Medtronic

INSYNC® ICD 7272

Dual Chamber Implantable Cardioverter Defibrillator with Cardiac Resynchronization Therapy

Prescriber's Package Insert

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

Before implanting the ICD, it is strongly recommended that you:

Thoroughly read this manual, prescribing the ICD manual, technical manuals for the leads used with the device, implant support instrument technical manual, and the device programming system reference guide for the programmer software.

Provide a copy of the patient manual to the patient and discuss it with him or her and any other interested parties.

If a physician is not familiar with implantation or follow-up of Implantable Cardioverter Defibrillators (ICDs) with cardiac resynchronization systems, the physician is required to:

1. Thoroughly read this manual, and all associated device and/or lead technical manuals.
2. Provide a copy of the patient manual to the patient and discuss it with him or her and any other interested parties.
3. Be trained on the following topics:

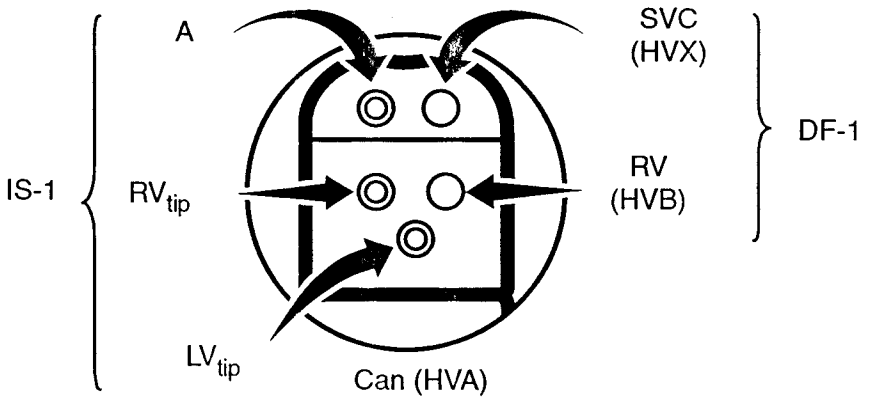
   Indications for use
   Device operation to ensure therapy delivery
   Measuring and managing biventricular thresholds
   Assembly and use of LV lead implant tools
   Placement of the LV lead
   Patient management and system follow-up

Medtronic will certify that physicians are trained prior to implanting the InSync ICD system.

Nominal specifications

Maximum shock energy	Lead[a,b,c,d,e] connections	Dimensions W x H x D	Volume	Mass
34 J	2 DF-1 1 IS-1 bipolar, 2 IS-1 unipolar	57 x 87 x 16 mm	66 cc	117 g
Case material	Titanium			
Header materials	Polyurethane, silicone rubber			
Power supply	Lithium silver vanadium oxide (6.4 V nominal)			

Lead connections



[a] The device case serves as a defibrillation electrode.

[b] For lead compatibility information, refer to the next page and "Lead System" on page 3.

[c] The DF-1 ports will not accept a 3.2 mm in-line bipolar lead.

[d] DF-1 refers to the international standard ISO 11318:1993. IS-1 refers to ISO 5841-3:1992.

[e] If the ICD is used with an RV lead that is not integrated bipolar, a thorough assessment of sensing should be performed, as the lead design may not provide optimal sensing characteristics. Improperly configured or connected leads prevent the appropriate delivery of the therapy by the ICD.

Lead compatibility

The InSync® ICD is designed to accept DF-1 and IS-1 lead connectors[1]. Contact your Medtronic representative for Medtronic preferred leads recommendations.

[1] DF-1 refers to the international standard ISO 11318:1993. IS-1 refers to ISO 5841-3:1992.

1 Device description

The Model 7272 InSync® ICD Dual Chamber Implantable Cardioverter Defibrillator (ICD) system, with biventricular pacing for cardiac resynchronization, is an implantable medical device system that automatically detects and treats episodes of ventricular fibrillation, ventricular tachycardia, fast ventricular tachycardia, and bradyarrhythmia, as well as providing biventricular pacing for cardiac resynchronization. The ICD system includes three major components:

ICD – The ICD senses the electrical activity of the patient's heart via the sensing electrodes of the implanted atrial and ventricular leads. It then analyzes the heart rhythm based on selectable sensing and detection parameters. If the ICD detects a tachyarrhythmia, it delivers defibrillation, cardioversion, or antitachycardia pacing therapy to the patient's heart. If the ICD identifies a bradyarrhythmia, it delivers bradycardia pacing therapy to the patient's heart.

The ICD provides biventricular pacing for cardiac resynchronization for patients with chronic symptomatic heart failure who have ventricular dysynchrony.

