Phylax XM Active Housing ICD, model number 121492; Phylax XM Replacement ICD, model number 121162 and mycroPhylax ICD, model number 121493; (b) ICD Lead - SPS 75 Lead System, model number 120398; SL-ICD Lead Systems (SL-ICD 75/13, model number 120395, SL-ICD 75/16, model number 120396, SL-ICD 75/18, model number 120397, SL-ICD 100/13, model number 116414, SL-ICD 100/16, model number 118375, SL-ICD 100/18, model number 119077); Kainox SL Lead Systems (Kainox SL 75/13, model number 124219, Kainox SL 75/16, model number 124218, Kainox SL 75/18, model number 124217, Kainox SL 100/13, model number 124238, Kainox SL 100/16, model number 124239, Kainox SL 100/18, model number 124240); Kainox RV 75 Lead System, model number 124005; and (c) Programming and Monitoring System - TMS 1000 Tachyarrhythmia Monitoring System, and Software Module SWM 1000 F00I01. This device is indicated for use in patients who are at risk of sudden death due to ventricular arrhythmias and have experienced one of the following situations: survival of at least one episode of cardiac arrest (manifested by a loss of consciousness) due to a ventricular tachyarrhythmia; or recurrent poorly tolerated sustained ventricular tachycardia (VT). NOTE: The clinical outcome for hemodynamically stable VT patients is not fully known. Safety and effectiveness studies for this indication have not been conducted. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval for Implantable Defibrillators and Programmers" (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, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) 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 also include the following information:

(a) the information outlined in item (1) through (5) of the "Conditions of Approval for Implantable Defibrillators and Programmable" must also be provided for the lead systems approved under this PMA, (b) update life-testing conducted on the pulse generator's power source (batteries), high energy defibrillation capacitors and leads, and (c) upgrade calculations of device longevity based on accumulating clinical experience.

Expiration dating for the pulse generators has been established and approved at 9 months after sterilization based on battery longevity. The expiration dating for the leads has been established and approved at 24 months after sterilization.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at <http://www.fda.gov/cdrh/pmapage.html>. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, 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, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

Page 3 - Mr. Jon Brumbaugh

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.

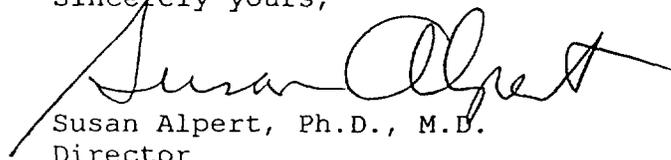
PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

Under section 519(e) of the act (as amended by the Safe Medical Devices Act in 1990), manufacturers of certain devices must track their products to the final user or patient so that devices can be located quickly if serious problems are occurring with the products. The tracking requirements apply to (1) permanent implants the failure of which would be reasonably likely to have serious adverse health consequences; (2) life sustaining or life supporting devices that are used outside of device user facilities the failure of which would be reasonably likely to have serious adverse health consequences; and (3) other devices that FDA has designated as requiring tracking. Under section 519(e), FDA believes that your device is a device that is subject to tracking because it is a permanent implant whose failure would be reasonably likely to have serious adverse consequences.

FDA's tracking regulations, published in the FEDERAL REGISTER on August 16, 1993, appear at 21 CFR Part 821. These regulations set out what you must do to track a device. In addition, the regulations list example permanent implant and life sustaining or life supporting devices that FDA believes must be tracked at 21 CFR 821.20(b) and the devices that FDA has designated for tracking at 21 CFR 821.20(c). FDA's rationale for identifying these devices is set out in the FEDERAL REGISTER (57 FR 10705-10709 (March 27, 1991), 57 FR 22973-22975 (May 29, 1992), and 58 FR 43451-43455 (August 16, 1993)).

If you have any questions concerning this approval order, please contact Carole C. Carey at (301) 443-8609 Ext-156.

Sincerely yours,



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

Enclosure

Issued: 3-4-98

CONDITIONS OF APPROVAL
FOR IMPLANTABLE DEFIBRILLATORS AND PROGRAMMERS

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401) Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Boulevard, Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement by FDA Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Boulevard, Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device. If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

In addition to the above and in order to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use, the annual postapproval reports shall include, separately for each model number (if applicable), the following information known by or reported to the applicant:

- (1) The number of pulse generators domestically implanted and the number of reported explants and deaths.
- (2) A breakdown of the reported deaths into pulse generator related and non-pulse generator related.
- (3) A breakdown of the reported explants into the numbers reported at end of battery life, having complications unresolvable by programming and for other reasons with safety and effectiveness issues which can be derived from the reports stated.
- (4) The number of pulse generators returned to the applicant for cause from domestic sources with a breakdown into the numbers currently in analysis, operating properly, at normal battery depletion and failed, with the failure mechanisms described.
- (5) A cumulative survival table for the pulse generators.
- (6) The number of programmers and modules shipped and the number of returns with a breakdown into the numbers currently in analysis, operating properly and failed, with the failure mechanisms described.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Boulevard, Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

- (1) A mix-up of the device or its labeling with another article.
- (2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a)has not been addressed by the device's labeling or

(b)has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3)Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION.

The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984. This regulation was replaced by the reporting requirements of the Safe Medical Devices Act of 1990 which became effective July 31, 1996 and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

- (1)May have caused or contributed to a death or serious injury; or
- (2)Has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for a PMA, the manufacturer shall submit the appropriate reports required by the MDR Regulation within the time frames as identified in 21 CFR 803.10(c) using FDA Form

3500A, i.e., 30 days after becoming aware of a reportable death, serious injury, or malfunction as described in 21 CFR 803.50 and 21 CFR 803.52 and 5 days after becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer is responsible for submitting a baseline report on FDA Form 3417 for a device when the device model is first reported under 21 CFR 803.50. This baseline report is to include the PMA reference number. Any written report and its envelope is to be specifically identified, e.g., "Manufacturer Report," "5-Day Report," "Baseline Report," etc. Any written report is to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
PO Box 3002
Rockville, Maryland 20847-3002

Copies of the MDR Regulation (FOD # 336&1336) and FDA publications entitled "An Overview of the Medical Device Reporting Regulation" (FOD # 509) and "Medical Device Reporting for Manufacturer" (FOD # 987) are available on the CDRH WWW Home Page. They are also available through CDRH's Fact-On-Demand (F-O-D) at 800-899-0381. Written requests for information can be made by sending a facsimile to CDRH's Division of Small Manufacturers Assistance (DSMA) at 301-443-8818.

Summary of Safety and Effectiveness

P980023

◆◆◆◆◆◆◆◆

BIOTRONIK, Inc.
Lake Oswego, OR 97035

Phylax ICD System:

Phylax XM ICD Family

Phylax XM ICD

Phylax XM Active Housing

Phylax XM Replacement ICD

mycroPhylax ICD

Phylax Lead System

SL-ICD Lead

SPS Lead System

Kainox RV Lead

Kainox SL Lead

TMS 1000 Tachyarrhythmia Monitoring
Systems

SWM 1000 F00.I01 Programmer Software

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Division of Cardiovascular Respiratory & Neurological Devices

Table of Contents

I.	GENERAL INFORMATION	3
II.	INDICATIONS AND USAGE	3
III.	DEVICE DESCRIPTION	3
IV.	CONTRAINDICATIONS.....	6
V.	WARNINGS AND PRECAUTIONS	6
VI.	ALTERNATIVE PRACTICES AND PROCEDURES	10
VII.	MARKETING HISTORY.....	10
VIII.	ADVERSE EVENTS	10
IX.	SUMMARY OF PRE-CLINICAL STUDIES.....	13
X.	CLINICAL STUDIES.....	16
XI.	CONCLUSIONS DRAWN FROM THE STUDIES	18
XII.	PANEL RECOMMENDATION	18
XIII.	FDA DECISION	19
XIV.	APPROVAL SPECIFICATIONS	19

Summary of Safety and Effectiveness

I. GENERAL INFORMATION

Device Generic Name: Implantable Cardioverter Defibrillator System, Lead System, & Programmer

Device Trade Name: Phylax XM ICD, Models 121491, 121492, 121162; mycroPhylax ICD Model 121493; SPS Lead System; Kainox RV Lead System; SL-ICD Lead Systems; Kainox SL Lead Systems; TMS 1000 Tachyarrhythmia Monitoring System

Applicant's Name: BIOTRONIK GmbH & Co.
Woermannkehre 1, Berlin, Germany

Premarket Approval (PMA)
Application Number: P980023

Date of Panel Meeting: Not Applicable

Date of Notice of Approval
To Applicant: OCT 27 1998

II. INDICATIONS AND USAGE

The Phylax ICD System is indicated for use in patients who are at high risk of sudden death due to ventricular arrhythmias and have experienced one of the following situations: (1) survival of at least one episode of cardiac arrest (manifested by a loss of consciousness) due to a ventricular tachyarrhythmia, (2) recurrent, poorly tolerated sustained ventricular tachycardia (VT). *NOTE: The clinical outcome for hemodynamically stable VT patients is not fully known. Safety and effectiveness studies for this indication have not been conducted.*

III. DEVICE DESCRIPTION

The BIOTRONIK Phylax Implantable Cardioverter Defibrillator System consists of implantable components (pulse generator and lead), external programming system and various accessories used during implantation and follow-up electrophysiological procedures. Similar to several commercially available ICD systems, the Phylax ICD System is a single-chamber pulse generator capable of delivering antitachycardia pacing (ATP), cardioversion and defibrillation shock therapy. The device shock output ranges from 0.5 to 30J in the form of monophasic or biphasic waveforms. In addition to ventricular defibrillation therapy, it also provides bradycardia pacing support (ventricular demand pacing). The system may also be used to collect diagnostic data to aid the physician's assessment of a patient's condition and the response of the implanted device.

ICD Pulse Generators –*Phylax XM ICD*, model number 121491; *Phylax XM Active Housing ICD*, model number 121492; *Phylax XM Replacement ICD*, model number 121162; and *mycroPhylax ICD*, model number 121493.

Each of the ICD devices has a hermetically sealed titanium can with an epoxy resin header. The Phylax XM, the Phylax XM Active Housing and the Phylax XM Replacement are identical except as noted below and are hereafter referred to, unless otherwise necessary, as the Phylax XM. The models differ primarily in the lead port design. The Phylax XM has three DF-1 and one IS-1 header ports. The Phylax XM Active Housing has two DF-1 and one IS-1 header ports and also uses the outer metallic housing of the ICD as an additional electrode to augment the implanted lead system. The Phylax XM Replacement has two 4.75mm sensing and pacing ports and two 6.1mm defibrillation ports. A downsized version of the Phylax XM (109g, 69cc, 76 x 63 x 17mm) is the mycroPhylax ICD (89g, 54cc, 76 x 63 x 14 mm). The mycroPhylax ICD has identical frontal dimensions as the Phylax XM with its thickness reduced by 3.0mm. Both use identical means to detect and treat ventricular tachyarrhythmias and provide bradycardia pacing support. An enhancement in the mycroPhylax ICD is the shock configuration programmability. The mycroPhylax can be programmed as either an active or passive device, while in the Phylax XM ICD family, these are two types of distinct pulse generators (i.e., the Phylax XM is passive and the Phylax XM Active Housing is active).

Shock Configuration Programmability of the mycroPhylax ICD. The mycroPhylax has been designed with the ability to program the housing as either electrically active or non-active. It is designed with three shock channels, of which only two are active for each shock. Two of the shock channels are identical, except that one is tied directly to the housing and the other is tied to the high voltage HV2 connector port. The third shock channel of the mycroPhylax is tied to the HV1 connector port. Through programming, the device selects which channels are active, thus resulting in a "programmable housing".

