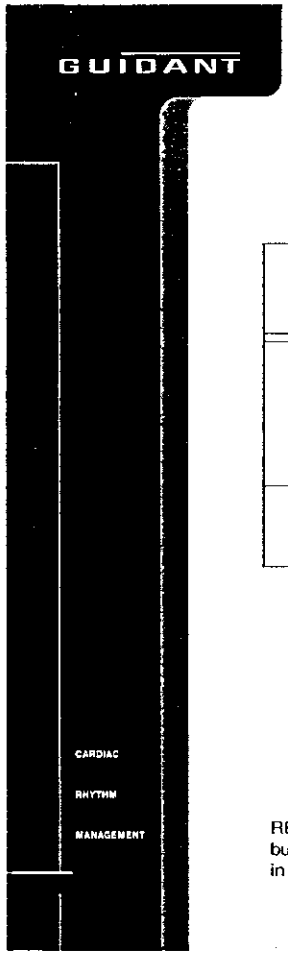


Physician's Technical Manual

Model 1900	VENTAK PRIZM® AVT™

Automatic Implantable Cardioverter Defibrillator

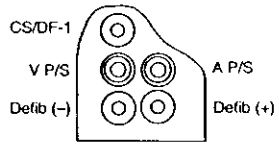
RESTRICTED DEVICE: Federal law (USA) restricts this device to sale, distribution, and use by, or on the lawful order of a physician trained or experienced in AICD implant and follow-up procedures.

Mechanical Specifications

Dimensions W x H x D (cm)	7.0 x 6.1 x 1.5
Volume (cc)	45
Mass (g)	109
Connector Size	IS-1/DF-1
Case Electrode Surface Area (mm^2)	7200
Case Material	Hermetically sealed titanium
Header Material	Implantation-grade polymer
Power Supply (WGL)	Lithium-silver vanadium oxide cell

Lead Connections

- The pulse generator case is used as a defibrillating electrode.
- For lead compatibility information, refer to the non-Guidant lead warning on page 2.
- DF-1 refers to the international standard ISO 11318:1993. IS-1 refers to the international standard ISO 5841.3:1992.



DF-1 Defib ports
IS-1 P/S ports
DF-1 CS (coronary sinus) defib port

X-Ray Identifier

Guidant pulse generators have an identifier that is visible on x-ray film. This provides noninvasive confirmation of manufacturer and pulse generator type. The identifier GDT108 identifies the Model 2849 programmer software application needed to communicate with the VENTAK PRIZM AVT pulse generator manufactured by Guidant.

Items Included in Device Packaging

The following items are packaged with the VENTAK PRIZM AVT pulse generator:

- Torque wrench
- DF-1 plug
- Product literature
- Patient Data Disk

NOTE: *Wrenches and plugs are intended for one-time use only and should not be re-sterilized or re-used.*

Factory Nominal Parameter Settings

Parameter	Factory Nominal Value at 37°C and 500 Ω load
Number of Zones	1 (atrial); 1 (ventricular)
Tachy Mode	Off (atrial); Storage (ventricular)
Rate	200 bpm (AFib); 165 bpm (VF)
Shock Energy Stored[a]	31 J
Waveform[b]	Biphasic
Brady Mode	DDD
Lower Rate Limit[c]	60 ppm
Amplitude[d, e]	3.5 V
Pulse Width[d, e, f]	0.4 ms
Atrial Refractory-PVARP	Dynamic
Ventricular Refractory Period–VRP	Dynamic
AV Delay	Dynamic

a. Tolerance is ±40% for < 3 J, ±20% for 3-29 J, and ±10% for 31 J.
b. Biphasic energy is specified. Monophasic energy is 6.7% less than biphasic energy.
c. The basic pulse period is equal to the brady pacing rate and the pulse interval (no hysteresis). Runaway protection circuitry allows the pacing rate to increase to a maximum of 190 ppm before the protection circuit would inhibit pacing. Runaway protection is not an absolute assurance that runaways will not occur. Magnet application does not affect pacing rate (test pulse interval). Tolerance is ±5 ms.
d. The minimum value of energy delivered at 5 V and 0.5 ms is 6.2 μJ with 200–500 Ω, and 3.3 μJ with 1000 Ω resistive load at 37°C±1°C for BOL and EOL.
e. The pulse generator uses an automatic gain control circuit for varying the sensitivity of its rate sensing amplifiers. Following paced pulses delivered by the pulse generator, sensitivity is set to 4.0 mV (±1.2 mV) at the end of the refractory period. Tolerance is ±0.03 V at ≤3 V and ±10% at > 3 V.
f. Tolerance is ±0.03 ms at < 1.8 ms and ±0.08 ms at ≥1.8 ms.

