Patient Safety Alert

Veterans Health Administration Warning System
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Item: Implantable Cardioverter Defibrillator (ICD), models Micro-Jewell II 7223Cx and GEM DR 7271 manufactured by Medtronic, Inc. and implanted in 1997 and 1998. Of 6268 units originally implanted, an estimated 1800 remain in use worldwide.

Specific Incident: During a cardiac event requiring cardioversion or defibrillation, internal capacitors may take longer to charge and can cause a delay or non-delivery of appropriate shock therapy.

Action:

1. Immediately check patient records in CPRS to identify patients with the ICD implants described in this notification.
2. Contact your local Medtronic sales representative (or Medtronic Technical Services, listed in the Contact section of this notification if you cannot reach the local representative) for assistance with determining whether the identified implant requires follow-up action as identified by Medtronic.
3. If follow-up action is necessary, see the attached letter from Medtronic describing required actions.

Source: Manufacturer and FDA

Contact: Medtronic Technical Services: 1-800-723-4636

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Letter from Medtronic (PDF Format)