ICD Leads - *SPS 75 Lead System*, model number 120398; *SL-ICD Lead Systems* (SL-ICD 75/13, model number 120395, SL-ICD 75/16, model number 120396, SL-ICD 75/18, model number 120397, SL-ICD 100/13, model number 116414, SL-ICD 100/16, model number 118375, SL-ICD 100/18, model number 119077); *Kainox RV 75 Lead System*, model number 124005; *Kainox SL Lead Systems* (Kainox SL 75/13, model number 124219, Kainox SL 75/16, model number 124218, Kainox SL 75/18, model number 124217, Kainox SL 100/13, model number 124238, Kainox SL 100/16, model number 124239, Kainox SL 100/18, model number 124240).

All lead designs are transvenous systems with the tip, ring, and shocking coil electrodes composed of platinum/iridium with an iridium fractal surface structure. The type of fixation is passive (tines). Table I below provides a comparison summary of the four different types of BIOTRONIK leads designed for use with the Phylax ICD System. All of these BIOTRONIK-manufactured devices are fully compatible with each other and may be used in any combination.

Table I. Phylax ICD Leads

Lead Characteristic	SL-ICD	SPS	Kainox SL	Kainox RV
Lead Length (cm)	75, 100	75	75, 100	75
Tip to SVC Coil Spacing (cm)	13, 16, 18	N/A	13, 16, 18	N/A
No. of Lead Connectors, 3.2mm IS-1 Bipolar, Pacing/Sensing	1	1	1	1
No. of Lead Connectors, 3.2mm DF-1, Defibrillation	2	1	2	1
Shock Coil Diameter (mm)				
Ventricular	3.7	3.5	3.5	2.9
SVC	3.7	N/A	3.5	N/A
Shock Coil Length (cm)				
Ventricular	4.0	4.0	4.0	5.0
SVC	7.0	N/A	7.0	N/A

Models with Two Defibrillation Electrodes. The SL-ICD Lead System is a single pass lead that has two sensing and pacing electrodes and two defibrillation electrodes. The tip and ring electrodes form the most distal portion of the lead and provide dedicated bipolar sensing and pacing. One shocking electrode is positioned in the apex of the right ventricle and the other shocking electrode is positioned in the superior cava (SVC). The model number of the lead provides the overall length along with the distance between the tip and the SVC electrode. A downsized version of the SL-ICD Lead System is the Kainox SL Lead System. All physical dimensions of this lead system are identical to the SL-ICD except that the diameter of the defibrillation electrodes has been reduced by 0.2mm.

Although the diameter has been reduced, the surface area of the shock electrodes remains the same. BIOTRONIK's manufacturing process has been slightly modified for the shock electrodes of the Kainox SL. The platinum/iridium ribbon used for each shock electrode is wound in a coil pattern (i.e., spring) to maximize the active surface area for delivery of defibrillation shocks. For the Kainox SL lead, the coils are wound with less space between coil turns to facilitate additional turns along the same length of shock electrode. Therefore, the shock electrodes of the Kainox SL and SL-ICD lead were designed with identical lengths and identical active surface areas.

Models with One Defibrillation Electrode. Another lead configuration is the SPS Lead System that has two sensing and pacing electrodes and one defibrillation electrode, all of which are also contained in one single-pass lead. The shock electrode is positioned in the apex of the right ventricle. A downsized version of the SPS Lead System is the Kainox RV Lead System. The Kainox RV Lead System has been designed with a reduced overall diameter. The defibrillation electrode diameter has been reduced by 0.6mm from the SPS Lead System without reducing the overall surface area of the electrode. The surface area has been maintained by increasing the length of the shock electrode. The dimensions of the tip and ring electrodes for the Kainox RV have also been reduced compared to the SPS leads.

Programming and Monitoring System - The Phylax ICD System is used with a new programmer device, the TMS 1000 Tachyarrhythmia Monitoring System, and a commercially available programming system, the PMS 1000C Programming and Monitoring System.

The TMS 1000 incorporates three separate major functions:

- *pacing system analyzer* - testing of the sensing and pacing portions of the implanted lead system, including measurement of intrinsic signal amplitudes (e.g., R-wave amplitude), slew rate, pacing impedance, and pacing threshold;
- *external defibrillation testing device* - testing of the defibrillation and cardioversion features of the implanted lead system, including induction of tachyarrhythmias, and measurement of defibrillation threshold (DFT), cardioversion energy requirement (CER), and shocking lead impedance; and,
- *programmer* - programming and interrogation of the ICD during the implant procedure.

In conjunction with a specific programmer software for the respective ICD, the PMS 1000C Programming and Monitoring System (approved for use with BIOTRONIK's implantable pacemakers under P820076/S19, January 24, 1996 and P950037/S1, March 13, 1998) can also be used with the Phylax ICD System. The external programmer is used to interrogate and program the implanted device during patient follow-up procedures.

IV. CONTRAINDICATIONS

The Phylax ICD System is contraindicated in: (1) patients whose ventricular tachyarrhythmias may have transient or reversible causes such as acute myocardial infarction, digitalis intoxication, drowning, electrocution, electrolyte imbalance, hypoxia, and sepsis; (2) patients with incessant VT or VF (ventricular fibrillation); (3) patients who have a unipolar pacemaker; and (4) patients whose only disorder is bradyarrhythmias or atrial arrhythmias.

V. WARNINGS AND PRECAUTIONS

- **MRI (Magnetic Resonance Imaging)** - Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient.
- **Electrical Isolation** - Electrically isolate the patient from potentially hazardous leakage current to prevent inadvertent arrhythmia induction.
- **Lead Systems** - The use of another manufacturer's ICD lead system may cause potential adverse consequences such as undersensing of cardiac activity and failure to deliver necessary therapy.
- **Resuscitation Availability** - In order to implant the ICD system, it is necessary to induce and convert the patient's ventricular tachyarrhythmias. Do not perform induction testing unless an alternate source of patient defibrillation such as an external defibrillator is readily available.

- **Unwanted Shocks** - Prior to handling the device during the implant procedure, program the detection status of the device to OFF to prevent the delivery of unwanted shocks to the patient or the person handling the device.

Sterilization, Storage, and Handling

- **Device Packaging** - Do not use the device if the device's packaging is wet, punctured, opened or damaged because the integrity of the sterile packaging may be compromised. Return the device to BIOTRONIK.
- **Resterilization** - Do not resterilize and re-implant explanted devices.
- **Storage (temperature)** - Store the device between 5° to 55° C (41° - 131° F) because temperatures outside this range could damage the device.
- **Storage (magnets)** - Store the device in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference (EMI) to avoid damage to the device.
- **Temperature Stabilization** - Allow the device to reach room temperature before programming or implanting the device because temperature extremes may affect initial device function.
- **Use Before Date** - Do not implant the device after the USE BEFORE DATE because the device may have reduced longevity.

Implantation and Programming

- **Blind Plug** - A blind plug must be inserted and firmly connected into any unused header port to prevent chronic fluid influx and possible shunting of high energy therapy.
- **Capacitor Reformation** - Infrequent charging of the high voltage capacitors may extend the charge times of the ICD. The capacitors may be manually reformed, or the ICD may be programmed to reform the capacitors automatically. For further information, please refer to Section 2.8.3 Capacitor Reforming of the Technical Manual.
- **Connector Compatibility** - ICD and lead system compatibility should be confirmed prior to the implant procedure. Consult your BIOTRONIK representative regarding lead/pulse generator compatibility prior to the implantation of an ICD system. For further information, please refer to Appendix A (of the Technical Manual).
- **ERI (Elective Replacement Indicator)** - Upon reaching ERI, the battery has sufficient energy remaining to continue monitoring for at least three months and to deliver a minimum of six 30 joule shocks. After this period, all tachyarrhythmia detection and therapy is disabled.
- **Magnets** - Positioning of a magnet or the programming wand over the ICD will suspend tachycardia detection and treatment.
- **Pacemaker/ICD Interaction** - In situations where an ICD and a pacemaker are implanted in the same patient, interaction testing should be completed. If the interaction between the ICD and the pacemaker cannot be resolved through repositioning of the leads or reprogramming of either the pacemaker or the ICD, the pacemaker should not be implanted (or explanted if previously implanted).
- **Programmed Parameters** – Program the device parameters to appropriate values based on the patient's specific arrhythmias and condition.
- **Programmings** - Use only BIOTRONIK programmers to communicate with the device.
- **Sealing System** - Failure to properly insert the torque wrench into the perforation at an angle perpendicular to the connector receptacle may result in damage to the sealing system and its self-sealing properties.

- **Shock Impedance** - Never implant the device with a lead system that has a measured shock impedance of less than thirty ohms. Damage to the device may result. If the shock impedance is less than thirty ohms, reposition the lead system to allow a greater distance between the electrodes.

Lead Evaluation and Connection

- **Capping Leads** - If a lead is abandoned rather than removed, it must be capped to ensure that it is not a pathway for currents to or from the heart.
- **Gripping Leads** - Do not grip the lead with surgical instruments or use excessive force or surgical instruments to insert a stylet into a lead.
- **Kinking Leads** - Do not kink leads. This may cause additional stress on the leads that can result in damage to the lead.
- **Liquid Immersion** - Do not immerse leads in mineral oil, silicone oil, or any other liquid.
- **Short Circuit** - Ensure that none of the lead electrodes are in contact (a short circuit) during delivery of shock therapy as this may cause current to bypass the heart or cause damage to the ICD system.
- **Suturing Leads** - Do not suture directly over the lead body as this may cause structural damage. Use the appropriate suture sleeve to immobilize the lead and protect it against damage from ligatures.
- **Tricuspid Valve Bioprosthesis** - Use ventricular transvenous leads with caution in patients with a tricuspid valvular bioprosthesis.

Follow-up Testing

- **Defibrillation Threshold** - Be aware that the changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT) which may result in nonconversion of the arrhythmia post-operatively. Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post operatively
- **Resuscitation Availability** - Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing should the patient require external rescue.

Pulse Generator Explant and Disposal

- **Device Incineration** - Never incinerate the ICD due to the potential for explosion. The ICD must be explanted prior to cremation.
- **Implanted Devices** - Return all explanted devices to BIOTRONIK.
- **Unwanted Shocks** - Prior to explanting the ICD, program the detection status of the device to OFF to prevent unwanted shocks.

Hospital and Medical Hazards

Electromagnetic interference (EMI) signals present in hospital and medical environments may affect the function of any ICD or pacemaker. The ICD is designed to selectively filter out EMI noise. However, due to the variety of EMI signals, absolute protection from EMI is not possible with this or any other ICD.

- **Diathermy** - Diathermy therapy is not recommended for ICD patients due to possible heating effects of the pulse generator and at the implant site. If diathermy therapy must be used, it should not be applied in the immediate vicinity of the pulse generator or lead system. Following the procedure, proper ICD function should be checked and monitored.
- **Electrocautery** - Electrosurgical cautery could induce ventricular arrhythmias and/or fibrillation, or may cause device malfunction or damage. If use of electrocautery is

necessary, the current path and ground plate should be kept as far away from the pulse generator and leads as possible.

