Medtronic

JEWEL® AF 7250

Dual Chamber Implantable Cardioverter Defibrillator

Prescriber's Package Insert

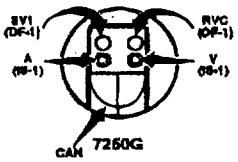
Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

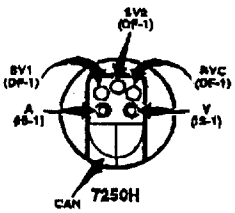
Nominal Specifications

Model #	Maximum Shock Energy	Defibrillating Lead*,†,‡,** Connection	Pacing Lead†,** Connection	Dimensions W x H x D	Volume	Mass
7250G	27 J	Two DF-1 (3.2 mm)	Two IS-1 bipolar (3.2 mm)	76 x 55 x 16 mm	56 cc	95 g
7250H	27 J	Three DF-1 (3.2 mm)	Two IS-1 bipolar (3.2 mm)	79 x 55 x 16 mm	57 cc	96 g
Case Material	Titanium					
Header Materials	Polyurethane, silicone rubber					
Power Supply	Lithium silver vanadium oxide (6.4 V nominal)					

* The ICD case serves as a defibrillation electrode.
† For lead compatibility information, refer to the next page and the warning "Lead System" on page 5.
‡ The DF-1 ports will not accept a 3.2 mm in-line bipolar lead.
** DF-1 refers to the international standard ISO 11318:1993.
IS-1 refers to ISO 5841-3:1992(E).

Lead Connections





Produced by Cardiovascular Technical Communications

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Lead Compatibility
The ICD is designed to accept DF-1 and IS-1 bipolar lead connectors.[1] The Medtronic leads listed below are directly compatible with the Jewel® AF ICD.

Model	Placement	Fixation
Multipolar Pacing / Sensing / High Voltage Leads		
Sprint 6932	RV	Tines
Sprint 6942	RV and SVC coils	Tines
Sprint 6943	RV or RA	Extendable Screw
Sprint 6945	RV and SVC coils	Extendable Screw
Transvene RV 6934S	RV	Tines
Transvene RV 6936	RV	Extendable Screw
IS-1 Bipolar Pacing / Sensing Leads		
SureFix 5072	Atrium	Fixed Screw
CapSure Fix 6940	Atrium	Extendable Screw
CapSure Fix 4568 / 5568	Atrium (J-curved)	Extendable Screw
CapSure Fix 4068 / 5068	Atrium or Ventricle	Extendable Screw
CapSure SP 5024M	Ventricle	Tines
DF-1 Unipolar Cardioversion / Defibrillation Leads		
Transvene 6933	SVC or CS	Passive
Transvene 6937	SVC	Passive
Transvene 6939	SQ patch	Suture
Model 6721	Epicardial Patch	Suture

1. DF-1 refers to the international standard ISO 11318:1993.
IS-1 refers to ISO 5841-3:1992(E).

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1 DEVICE DESCRIPTION

The Model 7250 Jewel® AF Implantable Cardioverter Defibrillator (ICD) System is a multiprogrammable, implantable cardioverter defibrillator that monitors and regulates a patient's heart rate by providing atrial and ventricular arrhythmia therapy, and single or dual chamber bradycardia pacing.

Therapies: The Jewel® AF is an implantable medical device that automatically detects and treats episodes of atrial fibrillation (AF), atrial tachycardia (AT), ventricular fibrillation (VF), ventricular tachycardia (VTs), and bradycardia. When an arrhythmia is detected, the implantable device delivers defibrillation, cardioversion, antitachycardia pacing, or bradycardia pacing therapy.

Leads: The Model 7250 Jewel® AF ICD, along with the Medtronic® Sprint™ Model 6943 Steroid Eluting, Screw-in, Atrial/Ventricular Lead, or other commercially available pace/sense leads and cardioversion/defibrillation leads, constitutes the implantable portion of the ICD system. The lead systems for the Jewel® AF system are implanted using standard transvenous placement techniques.

1.1 Programming Options

1.1.1 Tiered Therapy for AT

Up to six automatic AT therapies are available for device-detected AT:

AT Therapies 1 – 2	Programmable to Antitachycardia Pacing (or Skip)
AT Therapy 3	Programmable to 50 Hz Burst Pacing (or Skip)
AT Therapies 4 – 6	Programmable to A-Defib (or Skip)

1.1.2 AT Therapy Programming Sequence Options:

Antitachycardia Pacing only

Antitachycardia Pacing → 50 Hz Burst Pacing

Antitachycardia Pacing → 50 Hz Burst Pacing → A-Defib

50 Hz Burst Pacing only

50 Hz Burst Pacing → A-Defib

A-Defib only

1.1.3 Tiered Therapy for AF

Up to six automatic AF therapies are available for device-detected AF:

AF Therapy 1	Programmable to 50 Hz Burst Pacing (or Skip)
AT Therapies 2-6	Programmable to A-Defib (or Skip)

1.1.4 AF Therapy Programming Sequence Options:

50 Hz Burst Pacing only

50 Hz Burst Pacing → A-Defib.

A-Defib only

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2 INDICATIONS AND USAGE

The Model 7250 Jewel® AF system is indicated for use in ICD patients either with atrial tachyarrhythmias or who are at significant risk of developing atrial tachyarrhythmias. Patients indicated for an ICD are those patients who are at risk of sudden death due to ventricular arrhythmias and who have experienced one of the following:

- Survival of at least one episode of cardiac arrest (manifested by 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 have not been conducted.

Notes: Associated with atrial tachyarrhythmia treatment.

1. Use of the ICD system has not been demonstrated to decrease the morbidity related to atrial tachyarrhythmias.
2. The effectiveness of High Frequency Burst pacing (A-50 Hz-Burst therapy) in terminating atrial fibrillation (AF) and atrial tachycardia (AT) was found to be 16.8% and 17.0% respectively in the patient population studied.

3 CONTRAINDICATIONS

Do not use the Jewel® AF system in:

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

4 WARNINGS AND PRECAUTIONS

- **Resuscitation availability.** Do not perform ICD testing unless an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are readily available.
- **Lead system.** Do not use another manufacturer's lead system without demonstrated compatibility as undersensing of cardiac activity and failure to deliver necessary therapy could result.
- **Electrical isolation during implantation.** Do not permit the patient to contact grounded equipment which could produce hazardous leakage current during implantation. Resulting arrhythmia induction could result in the patient's death.
- **Avoiding shock during handling.** Program the ICD to OFF during surgical implant and explant, or post-mortem procedures, because the ICD can deliver a serious shock if you touch the defibrillation terminals while the ICD is charged.