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1. DEVICE DESCRIPTION

The Guidant VENTAK PRIZM® AVT
small, physiologic shape minimiz
atrial arrhythmia therapies. It is des
ventricular fibrillation (VF), as well
atrial fibrillation.

VENTAK PRIZM AVT provides fully p
schemes including Burst, Ramp,
rhythms. In addition, both low-
using either a biphasic or mo
features, is available to detect
defibrillation therapy.

The VENTAK PRIZM AVT sy
and atrial defibrillation ene
active electrode, combined
is sent via a dual-current pa
to the pulse generator ca
deliver A-TRIAD shocks fro
pulse generator case in pa

The ZOOM Programming
(PRM), the Model 2849 So
external portion of the A
programming of the puls
VENTAK PRIZM AVT sy
also can provide noninva

1.1. Related Manuals

The AICD System Guide fo
in conjunction with th
includes product spe
programming instruc
contacting your Guid

Recorder/Monitor provides information specific to the programmer, such as setting up the system, maintenance, and handling. Physician's manuals for the leads provide specific information and instructions regarding the implanted leads.

2. INDICATIONS FOR USE

The VENTAK PRIZM AVT AICD System is indicated for use in patients who are ICD indicated and who have atrial tachyarrhythmias or who are at risk of developing atrial tachyarrhythmias.

Patient populations who are indicated for a Guidant ICD include those who have had spontaneous and/or inducible life-threatening ventricular arrhythmias and those who are at high risk for developing such arrhythmias; or, patients who may benefit from prophylactic treatment due to a prior myocardial infarction and an ejection fraction ≤ 30% (as defined in the MADIT II Clinical Study appendix in the System Guide).

3. CONTRAINDICATIONS

Use of the VENTAK PRIZM AVT pulse generators are contraindicated in:

- Patients whose ventricular tachyarrhythmias may have reversible cause, such as 1) digitalis intoxication, 2) electrolyte imbalance, 3) hypoxia, or 4) sepsis, or whose ventricular tachyarrhythmias have a transient cause, such as 1) acute myocardial infarction, 2) electrocution, or 3) drowning.
- Patients who have a unipolar pacemaker.

4. WARNINGS

- **Labeling knowledge.** Read this manual thoroughly before implanting the pulse generator to avoid damage to the AICD system. Such damage can result in injury to or death of the patient.
- **Lead system.** The use of non-Guidant lead systems may cause potential adverse consequences such as undersensing of cardiac activity and failure to deliver necessary therapy.
- **Avoiding shock during handling.** Program the pulse generator ventricular Tachy Mode to Off during implant, explant, or post-mortem procedures to avoid inadvertent high voltage shocks.

- **Defibrillator paddles.** Always have sterile external and internal defibrillator paddles or an equivalent (eg, R2[1] pads) immediately available during conversion testing. If not terminated in a timely fashion, an induced ventricular tachyarrhythmia can result in the patient's death.
- **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.
- **MRI exposure.** Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient.

5. PRECAUTIONS

5.1. Sterilization, Storage, and Handling

- **For single use only—do not resterilize devices.** Do not resterilize the device or the accessories packaged with it because Guidant cannot ensure that resterilization is effective.
- **If package is damaged.** Guidant sterilizes the pulse generator blister trays and contents with ethylene oxide gas before final packaging. When the pulse generator is received, it is sterile, provided the container is intact. If the packaging is wet, punctured, opened, or otherwise damaged, return the device to Guidant.
- **Storage temperature and equilibration.** Recommended storage temperatures are 0°–50°C (32°–122°F). Allow the device to reach room temperature before programming or implanting the device because temperature extremes may affect initial device function.
- **Device storage.** Store the pulse generator in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference (EMI) to avoid device damage.
- **Use before date.** Do not implant the pulse generator after the USE BEFORE date (which appears on the device packaging) has passed because this date reflects a reasonable shelf life.

1. Trademark of R2 Corporation.

5.2. Implantation and Device Programming

- **Expected benefits.** Determine whether the expected device benefits outweigh the possibility of early device replacement for patients whose ventricular tachyarrhythmias require frequent shocks.
- **Device communication.** Use only a Guidant Programmer/Recorder/Monitor (PRM) and the Model 2849 Software Application to communicate with the VENTAK PRIZM AVT pulse generator.
- **STAT PACE settings.** Do not leave the device programmed in STAT PACE settings; these settings may significantly reduce the lifetime of the device due to the high output.