- **External Defibrillation** - The device is protected against energy normally encountered from external defibrillation. However, any implanted device may be damaged by external defibrillation procedures. In addition, external defibrillation may also result in permanent myocardial damage at the electrode-tissue interface as well as temporary or permanent elevated pacing thresholds. When possible, observe the following precautions:
 - Position the adhesive electrodes or defibrillation paddles of the external defibrillator anterior-posterior or along a line perpendicular to the axis formed by the implanted device and the heart.
 - Set the energy to a level not higher than is required to achieve defibrillation.
 - Place the paddles as far as possible away from the implanted device and lead system.
 - After delivery of an external defibrillation shock, interrogate the ICD to confirm device status and proper function.
- **Lithotripsy** - Lithotripsy may damage the ICD. If lithotripsy must be used, avoid focusing near the ICD implant site. Following the procedure, proper ICD function should be checked and monitored.
- **MRI (Magnetic Resonance Imaging)** - Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient.
- **Radiation** - High radiation sources such as cobalt 60 or gamma radiation should not be directed at the pulse generator. If a patient requires radiation therapy in the vicinity of the pulse generator, place lead shielding over the device to prevent radiation damage and confirm its function after treatment.
- **Radio Frequency Ablation** - Prior to performing an ablation procedure, deactivate the ICD. Avoid applying ablation energy near the implanted lead system whenever possible. The ICD system should be checked for proper operation after the procedure.

Home and Occupational Hazards

Patients should be directed to avoid devices that generate strong electromagnetic interference (EMI). EMI could cause device malfunction or damage resulting in non-detection or delivery of unneeded therapy. Moving away from the source or turning it off will usually allow the ICD to return to its normal mode of operation.

The following equipment (and similar devices) may affect normal ICD operation: electric arc or resistance welders, electric melting furnaces, radio/television and radar transmitters, power-generating facilities, high-voltage transmission lines, and electrical ignition systems (of gasoline-powered devices) if protective hoods, shrouds, etc., are removed.

- **Cellular Phones** - Testing has indicated there may be a potential interaction between cellular phones and the BIOTRONIK ICD systems. Potential effects may be due to either the cellular phone signal or the magnet within the telephone and may include inhibition of therapy when the telephone is within 6 inches (15 centimeters) of the ICD, when the ICD is programmed to standard sensitivity. Patients having an implanted BIOTRONIK ICD who operate a cellular telephone should:
 - Maintain a minimum separation of 6 inches (15 centimeters) between a hand-held personal cellular telephone and the implanted device.
 - Set the telephone to the lowest available power setting, if possible.

- Patients should hold the phone to the ear opposite the side of the implanted device. Patients should not carry the telephone in a breast pocket or on a belt over or within 6 inches (15 centimeters) of the implanted device as some telephones emit signals when they are turned ON, but not in use (i.e., in the listen or stand-by mode). Store the telephone in a location opposite the side of implant. Based on results to date, adverse effects resulting from interactions between cellular telephones and implanted ICDs have been transitory. If electromagnetic interference (EMI) emitting from a telephone does adversely affect an implanted ICD, moving the telephone away from the immediate vicinity of the ICD should restore normal operation. A recommendation to address every specific interaction of EMI with implanted ICDs is not possible due to the disparate nature of EMI.
- **Electronic Article Surveillance (EAS)** - equipment such as retail theft prevention systems may interact with pulse generators. Patients should be advised to walk directly through and not to remain near an EAS system longer than necessary.
- **Home Appliances** - Home appliances normally do not affect ICD operation if the appliances are in proper working condition and correctly grounded and shielded. There have been reports of the interaction of electric tools or other external devices (e.g. electric drills, older models of microwave ovens, electric razors, etc.) with ICDs when they are placed in close proximity to the device.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

Alternative therapies for the treatment of life-threatening ventricular arrhythmias as deemed appropriate by the physician are based upon electrophysiology (EP) testing and other diagnostic evaluations. These include the use of antiarrhythmic medication, electrical ablation, cardiac surgery, pacemakers and other commercially available implantable cardioverter defibrillators or a combination thereof.

VII. MARKETING HISTORY

The Phylax ICD System is CE marked and has been commercially distributed in the following countries: Germany, France, Great Britain, Argentina, Australia, Belgium, Brazil, Bulgaria, Chile, China, Israel, Italy, Austria, Poland, Russia, Slovakia, Spain, Czech Republic, Turkey, Hungary, and Switzerland. None of the BIOTRONIK Phylax ICD devices, leads, and programmers has been withdrawn from these markets for any reason.

VIII. ADVERSE EVENTS

Reported Adverse Events

The clinical study involved 155 devices implanted in 154 patients with a cumulative implant duration of 1286 months (mean implant duration 8.3 months). There were a total of five deaths during the course of the trial; none of the deaths were judged by the clinical study investigator to be device related. Heart failure was a major factor in two deaths. The other three deaths were related to renal failure, lung disease, and septic shock secondary to an ischemic bowel, respectively. All five of the deaths occurred more than one month post implant.

Two ICDs were explanted during the trial. One was secondary to the patient being unable to tolerate further testing required by the clinical protocol. The other was secondary to a systemic infection; the patient was subsequently implanted with another device.

Table II below provides a summary of the adverse events that were reported during the clinical study regardless of whether or not the event was related to the ICD system. A complication is defined as a clinical event that results in invasive intervention, injury, or death. An observation is defined as a clinical event that does not result in invasive intervention, injury, or death.

Table II. Reported Adverse Events (AEs)
Number of Patients = 154, Number of Patient-Years = 107.1

	# of pts with AEs	% of pts with AEs	# of AEs	AE/pt- yrs
Complications (total)	7	4.5%	8	0.07
Lead repositioning	2	1.3%	2	0.02
Hematoma	1	0.6%	1	0.01
Systemic infection	1	0.6%	1	0.01
Explant (patient unable to tolerate required testing)	1	0.6%	1	0.01
Insertion of separate rate-sensing lead system	1	0.6%	2	0.02
ICD/lead connection	1	0.6%	1	0.01
Observations (total)	79	51.3%	89	0.83
Inappropriate therapy (SVT)	18	11.7%	20	0.19
ICD response to magnet in programming wand ¹	13	8.4%	15	0.14
Software messages and errors ²	11	7.1%	13	0.12
Increased pacing threshold	7	4.5%	9	0.08
Decreased R-wave amplitude	7	4.5%	7	0.07
Frequent VT	5	3.2%	5	0.05
Oversensing	3	1.9%	3	0.03
TMS 1000 difficulties ³	3	1.9%	3	0.03
VT below rate cut-off	2	1.3%	3	0.03
High DFT's	1	0.6%	2	0.02
Minor stroke	1	0.6%	1	0.01
Renal failure	1	0.6%	1	0.01
Required additional antiarrhythmic drug therapy	1	0.6%	1	0.01
ICD/lead connection	1	0.6%	1	0.01
ICD therapy during lead connection	1	0.6%	1	0.01
Non-sustained VT	1	0.6%	1	0.01
Non-conversion of arrhythmia	1	0.6%	1	0.01
Interpretation of real-time markers	1	0.6%	1	0.01
Reconfirmation algorithm	1	0.6%	1	0.01

1. This category includes issues related to movement of the programmer wand that caused the reed switch to toggle during high voltage capacitor charging or tachyarrhythmia detection. As a result, appropriate therapy was not delivered in a timely manner. The orientation of the reed switch was optimized and is being monitored as part of the manufacturing process to prevent future occurrences of this type of event.
2. This category includes various software “bugs” that were related to error messages or the retrieval of diagnostic information. Each of these events has been resolved through revisions made to the software.
3. This category includes any difficulties encountered while using the TMS 1000 Tachyarrhythmia Monitoring System. Each of these events has been resolved through revisions to the software and hardware of the system.

Potential Adverse Events

Adverse events (in alphabetical order) associated with ICD systems include the following:

- Acceleration of arrhythmias (caused by device)
- Air embolism
- Bleeding
- Chronic nerve damage
- Erosion
- Excessive fibrotic tissue growth
- Extrusion
- Fluid accumulation
- Formation of hematomas or cysts
- Inappropriate shocks
- Infection
- Keloid formation
- Lead abrasion and discontinuity
- Lead migration/dislodgment
- Myocardial damage
- Pneumothorax
- Shunting current or insulating myocardium during defibrillation with internal or external paddles
- Potential mortality due to inability to defibrillate or pace
- Thromboemboli
- Venous occlusion
- Venous or cardiac perforation

Patients susceptible to frequent shocks despite antiarrhythmic medical management may develop psychological intolerance to an ICD system that may include the following:

- Dependency
- Depression
- Fear of premature battery depletion
- Fear of shocking while conscious
- Fear that shocking capability may be lost
- Imagined shocking (phantom shock)

IX. SUMMARY OF PRE-CLINICAL STUDIES

The following table (Table III) summarizes the validation testing (safety and performance) conducted on components and subassemblies of the BIOTRONIK Phylax ICD System, including testing of finished devices, packaging and shipping tests. Validation testing was performed to European, International or National standards, or BIOTRONIK specifications. In addition, biocompatibility testing and animal studies were also conducted. In the table below, "Pass" denotes that the test results met the company's device specifications.

Table III. Summary of Hardware and Software Tests, Biocompatibility, and Animal Studies

Test Performed	Sample Size	Test Results (pass/fail)
ICD Components		
Batteries		
Temperature Shock, Behavior vs. Temperature, Low and High Temperature Storage, Short-circuit Stability, Puncture, Compression, Charging, Temperature/Humidity	5 of each type	Pass
Mechanical Shock, Vibration, Pressure Stability, Vacuum Stability, High Temperature, Accelerated Pulse, Destructive Analysis	5 to 10 of each type	Pass
Rapid Discharge	2 of each type	Pass
High Voltage Capacitors		
2000 Charge/Discharge Cycles, Breakdown Voltage	4 to 8 of each type	Pass
Formation Behavior, Vacuum Stress, Continuous Operation at Rated Voltage, Pressure, Temperature Storage, Temperature Storage at Rated Voltage.	8 to 20 of each type	Pass
Solderability, Hot Solder, Humidity Storage, Temperature Cycle	5 to 10 of each type	Pass
Residual Gas Analysis	1 of each type	Pass
Electronic Modules – Control Hybrids + Flex Circuits		
Temperature Cycle, 1000 hour Life Testing at 125C	22 for original design, 5 with circuit modification	Pass
Generation of 1000 high energy shocks, adhesion of internal connector pins	5 of each type	Pass
Adhesion of Components and Bond Wires	2 of each type	Pass
Control Hybrids		
Constant Acceleration at 2000g, Pin bending Stress, Vibration, Mechanical Shock,	5	Pass
Flex Circuits		
Temperature Cycle	10	Pass
Flex Testing, Die Shear, Wire Bond Pull	5	Pass
Headers		
Mechanical Shock, Vibration, Temperature Cycle, Lead Retention with a Tightened Setscrew,	4 to 6	Pass

