



**Medtronic**

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**IMPORTANT PATIENT SAFETY INFORMATION**

Dear Doctor:

Medtronic is providing an update to previous advisory notices for **GEM® DR Model 7271 and Micro Jewel® II Model 7223Cx ICDs**. This update replaces recommendations made for the GEM DR Model 7271 in December 1999, and for the Micro Jewel II Model 7223Cx provided in August 1999 and November 2000 about suspect capacitors in identified populations. This notification is consistent with our commitment to provide you with ongoing performance updates.

Because of the concern that these ICDs with suspect capacitors may not be consistently capable of providing high voltage energy delivery near or at ERI (4.91 V) and continuing through EOL (4.57 V), we are issuing the following revised recommendations:

- **If the patient's last follow-up was within the previous three months, and records are available, verify the recorded battery voltage and capacitor charge time as below.**
- **For all others, schedule follow-up as soon as possible, and verify the charge time and battery voltages below.**
- **Schedule replacement for any device with:**
  - **battery voltage of 5.16 V or less, (NEW RECOMMENDATION)**
  - **OR charge time of 18 seconds or greater.**
- **If the battery voltage is greater than 5.16 volts, verify the charge time:**
  - **If less than 18 seconds but greater than 14 seconds, program the Automatic Capacitor Formation Interval to one month.**
  - **No additional reprogramming is required if verified charge time is less than 14 seconds, or if capacitor formation is already set to one month.**
- **Continue to follow these patients every three months, at a minimum.**

These recommendations relate only to the Micro Jewel II and Gem DR ICDs identified by serial number on the attached list. **No other Micro Jewel II Model 7223Cx or GEM DR Model 7271 devices are affected.**

This update supercedes earlier Micro Jewel II letters (August 1999 and November 2000) and a GEM DR letter (December 1999) regarding this same previously identified population of devices with capacitors from specific component lots. Those communications focused on managing performance of affected devices through the Automatic Capacitor Formation Interval and replacing devices with charge times of 18 seconds or greater.

Worldwide, we have now seen thirty (30) Micro Jewel II devices with suspect capacitors that have experienced unexpected performance of the charge circuit at battery voltages near ERI. Six (6) of these occurred during cardiac arrhythmias, resulting in therapy not being delivered.

Although all field reports to date have involved Micro Jewel II devices, it is possible that some GEM DR devices with suspect capacitors could exhibit similar behavior. Therefore, this recommendation applies to both Micro Jewel II (~1386 active units worldwide) and GEM DR (~435 active units worldwide) with suspect capacitors. These devices were implanted in 1997 and 1998.

The enclosure lists your patients who have received devices with suspect capacitors. If you no longer follow these patients, please forward this mailing to the new follow-up physician and notify Medtronic.

We sincerely apologize for any inconvenience this has caused to you and your patients. If you have questions, or would like information about our supplemental warranty for these devices, please contact your Medtronic Sales Representative or Medtronic Technical Service at 1-800-723-4636.

Sincerely,

Stan Myrum

Vice President, Cardiac Rhythm Management Operations

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