4.1 Sterilization, Storage, and Handling

- **Resterilization.** Do not resterilize and re-implant an explanted ICD.
- **"Use Before" Date.** Do not implant the ICD after the "Use Before" date, because the battery's longevity could be reduced.
- **If package is damaged.** Do not use the ICD or accessories if the packaging is wet, punctured, opened, or damaged, because the integrity of the sterile packaging might be compromised. Return the ICD to Medtronic.
- **ICD storage.** Store the ICD in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference to avoid ICD damage. Store and transport the ICD between -18 to 55 °C (0 to 131 °F), because temperatures outside this range could damage the ICD.
- **Equilibration.** Allow the ICD to reach room temperature before programming or implanting the ICD, because rapid temperature changes could affect initial ICD function.

4.2 Implantation and ICD Programming

- Infrequent charging of the high voltage capacitors could extend the ICD charge time. Program the ICD to condition the capacitors automatically, or perform a test charge to form the capacitors manually every six months (if the ICD has not charged to its maximum energy).
- Use only Medtronic programmers, application software, and accessories to communicate with the ICD.
- Positioning a magnet or the programming head over the ICD suspends detection and treatment. The magnet does not alter bradycardia therapy.
- End of Life (EOL). Replace the ICD when the programmer displays an EOL message and a battery voltage of 4.50 volts or less. Immediate replacement is recommended if the programmer displays a Charge Circuit Timeout or Charge Circuit Inactive message.
- Program ICD parameters such as sensitivity thresholds and detection intervals according to the recommendations in the technical manual.
- Program the first atrial defibrillation therapy to two times the atrial defibrillation threshold, or the maximum output.

  Note: Limit the number of automatic atrial defibrillation therapies in patients who experience frequent episodes of atrial tachyarrhythmias.

4.3 Lead Evaluation and Lead Connection

- For lead resterilization, use ethylene oxide only. Do not resterilize more than one time.
- Do not tie a ligature directly to the lead body, tie it too tightly, or otherwise create excessive strain at the insertion site as this can damage the lead.
- Do not immerse leads in mineral oil, silicone oil, or any other liquid.
- Do not grip the lead with surgical instruments.
- Do not use excessive force or surgical instruments to insert a stylet into a lead.
- Use the same polarity evaluated during testing when connecting the leads to the ICD to ensure defibrillation effectiveness.
- Do not use ventricular transvenous leads in patients with tricuspid valve disease or a mechanical prosthetic tricuspid valve. Use with caution in patients with a bioprosthetic valve.
- Use the correct suture sleeve (when needed) for each lead to immobilize the lead and protect it against damage from ligatures.
- Ensure that the defibrillation lead impedance is greater than 10 ohms. An impedance below 10 ohms could damage the ICD.
- Do not kink the leads. Kinking leads can cause additional stress on the leads, possibly resulting in lead fracture.

- Do not suture directly over the lead body as this may cause structural damage. Use the lead anchoring sleeve to secure the lead lateral to the venous entry site.
- Lead or Active Can® electrodes in electrical contact during a high voltage therapy could cause current to bypass the heart, possibly damaging the ICD and leads. While the ICD is connected to the leads, make sure that no therapeutic electrodes, styles, or guidewires are touching or connected by an accessory low impedance conductive pathway. Move objects made from conductive materials (e.g., an implanted guidewire) well away from all electrodes before a high voltage shock is delivered.
- If a pacing 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.
- If a header port is unused on the ICD, the port must be plugged to protect the ICD.
- Refer to the lead technical manuals for specific instructions and precautions.

4.4 Follow-up Testing

- Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant ICD testing should the patient require external rescue.
- Be aware that 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 testing is no assurance that conversion will occur post-operatively.

4.5 ICD Explant and Disposal

- Interrogate the ICD, and program the ICD to OFF and disable ICD functions prior to explanting, cleaning, or shipping the ICD to prevent unwanted shocks.
- Return all explanted pulse generators and leads to Medtronic.
- Never incinerate the ICD due to the potential for explosion. The ICD must be explanted before cremation.

4.6 Environmental and Medical Therapy Hazards

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

4.6.1 Hospital and Medical Environments

- Electrosurgical cautery could induce ventricular arrhythmias and/or fibrillation, or may cause device malfunction or damage. If use of electrocautery is necessary, the bipolar configuration is recommended whenever practical. Also, the current path and (if monopolar electrocautery is used) the ground plate should be kept as far away from the ICD and leads as possible (minimum of 15 cm (six inches)).
- External defibrillation may damage the ICD or may result in temporary and/or permanent myocardial damage at the electrode tissue interface as well as temporary or permanent elevated pacing thresholds. Minimize current flowing through the ICD and lead system by following these precautions when using external defibrillation on a patient with an ICD:
  - Position defibrillation paddles as far from the ICD as possible (minimum of 13 cm (five inches)). Minimize current flowing through the ICD and lead system by positioning the defibrillation paddles perpendicular to the implanted ICD-lead system.
  - Use the lowest clinically appropriate energy output (watt seconds).
  - Confirm ICD function following any defibrillation.
- High radiation sources such as cobalt 60 or gamma radiation should not be directed at the ICD. If a patient requires radiation therapy in the vicinity of the ICD, place lead shielding over the device to prevent radiation damage and confirm its function after treatment.

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- **Lithotripsy** may permanently damage the ICD if it is at the local point of the lithotripsy beam. If lithotripsy must be used, keep the ICD at least 2.5 to 5 cm (one to two inches) from the local point of the lithotripsy beam.
- **Magnetic Resonance Imaging (MRI)** should not be used on patients who have an ICD because of the potential damage to the ICD.
- **Radio frequency ablation** procedure in a patient with an ICD could cause ICD malfunction or damage. RF ablation risks can be minimized by:
  - Programming the ICD to **Off**.
  - Avoiding direct contact between the ablation catheter and the implanted lead or ICD.
  - Positioning the ground plate so that the current pathway does not pass through or near the ICD system: i.e., place the ground plate under the patient's buttocks or legs.
  - Having defibrillation equipment available.

