URGENT MEDICAL DEVICE CORRECTION

InSync® III Cardiac Resynchronization Therapy Pacemakers (CRT-P) Models 8042, 8042B, 8042U

November 2015

Dear Doctor,

Medtronic is writing to inform you of an issue with InSync® III CRT-pacemakers, related to long-term battery performance. Through 27 October 2015, Medtronic has confirmed 30 devices (0.03%) worldwide have been impacted by this issue, for which the root cause is unexpected high battery impedance.

Unexpected high battery impedance can result in the battery's inability to supply sufficient electrical current, impacting device function. Twelve (12) of the 30 devices had reports of unexpected loss of pacing capture. The other 18 devices experienced some form of erratic behavior, including early elective replacement indication (ERI), significant fluctuations in remaining longevity estimates, and inaccurate lead impedances. Through 27 October 2015, events associated with this issue have occurred in devices with implant durations of 53 months or more. Medtronic has received one report of a patient death, where it is possible, but unconfirmed, that this issue was a contributing factor.

If pacing capture is compromised, some patients may experience a return of heart failure symptoms due to loss of biventricular pacing. In cases involving pacemaker-dependent patients, a loss of pacing capture could result in serious injury or death.

Globally, there are approximately 22,000 active devices remaining, from an original implant population of 96,800. In the United States, just over 9,300 active devices remain. Our modeling predicts an estimated failure rate between 0.16% and 0.6% for the remaining active devices. Due to the unpredictable nature of this issue, it is not possible to identify which devices might fail or when they might fail. The issue cannot be mitigated by programming changes or increasing patient follow-up frequency. InSync III CRT-pacemakers are no longer distributed. Current devices have a modified battery design that is not susceptible to this issue.

Patient Management Recommendations
We realize that each patient requires unique clinical consideration. After consultation with Medtronic's Independent Physician Quality Panel (IPQP), Medtronic offers the following recommendations for patients with an InSync III CRT-pacemaker:

- Prophylactic device replacement in **non-pacemaker-dependent** patients is not recommended.
- For **pacemaker-dependent** patients, physicians should carefully weigh the risks and benefits of device replacement to mitigate this issue on an individual patient basis.
    - The estimated per patient mortality risk of this issue (0.007% to 0.02%) is comparable to the estimated per patient mortality risk of complications associated with an incremental, early device replacement (0.005%).
- Continue routine patient follow up in accordance with standard practice, and advise patients to seek medical attention immediately if they experience new or unexpected symptoms.

Medtronic

Medtronic records indicate you are following one or more patients with this device. Please see the enclosed Physician/Patient Detail Report.

We regret any difficulties this may cause you and your patients. We will continue to monitor device performance and provide regular updates in our product performance report available at wwwp.medtronic.com/productperformance/. Medtronic Patient Services is available to assist patients at 800-551-5544.

<Medtronic will offer a supplemental device warranty. Contact your sales representative for terms and conditions. If you have any questions, please contact your local Medtronic Representative or Medtronic Technical Services at 800-505-4636.>

Sincerely,

David Cleghorn
Country Regional Business Director CRHF

Medtronic encourages health care professionals and consumers to report any serious adverse effects with the use of any our products by calling Medtronic Technical Services at 800-505-4636 and FDA's MedWatch Adverse Reporting program online or at 1-800-332-1088