Test Performed	Sample Size	Test Results (pass/fail)
2000 Hour in vitro	3	Pass
Dimensional Verification, Header Shear, Temperature Shock, High Voltage Isolation during 5000 hours of in vitro exposure	9 to 11	Pass
42 amp Current Load, Ultrasound exposure	1	Pass
Embedded Software		
Source Code Verification, Binary Code Comparison, Detection, Therapy, Redetection, ERI/EOS Behavior, Holter and Memory Functions, Pace/Sense Counter, Emergency Shock, Shock Cap Formation, Induction Verification, Functional Testing	Current Version of Embedded Software	Pass
EMC (Electromagnetic Compatibility) Testing		
Defibrillation Resistance, Resistance to HF-Surgery Equipment	5	Pass
Exposure to Unmodulated EMI	2	Pass
Exposure to Modulated EMI	1	Pass
Exposure to HF-Surgery Equipment	4	Pass
Programming Behavior during EMI	1	Pass
Resistance to Interference from Cellular Telephones (850 to 2500Mhz, 79 to 1100 Mhz and NADC=TDMA-11)	1	Pass
Defibrillation Resistance, Resistance to HF-Surgery Equipment	5	Pass
Finished Device		
Device Protection in Shipping Container, Helium Leakage, Label Adhesion	10	Pass
Sterility Confirmation, EtO Residual Gas Analysis, Wipe Test of Labels, Defibrillation Resistance, Electrical Neutrality, IEGM Transmission Bandwidth, IEGM Amplification, IEGM Noise Suppression, Lead Retention Force, Electrode Deformation, Header Shear	5 of each type	Pass
Microbial Impermeability, Mechanical Shock, ESD Exposure	2 to 3 of each type	Pass
Transportation Test, Vibration, Temperature Cycle, 2000 Hour in vitro, Temperature Shock, Packaging	3 to 6 of each type	Pass
Safety Tests of Injected Currents, Exposure to Static Magnetic Fields, Noise Mode Switching, AC Leakage during Shock Charging, High Rate Protection, Internal Circuit Protection during Shocks, Input Impedance, Input Filter Characteristics, Pulse Behavior as a Function of Load, Battery Voltage and Temperature, Refractory Period Response, Synchronization Response, Functional Test at Operating Voltage and Temperature Minimums, Magnet Effect, Programmability during Internal and External Influences, Programmability at various Battery Voltages, Influence of Non-BIOTRONIK Programmers, Latch-up Resistance, Turn-on Behavior, Influence of Alternating Magnetic Fields, Application of Electrocautery in Saline, Sensitivity, Crosstalk Analysis, Operating Voltage Measurements, Battery Management, Exposure to Diagnostic Ultrasound, Device Warming during Shock Release	1 of each type	Pass
Visual Inspection, Determination of Programming and Interrogation Distances	4 to 10 of each type	Pass

Test Performed	Sample Size	Test Results (pass/fail)
ICD Lead Testing		
Styler Insertion/Extraction, Thermal Shock, Resistance to Damage from Temperature Changes, Bending Endurance Testing, Abrasion Testing, Silicone Tubing Burst Pressure, Weld and Crimp Connection Tensile Testing, Tensile Test of Shock Coils, 2000 hour in vitro with Impedance Measurements, DC Resistance, Impedance, Current Spike, Dimensional, Insulation Strength, Tensile Loading, Insertion/Extraction Force, Extraction Force with Tightened Setscrew, Connector Pin Deformation	2 to 10 of each type	Pass
Device Packaging (ICDs and Leads)		
Packaging Conformity, Blister Seal Integrity	10 to 15	Pass
Visual, Mechanical and Electrical Testing prior to and following exposure to 60 month accelerated storage conditions	5	Pass
TMS 1000 Programmer		
Safety Testing		
Leakage Currents, Separation Of Internal Components, Residual Voltage And Energy, Electrical Neutrality, Ground Lead Control, External Device Temperature, Protection Against Unmodulated EMI, Resistance against HF Surgery Devices, Pacing Function in the Presence of Interference Signals from HF Surgery, Application of Electrocautery in Saline, High Rate Protection, Defibrillation Strength, Resistance to Defibrillation, ESD Resistance, Demodulation Response, User Contact with Patient Cable and Adapter, Noise	1	Pass
Environmental Testing		
Voltage Stability, Humidity, Wipe-Proof Labeling, Conformance to Standards, EMC Testing, Monitoring of Modulated EMI, Protection against Injected Currents, Drop Test, Handle Load Capacity, Housing Stability under Load, Mechanical Shock of Housing, Transportation Test, AC-Voltage	1	Pass
Functional Testing		
Input Impedance, Power Consumption, ECG Gain Stability, Crosstalk Response, Input Dynamic Range, Timebase Accuracy, Frequency and Impulse Response, Hysteresis, Common Mode Rejection, Channel Cross Talk, Reset, Baseline Stability, Operational Response of the TMS 1000 at Maximum Power Consumption	1	Pass
Biocompatibility (ICDs and Leads)		
Cytotoxicity, Sensitization, Irritation/Intracutaneous Reactivity, Systemic Toxicity, Subchronic Toxicity, Genotoxicity	Various	Pass
Animal Studies		
Canine – Fractal Surface Treatment		
Chronic implantation of BIOTRONIK leads with fractal surface treatment to determine their stability, electrochemical and	Ten dogs	Pass

Test Performed	Sample Size	Test Results (pass/fail)
corrosion resistance.		
Porcine – ICD Lead Functionality		
Chronic implantation of BIOTRONIK ICD leads to determine functionality, stability, electrochemical and corrosion resistance.	Six swine	Pass
Canine – Phylax XM Replacement ICD Sensing		
Acute implantation of BIOTRONIK ICD and competitor’s leads to determine functionality, stability, electrochemical and corrosion resistance.	One dog	Pass

Bench Testing

Bench testing of BIOTRONIK’s ICDs, ICD Leads and the TMS 1000 Tachyarrhythmia Monitoring System, as detailed above, has been successfully completed.

Biocompatibility (ICDs and Leads)

All tissue-contacting materials of BIOTRONIK’s ICDs and ICD Leads are currently utilized in BIOTRONIK market-released products in the US. Biocompatibility testing of all tissue-contacting materials utilized in BIOTRONIK’s ICDs and ICD Leads has been successfully completed.

Animal Studies

Canine Studies - Ten dogs were chronically implanted with BIOTRONIK pulse generators and three different configurations of pacing leads. The study assessed the electrical performance, biocompatibility, and biostability, including corrosion resistance, of endocardial leads with fractal iridium surface structured electrodes. Electrochemical and corrosion resistance analysis results indicated that fractal iridium structured electrode surfaces are stable against any measurable corrosion attack when electrically stressed and chronically implanted.

Porcine Study - A chronic animal study was performed in order to assess the safety of the BIOTRONIK’s ICD leads under in vivo conditions. The test animals were implanted, tested acutely, and re-evaluated at one, two, and three months into the study. Histological examination and pathology evaluation were performed. The results demonstrated lead material stability and function in a chronic in-vivo environment.

Canine Study (Replacement Header) - Sensing and pacing characteristics of specific lead systems were performed to evaluate the function of the Phylax XM Replacement ICD with the implanted lead systems. The results demonstrated appropriate compatibility of the Phylax Replacement ICD in each of the types of lead systems tested.

X. CLINICAL STUDIES

Two separate IDE clinical investigations were conducted in support of this PMA application. Both of the studies were similar in nature with identical study design, pre-defined objectives, endpoints, clinical requirements, as well as data collection and analyses methods. The studies differed in the types of lead systems included; due to the similarities in patient populations, therapy provided, and study endpoints, the data were pooled for the following analysis.

The multicenter studies were prospective, non-randomized clinical trials. Sample size justification was based on the primary endpoint, tachyarrhythmia conversion efficacy. Each outcome was classified as a success (tachyarrhythmia converted) or as a failure (tachyarrhythmia not converted). From these data, a conversion efficacy rate was estimated as: Conversion Efficacy = total number of successes / total number of trials.

Patients Studied. The clinical investigations involved 154 patients (121 male and 33 female) with a mean age of 64.9 years (range: 26 to 95 years) and a mean left ventricular ejection fraction of 33% (range: 10% to 80%). Most (72%) presented with coronary artery disease/ischemic cardiomyopathy; 71% presented with monomorphic ventricular tachycardia (MVT) as their primary tachyarrhythmia.

Methods. The multicenter clinical investigation was designed to validate the safety and effectiveness of the ICD System to detect and treat monomorphic ventricular tachycardia (MVT), polymorphic ventricular tachycardia (PVT), ventricular fibrillation (VF), and bradycardia. The specific predefined objectives of the investigation included the determination of ventricular tachyarrhythmia conversion rate, sudden cardiac death (SCD) survival rate, morbidity rate, and the appropriate sensing and pacing rate.

Primary Endpoint. The primary endpoint of the study was to evaluate the ventricular tachyarrhythmia conversion rate. Patients underwent standard ICD implantation and then were evaluated at pre-discharge and regular follow-up visits every three months. Induction and conversion of the patient's tachyarrhythmias were required at the implant procedure and pre-discharge follow-up.

Results. The mean implant duration was 8.3 ± 0.4 months with a cumulative implant duration of 1286 months. There were 39 patients followed for over twelve months and 108 patients followed for over six months during the study period between March 11, 1997 to July 17, 1998. The patient follow-up compliance rate was 99.6% out of 473 follow-up procedures. Table IV below provides a summary of the results of the study.

Gender Analyses were performed to observe any outcome differences between males and females. The first type of analysis compared enrollment by patient gender to other clinical studies; the enrollment in the IDE clinical investigations was consistent with other similar clinical studies. The second type of analysis compared the safety and effectiveness in each gender. Statistically significant differences between males and females were found in two of the six endpoints. Additional analyses were completed that suggested that the arrhythmia treated and anti-arrhythmic medication may account for these gender differences.

Table IV. Clinical Study Results

Description	Study Group [95% CI]
Tachyarrhythmia Conversion Rate¹	
Induced	95.8% (496/518) [93.6%, 97.3%]
Spontaneous	99.7% (1540/1544) [99.3%, 99.9%]
Total	98.7% (2036/2062) [98.2%, 99.2%]
Sudden Cardiac Death Survival (at one year)	100.0% (39/39) [91.0%, 100.0%]
Complication Rate (per total number of patients)	5.2% (8/154) [2.3%, 10.0%]
Appropriate Sensing and Pacing Rate²	98.0% (703/717) [96.8%, 98.9%]

1. Conversion data were collected in the clinical study for both induced and spontaneous tachyarrhythmia episodes. Therefore, both types of tachyarrhythmia episodes were included in the analysis.
2. The investigator determined the appropriateness of bradycardia sensing and pacing. The rate will be determined by the number of appropriate bradycardia sensing and pacing evaluations divided by the total number of evaluations.

XI. CONCLUSIONS DRAWN FROM THE STUDIES

In-vitro testing included component, device, and system level tests. These tests were performed extensively in conformance to various established industry consensus standards. Biocompatibility testing of all tissue-contacting materials utilized in BIOTRONIK's ICDs and ICD Leads has also been performed. The multi-center clinical investigation evaluated the safety and effectiveness of the Phylax ICD System to detect and treat monomorphic ventricular tachycardia (MVT), polymorphic ventricular tachycardia (PVT), ventricular fibrillation (VF), and bradycardia. The in-vitro testing, animal testing, and clinical studies provide reasonable assurance that the Phylax ICD system is safe and effective, when used as indicated in the labeling.

XII. PANEL RECOMMENDATION

Pursuant to the provisions of section 515(c)(2) of the Food, Drug and Cosmetic Act (FD&C) as amended by the Safe Medical Devices Act of 1990 (SMDA 1990), this PMA application was not referred to the Circulatory System Devices Panel, an FDA advisory

panel committee, for review and recommendation because the information in the PMA application substantially duplicates information previously reviewed by this panel.

XIII. FDA DECISION

Based on the reviews of the original PMA application and its amendments, FDA determined that the device provides reasonable assurance of safety and effectiveness when used as indicated in the labeling. FDA found BIOTRONIK, Inc.'s manufacturing facility to be in compliance with the Device Good Manufacturing Practices regulation (21 CFR part 820).

XIV. APPROVAL SPECIFICATIONS

Directions for use: See the labeling.