4.6.2 Home and Occupational Environments

- **High voltage power transmission lines** could generate enough EMI to interfere with ICD operation if approached too closely.
- **Communication equipment** such as microwave transmitters, line power amplifiers, or high power amateur transmitters could generate enough EMI to interfere with ICD operation if approached too closely.
- **Commercial electrical equipment** such as arc welders, induction furnaces, or resistance welders could generate enough EMI to interfere with ICD operation if approached too closely.
- **Home appliances** which are in good working order and properly grounded do not usually produce enough EMI to interfere with ICD operation. There are reports of ICD disturbances caused by electrical hand tools or electric razors used directly over the ICD implant site.
- **Static magnetic fields.** Patients should avoid equipment or situations where they would be exposed to static magnetic fields (greater than 10 gauss or 1 millitesla) magnetic fields since it could suspend detection. Examples of magnetic sources that could interfere with normal ICD operation include: stereo speakers, bingo wand, extractor wand, magnetic badges, or magnetic therapy products.

Electronic Article Surveillance (EAS) – Electronic Article Surveillance (EAS) equipment such as retail theft prevention systems may interact with the ICD. Patients should be advised to walk directly through, and not to remain near an EAS system longer than is necessary.

Cellular Phones – The ICD has been tested to the frequency ranges used by the cellular phones included in Table 1. Based on this testing, the ICD should not be affected by the normal operation of such cellular phones.

- The ICD contains circuitry that allows usage without interaction (when programmed to nominal sensitivity) of all cellular phones having one of the transmission technologies listed in Table 1. These transmission technologies represent most of the cellular phones in use worldwide. Patients can contact their local cellular phone service provider to confirm that the provider uses one of these technologies.

Table 1. Cellular Phone Transmission Technologies

Transmission Technology	Frequency Range
Analog	
FM (Frequency Modulation)	824 - 849 MHz
Digital TDMA[a]	
North American Standards	
NADC[b] (TDMA - 50 Hz)	824 - 849 MHz
PCS[c] 1800	1850 - 1910 MHz
International Standards	
GSM[d] [minimum of 2.5 cm from ICD recommended]	880 - 915 MHz
DCS[e]	1710 - 1785 MHz
Digital CDMA	
CDMA - DS[f]	824 - 849 MHz

[a]Time Division Multiple Access
[b]North American Digital Cellular
[c]Personal Communication System
[d]Global System for Mobile Communications
[e]Digital Cellular System
[f]Code Division Multiple Access - Direct Sequence

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5 ADVERSE EVENTS

The clinical study of the Model 7250 Jewel® AF system is summarized below.

Table 2. Patient Enrollment, Device Implantations, and Follow-Up

Patient enrollment (worldwide)	303 patients
Patients implanted with Jewel® AF	293 patients
Cumulative patient follow-up	2393 patient-months
Average individual patient follow-up	7.9 months (range 0 - 20.0 months)

There were 26 deaths (8.6%) in the 303-patient clinical study. Causes of death as classified by the investigator and the independent clinical events committee were as follows: nine deaths attributed to congestive heart failure (1 death prior to implant of the device; the other eight deaths at 18, 32, 122, 129, 171, 175, 209 and 421 days post-implant); six deaths attributed to cardiac and/or respiratory arrest (at 49, 94, 109, 143, 272 and 307 days post-implant); two deaths attributed to multiple organ failure (213 and 315 days post-implant); one death attributed to ischemic cerebrovascular infarction (11 days post-implant); one death attributed to ischemic cardiomyopathy (29 days post-implant); one death attributed to intracranial hemorrhage (98 days post-implant); one death attributed to intestinal cancer (125 days post-implant); one death attributed to acute myocardial ischemia (134 days post-implant); one death attributed to sepsis secondary to GI abcess (188 days post-implant); one death attributed to hypoxic encephalopathy (231 days post-implant); one death attributed to cerebral hemorrhage caused by lisi (284 days post-implant); one death caused by low cardiac output post-valve replacement surgery (301 days post-implant).

Table 3 summarizes adverse events experienced during the clinical investigation.

Table 3. Adverse Event Summary

Adverse Event Summary (N= 303)*	Number of events	Number of patients	Percent of patients
Adverse Events at Implant	23	23	7.6 %
Complications	43	37	12.2 %
Observations	144	101	33.3 %
Non System-Related Adverse Events	56	39	12.9 %
Total Adverse Events	**266**	**155**	**51.2 %**

* Over a cumulative follow-up of 2393 patient-months.

Table 4 reports system-related adverse events at implant. Table 5 reports system-related complications post-implant. Table 6 reports system-related observations. Each adverse event was reviewed by an independent clinical events committee to determine whether it was related to the ICD system. Lead-related adverse events are grouped together and listed first in each table.

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Table 4. Adverse Events Related to ICD System at Implant (N= 303)

	# of Events	# of Patients	% of Patients
Lead Related	11	11	3.6 %
Atrial lead dislodgement* Model 6943 (n= 96): 3 patients, 3.1 % Model 6940 (n= 163): 2 patients, 1.0 %	5	5	1.6 %
Ventricular lead dislodgement Model 6942 (n= 128): 1 patient, 0.8 %	1	1	0.3 %
Failure to extend lead helix†	4	4	1.3 %
Lead perforation	1	1	0.3 %
Not Lead Related	12	12	4.0 %
Poor pin plug fit in header	2	2	0.7 %
Software related	2	2	0.7 %
Device failure	1	1	0.3 %
Inappropriate AT/AF detection	1	1	0.3 %
Inappropriate VT/VF detection	1	1	0.3 %
Inappropriate atrial defibrillation synchronization	1	1	0.3 %
Pneumothorax	1	1	0.3 %
Spontaneous AT/AF episodes	1	1	0.3 %
Subclavian vein thrombosis	1	1	0.3 %
Unable to position lead	1	1	0.3 %
Total	23	23	7.6 %

* In one patient, VF was induced by atrial 50 Hz Burst pacing via an atrial lead (Model 6940) that migrated into the ventricle. VF was detected and terminated with a shock, and atrial therapies were disabled as designed.

† The lead design has been modified.