5.3. Follow-up Testing

- **Conversion testing.** If the patient's condition or drug regimen has changed or device parameters have been reprogrammed, consider performing a conversion test to ensure that the patient's tachyarrhythmias can be detected and terminated by the AICD system.

5.4. Pulse Generator Explant and Disposal

- **Incineration.** Be sure the pulse generator is removed before cremation. Cremation and incineration temperatures might cause the pulse generator to explode.
- **Device handling.** Program the pulse generator ventricular Tachy Mode to Off, disable the magnet feature, and disable the Beep When ERI Is Reached beeper before explanting, cleaning, or shipping the device to prevent unwanted shocks, overwriting of important therapy history data, and audible tones.
- Return all explanted pulse generators and leads to Guidant.

5.5. Environmental and Medical Therapy Hazards

- **Avoiding EMI.** Advise patients to avoid sources of EMI (electromagnetic interference) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Examples of EMI sources are: electrical power sources, arc welding equipment and robotic jacks, electrical smelting furnaces, large RF transmitters such as RADAR, radio transmitters including those used to control toys, electronic surveillance (anti-theft) devices, and an alternator on a car that is running.

5.5.1. Hospital and Medical Environments

- **Do not use internal defibrillation** paddles unless the pulse generator is disconnected from the leads because it may shunt energy causing injury to the patient, and may damage the pulse generator.
- **External defibrillation.** Use of external defibrillation can damage the pulse generator. To help prevent defibrillation damage to the pulse generator: position the defibrillation paddles as far from the pulse generator as possible, position the defibrillation paddles perpendicular to the implanted pulse generator-lead system, and set energy output of defibrillation equipment as low as clinically acceptable.

  Following any external defibrillation episode, verify pulse generator function since external defibrillation may have damaged the pulse generator. To verify proper function: interrogate the device, perform a manual capacitor re-formation, verify battery status, check the shock counters, and ensure that programmable parameters did not change.
- **Electrical interference** or "noise" from devices such as electrosurgical and monitoring equipment may interfere with establishing or maintaining telemetry for interrogating or programming the device. In the presence of such interference, move the programmer away from electrical devices and ensure that the wand cord and cables are not crossing one another.
- **Electrosurgical cautery.** Do not use electrosurgery devices until the pulse generator's tachyarrhythmia therapy is deactivated. If active, the pulse generator may deliver an inappropriate shock to the patient. Remember to reactivate the pulse generator after turning off the electrosurgery equipment.
- **Diathermy.** Do not subject a patient with an activated implanted pulse generator to diathermy since diathermy may damage the pulse generator.
- **Ionizing radiation therapy may adversely affect device operation.** During ionizing radiation therapy (eg, radioactive cobalt, linear accelerators, and betatrons), the pulse generator **must** be shielded with a radiation-resistive material, regardless of the distance of the device to the radiation beam. Do not project the radiation port directly at the device. After waiting a minimum of one hour following radiation treatment (to allow for a device memory check to occur), always evaluate device operation including interrogation and sensing and pacing threshold testing. At the completion of the entire course of treatments, perform device

interrogation and follow-up, including sensing and pacing threshold testing and capacitor reformation.

- **Lithotripsy may damage the pulse generator.** If lithotripsy must be used, avoid focusing near the pulse generator site.
- **Therapeutic ultrasound energy may damage the pulse generator.** If therapeutic ultrasound energy must be used, avoid focusing near the pulse generator site.
- **Radio frequency ablation.** Exercise caution when performing radio frequency ablation procedures in ICD patients. If the pulse generator Tachy Mode is programmed On during the procedure, the device may inappropriately declare a tachycardia episode and deliver therapy, or may cause inhibition of pacing therapy. Minimize risks by following these steps:
  - Program the ventricular Tachy Mode to Off to avoid inadvertent tachycardia detection (sensing) or therapy.
  - Avoid direct contact between the ablation catheter and the implanted lead and pulse generator.
  - Keep the current path (electrode tip to ground) as far away from the pulse generator and leads as possible.
  - Have external defibrillation equipment available.
  - Consider the use of external pacing support for pacemaker-dependent patients.

