Important Medical Device Notice

BIOTRONIK reference: BIO-LQC March 2021

Dear Patient,

BIOTRONIK has recently issued a global notice about a rare event that may occur in a small number of implantable cardiac defibrillator (ICD) and cardiac resynchronization therapy defibrillator (CRT-D) devices. If specific conditions are met, over time the battery in affected devices may begin to lose power faster than expected. The likelihood of this affecting your therapy is very low and BIOTRONIK has alerted the medical community and medical authorities to this with a "Field Safety Notice". This is so that doctors can take appropriate action to monitor affected devices for any unexpected changes.

How do I know if my device is affected?

The notice covers a specific group of devices that use a certain model of battery. BIOTRONIK is taking steps to alert all clinics and doctors that have implanted these devices.

Our online lookup tool can also be searched, using the serial number of your device, to see if it is covered by this notice. To check if your device is affected, please visit **www.biotronik.com/devicelookup** and enter the serial number in the search field. The serial number can be found on your BIOTRONIK patient ID card.

My device is part of the notice, what should I do?

If your device is part of this notice, your doctor will be able to determine the best course of action for your individual needs. BIOTRONIK has provided various recommendations for your doctor to consider in determining how best to treat you based on your individual medical situation.

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In general, BIOTRONIK asks you to please

- Attend all scheduled appointments with your doctor.
- Speak with your doctor about the best way to monitor your device. In addition to in-office follow-ups there may be an opportunity to include a remote follow-up option called Home Monitoring to monitor your device on a daily basis.
- If you have previously been on Home Monitoring but are unsure about whether the system is still active, please consult your doctor.

Patient safety is our highest priority at BIOTRONIK. We recommend that you discuss this information, and any questions that you have, with your doctor who can advise you how to proceed. We are also here to assist you with any device-related questions.

We sincerely apologize for any inconvenience that you or your caregivers experience as a result of this notice.

Signed,

Roman Borkowski
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