Table 5. Complications Related to ICD System Post-Implant (N= 303)*

	# of Events	# of Patients	% of Patients
Lead Related	14	12	4.0 %
Atrial lead dislodgement Model 6943 (n=96): 5 events, 5 patients, 5.2 % Model 6940 (n=183): 2 events, 2 patients, 1.1 %	7	7	2.3 %
Ventricular lead dislodgement Model 6932 (n=18): 1 event, 1 patient, 5.6 % Model 6942 (n=128): 2 events, 2 patients, 1.6 %	3	3	1.0 %
CS lead dislodgement	1	1	0.3 %
Pulmonary artery lead dislodgement	1	1	0.3 %
Lead insulation breach	1	1	0.3 %
Lead perforation	1	1	0.3 %
Not Lead Related†	29	27	8.9 %
Device failure	6	5	1.7 %
Increased ventricular defibrillation requirements	5	4	1.3 %
Pocket infection	4	4	1.3 %
Device migration	3	3	1.0 %
Inappropriate VT/VF detection	2	2	0.7 %
Diaphragmatic stimulation	1	1	0.3 %
Failure to defibrillate AT/AF	1	1	0.3 %
Incessant AT	1	1	0.3 %
Pocket trauma	1	1	0.3 %
Septicemia	1	1	0.3 %
Seroma	1	1	0.3 %
Spontaneous AT/AF episodes	1	1	0.3 %
Spontaneous VT/VF episodes	1	1	0.3 %
Subclavian vein thrombosis	1	1	0.3 %
Total	43	37	12.2 %

* Complications are adverse events that required invasive intervention.
† These patients are not mutually exclusive.

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Table 6. Observations Related to ICD System (N= 303)*

Adverse Event	# of Events	# of Patients	% of Patients
Lead Related	13	13	4.3%
Atrial lead dislodgement Model 6940 (n=183): 3 events, 3 pts, 1.6% Model 6943 (n=96): 1 event, 1 pt, 1.0%	4	4	1.3%
Failure to capture (Models 6936, 6943, and 6945)	3	3	1.0%
Subcutaneous lead dislodgement (Model 6996)	2	2	0.7%
Increased pacing threshold (Models 6936 and 6942)	2	2	0.7%
Undersensing (Model 6940)	2	2	0.7%
Not Lead Related	131	88	29.0%
Inappropriate VT/VF detection	41	30	9.9%
Loss of atrial pacing (known software issue; since fixed)	11	11	3.6%
Spontaneous VT/VF episodes	12	10	3.3%
Inappropriate AT/AF detection	10	9	3.0%
Failure to defibrillate AT/AF	8	8	2.6%
Hematoma	5	5	1.7%
Oversensing	5	5	1.7%
Software related	4	4	1.3%
Spontaneous AF/AT episodes	4	4	1.3%
No ventricular pacing during atrial pacing therapy	3	3	1.0%
Pacemaker mediated tachycardia	2	2	0.7%
Stroke	2	2	0.7%
Syncope	2	2	0.7%
Pain, arm	2	1	0.3%
Total Observations† **(including single observations)**	144	101	33.3 %

* Observations are adverse events that did not require invasive intervention.

† Observations that occurred in only one patient are listed following the table. Some patients had more than one type of adverse event.

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Single Observations – Each of the following was observed once in one patient:

- Ancillary Testing Equipment Failure
- Arm Swelling
- Atrial Exit Block (Model 6940)
- Atrial Standstill
- Atrial Therapies Disabled
- Chest Pain
- Congestive Heart Failure
- Device Migration
- Dizziness
- Fever
- Hypotension / Shortness Of Breath
- Increased Atrial Defibrillation Requirements
- Loss Automatic Capacitor Formation
- Patient Fall
- Programmer Related
- Pulmonary Embolism
- Right Atrial Thrombus
- Sarcoma
- Shortness of Breath
- Twiddler's Syndrome

5.1 Potential Adverse Events

Adverse events associated with ICD systems, in addition to those reported in the tables above, include: Cardiac perforation; Cardiac tamponade; Erosion through the skin; Extrusion; False sensing; Fibrotic tissue growth; Fluid accumulation; Formation of hematomas or cysts; Inappropriate pulsing or inhibition of normal electrical conduction; Infection; Keloid formation; Lead dislodgement; Loss of sensing; Muscle and nerve stimulation; Myocardial irritability at implant; Pericarditis; Psychological effects, including psychological intolerance to the ICD, imagined therapies, dependency, fear of inappropriate therapies, and fear that therapeutic capability may be lost.; Rejection phenomena (local tissue reaction and fibrotic tissue formation); and Venous perforation.

6 CLINICAL STUDIES

6.1 Jewel® AF Clinical Study Design

A global (USA, Europe, and Canada), multicenter, prospective non-randomized clinical study was performed to evaluate the safety (incidence of system-related complications) and effectiveness (treatment of atrial tachyarrhythmias) of the Model 7250 Jewel® AF System in 303 patients.

6.1.1 Patient Population

The study specified that patients eligible for enrollment included those who met the standard ICD Indications for Use. In addition, these patients were further divided into two groups:

VT/AT – Patients with at least two documented episodes of atrial fibrillation (AF) or atrial tachycardia including atrial flutter (AT) within the year prior to implant.

VT-Only – Patients with documented VT/VF but without documented AT or AF.

6.1.2 Crossover Study

The Jewel® AF clinical trial included a two-period, two-arm, cross-over design for the VT/AT subgroup. The study was designed with the intent to randomly assign patients in the VT/AT subgroup to have atrial therapies programmed ON vs. OFF during the first three months of follow-up, then reversed during the second three months of follow-up (with patients acting as their own controls). This design was intended to assess the ability of the AT therapies to reduce the frequency and duration of atrial arrhythmias. From the sixth month onward, AT therapies were programmed or disabled at the discretion of the investigator.

6.1.3 Primary Objectives

- **System-Related Complications (complication-free survival):** assess the relative risk of system-related complications following the implant of a Jewel® AF ICD system compared to a Model 7271 GEM® DR system and the Model 7219C system;

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- **AF Therapy:** estimate the effectiveness of atrial defibrillation therapy in terminating spontaneous AF episodes;
- **AT and Burst Therapy:** estimate the effectiveness of atrial antitachycardia pacing and high-frequency (50 Hz) burst therapies in terminating spontaneous AT episodes;
- **Dual Chamber Algorithm:** estimate the relative sensitivity of the dual-chamber detection algorithm.

6.1.4 Secondary Objectives

- **Overall Mortality:** assess the relative risk of death associated with the Model 7250 Jewel® AF versus the control Model 7219C (study later revised to include Model 7271 as the control).
- **Change in Frequency and Duration of Atrial Tachyarrhythmias (AT/AF Burden):** assess the frequency and duration of atrial tachyarrhythmias.
- **Atrial Defibrillation Thresholds (aDFTs) at Implant and 3 Months Post-Implant:** determine atrial DFT at implant and three months post-implant.
- **Specificity of the Dual Chamber Detection Algorithm:** assess the ability of the supraventricular tachycardia (SVT) rules of the dual chamber detection algorithm to prevent delivery of ventricular therapies for SVTs.
- **Sensing, Pacing, and Detection Analysis:** assess the pacing and sensing functions (Atrial Rate Stabilization, Mode Switch, and far-field oversensing).
- **Pacing and Sensing Performance of the Model 6943 Lead for Atrial Use:** assess the performance of the Model 6943 lead by obtaining lead measurements at implant and three months post-implant.