5.6. Home and Occupational Environments

- **Static magnetic fields.** Advise patients to avoid equipment or situations where they would have extended exposure to strong (>10 gauss or 1 mTesla) magnetic fields since the pulse generator mode could change. To prevent mode change in the presence of magnets, the Change Tachy Mode With Magnet feature may be programmed Off. Examples of magnetic sources are: industrial transformers and motors, magnetic resonance imaging (MRI) devices, large stereo speakers, telephone receivers if held within 0.5 inches (1.27 cm) of the pulse generator, and magnetic wands such as those used for airport security and in the game "Bingo."

5.6.1. Electronic Article Surveillance (EAS)

- Advise patients to avoid lingering near anti-theft devices, such as those found in entrances and exits of department stores and public libraries, and to walk through them at a normal pace, because such devices may cause inappropriate pulse generator operation.

5.6.2. Cellular Phones

- Advise patients to hold cellular phones to the ear opposite the side of the implanted device. Patients should not carry a cellular phone in a breast pocket or on a belt over or within 6 inches (15 cm) of the implanted devices since some cellular phones may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

6. POTENTIAL ADVERSE EVENTS

Based on the literature and AICD implant experience, the following alphabetical list includes possible adverse events associated with implantation of an AICD system:

- Acceleration of arrhythmias
- 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
- Lead discontinuity
- Lead migration/dislodgement
- Myocardial damage
- Pneumothorax

- Potential mortality due to inability to defibrillate or pace
- Shunting current or insulating myocardium during defibrillation with internal or external paddles
- Thromboemboli
- Venous occlusion
- Venous or cardiac perforation

Patients susceptible to frequent shocks despite antiarrhythmic medical management may develop psychologic intolerance to an AICD 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

7. DEVICE FEATURES

By programming device parameters, the pulse generator is able, for a given patient, to detect and treat ventricular tachycardia and ventricular fibrillation, as well as to detect and treat supraventricular tachycardias and atrial fibrillation. Therapies include a combination of antitachycardia pacing and monophasic or biphasic cardioversion/defibrillation shocks to the atrium and ventricle. Detection of the atrial rate is available using an atrial lead. The pulse generator also detects and treats bradycardia conditions with pacing pulses in both the atrium and ventricle. Pulse generator memory provides a record of patient data, therapy delivery counts, and a therapy history consisting of arrhythmia episode data, conversion attempt data, stored electrograms (EGM), and annotated P-P and R-R intervals present during and following a ventricular tachyarrhythmic episode. The pulse generator automatically re-forms its capacitors and provides diagnostic data for evaluating battery status, lead integrity, and pacing thresholds.

The total system allows the physician to noninvasively interact with the pulse generator as listed below:

- Interrogate and program the pulse generator's tachycardia and bradycardia detection and therapy parameters
- Deliver a maximum-output STAT SHOCK with the STAT SHOCK command
- Deliver emergency VVI pacing with the STAT PACE command
- Divert therapy delivery
- Access the pulse generator memory to review therapy history and stored electrograms
- View real-time electrograms and event markers
- Induce, monitor, and terminate arrhythmias during electrophysiologic testing
- Program optional features such as magnet use and audible tones
- Review the pulse generator battery status and perform diagnostic tests
- Print reports and save patient information on disk

8. MAINTAINING DEVICE EFFECTIVENESS

Perform follow-up testing to maintain continued verification of detection and therapy efficacy. Refer to the VENTAK PRIZM AVT AICD System Guide.

8.1. Pulse Generator Longevity

Based on simulated studies, it is anticipated that VENTAK PRIZM AVT pulse generators have average longevity to ERI as indicated below. The longevity expectations, accounting for the energy used during manufacture and storage (approximately six months), apply at the conditions shown below. Values apply whether Electrogram Storage options are programmed On or Off.

Table 1. Pulse Generator Life Expectancy Estimation (Implant to ERI)[a]

	VVI Mode (Years)		VVIR Mode (Years)		DDD Mode (Years)		DDDR Mode (Years)	
	Maximum-Energy Charging Frequency (Quarterly and Monthly)[b]							
	Quarterly	Monthly	Quarterly	Monthly	Quarterly	Monthly	Quarterly	Monthly
0% pacing	7.3	6.0	7.2	5.9	7.1	5.9	7.0	5.8
15% pacing	7.2	6.0	7.1	5.9	6.9	5.8	6.8	5.7
50% pacing	7.0	5.8	6.9	5.7	6.5	5.5	6.4	5.4
100% pacing	6.7	5.6	6.6	5.6	6.1	5.2	6.0	5.1

a. 60 ppm LRL, and ventricular and atrial settings of 2.5 V pacing pulse amplitude and 0.4 ms pacing pulse width, and 900 Ω pacing impedance.
b. Charging frequency includes atrial and ventricular therapies.