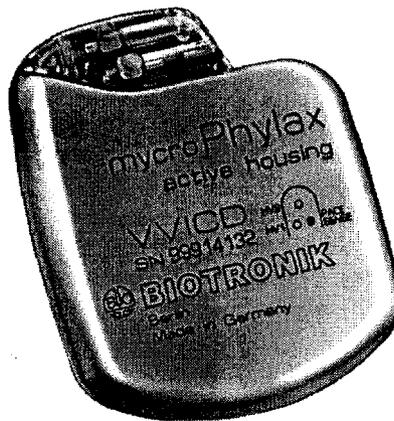
Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions and Adverse Events in the labeling.

Post-approval Requirements and Restrictions: See approval order.

The Approval Order, Summary of Safety and Effectiveness Data, and labeling can be found on the Internet at <http://www.fda.gov/cdrh/pmapage.html>.

mycroPhylax

Implantable Cardioverter Defibrillator



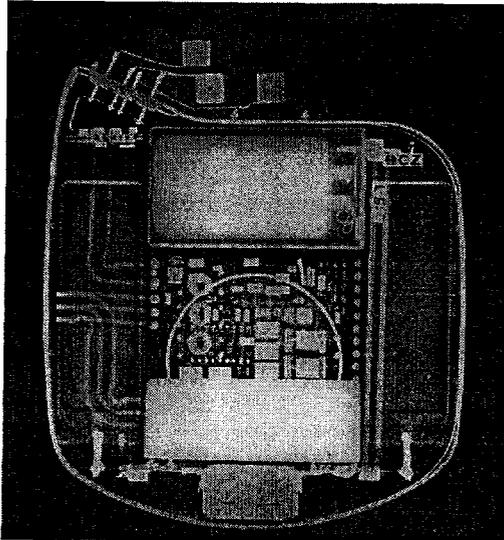
Technical Manual

 **BIOTRONIK**

mycroPhylax
Implantable Cardioverter Defibrillator

X-Ray identification
inside the housing, top right-hand side:

X-Ray identification
Year of manufacture



CAUTION

Federal (U.S.A.) law restricts this device to sale by, or on the order of, a physician.

©1998 BIOTRONIK, Inc., all rights reserved.

1. General

1.1 Description

The mycroPhylax is a single-chamber implantable cardioverter defibrillator used to detect and treat ventricular tachyarrhythmias and to provide bradycardia pacing support. The various programmable parameters of the ICD may be optimized to meet the specific needs of each individual patient. In response to a detected tachyarrhythmia, the ICD is capable of delivering antitachycardia pacing (ATP) as well as cardioversion and defibrillation shock therapy. The ICD may also be used to collect diagnostic data to aid the physician's assessment of a patient's condition and the response of the implanted device.

The mycroPhylax has two DF-1 and one IS-1 header ports. IS-1 refers to the international standard whereby leads and generators from different manufacturers are assured a basic fit [Reference ISO 5841-3:1992]. DF-1 refers to the international standard for defibrillation lead connectors [Reference ISO 11318:1993].

1.2 Indications and Usage

The microPhylax is indicated for use in patients who are at high risk of sudden death due to ventricular arrhythmias and have experienced one of the following situations:

- survival of at least one episode of cardiac arrest (manifested by a loss of consciousness) due to a ventricular tachyarrhythmia
- recurrent, poorly tolerated sustained ventricular tachycardia (VT)

NOTE:

The clinical outcome for hemodynamically stable VT patients is not fully known. Safety and effectiveness studies for this indication have not been conducted.

1.3 Contraindications

Do not use the microPhylax in:

- Patients whose ventricular tachyarrhythmias may have transient or reversible causes such as:
 - acute myocardial infarction
 - digitalis intoxication
 - drowning
 - electrocution
 - electrolyte imbalance
 - hypoxia
 - sepsis
- Patients with incessant VT or VF
- Patients who have a unipolar pacemaker
- Patients whose only disorder is bradyarrhythmias or atrial arrhythmias

1.4 Warnings and Precautions

- **MRI (Magnetic Resonance Imaging)** - Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient.
- **Electrical Isolation** - Electrically isolate the patient from potentially hazardous leakage current to prevent inadvertent arrhythmia induction.
- **Lead Systems** - The use of another manufacturer's ICD lead system may cause potential adverse consequences such as undersensing of cardiac activity and failure to deliver necessary therapy.
- **Resuscitation Availability** - In order to implant the ICD system, it is necessary to induce and convert the patient's ventricular tachyarrhythmias. Do not perform induction testing unless an alternate source of patient defibrillation such as an external defibrillator is readily available.
- **Unwanted Shocks** - Prior to handling the device during the implant procedure, program the detection status of the device to OFF to prevent the delivery of unwanted shocks to the patient or the person handling the device.

1.4.1 Sterilization, Storage, and Handling

- **Device Packaging** - Do not use the device if the device's packaging is wet, punctured, opened or damaged because the integrity of the sterile packaging may be compromised. Return the device to BIOTRONIK.
- **Resterilization** - Do not resterilize and re-implant explanted devices.
- **Storage (temperature)** - Store the device between 5° to 55°C (41° - 131° F) because temperatures outside this range could damage the device.
- **Storage (magnets)** - Store the device in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference (EMI) to avoid damage to the device.

- **Temperature Stabilization** - Allow the device to reach room temperature before programming or implanting the device because temperature extremes may affect initial device function.
- **Use Before Date** - Do not implant the device after the USE BEFORE DATE because the device may have reduced longevity.

1.4.2 Implantation and Programming

- **Blind Plug** - A blind plug must be inserted and firmly connected into any unused header port to prevent chronic fluid influx and possible shunting of high energy therapy.
- **Capacitor Reformation** - Infrequent charging of the high voltage capacitors may extend the charge times of the ICD. The capacitors may be reformed manually, or the ICD may be programmed to reform the capacitors automatically. For further information, please refer to Section 2.8.3 Capacitor Reforming.
- **Connector Compatibility** - ICD and lead system compatibility should be confirmed prior to the implant procedure. Consult your BIOTRONIK representative regarding lead/pulse generator compatibility prior to the implantation of an ICD system. For further information, please refer to Appendix A.
- **ERI (Elective Replacement Indicator)** - Upon reaching ERI, the battery has sufficient energy remaining to continue monitoring for at least three months and to deliver a minimum of six 30 joule shocks. After this period, all tachyarrhythmia detection and therapy is disabled.
- **Magnets** - Positioning of a magnet or the programming wand over the ICD will suspend tachycardia detection and treatment.
- **Pacemaker/ICD Interaction** - In situations where an ICD and a pacemaker are implanted in the same patient, interaction testing should be completed. If the interaction between the ICD and the pacemaker cannot be resolved through repositioning of the leads or reprogramming of either

the pacemaker or the ICD, the pacemaker should not be implanted (or explanted if previously implanted).

- **Programmed Parameters** – Program the device parameters to appropriate values based on the patient's specific arrhythmias and condition.
- **Programmings** - Use only BIOTRONIK programmers to communicate with the device.
- **Sealing System** - Failure to properly insert the torque wrench into the perforation at an angle perpendicular to the connector receptacle may result in damage to the sealing system and its self-sealing properties.
- **Shock Impedance** - Never implant the device with a lead system that has a measured shock impedance of less than thirty ohms. Damage to the device may result. If the shock impedance is less than thirty ohms, reposition the lead system to allow a greater distance between the electrodes.

1.4.3 Lead Evaluation and Connection

- **Capping Leads** - If a lead is abandoned rather than removed, it must be capped to ensure that it is not a pathway for currents to or from the heart.
- **Gripping Leads** - Do not grip the lead with surgical instruments or use excessive force or surgical instruments to insert a stylet into a lead.
- **Kinking Leads** - Do not kink leads. This may cause additional stress on the leads that can result in damage to the lead.
- **Liquid Immersion** - Do not immerse leads in mineral oil, silicone oil, or any other liquid.
- **Short Circuit** - Ensure that none of the lead electrodes are in contact (a short circuit) during delivery of shock therapy as this may cause current to bypass the heart or cause damage to the ICD system.
- **Suturing Leads** - Do not suture directly over the lead body as this may cause structural damage. Use the appropriate

suture sleeve to immobilize the lead and protect it against damage from ligatures.

- **Tricuspid Valve Bioprosthesis** - Use ventricular transvenous leads with caution in patients with a tricuspid valvular bioprosthesis.

1.4.4 Follow-up Testing

- **Defibrillation Threshold** - Be aware that the changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT) which may result in nonconversion of the arrhythmia post-operatively. Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post operatively
- **Resuscitation Availability** - Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing should the patient require external rescue.

1.4.5 Pulse Generator Explant and Disposal

- **Device Incineration** - Never incinerate the ICD due to the potential for explosion. The ICD must be explanted prior to cremation.
- **Explanted Devices** - Return all explanted devices to BIOTRONIK.
- **Unwanted Shocks** - Prior to explanting the ICD, program the detection status of the device to OFF to prevent unwanted shocks.

1.4.6 Hospital and Medical Hazards

Electromagnetic interference (EMI) signals present in hospital and medical environments may affect the function of any ICD or pacemaker. The ICD is designed to selectively filter out EMI noise. However, due to the variety of EMI signals, absolute protection from EMI is not possible with this or any other ICD.

- **Diathermy** - Diathermy therapy is not recommended for ICD patients due to possible heating effects of the pulse generator and at the implant site. If diathermy therapy must be used, it should not be applied in the immediate vicinity of the pulse generator or lead system. Following the procedure, proper ICD function should be checked and monitored.
- **Electrocautery** - Electrosurgical cautery could induce ventricular arrhythmias and/or fibrillation, or may cause device malfunction or damage. If use of electrocautery is necessary, the current path and ground plate should be kept as far away from the pulse generator and leads as possible.
- **External Defibrillation** - The device is protected against energy normally encountered from external defibrillation. However, any implanted device may be damaged by external defibrillation procedures. In addition, external defibrillation may also result in permanent myocardial damage at the electrode-tissue interface as well as temporary or permanent elevated pacing thresholds. When possible, observe the following precautions:
 - Position the adhesive electrodes or defibrillation paddles of the external defibrillator anterior-posterior or along a line perpendicular to the axis formed by the implanted device and the heart.
 - Set the energy to a level not higher than is required to achieve defibrillation.
 - Place the paddles as far as possible away from the implanted device and lead system.
 - After delivery of an external defibrillation shock, interrogate the ICD to confirm device status and proper function.

- **Lithotripsy** - Lithotripsy may damage the ICD. If lithotripsy must be used, avoid focusing near the ICD implant site. Following the procedure, proper ICD function should be checked and monitored.
- **MRI (Magnetic Resonance Imaging)** - Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient.
- **Radiation** - High radiation sources such as cobalt 60 or gamma radiation should not be directed at the pulse generator. If a patient requires radiation therapy in the vicinity of the pulse generator, place lead shielding over the device to prevent radiation damage and confirm its function after treatment.
- **Radio Frequency Ablation** - Prior to performing an ablation procedure, deactivate the ICD. Avoid applying ablation energy near the implanted lead system whenever possible. The ICD system should be checked for proper operation after the procedure.

1.4.7 Home and Occupational Hazards

Patients should be directed to avoid devices that generate strong electromagnetic interference (EMI). EMI could cause device malfunction or damage resulting in non-detection or delivery of unneeded therapy. Moving away from the source or turning it off will usually allow the ICD to return to its normal mode of operation.

The following equipment (and similar devices) may affect normal ICD operation: electric arc or resistance welders, electric melting furnaces, radio/television and radar transmitters, power-generating facilities, high-voltage transmission lines, and electrical ignition systems (of gasoline-powered devices) if protective hoods, shrouds, etc., are removed.