6.1.5 Control Devices

Although the investigational plan prospectively specified the Model 7219C as the safety control, the study was later revised to identify the Model 7271 GEM® DR as a safety comparison because the GEM® DR and the Jewel® AF share the following characteristics: (1) both are dual chamber ICDs; (2) both share identical detection algorithms; and (3) both studies used a similar adverse event reporting classification.

6.1.6 Follow-up

The study specified that patients were to be followed-up with an office visit at one, three, and six months post-implant, and every six months thereafter until completion of the study.

6.1.7 Gender Bias

In a tabulation of ICD implants entered into Medtronic's Device Registry database from 1990 through 1997, 20.3% of the 39,661 patients were female. Thus, the proportion of females enrolled in this study (19.8%) reflects the distribution of females in the population of patients implanted with an ICD.

6.2 Clinical Results

Table 7. Patient Population

Patient Cohort	Patients	Percent	Mean Follow-Up
VT/AT Group	230	76%	8.2 ± 4.8 months
VT Only Group	73	24%	7.0 ± 4.5 months
Total	303	100%	7.9 months*

* Cumulative follow-up = 2,393 patient-months

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Demographic	Patient Population (N=303)	
Gender	243 (80%) Male ; 60 (20%) Female	
Age	63.6 years (18 - 84 years)	
LV Ejection Fraction	37.7% (10% - 86%)	
History of AT/AF	230 (76%)	
Primary Indication	Ventricular Arrhythmias	59%
	Sudden Cardiac Death (SCD)	27%
	Ventricular Arrhythmias & SCD	13%
Primary Cardiovascular History (non-exclusive)	Coronary Artery Disease and/or Myocardial Infarction	66%
	Cardiomyopathy	45%
	Congestive Heart Failure	25%

Table 8. Implant Experience

ICD and Lead Implant Success (N=303)	Patients
Patients in whom an implant was attempted	97%
Patients who received a two-lead system	89%
Reason Not Implanted (10 patients, 3.3 %)	**Patients**
Failure to meet ventricular implant criteria	4
Inability to implant leads	2
Patient died after enrollment, but prior to implant	1
Need to minimize implant time due to patient condition	1
Clinical study was temporarily suspended by sponsor	1
No reason provided	1

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6.2.1 Lead Configurations

The figure below depicts the most common two-lead configurations used in the clinical study, and identifies the percentage of the 253 patients implanted with each lead system.

54%

30%

2 Lead System
- Atrial P/S
- Ventricular P/S/HV (SVC and RV coils)
- Active device can

2 Lead System
- Atrial P/S/HV (RA coil)
- Ventricular P/S/HV (RV coil)
- Active device can

Figure 1. Implanted Lead Configurations

Other two-lead systems:

Atrial P/S; Ventricular P/S/HV (RV coil) – 4%
Atrial P/S/HV (RA coil); Ventricular P/S/HV (SVC and RV coils) – 0.3%

Three-lead systems:

Atrial P/S; Ventricular P/S/HV (SVC and RV coils); Coronary Sinus HV (CS coil[1]) – 3%
Atrial P/S/HV (RA coil); Ventricular P/S/HV (RV coil); Coronary Sinus HV (CS coil[1]) – 3%
Atrial P/S; Ventricular P/S/HV (RV coil); Subcutaneous HV Patch – 1.7%
Atrial P/S; Ventricular P/S/HV (RV coil); SVC HV coil – 1%
Atrial P/S; Ventricular P/S/HV (RV coil); Subcutaneous HV Patch – 0.7%
Atrial P/S/HV (RA coil); Ventricular P/S/HV (RV coil); Subcutaneous HV Patch – 0.3%

6.2.2 Tiered Therapy Programming Sequences

Programmed settings for atrial therapy parameters that occurred in the PMA patients at baseline, three months, and the six month follow-up (database cutoff December 31, 1998) are presented in the following tables.

VT/AT patients were randomized to atrial therapies On or Off at implant, with a cross-over to the opposite therapy setting at the three month follow-up. VT-Only patients were not required to have atrial therapies programmed On. Randomization was competed as of the six month follow-up, at which time the investigator could program the patient's device at his/her discretion.

1. Investigational device.

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Table 9. Device Programming at Baseline, Three Months and Six Months (VT/AT patients implanted with the Model 7250 Jewel® AF)

	Baseline (n= 221)	Three Months (n=161)	Six Months (n=139)
AT Treatment Therapies			
ATP+HFB	15.8%	16.8%	18.7%
HFB Only	5.4%	8.7%	10.1%
ATP Only	2.7%	3.7%	5.0%
ATP+HFB+Atrial Shock	2.7%	3.1%	2.2%
HFB+Atrial Shock	2.3%	1.9%	2.9%
ATP+Atrial Shock	1.4%	1.2%	2.2%
Atrial Shock Only	0.9%	- 0 -	- 0 -
All AT therapies Off	68.8%	64.6%	59.0%
AF Treatment Therapies			
HFB Only	24.4%	30.4%	30.9%
HFB+Atrial Shock	11.3%	8.1%	10.8%
Atrial Shock Only	6.6%	5.0%	5.0%
All AF therapies Off	57.5%	56.5%	53.2%

Table 10. Device Programming at PMA Cutoff Date (12/31/1998), VT/AT Patients

	Baseline (n= 221)	Three Months (n= 161)	Last Interrogation (n= 139)
All atrial therapies Off	54.3%	52.8%	36.7%
At least one atrial therapy On	45.7%	47.2%	63.3%

6.3 Primary Objectives

6.3.1 System Related Complications

Hypothesis – The objective is met when the ratio of the upper one-sided 95 percent confidence bound for the Crude Hazard Rate and the Cox Hazard Rate of the study group, Jewel® AF, versus the control, GEM® DR, is less than or equal to three.