The longevity of the pulse generator decreases with an increase in the pacing rate, pacing pulse amplitude, pacing pulse width, percentage of bradycardia paced to sensed events, or charging frequency, or with a decrease in pacing impedance. A maximum-energy shock is equal to approximately 11 days of monitoring.

8.2. Warranty Information

A limited warranty certificate for the pulse generator accompanies the pulse generator. For additional copies, please contact Guidant Corporation at the address and phone number on the back cover of this manual.

9. PATIENT COUNSELING INFORMATION

- The AICD 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 AICD system delivers a shock.
- Advise patients to contact their physician immediately if they hear tones coming from their device.

9.1. Patient Manual

A copy of the patient manual is provided with each device 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 nearest Guidant sales representative or contact Guidant at the phone number on the back cover of this manual.)

60

GUIDANT

CARDIAC

RHYTHM

MANAGEMENT

Physician's Manual

PERIMETER™ CS

Coronary Sinus Defibrillation Lead

Models 0202/0203/0204

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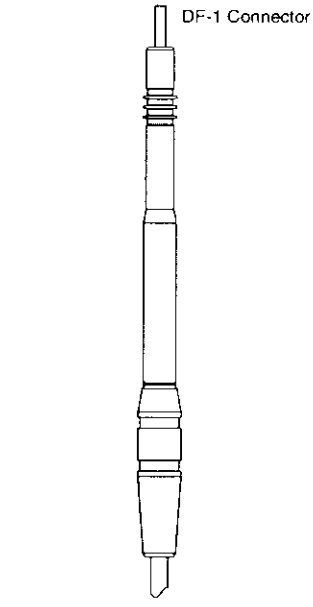
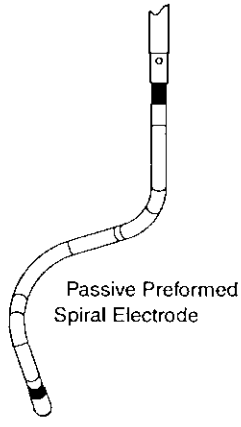
PERIMETER™ CS Lead
Models 0202/0203/0204





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INFORMATION FOR USE

Device Description

The PERIMETER™ CS lead, Models 0202/0203/0204, is an implantable coronary sinus defibrillation lead designed specifically for use with the Guidant VENTAK® PRIZM™ AVT™ pulse generator. The PERIMETER CS is an optional defibrillation electrode for use in patients requiring lowered atrial defibrillation thresholds.

The PERIMETER CS lead, the proximal coil of a Guidant ENDOTAK® lead, and the metallic housing of the VENTAK PRIZM AVT pulse generator form the Guidant A-TRIAD™ electrode configuration for defibrillation energy delivery. Appropriately positioned in the heart (refer to Figure 9 on page 18), the shock electrodes of the PERIMETER CS lead, an ENDOTAK lead proximal coil, and the pulse generator case are intended to form a bidirectional vector for effective delivery of defibrillation pulses to the atria.

Instructions in this manual should be used in conjuntion with other resource material including the VENTAK PRIZM AVT AICD physician's manual, and the applicable ENDOTAK lead physician's manual.

Indications

The PERIMETER CS lead, Models 0202/0203/0204, delivers cardioversion and defibrillation shocks for atrial arrhythmias. It is intended for use only as an optional component of the VENTAK PRIZM AVT AICD system when the A-TRIAD electrode configuration for defibrillation energy delivery is desired.

Contraindications

The use of transvenous atrial defibrillation leads may be contraindicated in the presence of a venous graft, certain anatomical abnormalities of the heart, or arterio-venous malformations.

Warnings

In the following list of warnings, page numbers are indicated for those warnings that are specific to other areas of the manual. Refer to the indicated pages for information relevant to the warning.

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AICD/Lead Compatibility

- Do not attempt to use the PERIMETER CS lead with any device other than the VENTAK PRIZM AVT AICD as it has been tested and demonstrated to be a safe and effective component of that system. The potential adverse consequence of using a combination that has not been tested and demonstrated to be safe and effective may include, but is not limited to, failure to deliver necessary therapy.