Leads – The ICD can be used with transvenous or epicardial defibrillation leads. The lead system should consist of bipolar or paired unipolar[1] pacing/sensing leads in the right atrium and right ventricle of the heart, a pacing lead for the left ventricle, and one or two high voltage cardioversion/ defibrillation electrodes. In addition to the lead system, the Active Can acts as one of the high voltage electrodes. The ICD delivers pacing and cardiac resynchronization therapy via the atrial (A), right ventricular (RV), and left ventricular (LV) leads. The ICD senses via the atrial and RV leads. Cardioversion defibrillation therapy is delivered via the Active Can and one or two lead-based high voltage electrodes.

Programmer, software, and accessories – The Model 9790C programmer or Medtronic CareLink Model 2090 programmer, Model 9969 software, Model 9466 Patient Magnet, and a telemetry programming head constitute the external portion of the device system.

2 Indications and usage

The InSync ICD Model 7272 is indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening ventricular arrhythmias. The system is also indicated for the reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy (as defined in the clinical trials section), and have a left ventricular ejection fraction ≤ 35% and a QRS duration ≥ 130 ms.

3 Contraindications

Do not use the InSync ICD system in:

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

[1] With an appropriate unipolar to bipolar adapter kit.

4 Warnings

4.1 General

- **Labeling knowledge.** Thoroughly read this manual prior to implanting the device to avoid damage to the implanted system. Such damage can result in injury to or death of the patient.
- **Resuscitation availability.** Do not perform device testing unless an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are readily available.
- **Electrical isolation.** Do not permit the patient to contact grounded equipment which could produce hazardous leakage current. Resulting arrhythmia induction could result in the patient's death.
- **Avoiding shock during handling.** Program VF Detection to OFF during surgical implant and explant, or post-mortem procedures, because the device can deliver a serious shock if you touch the defibrillation terminals in certain situations if device detection is ON.
- **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.
- **Magnetic Resonance Imaging (MRI)** should not be used on patients who have a device because of the potential damage to the device.
- **Diathermy.** People with metal implants such as pacemakers, implantable cardioverter defibrillators (ICDs), and accompanying leads should not receive diathermy treatment. The interaction between the implant and diathermy can cause tissue damage, fibrillation, or damage to the device components, which could result in serious injury, loss of therapy, and/or the need to reprogram or replace the device.

4.2 Implantation, programming, and device operation

- **Atrial tracking modes.** Do not use atrial tracking modes in those patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in VT or VF.
- **Atrial only modes.** Do not use atrial only modes in the following patients:
  - patients with heart failure because such modes do not provide cardiac resynchronization.
  - patients with impaired AV nodal conduction because ventricular capture cannot be assured.
- **Single chamber hysteresis.** For heart failure patients, the use of single chamber hysteresis will not provide cardiac resynchronization.
- **Slow VT.** Use caution when implanting this device in patients presenting with slow VT. Programming therapy for slow monomorphic VT will prevent cardiac resynchronization therapy delivery at faster rates if these rates are in the tachyarrhythmia detection zones.
- **End of Life (EOL).** Replace the device when the programmer displays an EOL message and a battery voltage of 4.57 volts or less. Immediate replacement is recommended if the programmer displays a Charge Circuit Timeout or Charge Circuit Inactive message.
- **Pacemaker dependent patients.** Always program Ventricular Safety Pacing (VSP) **On** for pacemaker dependent patients. Ventricular Safety Pacing prevents ventricular systole due to inappropriate inhibition of ventricular pacing caused by cross talk or ventricular asystole.

5 Precautions

5.1 Sterilization, storage, and handling

- **For single use only.** Do not resterilize and re-implant an explanted device.
- **"Use Before" Date.** Do not implant the device after the "Use Before" date, because the battery's longevity could be reduced.
- **If package is damaged.** Do not use the device or accessories if the packaging is wet, punctured, opened, or damaged, because the integrity of the sterile packaging might be compromised. Return the device to Medtronic.

- **Device storage.** Store the device in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference to avoid device damage. Store and transport the device between -18 to 55 °C (0 to 131 °F), because temperatures outside this range could damage the device.
- **Dropped device.** Do not implant the device if it has been dropped on a hard surface from a height of 30 cm (12 inches) or more because this could have damaged ICD components;
- **Equilibration.** Allow the device to reach room temperature before programming or implanting the device, because rapid temperature changes could affect initial device function.