Results – The primary objective of complication-free survival was met. The results included the following:

System Related Complications	Relative Risk	Confidence Interval
Model 7250 Jewel® AF vs. Model 7271 GEM® DR	0.97	0.60, 1.55
Model 7250 Jewel® AF vs. Model 7219C	1.83	1.17, 2.84

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Table 11. Complication-Free Survival

Group	ICD Model	Three Months	Six Months
Study	Model 7250 Jewel® AF	92.1%	87.9%
Control	7219C	95.3%	93.5%
Control	Model 7271 GEM® DR	92.0%	91.2%

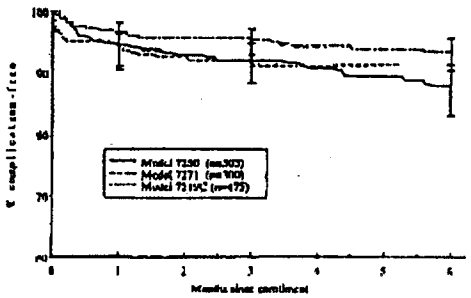

Figure 2. Complication-Free Survival (Kaplan-Meier Plot) For the Model 7250 and Control Clinical Studies

6.3.2 AT/AF Episode Summary

Utilizing data from the ICD's stored episode records and the investigators' classifications of the episodes, spontaneous treated AT/AF episodes were evaluated for performance of the atrial detection algorithms and effectiveness of the device's features for treating atrial tachyarrhythmias.

Parameter	Result
Total Spontaneous Non-Treated* AT/AF Episodes	8112
Total Spontaneous Non-Treated AT/AF Episodes	1107
Number of Treated AT/AF Episodes Appropriately Detected	1052
Positive Predictive Value (PPV) [1052/1107]	95.0 %

* 61.0 % of these non-treated AT/AF episodes were due to atrial therapies being programmed Off; 39.0 % were not treated because the atrial episode duration was shorter than the programmed time to deliver atrial therapy.

The clinical study did not evaluate the ability of the Jewel® AF ICD to discriminate between AT vs. AF episodes, since these classifications are considered device designations which may or may not correspond to specific atrial arrhythmias.

The number of treated AT and AF episodes as classified by the Jewel® AF ICD are shown in the table below.

Parameter	Result
Treated Episodes Classified by Model 7250 Jewel® AF as AT	695
Treated Episodes Classified by Model 7250 Jewel® AF as AF	357

In summary, the Jewel® AF ICD detected 1107 AT/AF episodes in 78 patients. Seventy-four of the 78 patients experienced 1052 appropriately detected AT/AF episodes. Ten of the 78 patients experienced 55 inappropriately detected AT/AF episodes, all of them due to far-field R-wave sensing. Table 12 describes the programming changes made to resolve far-field R-wave sensing.

Table 12. Inappropriately Detected AT/AF Episodes

Patient	Inappropriately Detected AT/AF	Adverse Event Reported?	Resolution
1	23	Yes	Atrial sensing threshold increased from 0.45 mV to 0.6 mV.
2	1	Yes	Atrial sensing threshold increased from 0.3 mV to 0.45 mV.
3	2	Yes	Atrial sensing threshold increased from 0.3 mV to 0.45 mV.
4	5	Yes	Atrial sensing threshold increased from 0.6 mV to 0.9 mV.
5	1	Yes	Atrial sensing threshold increased from 0.6 mV to 0.9 mV.
6	1	No	Atrial sensing threshold increased from 0.3 mV to 0.6 mV.
7	1	No	Atrial sensing threshold increased from 0.3 mV to 0.45 mV.
8	1	No	Atrial sensing threshold increased from 0.3 mV to 0.45 mV.
9	3	No	Atrial therapies programmed Off.
10	1	No	Atrial sensing threshold increased from 0.45 mV to 0.6mV.
Total	55		

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Table 13 provides a detailed breakdown of the 1052 appropriately detected AT/AF episodes by the sequence of therapies delivered.

Table 13. Breakdown of Spontaneous AF/AT Episodes by Therapy Sequence

		AT		AF	
	Therapy Sequences	Episodes	Successes	Episodes	Successes
1	ATP	379	317	0	0
2	ATP, 50 Hz	115	31	93	10
3	ATP, 50 Hz, ATP	2	0	0	0
4	ATP, 50 Hz, ATP, 50 Hz	1	0	0	0
5	ATP, 50 Hz, A-Defib	12	11	5	3
6	ATP, 50 Hz, A-Defib, ATP, 50 Hz	1	0	0	0
7	ATP, A-Defib	2	2	3	3
8	50 Hz	54	21	146	39
9	50 Hz, ATP	53	17	0	0
10	50 Hz, ATP, 50 Hz	34	6	30	9
11	50 Hz, ATP, A-Defib	1	1	1	1
12	50 Hz, ATP, 50 Hz, A-Defib	0	0	3	2
13	50 Hz, A-Defib	0	0	33	26
14	A-Defib	10	5	42	32
15	A-Defib, 50 Hz	0	0	1	0
16	A-Defib, ATP, 50 Hz, A-Defib, 50 Hz	1	0	0	0
	Total	695	411	357	125

6.3.3 AF Therapy

Hypothesis – The objective is met when the lower one-sided 95 percent confidence bound on atrial shock efficacy for termination of spontaneous AF episodes is greater than 50 percent.

Results – The primary objective that estimated the effectiveness of AF therapy in terminating spontaneous AF episodes was met. The results included the following:

A total of 2688 spontaneous AF episodes were observed in the clinical study. Of these, 357 (13.3%) were treated by the Jewel® AF ICD. (See Table 13 above.) With high frequency burst (A-50 Hz Burst) therapy, 56 of 345 AF episodes were successfully terminated (16.8%). With atrial defibrillation shock therapy, 67 of 88 AF episodes were successfully terminated (76.1%).

Table 14. Spontaneous AF Episode Termination

	Result	95% Confidence Interval
Effectiveness of high frequency burst therapy (n= 48 patients*)	17 % (58 / 345*)	(11%, 26%)
Effectiveness of atrial defibrillation therapy (n= 29 patients*)	76 % (67 / 88*)	(61%, 85%)
AF Termination Effectiveness (n= 54 patients)	**35 % (125 / 357)**	**(33%, 53%)**

* Not mutually exclusive.

6.3.4 ATP and Burst Therapy

Hypothesis – The objective is met when the lower one-sided 95 percent confidence bound for ATP and high frequency burst (A-50 Hz Burst) therapy effectiveness for termination of spontaneous AT episodes is greater than 50 percent.

Results – A total of 6476 spontaneous AT episodes were observed in the clinical study. Of these, 695 (10.7%) were treated by the Jewel® AF ICD. (See Table 13 on page 21.) With atrial ATP therapy, 334 of 605 AT episodes were successfully terminated (55.2%). With high frequency burst (A-50 Hz Burst) therapy, 58 of 341 AT episodes were successfully terminated (17.0%). With atrial defibrillation shock therapy, 19 of 28 AT episodes were successfully terminated (67.9%). This performance did not satisfy the study objective as stated.