Implantation

- Lead fracture, dislodgement, abrasion and/or an incomplete connection can cause inadequate delivery of converting energy.
- Although pliable, the lead is not designed to tolerate excessive flexing, bending, or tension. This could cause structural weaknesses, conductor discontinuity, and/or lead dislodgement. (Page 10)
- In addition to the PERIMETER CS coronary sinus atrial defibrillation lead, the VENTAK PRIZM AVT AICD system requires connection of the VENTAK PRIZM AVT pulse generator to an ENDOTAK lead and an atrial pacing lead.

Electrical Performance

- When connecting the PERIMETER CS lead/ENDOTAK lead system to the pulse generator, it is very important that proper connections are made. Damage to the heart could result if a high-voltage defibrillating pulse were delivered through the tip electrode of an ENDOTAK lead. (Page 16)

Conversion Testing

- Use of any component of the lead system to assist in delivery of external-source rescue shocks could cause extensive tissue damage. (Page 17)

Securing and Tunneling

- Do not kink, twist, or braid the lead terminal with other leads as doing so could cause lead insulation abrasion damage. (Page 20)

Precautions

- The lead and its accessories are intended only for one-time use. Do not reuse.
- Refer to the Implant Information, Implantation and Post-Implant Evaluation sections of this manual for cautions specific to handling, implanting, and testing the PERIMETER CS lead. Failure to observe these cautions could result in incorrect lead implantation, lead damage, and/or harm to the patient.

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- Take care to ensure appropriate electrode position. Failure to do so may result in higher defibrillation thresholds or may render the lead unable to defibrillate a patient whose tachyarrhythmia(s) might otherwise be convertible by the VENTAK PRIZM AVT AICD system. (Page 15)

Clinical Trial

The following is a summary of the findings from the Guidant/ InControl METRIX™ Automatic Atrial Defibrillator System clinical investigaton which included the PERIMETER CS lead, Model 7109. The PERIMETER CS lead, Models 0202/0203/ 0204, has the same design characteristics as the PERIMETER CS lead, Model 7109.

Clinical Investigation

The object of the Metrix study was to determine the safety and efficacy of shocks delivered from an implantable defibrillator for the termination of atrial fibrillation. The study was a non-randomized historical control study comparing the lead-related complications to historical controls. One hundred eleven patients were successfully implanted with the PERIMETER CS lead. The mean implant duration of the study was 21.3 months. The study population is presented in Table 1.

Table 1. Metrix Study Patient Demographics

Category	N	Mean ± std	Range	Median
Patients implanted	111			
Implant duration (months)	111	21.3 ± 9.7	0.4–48.02	23.1
Age at implant (years)	111	60.4 ± 11.5	26–79	63
Ejection fraction (%)	109	56.7 ± 7.5	40–78	60
Left atrial size	87	4.3 ± 0.9	3.1–6.8	4.2
Number of AA drugs used prior to implant	111	4.7 ± 2.1	1.0–11.0	4
	Category	**N**	**%**	
Gender	Male	80	72.1	
	Female	31	27.9	
NYHA during sinus rhythm	I	93	83.8	
	II	12	10.8	
	III	0	0	
	IV	0	0	

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Table 1. Metrix Study Patient Demographics (Continued)

Category	N	Mean ± std	Range	Median
	Not identified	6	5.4	
NYHA during AF	I	11	9.9	
	II	72	64.9	
	III	10	9.0	
	IV	1	0.9	
	Not identified	17	15.3	

All lead-related complications reported in the study population are summarized to provide a comparison of the PERIMETER CS lead-related complications at the time of the May 2000 annual report. At the time of the report, there was a single PERIMETER CS lead-related complication as a result of lead migration from the SVC, a non-indicated implant location. Complications are presented in Table 4 on page 5.

The study demonstrated safe and effective atrial defibrillation with the PERIMETER CS lead. Key aspects of that study are outlined in Table 2 and Table 3.

Table 2. Shock Safety

Total number of shocks delivered	5,616
Incidence of ventricular proarrhythmia	0

Table 3. Clinical Conversion Efficacy in Out-of-hospital Therapy Phase

Patients	N = 65
Spontaneous episodes treated	619
Episodes converted by device with SR sustained for > 1 hour	557
Clinical Conversion Efficacy (%)	90.0

Adverse Events

A total of 16 complications and 7 observations related to all lead systems (RA, SVC, RV, and CS) were reported during the clinical investigation of the METRIX Automatic Atrial Defibrillator System clinical investigation using the InControl PERIMETER CS lead, Model 7109. One hundred eleven

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patients were enrolled in the investigation with 21.3 mean month implants.