5.2 Implantation and device programming

- **Rate responsive pacing.** Rate responsive modes are available for those heart failure patients who may develop a need for rate responsive pacing. Rate responsive pacing was not studied in this patient population. These modes should not be programmed unless the patient needs this type of support.
- **Mode Switch.** Mode Switch should be programmed OFF unless the patient has a history of atrial fibrillation. Mode Switch automatically selects values for PVARP and Rate Adaptive AV that may not be optimal for providing cardiac resynchronization.
- **Infrequent charging.** Infrequent charging of the high voltage capacitors could extend the device charge time. Program the device to condition the capacitors automatically, or perform a test charge to form the capacitors manually every six months (if the device has not charged to its maximum energy).
- **Use of a magnet.** Positioning a magnet or the programming head over the device suspends detection and treatment. The magnet does not alter bradycardia therapy.
- **Programmer.** Use only Medtronic programmers and application software to communicate with the ICD.
- **Programming device parameters.** Program device parameters such as sensitivity thresholds and VT and VF detection intervals according to the recommendations in the technical manual.
- **Concurrent pacemaker use.** If a pacemaker is used concurrently with the ICD:
  - Verify that the ICD will not sense the pacemaker output pulses and
  - program the pacemaker so that pacing pulses are delivered at intervals longer than the ICD tachyarrhythmia detection intervals.

5.3 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 device to ensure defibrillation effectiveness.
- If a thoracotomy is required to place epicardial patches, it should be done during a separate procedure to reduce the risk of morbidity and mortality.
- Do not place the patch lead over nerve tissue as this can cause nerve damage.
- Place the patch lead with the conducting coil side facing the heart to ensure delivery of energy to the heart.
- Place the sutures well outside the coil of the patch lead or in the area between the coils to avoid possible coil fracture.
- If countershock is unsuccessful using external paddles, adjust the external paddle position (e.g., anterior-lateral to anterior- posterior) and be sure that the external paddle is not positioned over the patch.

- Do not fold, alter, or remove any portion of the patch, because it could compromise electrode function or longevity.
- 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 device.
- 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 device and leads. While the device is connected to the leads, make sure that no therapeutic electrodes, stylets, 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 device, the port must be plugged to protect the device.
- Refer to the lead technical manuals for specific instructions and precautions.
- If the high voltage path impedance value exceeds 200 ohms and the delivered energy is less than 0.6 joules, the ICD short circuit protection feature may have interrupted delivery of the shock into a short circuit. Perform a lead impedance test to assess high voltage circuit integrity.

5.4 Follow-up testing

- 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.
- **Conversion Testing.** 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.

5.5 Device explant and disposal

- To prevent unwanted shocks, program the ICD VF, FVT, and VT detections OFF prior to explanting, cleaning, or shipping the ICD.
- Return all explanted devices and leads to Medtronic.
- Never incinerate the device due to the potential for explosion. The device must be explanted before cremation.

5.6 Environmental and medical therapy hazards

Avoid sources of EMI. 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.

5.6.1 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 current path and ground plate should be kept as far away from the device and leads as possible (minimum of 15 cm [six inches]).

- **External defibrillation** may damage the device 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 device and lead system by following these precautions when using external defibrillation on a patient with a device:
  - Position defibrillation paddles as far from the device as possible (minimum of 13 cm [five inches]). Minimize current flowing through the device and lead system by positioning the defibrillation paddles perpendicular to the implanted device-lead system.
  - Use the lowest clinically appropriate energy output (watt seconds).
  - Confirm device function following any defibrillation.
- **After direct or transthoracic defibrillation**, check lead and ICD integrity by performing lead impedance and pacing threshold tests as described in the ICD System Reference Guide.
- **High radiation sources** such as cobalt 60 or gamma radiation should not be directed at the device. If a patient requires radiation therapy in the vicinity of the device, place lead shielding over the device to prevent radiation damage and confirm its function after treatment.
- **Lithotripsy** may permanently damage the device if it is at the focal point of the lithotripsy beam. If lithotripsy must be used, keep the device at least 2.5 to 5 cm [one to two inches] from the focal point of the lithotripsy beam.
- **Radio frequency ablation** procedure in a patient with an ICD could cause ICD malfunction or damage. RF ablation risks can be minimized by:
  - Programming VF, VT, and FVT detection 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.
- **Therapeutic ultrasound.** Exposure of the device to therapeutic ultrasound is not recommended as it may permanently damage the device. Damage to the device may affect therapy.

5.6.2 Home and occupational environments

- **High voltage power transmission lines** could generate enough EMI to interfere with device 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 device operation if approached too closely.
- **Commercial electrical equipment** such as arc welders, induction furnaces, or resistance welders could generate enough EMI to interfere with device 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 device operation. There are reports of device disturbances caused by electrical hand tools or electric razors used directly over the device 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) since it could suspend detection. Examples of magnetic sources that could interfere with normal device operation include: stereo speakers, bingo wand, extractor wand, magnetic badges, or magnetic therapy products.

5.6.3 Electronic Article Surveillance (EAS)

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

5.6.4 Cellular phones

- Cellular phones may interact with the implanted ICD when placed in close proximity to the device. Patients should maintain a minimum separation of six inches (15 centimeters) between the phone and the implanted ICD, hold the phone to the ear opposite the side of the implanted ICD, and store the phone in a location opposite the side of the implanted device.