Table 16. Spontaneous AT Episode Termination

	Result	95% Confidence Interval
Effectiveness of ATP therapy (n= 40 patients*)	55 % (334 / 605*)	(31%, 51%)
Effectiveness of HFB therapy (n= 35 patients*)	17 % (58 / 341*)	(7%, 23%)
Effectiveness of atrial defibrillation therapy (n= 9 patients*)	68 % (19 / 28*)	(41%, 87%)
AT Termination Effectiveness (n= 46 patients)	**59.1 % (411 / 695)**	**(35%, 56%)**

* Not mutually exclusive.

6.2.5 Dual Chamber Detection Algorithm

Hypothesis – The objective is met when the lower one-sided 95 percent confidence bound for relative sensitivity of VT/VF detection is greater than 95 percent.

Methods – Utilizing data from the ICD's stored episode records, 24 Holter recordings, and the investigators' classifications of the episodes, spontaneous VT/VF episodes were evaluated for performance of the dual-chamber detection algorithm. Overall, 67 Holter recordings from 48 patients with a combined total of 1153 hours ECG and telemetered markers/EGM were analyzed.

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Results – One hundred forty-four spontaneous VT/VF episodes were detected on the 24-hour Holter recordings. All 144 of these VT/VF episodes were appropriately detected by the device. No VT/VF episodes were missed. Based on the findings of the Holter analysis and review of adverse events, sensitivity of VT/VF detection was determined to be 100%.

Of the 1192 spontaneous ventricular episodes detected by the device, 1056 (88.6%) were classified by the investigator as appropriately detected yielding a positive predictive value (PPV) of 88.6%.

Table 16. Detection of Spontaneous VT/VF Episodes

Parameter	Result
Spontaneous Ventricular Episodes	1192
Number of VT/VF Episodes Appropriately Detected	1056
Number of VT/VF Episodes Inappropriately Detected	136
PPV (1056/1192)	88.6%

6.4 Secondary Objectives

There were no prospectively defined study hypotheses for the secondary study objectives. Instead, observational data were collected and compared to performance data from the control ICD(s).

6.4.1 Overall Mortality

Methods – All patient deaths were reviewed by an Adverse Events Advisory Committee (AEAC), an independent panel of physicians, and categorized as believed to be Sudden Cardiac, Non Sudden Cardiac, Non Cardiac, or Unknown.

Results – Twenty-six deaths occurred during the study. The AEAC believes that none of the deaths was related to the Jewel® AF ICD.

For the Model 7250 Jewel® AF ICD, overall survival at three months was 97.9%, and at six months was 93.8%. For the Model 7271 GEM® DR ICD, overall survival at three months was 94.7%, and at six months was 91.7% (p = 0.12 vs. Model 7250 Jewel® AF).

6.4.2 Changes in Frequency and Duration of AT

Methods – A crossover substudy was performed with patients in the VT/AT group being randomized to atrial therapies ON vs. OFF for 3 months. Each patient acted as their own control to assess the safety and effectiveness of the atrial tachyarrhythmia therapies.

Results – Data from 48 patients showed that there was at least a 50% reduction in the frequency of AT/AF per day with the therapies On versus Off (p = 0.18), and an average five-hour reduction per week in the total duration of spontaneous AT/AF episodes (p = 0.088). However, these data were not considered statistically significant. In addition, use of the ICD system has not been demonstrated to decrease the morbidity related to atrial tachyarrhythmias.

6.4.3 Atrial Defibrillation Thresholds at Implant and 3 Months Post-Implant

Methods – Atrial defibrillation thresholds (DFTs) were determined in VT/AT patients using the one-step and two-tiered protocols. The one-step protocol consisted of programming the atrial DFT at the first successful energy. The two-tiered method involved using the step-up method in determining DFTs and after the DFT was obtained, energy was stepped-up until a second success is attained.

Results – The mean atrial DFT at implant using the two-tiered protocol was 8.6 joules +/- 4.9 joules (n= 72). Using the one-step protocol, the mean atrial DFT at implant was 5.7 joules +/- 4.3 joules (n= 126). The mean atrial DFT at three months was 5.6 joules +/- 3.3 joules (n= 15). Atrial DFTs remained stable over three months.

Based on the experience as described above, it is recommended that the first atrial defibrillation therapy be programmed to two times the atrial defibrillation threshold, or to the maximum output.

6.4.4 Specificity of the Dual Chamber Detection Algorithm

Methods – The positive predictive value (PPV) of AT/AF detection was measured. PPV measures the accuracy of the dual chamber detection algorithm and is the ratio of true positive AT/AF detections to the sum of true positive and false positive AT/AF detections.

Results – Of the 1107 spontaneous atrial episodes, 1052 (94.8%) were classified as appropriately detected, yielding a positive predictive value (PPV) of 94.8%.

6.4.5 Sensing, Pacing, and Detection Analysis

Methods – Pacing and sensing functions of the Jewel® AF ICD were evaluated via ambulatory Holter monitoring of 48 patients to verify appropriate sensing, pacing, and detection functions; to verify appropriate ARS performance; and to evaluate far-field R-wave sensing.

Results – On the average, 52.3% of the ventricular events and 28.4% of the atrial events were paced. 85.1% were programmed to DDD mode. Three hundred thirty-one ventricular safety paces occurred during two of the recordings. Atrial Rate Stabilization (ARS) pulses occurred during 23 recordings. On the average, 4.7 percent of cardiac cycles involved an ARS pulse. Seventy-two percent of the recordings had no far-field R-wave oversensing. Far-field R-wave oversensing was one of the most common causes of ARS and mode switching. The recordings demonstrated that the device functions performed as intended.

Two hundred fifty-six of 256 spontaneous VF episodes were terminated (100%) and 854/875 spontaneous VT episodes were terminated (97.6%). One thousand seventy-two of 1072 (100%) atrial defibrillation shocks (induced and spontaneous) were appropriately synchronized to the R-wave, and did not result in proarrhythmia.

6.4.6 Pacing and Sensing Performance of the Model 6943 Lead

Methods – Several pacing and sensing parameters were measured at implant, and at one, three, and six months post-implant. Pulse width threshold, pacing impedance, and P-wave amplitude were measured.

Results – Ninety-six patients in the PMA population were implanted with the Model 6943 lead. The measurements remained relatively stable throughout 6 months.