Observed Adverse Events

Table 4 reports all lead-related complications and observations for the METRIX Automatic Atrial Defibrillator System clinical investigation. The clinical investigation evaluated the PERIMETER CS lead as part of the METRIX system which also included the RA (pace/sense), RV (pace/sense) and SVC (defibrillation) leads. Although only 1 complication related to the PERIMETER CS lead was noted, all lead-related complications and observations observed during the clinical study are shown below.

Table 4. All Lead-related Complications and Observations from the METRIX System Clinical Investigation

Complication	# of patients (n=111)
Cardiac perforation, RA, RV	2
Lead dislodgement, SVC/RA	1
Lead dislodgement, RA	4
Lead dislodgement, RV	6
Increased ADFL threshold, RA	1
Increased ADFL threshold, SVC	1
Migration of CS lead[a]	1
TOTAL	16
Observations	
RA Helix deformation/detachment	5
High threshold/lead impedance	2
TOTAL	7

a. The migration occurred in a patient in which the PERIMETER CS lead had been implanted in the SVC, a non-indicated implant location.

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Potential Adverse Events

Based on the literature and lead implant experience, the possible physical effects from implantation of a PERIMETER CS lead are listed below in alphabetical order:

- Air embolism
- Allergic reaction
- Bleeding
- Cardiac perforation
- Chronic nerve damage
- Displacement/dislodgement
- Erosion/extrusion
- Fibrotic tissue formation
- Hematoma
- Inappropriate therapy
- Incomplete connection with pulse generator
- Infection
- Keloid formation
- Lead abrasion
- Lead fracture, insulation break
- Lead tip deformation and/or breakage
- Local tissue reaction
- Myocardial injury
- Myocardial irritability
- Pneumothorax
- Post-shock disturbances
- Random component failures
- Shunting of current or insulation of myocardium during defibrillation with internal or external paddles
- Transvenous lead-related thrombosis
- Threshold elevation
- Venous occlusion
- Venous perforation

Warranty

See the enclosed Lead Information card for warranty and guarantee information. For additional copies, please contact Guidant Corporation at the address on the back cover.

Refer to the Contraindications, Warnings, Precautions, and Adverse Events sections of this manual for information concerning the performance of this device.

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LEAD FEATURES

Features of the PERIMETER CS lead include the following:

- **Lead Body:** The lead body has a quadfilar conductor coil made of MP35N alloy with a silver core, and is insulated with PolySil®, silicone rubber covered with a polyurethane protective sleeve. If an introducer is to be used as an aid in inserting the lead, a minimum introducer size of 7 French without a retained guidewire or 9 French with a retained guidewire is required.
- **Passive Preformed Spiral Electrode:** The lead's platinum-iridium electrode array, collectively referred to as the "shock" electrode, comprises a coil electrode with an electrically active distal tip and a proximal electrode ring. The lead is anchored in position by removing the stylet and allowing the electrode to assume a spiral shape that lodges in the coronary sinus (Figure 1).

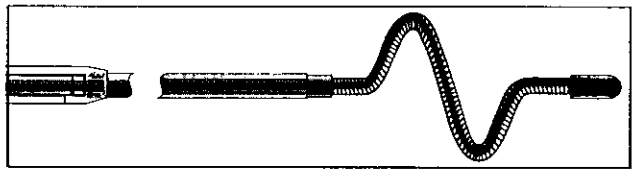

Figure 1. Electrode array with stylet withdrawn.

- **Terminal:** The DF-1 lead connector incorporates a titanium connector pin and a clear silicone rubber insulation grip zone.

Nominal overall length of the PERIMETER CS lead is 59 cm for the Model 0202 lead, 64 cm for the Model 0203 lead, and 80 cm for Model 0204 lead.The lead's platinum-iridium electrode array is approximately 7.7 cm in length (Figure 2).

Figure 2. Electrode array with stylet inserted.

Implant Information

Proper surgical procedures and techniques are the responsibility of the medical professional. The described implant procedures are furnished for informational purposes only. Each

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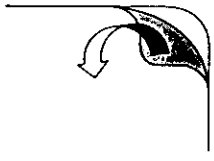
physician must apply the information in these instructions according to professional medical training and experience.