- **Cellular Phones** - Testing has indicated there may be a potential interaction between cellular phones and BIOTRONIK ICD systems. Potential effects may be due to either the cellular phone signal or the magnet within the telephone and may include inhibition of therapy when the

telephone is within 6 inches (15 centimeters) of the ICD, when the ICD is programmed to standard sensitivity.

Patients having an implanted BIOTRONIK ICD who operate a cellular telephone should:

- Maintain a minimum separation of 6 inches (15 centimeters) between a hand-held personal cellular telephone and the implanted device.
- Set the telephone to the lowest available power setting, if possible.
- Patients should hold the phone to the ear opposite the side of the implanted device. Patients should not carry the telephone in a breast pocket or on a belt over or within 6 inches (15 centimeters) of the implanted device as some telephones emit signals when they are turned ON, but not in use (i.e., in the listen or stand-by mode). Store the telephone in a location opposite the side of implant.

Based on results to date, adverse effects resulting from interactions between cellular telephones and implanted ICDs have been transitory. If electromagnetic interference (EMI) emitting from a telephone does adversely affect an implanted ICD, moving the telephone away from the immediate vicinity of the ICD should restore normal operation. A recommendation to address every specific interaction of EMI with implanted ICDs is not possible due to the disparate nature of EMI.

- **Electronic Article Surveillance (EAS)** - equipment such as retail theft prevention systems may interact with pulse generators. Patients should be advised to walk directly through and not to remain near an EAS system longer than necessary.
- **Home Appliances** - Home appliances normally do not affect ICD operation if the appliances are in proper working condition and correctly grounded and shielded. There have been reports of the interaction of electric tools or other external devices (e.g. electric drills, older models of

microwave ovens, electric razors, etc.) with ICDs when they are placed in close proximity to the device.

1.5 Adverse Events

1.5.1 Observed Adverse Events

The clinical study involved 155 devices implanted in 154 patients with a cumulative implant duration of 1286 months (mean implant duration 8.3 months).

There were a total of five deaths during the course of the trial; none of the deaths were judged by the clinical study investigator to be device related. Heart failure was a major factor in two deaths. The other three deaths were related to renal failure, lung disease, and septic shock secondary to an ischemic bowel, respectively. All five of the deaths occurred more than one month post implant.

Two ICDs were explanted during the trial. One was secondary to the patient being unable to tolerate further testing required by the clinical protocol. The other was secondary to a systemic infection; the patient was subsequently implanted with another device.

Table 1 provides a summary of the adverse events that were reported during the clinical study regardless of whether or not the event was related to the ICD system. A complication is defined as a clinical event that results in invasive intervention, injury, or death. An observation is defined as a clinical event that does not result in invasive intervention, injury, or death.

Table 1 Reported Adverse Events (AEs)

Number of Patients = 154, Number of Patient-Years = 107.1

	# of pts with AEs	% of pts with AEs	# of AEs	AE/pt-yrs
Complications (total)	7	4.5%	8	0.07
Lead repositioning	2	1.3%	2	0.02
Hematoma	1	0.6%	1	0.01
Systemic infection	1	0.6%	1	0.01
Explant (patient unable to tolerate required testing)	1	0.6%	1	0.01
Insertion of separate rate-sensing lead system	1	0.6%	2	0.02
ICD/lead connection	1	0.6%	1	0.01
Observations (total)	79	51.3%	89	0.83
Inappropriate therapy (SVT)	18	11.7%	20	0.19
ICD response to magnet in programming wand ¹	13	8.4%	15	0.14
Software messages and errors ²	11	7.1%	13	0.12
Increased pacing threshold	7	4.5%	9	0.08
Decreased R-wave amplitude	7	4.5%	7	0.07
Frequent VT	5	3.2%	5	0.05
Oversensing	3	1.9%	3	0.03
TMS 1000 difficulties ³	3	1.9%	3	0.03
VT below rate cut-off	2	1.3%	3	0.03
High DFT's	1	0.6%	2	0.02
Minor stroke	1	0.6%	1	0.01
Renal failure	1	0.6%	1	0.01
Required additional antiarrhythmic drug therapy	1	0.6%	1	0.01
ICD/lead connection	1	0.6%	1	0.01
ICD therapy during lead connection	1	0.6%	1	0.01
Non-sustained VT	1	0.6%	1	0.01
Non-conversion of arrhythmia	1	0.6%	1	0.01
Interpretation of real-time markers	1	0.6%	1	0.01
Reconfirmation algorithm	1	0.6%	1	0.01

1. This category includes issues related to movement of the programmer wand that caused the reed switch to toggle during high voltage capacitor charging or tachyarrhythmia detection. As a result, appropriate therapy was not delivered in a timely manner. The orientation of the reed switch was optimized and is being monitored as part of the manufacturing process to prevent future occurrences of this type of event.
2. This category includes various software "bugs" that were related to error messages or the retrieval of diagnostic information. Each of these events has been resolved through revisions made to the software.
3. This category includes any difficulties encountered while using the TMS 1000 Tachyarrhythmia Monitoring System. Each of these events has been resolved through revisions to the software and hardware of the system.

1.5.2 Potential Adverse Events

Adverse events (in alphabetical order) associated with ICD systems include:

- Acceleration of arrhythmias (caused by device)
- Air embolism
- Bleeding
- Chronic nerve damage
- Erosion
- Excessive fibrotic tissue growth
- Extrusion
- Fluid accumulation
- Formation of hematomas or cysts
- Inappropriate shocks
- Infection
- Keloid formation

- Lead abrasion and discontinuity
- Lead migration/dislodgment
- Myocardial damage
- Pneumothorax
- Shunting current or insulating myocardium during defibrillation with internal or external paddles
- Potential mortality due to inability to defibrillate or pace
- Thromboemboli
- Venous occlusion
- Venous or cardiac perforation

Patients susceptible to frequent shocks despite antiarrhythmic medical management may develop psychological intolerance to an ICD system that may include the following:

- Dependency
- Depression
- Fear of premature battery depletion
- Fear of shocking while conscious
- Fear that shocking capability may be lost
- Imagined shocking (phantom shock)

1.6 Clinical Studies

1.6.1 Patients Studied

The clinical study involved 154 patients (121 male and 33 female) with a mean age of 64.9 years (range: 26 to 95 years) and a left ventricular ejection fraction of 33% (range: 10% to 80%). Most (72%) presented with coronary artery disease / ischemic cardiomyopathy; 71% presented with monomorphic ventricular tachycardia (MVT) as their primary tachyarrhythmia. The clinical study was performed on the Phylax XM ICD and is applicable because the mycroPhylax is simply a downsized version of the Phylax XM.

1.6.2 Methods

The multicenter clinical investigation was designed to validate the safety and effectiveness of the ICD System to detect and treat monomorphic ventricular tachycardia (MVT), polymorphic ventricular tachycardia (PVT), ventricular fibrillation (VF), and bradycardia. The specific predefined objectives of the investigation included the determination of ventricular tachyarrhythmia conversion rate, sudden cardiac death (SCD) survival rate, morbidity rate, and the appropriate sensing and pacing rate.

The primary endpoint of the study was to evaluate the ventricular tachyarrhythmia conversion rate. Patients underwent standard ICD implantation and then were evaluated at predischarge and regular follow-ups every three months. Induction and conversion of the patient's tachyarrhythmias was required at the implant procedure and predischarge follow-up.

1.6.3 Results

The mean implant duration was 8.3 ± 0.4 months with a cumulative implant duration of 1286 months. There were 39 patients followed for over twelve months and 108 patients followed for over six months. The patient follow-up compliance rate was 99.6% out of 473 follow-up procedures. Table 2 provides a summary of the results of the study group for the predefined endpoints.

Table 2 Clinical Study Results

Description	Study Group [95% CI]
Tachyarrhythmia Conversion Rate ¹	
Induced	95.8% (496/518) [93.6%, 97.3%]
Spontaneous	99.7% (1540/1544) [99.3%, 99.9%]
Total	98.7% (2036/2062) [98.2%, 99.2%]
Sudden Cardiac Death Survival (at one year)	100.0% (39/39) [91.0%, 100.0%]
Complication Rate (per total number of patients)	5.2% (8/154) [2.3%, 10.0%]
Appropriate Sensing and Pacing Rate ²	98.0% (703/717) [96.8%, 98.9%]

1. Conversion data were collected in the clinical study for both induced and spontaneous tachyarrhythmia episodes. Therefore, both types of tachyarrhythmia episodes were included in the analysis.
2. The investigator determined the appropriateness of bradycardia sensing and pacing. The rate will be determined by the number of appropriate bradycardia sensing and pacing evaluations divided by the total number of evaluations.

1.7 Patient Selection and Treatment

1.7.1 Individualization of Treatment

- Determine whether the expected device benefits outweigh the possibility of early device replacement for patients whose ventricular tachyarrhythmias require frequent shocks.
- Determine if the device and programmable options are appropriate for patients with drug-resistant supraventricular tachyarrhythmias (SVTs), because drug-resistant SVTs can initiate unwanted device therapy.

- Direct any questions regarding individualization of patient therapy to your BIOTRONIK representative or BIOTRONIK technical services at 1-800-547-0394.

The prospective patient's size and activity level should be evaluated to determine whether a pectoral or abdominal implant is suitable. It is strongly recommended that candidates for an ICD have a complete cardiac evaluation including EP testing prior to device implant to gather electrophysiologic information, including the rates and classifications of all the patient's cardiac rhythms. When gathering this information, delineate all clinically significant ventricular and atrial arrhythmias, whether they occur spontaneously or during EP testing.

If the patient's condition permits, use exercise stress testing to do the following:

- Determine the maximum rate of the patient's normal rhythm
- Identify any supraventricular tachyarrhythmias
- Identify exercise-induced tachyarrhythmias

The maximum exercise rate or the presence of supraventricular tachyarrhythmias may influence selection of programmable parameters. Holter monitoring or other extended ECG monitoring also may be helpful.

If the patient is being treated with antiarrhythmic or cardiac drugs, the patient should be on a maintenance drug dose rather than a loading dose at the time of pulse generator implantation. If changes to drug therapy are made, repeated arrhythmia inductions are recommended to verify pulse generator detection and conversion. The pulse generator also may need to be reprogrammed.

Changes in a patient's antiarrhythmic drug or any other medication that affect the patient's normal cardiac rate or conduction can affect the rate of tachyarrhythmias and/or efficacy of therapy.

If another cardiac surgical procedure is performed prior to implanting the pulse generator, it may be preferable to implant

the lead system at that time. This may prevent the need for an additional thoracic operation.

1.7.2 Specific Patient Populations

- **Pregnancy** - If there is a need to image the device, care should be taken to minimize radiation exposure to the fetus and the mother.
- **Nursing Mothers** - Although appropriate biocompatibility testing has been conducted for this implant device, there has been no quantitative assessment of the presence of leachables in breast milk.
- **Geriatric Patients** - Most (72%) of the patients receiving this device in clinical studies were over the age of 60 years (see Clinical Studies).
- **Handicapped and Disabled Patients** - Special care is needed in using this device for patients using electrical wheel chair or other electrical (external or implanted devices).