6.4.7 Gender Bias Analysis

Differences between males and females with respect to complication-free survival, overall survival, spontaneous AF episode termination with atrial defibrillation therapy, and spontaneous AT episode termination with ATP followed by high frequency burst (HFB) were examined.

The Kaplan-Meier estimates of complication-free survival at 3 months are 90.6% for males and 97.9% for females. While females appear to be at a lower risk of experiencing a complication, the comparison of complication-free survival curves is not statistically significant at the 5% level (p=.082). With respect to overall mortality, the Kaplan-Meier estimates of survival at 3 months are 97.9% for males and 98.1% for females. There is no significant difference between the survival curves for males and females (p=.471).

The percentages of males and females experiencing spontaneous AF episodes treated with atrial defibrillation therapy were 13% and 15%, respectively. The mean rate of successful spontaneous AF episode termination with atrial defibrillation therapy was 71% in males and 76% in females (p=.915). The percentages of males and females experiencing spontaneous AT episodes treated with ATP followed by HFB were 19% and 21%, respectively. The mean rate of successful spontaneous AT episode termination with ATP followed by HFB was 55% in males and 53% in females (p=.917).

In summary, based on univariate analyses, there are no statistically significant differences between males and females with respect to any of the primary outcomes.

7 PATIENT SELECTION AND TREATMENT

7.1 Individualization of Treatment

Pectoral or abdominal implant site – Evaluate the prospective patient's size and activity level to determine whether a pectoral or abdominal implant is suitable.

Exercise stress testing – If the patient's condition permits, use exercise stress testing to:

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- 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.

Electrophysiologic (EP) testing – It is strongly recommended that candidates for ICD therapy have a complete cardiac evaluation including EP testing. EP testing should identify the classifications and rates of all the ventricular and atrial arrhythmias, whether spontaneous or induced during EP testing.

Drug resistant supraventricular tachyarrhythmias (SVTs) may initiate frequent unwanted device therapy. A careful choice of programming options is necessary for such patients.

Antiarrhythmic drug therapy – 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 ICD implantation. If changes to drug therapy are made, repeated arrhythmia inductions are recommended to verify ICD detection and conversion. The ICD also may need to be reprogrammed.

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

Selection of atrial tachyarrhythmia therapies – The therapy sequence for treatment of AF/AT was not controlled in the study of the ICD. The relative effectiveness of various AF/AT therapy programming sequences cannot be determined from the study data.

Direct any questions regarding the individualization of patient therapy to Medtronic's representative at 1-800-PCD-INFO (1-800-723-4636).

7.2 Specific Patient Populations

Pregnancy – If there is a need to image the ICD, 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.

Pediatric Patients – This ICD has not been studied in patients younger than 13 years of age.

Geriatric Patients – Most (67%) of the patients receiving this device ICD in clinical studies were over the age of 60 years – see "CLINICAL STUDIES").

Handicapped and Disabled Patients – Special care is needed in using this ICD for patients using electrical wheelchairs or other electrical (external or implanted) devices.

8 PATIENT COUNSELING INFORMATION

Physicians should consider the following points in counseling the patient about this ICD:

- 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.
- Encourage patients to use identification cards (issued by Medtronic) and/or identification bracelets documenting their ICD system.

Discuss information in the Patient Manual (*Restoring the Rhythms of Life*) with patients before and after ICD implantation so they are fully familiar with operation of the ICD. Advise patients how to obtain additional copies of the patient manuals.

9 CONFORMANCE TO STANDARDS

This ICD was developed in conformance with all or parts of the following standards:

- ISO 5841-3:1992(E), IS-1 IPG Connector Standard.
- ISO 11318:1993(E), DF-1 Defibrillator Connector Standard.

This information should not be used as a basis of comparisons among devices since different parts of the standards mentioned may have been used.

10 HOW SUPPLIED

The Model 7250 Jewel® AF is packaged one per package in a sterile package.

11 CLINICIAN USE INFORMATION

11.1 Physician Training

Physicians should be familiar with sterile ICD implant procedure and familiar with follow-up evaluation and management of patients with a defibrillator (or referral to such a physician).

11.2 Directions for Use

ICD operating characteristics should be verified at the time of implantation and recorded in the patient file. Complete the Device Registration Form and return it to Medtronic as it provides necessary information for warranty purposes and patient tracking.

The Model 7250 Product Information Manual (PIM) is a separate document supplied with each ICD. This manual includes product specifications, operating characteristics, and implant and follow-up recommendations. The Jewel® AF System Reference Guide (SRG), supplied with the 9961E software, provides complete programming instructions and recommendations. Copies can be obtained by contacting the Medtronic representative, or by calling 1-800-PCD-INFO (1-800-723-4636). The PIM and SRG were last updated in February 2000.

This Prescriber's Package Insert was last updated February 2000.

11.3 Maintaining Device Effectiveness

11.3.1 ICD Storage

FOR SINGLE USE ONLY. Do not resterilize and reimplant an explanted ICD. Medtronic has sterilized the ICD with ethylene oxide prior to shipment. Resterilizing the ICD is necessary if the seal on the sterile package is broken. Resterilization does not affect the "Use Before" date because this date is based on battery life and sterility.

Do not implant the ICD when:

- It has been dropped on a hard surface from a height of 45 cm (18 inches) or more because this could have damaged pulse generator components;
- Its storage package has been pierced or altered, because this could have rendered it non-sterile;
- It has been stored or transported outside the environmental temperature limits of -18 to 55 °C (0 to 131 °F), as the ICD circuitry may have been damaged; or
- Its "Use Before" date has expired, because this can adversely affect ICD longevity or sterility.

11.3.2 Sterilization Instructions

Do not resterilize the ICD or the torque wrench using an autoclave, gamma radiation, organic cleaning agents (e.g., alcohol, acetone, etc.), or ultrasonic cleaners.

Should sterilization be required:

- Repackage all items in a gas permeable container;
- Use a validated ethylene oxide gas process;
- Follow the manufacturer's operation instructions so long as the maximum temperature does not exceed 55 °C (131 °F);
- Store the resterilized components for an appropriate period to permit aeration of ethylene oxide gas.

12 PATIENT INFORMATION

Information for the patient is available in a separate booklet, *Restoring the Rhythms of Life*, from Medtronic. To obtain a copy, contact the Medtronic representative or call 1-800-PCD-INFO (1-800-723-4636). This information should be given to each patient with their ICD, and offered to the patient on each return visit or as deemed appropriate.

Restoring the Rhythms of Life was developed using patient and clinician input to ensure that it is understandable. *Restoring the Rhythms of Life* was last updated October 1999.

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