Included Items

The following items are packaged with the PERIMETER CS lead:

- Lead cap
- Vein pick
- Stylet guide
- Firm stylets (0.016-in/0.41-mm diameter)
- Extra Firm stylets (0.017-in/0.43-mm diameter, long taper)
- Ultra Firm stylets (0.017-in/0.43-mm diameter, short taper)
- Literature packet

Opening Instructions



The outer package and inner sterile tray may be opened by authorized personnel under clean conditions. To ensure sterility, the sealed inner sterile tray must be opened using accepted aseptic technique by scrubbed, masked, sterile-gowned personnel. The sterile tray is opened by peeling back the cover.

Sterilization

Guidant sterilizes the lead and accessories with ethylene oxide gas (EO) before final packaging. When they are received, they are sterile and ready for use. If the container is wet, damaged, punctured, or if the seal is broken, return the lead to the nearest Guidant representative. Never attempt to resterilize the lead. Instead, return the lead to Guidant.

Surgical Preparation

Instrumentation for cardiac monitoring, imaging (fluoroscopy), defibrillation, and lead signal measurements must be available during implant. When using electrical instrumentation, electrically isolate the patient from potentially hazardous current leakage. Guidant also recommends availability of sterile duplicates of all implantable items in case of accidental damage or contamination.

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Accessory Options

Suture Sleeves

Suture sleeves are an adjustable, tubular reinforcement positioned over the outer lead insulation. They are designed to secure and protect the lead at the venous entry site after distal electrode fixation. Using suture sleeves optimizes lead longevity and reduces the possibility of structural damage caused by suturing directly over the lead body.

To move a suture sleeve, gently twist and pull it over the lead until it is in the desired position.

CAUTION: Do not suture directly over the lead body as this may cause structural damage. Use the suture sleeves to secure the lead lateral to the venous entry site.

If a suture sleeve supplied on the lead becomes damaged, a lead anchor should be used in its place. It is available from Guidant as an accessory item.

The following items are packaged with the lead and are also available from Guidant as accessory items:

Stylets

Stylets of varying stiffness are packaged with each lead. Stylets are also available as accessory items. A stylet inserted in the lead aids in positioning the lead tip in the heart. The stylet length is imprinted on the color-coded cap of the knob (Table 5). Also, refer to "Inserting the Stylet" (Page 11) for more information.

Table 5. Stylets

	Stylet Length	Body Color	Cap Color
Straight	59 cm	Red = Firm Purple= Extra Firm Blue = Ultra Firm	Yellow
	64 cm		Green
	80 cm		Purple

Stylet Guide

A stylet guide is packaged with the lead and is intended to ease insertion of a stylet into the DF-1 terminal of the lead (Figure 3).

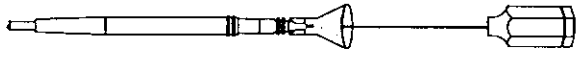

Figure 3. Using the stylet guide.

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Vein Pick

The vein pick is a sterile, disposable, nontoxic, nonpyrogenic, plastic device designed to assist the physician during entry of the lead's electrode tip into the vein.

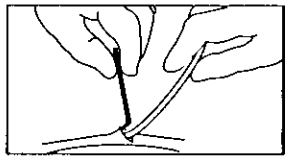

Figure 4. Using the vein pick.

To use the vein pick during a cutdown procedure, isolate and open the selected vein using an appropriate scalpel or scissors. Introduce the point of the vein pick via this incision into the lumen of the vein (Figure 4). With the point of the vein pick facing in the direction of the desired lead passage, gently raise and tilt the pick. Pass the lead under the vein pick and into the vein.

CAUTION: The vein pick is not intended either for puncturing the vein or for dissecting tissue during a cutdown procedure. Be sure that the vein pick does not puncture the silicone rubber insulation of the lead. This might allow body fluids to seep into the lead and could prevent proper lead function.

Lead Cap

The silicone rubber lead cap should be used to protect the lead terminal during the procedure. A lead cap may also be used to isolate or cap any lead terminal not inserted into the pulse generator. Placing a suture in the lead cap groove will secure the lead cap to the lead terminal.

Handling the Lead

Observe the following when handling the lead:

WARNING: Although pliable, the lead is not designed to tolerate excessive flexing, bending, or tension. This could cause structural weaknesses, conductor discontinuity, and/or lead dislodgment.

CAUTIONS:

- Do not attempt to alter the electrodes. Do not apply pressure to the tip of the electrode.
- Do not expose the lead or stylet to lint, dust and other particulate surface contaminants; do not contaminate the stylet with blood residue.

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