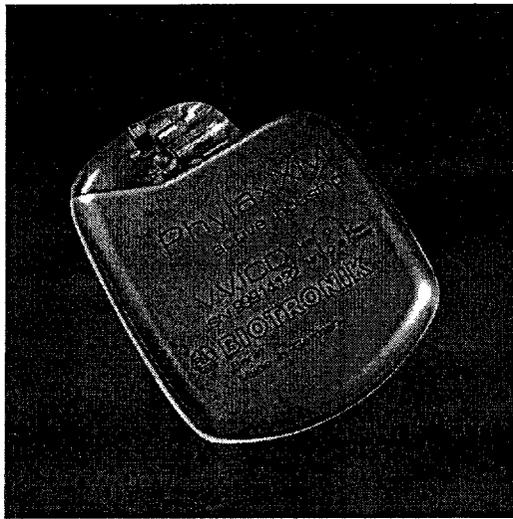
1.8 Patient Counseling Information

- The pulse generator is subject to random component failure. Such failure could cause inappropriate shocks, induction of arrhythmias or inability to sense arrhythmias, and could lead to the patient's death.
- Persons administering CPR may experience the presence of voltage on the patient's body surface (tingling) when the patient's ICD system delivers a shock.

A patient manual is available for the patient, patient's relatives, and other interested people. Discuss the information in the manual with concerned individuals both before and after pulse generator implantation so they are fully familiar with operation of the device. (For additional copies of the patient manual, contact the BIOTRONIK at the address listed in this manual.)

Phylax XM

Implantable Cardioverter Defibrillator



Technical Manual

 **BIOTRONIK**

Phylax XM
Implantable Cardioverter Defibrillator

X-Ray Identification

One of these identification codes is visible on a standard x-ray of the device and uniquely identifies the pulse generator family.



CAUTION

Federal (U.S.A.) law restricts this device to sale by, or on the order of, a physician.

©1998 BIOTRONIK, Inc., all rights reserved.

1. General

1.1 Description

The Phylax XM is a single-chamber implantable cardioverter defibrillator used to detect and treat ventricular tachyarrhythmias and to provide bradycardia pacing support. The various programmable parameters of the ICD may be optimized to meet the specific needs of each individual patient. In response to a detected tachyarrhythmia, the ICD is capable of delivering antitachycardia pacing (ATP) as well as cardioversion and defibrillation shock therapy. The ICD may also be used to collect diagnostic data to aid the physician's assessment of a patient's condition and the response of the implanted device.

The Phylax XM ICD is available in three different models: the Phylax XM, the Phylax XM Active Housing and the Phylax XM Replacement. The Phylax XM has three DF-1 and one IS-1 header ports. The Phylax XM Active Housing has two DF-1 and one IS-1 header ports; this device also uses the outer metallic housing of the ICD as an additional electrode to augment the implanted lead system. The Phylax XM Replacement has two 4.75mm sensing and pacing ports and two 6.1mm cardioversion/defibrillation ports. Each of these devices is identical in all other respects and is referred to, unless otherwise necessary, as the Phylax XM.

IS-1 refers to the international standard whereby leads and generators from different manufacturers are assured a basic fit [Reference ISO 5841-3:1992]. DF-1 refers to the international standard for defibrillation lead connectors [Reference ISO 11318:1993].

1.2 Indications and Usage

The Phylax XM is indicated for use in patients who are at high risk of sudden death due to ventricular arrhythmias and have experienced one of the following situations:

- survival of at least one episode of cardiac arrest (manifested by a loss of consciousness) due to a ventricular tachyarrhythmia
- recurrent, poorly tolerated sustained ventricular tachycardia (VT)

NOTE:

The clinical outcome for hemodynamically stable VT patients is not fully known. Safety and effectiveness studies for this indication have not been conducted.

1.3 Contraindications

Do not use the Phylax XM in:

- Patients whose ventricular tachyarrhythmias may have transient or reversible causes such as:
 - acute myocardial infarction
 - digitalis intoxication
 - drowning
 - electrocution
 - electrolyte imbalance
 - hypoxia
 - sepsis
- Patients with incessant VT or VF
- Patients who have a unipolar pacemaker
- Patients whose only disorder is bradyarrhythmias or atrial arrhythmias

1.4 Warnings and Precautions

- **MRI (Magnetic Resonance Imaging)** - Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient.
- **Electrical Isolation** - Electrically isolate the patient from potentially hazardous leakage current to prevent inadvertent arrhythmia induction.
- **Lead Systems** - The use of another manufacturer's ICD lead system may cause potential adverse consequences such as undersensing of cardiac activity and failure to deliver necessary therapy.
- **Resuscitation Availability** - In order to implant the ICD system, it is necessary to induce and convert the patient's ventricular tachyarrhythmias. Do not perform induction testing unless an alternate source of patient defibrillation such as an external defibrillator is readily available.
- **Unwanted Shocks** - Prior to handling the device during the implant procedure, program the detection status of the device to OFF to prevent the delivery of unwanted shocks to the patient or the person handling the device.

1.4.1 Sterilization, Storage, and Handling

- **Device Packaging** - Do not use the device if the device's packaging is wet, punctured, opened or damaged because the integrity of the sterile packaging may be compromised. Return the device to BIOTRONIK.
- **Resterilization** - Do not resterilize and re-implant explanted devices.
- **Storage (temperature)** - Store the device between 5° to 55°C (41° - 131° F) because temperatures outside this range could damage the device.
- **Storage (magnets)** - Store the device in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference (EMI) to avoid damage to the device.

- **Temperature Stabilization** - Allow the device to reach room temperature before programming or implanting the device because temperature extremes may affect initial device function.
- **Use Before Date** - Do not implant the device after the USE BEFORE DATE because the device may have reduced longevity.

1.4.2 Implantation and Programming

- **Blind Plug** - A blind plug must be inserted and firmly connected into any unused header port to prevent chronic fluid influx and possible shunting of high energy therapy.
- **Capacitor Reformation** - Infrequent charging of the high voltage capacitors may extend the charge times of the ICD. The capacitors may be reformed manually, or the ICD may be programmed to reform the capacitors automatically. For further information, please refer to Section 2.8.3 Capacitor Reforming.
- **Connector Compatibility** - ICD and lead system compatibility should be confirmed prior to the implant procedure. Consult your BIOTRONIK representative regarding lead/pulse generator compatibility prior to the implantation of an ICD system. For further information, please refer to Appendix A.
- **ERI (Elective Replacement Indicator)** - Upon reaching ERI, the battery has sufficient energy remaining to continue monitoring for at least three months and to deliver a minimum of six 30 joule shocks. After this period, all tachyarrhythmia detection and therapy is disabled.
- **Magnets** - Positioning of a magnet or the programming wand over the ICD will suspend tachycardia detection and treatment.
- **Pacemaker/ICD Interaction** - In situations where an ICD and a pacemaker are implanted in the same patient, interaction testing should be completed. If the interaction between the ICD and the pacemaker cannot be resolved through repositioning of the leads or reprogramming of either

the pacemaker or the ICD, the pacemaker should not be implanted (or explanted if previously implanted).

- **Programmed Parameters** – Program the device parameters to appropriate values based on the patient's specific arrhythmias and condition.
- **Programmings** - Use only BIOTRONIK programmers to communicate with the device.
- **Sealing System** - Failure to properly insert the torque wrench into the perforation at an angle perpendicular to the connector receptacle may result in damage to the sealing system and its self-sealing properties.
- **Shock Impedance** - Never implant the device with a lead system that has a measured shock impedance of less than thirty ohms. Damage to the device may result. If the shock impedance is less than thirty ohms, reposition the lead system to allow a greater distance between the electrodes.

1.4.3 Lead Evaluation and Connection

- **Capping Leads** - If a lead is abandoned rather than removed, it must be capped to ensure that it is not a pathway for currents to or from the heart.
- **Gripping Leads** - Do not grip the lead with surgical instruments or use excessive force or surgical instruments to insert a stylet into a lead.
- **Kinking Leads** - Do not kink leads. This may cause additional stress on the leads that can result in damage to the lead.
- **Liquid Immersion** - Do not immerse leads in mineral oil, silicone oil, or any other liquid.
- **Short Circuit** - Ensure that none of the lead electrodes are in contact (a short circuit) during delivery of shock therapy as this may cause current to bypass the heart or cause damage to the ICD system.
- **Suturing Leads** - Do not suture directly over the lead body as this may cause structural damage. Use the appropriate

suture sleeve to immobilize the lead and protect it against damage from ligatures.

- **Tricuspid Valve Bioprosthesis** - Use ventricular transvenous leads with caution in patients with a tricuspid valvular bioprosthesis.

1.4.4 Follow-up Testing

- **Defibrillation Threshold** - Be aware that the changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT) which may result in nonconversion of the arrhythmia post-operatively. Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post operatively
- **Resuscitation Availability** - Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing should the patient require external rescue.

1.4.5 Pulse Generator Explant and Disposal

- **Device Incineration** - Never incinerate the ICD due to the potential for explosion. The ICD must be explanted prior to cremation.
- **Explanted Devices** - Return all explanted devices to BIOTRONIK.
- **Unwanted Shocks** - Prior to explanting the ICD, program the detection status of the device to OFF to prevent unwanted shocks.

1.4.6 Hospital and Medical Hazards

Electromagnetic interference (EMI) signals present in hospital and medical environments may affect the function of any ICD or pacemaker. The ICD is designed to selectively filter out EMI noise. However, due to the variety of EMI signals, absolute protection from EMI is not possible with this or any other ICD.

- **Diathermy** - Diathermy therapy is not recommended for ICD patients due to possible heating effects of the pulse generator and at the implant site. If diathermy therapy must be used, it should not be applied in the immediate vicinity of the pulse generator or lead system. Following the procedure, proper ICD function should be checked and monitored.
- **Electrocautery** - Electrosurgical cautery could induce ventricular arrhythmias and/or fibrillation, or may cause device malfunction or damage. If use of electrocautery is necessary, the current path and ground plate should be kept as far away from the pulse generator and leads as possible.
- **External Defibrillation** - The device is protected against energy normally encountered from external defibrillation. However, any implanted device may be damaged by external defibrillation procedures. In addition, external defibrillation may also result in permanent myocardial damage at the electrode-tissue interface as well as temporary or permanent elevated pacing thresholds. When possible, observe the following precautions:
 - Position the adhesive electrodes or defibrillation paddles of the external defibrillator anterior-posterior or along a line perpendicular to the axis formed by the implanted device and the heart.
 - Set the energy to a level not higher than is required to achieve defibrillation.
 - Place the paddles as far as possible away from the implanted device and lead system.
 - After delivery of an external defibrillation shock, interrogate the ICD to confirm device status and proper function.

- **Lithotripsy** - Lithotripsy may damage the ICD. If lithotripsy must be used, avoid focusing near the ICD implant site. Following the procedure, proper ICD function should be checked and monitored.
- **MRI (Magnetic Resonance Imaging)** - Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient.
- **Radiation** - High radiation sources such as cobalt 60 or gamma radiation should not be directed at the pulse generator. If a patient requires radiation therapy in the vicinity of the pulse generator, place lead shielding over the device to prevent radiation damage and confirm its function after treatment.
- **Radio Frequency Ablation** - Prior to performing an ablation procedure, deactivate the ICD. Avoid applying ablation energy near the implanted lead system whenever possible. The ICD system should be checked for proper operation after the procedure.

1.4.7 Home and Occupational Hazards

Patients should be directed to avoid devices that generate strong electromagnetic interference (EMI). EMI could cause device malfunction or damage resulting in non-detection or delivery of unneeded therapy. Moving away from the source or turning it off will usually allow the ICD to return to its normal mode of operation.

The following equipment (and similar devices) may affect normal ICD operation: electric arc or resistance welders, electric melting furnaces, radio/television and radar transmitters, power-generating facilities, high-voltage transmission lines, and electrical ignition systems (of gasoline-powered devices) if protective hoods, shrouds, etc., are removed.

- **Cellular Phones** - Testing has indicated there may be a potential interaction between cellular phones and BIOTRONIK ICD systems. Potential effects may be due to either the cellular phone signal or the magnet within the telephone and may include inhibition of therapy when the

telephone is within 6 inches (15 centimeters) of the ICD, when the ICD is programmed to standard sensitivity.

Patients having an implanted BIOTRONIK ICD who operate a cellular telephone should:

- Maintain a minimum separation of 6 inches (15 centimeters) between a hand-held personal cellular telephone and the implanted device.
- Set the telephone to the lowest available power setting, if possible.
- Patients should hold the phone to the ear opposite the side of the implanted device. Patients should not carry the telephone in a breast pocket or on a belt over or within 6 inches (15 centimeters) of the implanted device as some telephones emit signals when they are turned ON, but not in use (i.e., in the listen or stand-by mode). Store the telephone in a location opposite the side of implant.

Based on results to date, adverse effects resulting from interactions between cellular telephones and implanted ICDs have been transitory. If electromagnetic interference (EMI) emitting from a telephone does adversely affect an implanted ICD, moving the telephone away from the immediate vicinity of the ICD should restore normal operation. A recommendation to address every specific interaction of EMI with implanted ICDs is not possible due to the disparate nature of EMI.

- **Electronic Article Surveillance (EAS)** - equipment such as retail theft prevention systems may interact with pulse generators. Patients should be advised to walk directly through and not to remain near an EAS system longer than necessary.
- **Home Appliances** - Home appliances normally do not affect ICD operation if the appliances are in proper working condition and correctly grounded and shielded. There have been reports of the interaction of electric tools or other external devices (e.g. electric drills, older models of microwave ovens, electric razors, etc.) with ICDs when they are placed in close proximity to the device.

1.5 Adverse Events

1.5.1 Observed Adverse Events

The clinical study involved 155 devices implanted in 154 patients with a cumulative implant duration of 1286 months (mean implant duration 8.3 months).

There were a total of five deaths during the course of the trial; none of the deaths were judged by the clinical study investigator to be device related. Heart failure was a major factor in two deaths. The other three deaths were related to renal failure, lung disease, and septic shock secondary to an ischemic bowel, respectively. All five of the deaths occurred more than one month post implant.

Two ICDs were explanted during the trial. One was secondary to the patient being unable to tolerate further testing required by the clinical protocol. The other was secondary to a systemic infection; the patient was subsequently implanted with another device.

Table 1 provides a summary of the adverse events that were reported during the clinical study regardless of whether or not the event was related to the ICD system. A complication is defined as a clinical event that results in invasive intervention, injury, or death. An observation is defined as a clinical event that does not result in invasive intervention, injury, or death.

Table 1 Reported Adverse Events (AEs)**Number of Patients = 154, Number of Patient-Years = 107.1**

	# of pts with AEs	% of pts with AEs	# of AEs	AE/pt-yrs
Complications (total)	7	4.5%	8	0.07
Lead repositioning	2	1.3%	2	0.02
Hematoma	1	0.6%	1	0.01
Systemic infection	1	0.6%	1	0.01
Explant (patient unable to tolerate required testing)	1	0.6%	1	0.01
Insertion of separate rate-sensing lead system	1	0.6%	2	0.02
ICD/lead connection	1	0.6%	1	0.01
Observations (total)	79	51.3%	89	0.83
Inappropriate therapy (SVT)	18	11.7%	20	0.19
ICD response to magnet in programming wand ¹	13	8.4%	15	0.14
Software messages and errors ²	11	7.1%	13	0.12
Increased pacing threshold	7	4.5%	9	0.08
Decreased R-wave amplitude	7	4.5%	7	0.07
Frequent VT	5	3.2%	5	0.05
Oversensing	3	1.9%	3	0.03
TMS 1000 difficulties ³	3	1.9%	3	0.03
VT below rate cut-off	2	1.3%	3	0.03
High DFT's	1	0.6%	2	0.02
Minor stroke	1	0.6%	1	0.01
Renal failure	1	0.6%	1	0.01
Required additional antiarrhythmic drug therapy	1	0.6%	1	0.01
ICD/lead connection	1	0.6%	1	0.01
ICD therapy during lead connection	1	0.6%	1	0.01
Non-sustained VT	1	0.6%	1	0.01
Non-conversion of arrhythmia	1	0.6%	1	0.01
Interpretation of real-time markers	1	0.6%	1	0.01
Reconfirmation algorithm	1	0.6%	1	0.01

1. This category includes issues related to movement of the programmer wand that caused the reed switch to toggle during high voltage capacitor charging or tachyarrhythmia detection. As a result, appropriate therapy was not delivered in a timely manner. The orientation of the reed switch was optimized and is being monitored as part of the manufacturing process to prevent future occurrences of this type of event.
2. This category includes various software "bugs" that were related to error messages or the retrieval of diagnostic information. Each of these events has been resolved through revisions made to the software.
3. This category includes any difficulties encountered while using the TMS 1000 Tachyarrhythmia Monitoring System. Each of these events has been resolved through revisions to the software and hardware of the system.

1.5.2 Potential Adverse Events

Adverse events (in alphabetical order) associated with ICD systems include:

- Acceleration of arrhythmias (caused by device)
- Air embolism
- Bleeding
- Chronic nerve damage
- Erosion
- Excessive fibrotic tissue growth
- Extrusion
- Fluid accumulation
- Formation of hematomas or cysts
- Inappropriate shocks
- Infection
- Keloid formation

- Lead abrasion and discontinuity
- Lead migration/dislodgment
- Myocardial damage
- Pneumothorax
- Shunting current or insulating myocardium during defibrillation with internal or external paddles
- Potential mortality due to inability to defibrillate or pace
- Thromboemboli
- Venous occlusion
- Venous or cardiac perforation

Patients susceptible to frequent shocks despite antiarrhythmic medical management may develop psychological intolerance to an ICD system that may include the following:

- Dependency
- Depression
- Fear of premature battery depletion
- Fear of shocking while conscious
- Fear that shocking capability may be lost
- Imagined shocking (phantom shock)

1.6 Clinical Studies

1.6.1 Patients Studied

The clinical study involved 154 patients (121 male and 33 female) with a mean age of 64.9 years (range: 26 to 95 years) and a left ventricular ejection fraction of 33% (range: 10% to 80%). Most (72%) presented with coronary artery disease / ischemic cardiomyopathy; 71% presented with monomorphic ventricular tachycardia (MVT) as their primary tachyarrhythmia.

1.6.2 Methods

The multicenter clinical investigation was designed to validate the safety and effectiveness of the ICD System to detect and treat

monomorphic ventricular tachycardia (MVT), polymorphic ventricular tachycardia (PVT), ventricular fibrillation (VF), and bradycardia. The specific predefined objectives of the investigation included the determination of ventricular tachyarrhythmia conversion rate, sudden cardiac death (SCD) survival rate, morbidity rate, and the appropriate sensing and pacing rate.

The primary endpoint of the study was to evaluate the ventricular tachyarrhythmia conversion rate. Patients underwent standard ICD implantation and then were evaluated at pre-discharge and regular follow-ups every three months. Induction and conversion of the patient's tachyarrhythmias was required at the implant procedure and pre-discharge follow-up.

1.6.3 Results

The mean implant duration was 8.3 ± 0.4 months with a cumulative implant duration of 1286 months. There were 39 patients followed for over twelve months and 108 patients followed for over six months. The patient follow-up compliance rate was 99.6% out of 473 follow-up procedures. Table 2 provides a summary of the results of the study group for the predefined endpoints.

Table 2 Clinical Study Results

Description	Study Group [95% CI]
Tachyarrhythmia Conversion Rate ¹	
Induced	95.8% (496/518) [93.6%, 97.3%]
Spontaneous	99.7% (1540/1544) [99.3%, 99.9%]
Total	98.7% (2036/2062) [98.2%, 99.2%]
Sudden Cardiac Death Survival (at one year)	100.0% (39/39) [91.0%, 100.0%]
Complication Rate (per total number of patients)	5.2% (8/154) [2.3%, 10.0%]
Appropriate Sensing and Pacing Rate ²	98.0% (703/717) [96.8%, 98.9%]

- Conversion data were collected in the clinical study for both induced and spontaneous tachyarrhythmia episodes. Therefore, both types of tachyarrhythmia episodes were included in the analysis.
- The investigator determined the appropriateness of bradycardia sensing and pacing. The rate will be determined by the number of appropriate bradycardia sensing and pacing evaluations divided by the total number of evaluations.

1.7 Patient Selection and Treatment

1.7.1 Individualization of Treatment

- Determine whether the expected device benefits outweigh the possibility of early device replacement for patients whose ventricular tachyarrhythmias require frequent shocks.
- Determine if the device and programmable options are appropriate for patients with drug-resistant supraventricular tachyarrhythmias (SVTs), because drug-resistant SVTs can initiate unwanted device therapy.

- Direct any questions regarding individualization of patient therapy to your BIOTRONIK representative or BIOTRONIK technical services at 1-800-547-0394.

The prospective patient's size and activity level should be evaluated to determine whether a pectoral or abdominal implant is suitable. It is strongly recommended that candidates for an ICD have a complete cardiac evaluation including EP testing prior to device implant to gather electrophysiologic information, including the rates and classifications of all the patient's cardiac rhythms. When gathering this information, delineate all clinically significant ventricular and atrial arrhythmias, whether they occur spontaneously or during EP testing.

If the patient's condition permits, use exercise stress testing to do the following:

- Determine the maximum rate of the patient's normal rhythm
- Identify any supraventricular tachyarrhythmias
- Identify exercise-induced tachyarrhythmias

The maximum exercise rate or the presence of supraventricular tachyarrhythmias may influence selection of programmable parameters. Holter monitoring or other extended ECG monitoring also may be helpful.

If the patient is being treated with antiarrhythmic or cardiac drugs, the patient should be on a maintenance drug dose rather than a loading dose at the time of pulse generator implantation. If changes to drug therapy are made, repeated arrhythmia inductions are recommended to verify pulse generator detection and conversion. The pulse generator also may need to be reprogrammed.

Changes in a patient's antiarrhythmic drug or any other medication that affect the patient's normal cardiac rate or conduction can affect the rate of tachyarrhythmias and/or efficacy of therapy.

If another cardiac surgical procedure is performed prior to implanting the pulse generator, it may be preferable to implant

the lead system at that time. This may prevent the need for an additional thoracic operation.

1.7.2 Specific Patient Populations

- **Pregnancy** - If there is a need to image the device, care should be taken to minimize radiation exposure to the fetus and the mother.
- **Nursing Mothers** - Although appropriate biocompatibility testing has been conducted for this implant device, there has been no quantitative assessment of the presence of leachables in breast milk.
- **Geriatric Patients** - Most (72%) of the patients receiving this device in clinical studies were over the age of 60 years (see Clinical Studies).
- **Handicapped and Disabled Patients** - Special care is needed in using this device for patients using electrical wheel chair or other electrical (external or implanted devices).

1.8 Patient Counseling Information

- The pulse generator is subject to random component failure. Such failure could cause inappropriate shocks, induction of arrhythmias or inability to sense arrhythmias, and could lead to the patient's death.
- Persons administering CPR may experience the presence of voltage on the patient's body surface (tingling) when the patient's ICD system delivers a shock.

A patient manual is available for the patient, patient's relatives, and other interested people. Discuss the information in the manual with concerned individuals both before and after pulse generator implantation so they are fully familiar with operation of the device. (For additional copies of the patient manual, contact the BIOTRONIK at the address listed in this manual.)

65