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Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Medical Devices & Diagnostics Division)

Food & Drugs Administration Bhawan,

Kotla Road, New Delhi

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MEDICAL DEVICE ALERT

Safety Communication to Alert Providers and Patients to Check for Premature Battery Depletion in Certain Medtronic Pacemakers has been issued by US FDA, which is attached herewith for taking necessary precautions & actions by health care providers, patients & other stakeholders etc. as indicated in it.

Contact details in India for further information are as following:

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FDA Alerts Providers and Patients to Check for Premature Battery Depletion in Certain Medtronic Pacemakers: FDA Safety Communication

Date Issued:

May 7, 2019

Audience:

- Patients with a Medtronic pacemaker or cardiac resynchronization therapy pacemaker (CRT-P)
- Caregivers of patients with a Medtronic pacemaker or CRT-P
- Cardiologists, electrophysiologists, cardiac surgeons, and primary care physicians treating patients with heart failure or heart rhythm problems using a Medtronic pacemaker or CRT-P

Medical Specialties:

Cardiac Electrophysiology, Cardiology, Cardiothoracic Surgery, Heart Failure

Purpose:

The U.S. Food and Drug Administration (FDA) is issuing this safety communication to alert health care providers and patients about issues that may cause batteries in certain Medtronic implantable pacemakers or cardiac resynchronization therapy pacemakers (CRT-Ps) to drain more quickly than expected without warning patients or health care providers.

Devices:

Medtronic's implantable pacemakers or cardiac resynchronization therapy pacemakers (CRT-Ps) are devices that provide pacing for slow heart rhythms and heart failure. Pacemakers and CRT-Ps are both implanted under the skin in the upper chest area with connecting insulated wires called leads that go into the heart. A patient may need a pacemaker or CRT-P if their heartbeat is too slow (bradycardia) or needs coordination to treat heart failure.

Implanted pacemakers and CRT-Ps have electronics and are powered by lithium-ion batteries. One of the key electronic components is a capacitor, which stores electrical energy.

Patients can use remote monitoring systems, such as Medtronic's MyCareLink Monitor, to help their health care providers monitor battery status and general functioning of their implanted pacemaker or CRT-P. Health care providers receive CareAlert notifications through manual transmissions from the patient or wirelessly connecting to the patient's implanted pacemaker or CRT-P when the patient's device has CareAlerts programmed "ON." The patient and health care provider receive an Elective Replacement Indicator (ERI) CareAlert notification when the battery level drops below a certain limit.

Affected Medtronic implantable pacemaker and CRT-P device models include:

- Azure models: W1DR01, W2DR01, W3DR01, W1SR01, W2SR01, W3SR01
- Astra models: X1DR01, X2DR01, X3DR01, X1SR01, X2SR01, X3SR01
- Percepta models: W1TR01, W1TR04, W4TR01, W4TR04
- Serena models: W1TR02, W1TR05, W4TR02, W4TR05
- Solara models: W1TR03, W1TR06, W4TR03, W4TR06

Summary of Problem and Scope:

The FDA is aware of three medical device reports in which a Medtronic implantable pacemaker or CRT-P battery had fully drained because of a crack in the device's capacitor, without any warning to the patient or health care provider. As of April 10, 2019, 131,889 have been sold in the U.S.

If a capacitor in an implanted pacemaker or CRT-P is cracked, it can create an electric short, which can cause a battery to drain earlier than expected. If the battery is completely drained, the device will no longer deliver pacing therapy. The patients who rely heavily on pacing or who are pacemaker dependent may be most at risk for having an adverse outcome.

In all three medical device reports the FDA received, Medtronic reported that health care providers were unable to communicate with the device due to battery depletion, resulting in loss of pacemaker function. Medtronic also reported these events occurred within one year after the patient was implanted with the pacemaker or CRT-P, on average within seven months of getting the device implanted. The devices are designed to last between approximately 7.5 and 15 years or 6 and 10 years before requiring battery replacement, depending on the device and the amount of pacing. One of the reported events resulted in the death of a pacemaker-dependent patient. In a second reported event, the patient experienced dizziness during follow-up and the health care provider was unable to communicate with the device, which resulted in the patient getting their device replaced. In the third reported event, there was no harm to the patient because the device was not implanted when the health care provider became aware that a connection with the device could not be established.

Steps Taken for Newly-Manufactured Devices

This year, Medtronic received the FDA's approval for a new step in the manufacturing process developed to better detect capacitor failures and for a different capacitor to reduce the risk of rapid battery depletion in newly-manufactured devices.

Recommendations for Health Care Providers:

- Prophylactic removal and replacement of affected devices is **NOT** recommended, but the FDA recognizes that some patients who depend on pacing for survival may determine, in consultation with you, that device replacement is appropriate for their needs. Consider whether elective device replacement is warranted for any of your pacemaker patients due to pacemaker dependent status or other high-risk features.
- Be aware of sudden battery level drops during follow up visits and remote transmissions. Watch for decreases in battery level out of proportion to the life of the device from the time of implant even if the level remains within the normal range.
- Advise your patients to continue to use their remote monitors.
 - For Azure, Percepta, Serena, and Solara devices:

- These devices have wireless CareAlerts programmed by the health care provider. The monitor must remain powered on to ensure automatically scheduled transmissions are sent. CareAlerts should be programmed to “ON.”
- For Astra devices:
 - These devices do not have wireless capability and require manual transmission by the patient. To ensure timely transmission of any CareAlerts done manually by the patient, the patient should have a transmission schedule and CareAlerts should be programmed “ON.”
- Replace the pacemaker or CRT-P immediately at the time of an ERI alert. Currently, there is not a factor, method, or test to identify when devices with this form of premature battery depletion are approaching ERI, or to accurately predict remaining battery life once ERI appears. Once ERI is reached, an affected device is unlikely to have the standard three months of battery life remaining.
- Treat pacemaker-dependent patients with a device that has reached ERI as a medical emergency.

Recommendations for Patients and Caregivers:

- Check that home monitoring transmissions are successful and occurring at the prescribed times so health care providers receive notifications of battery level drops to help inform care decisions.
- Always keep the remote monitor plugged in.
 - The remote monitor must remain plugged in to ensure any wireless CareAlerts programmed by your health care provider and any automatically scheduled remote transmissions occur on time.
 - If you have an Astra device, do the manual transmission according to the schedule provided.
- Monitor your MyCareLink Heart App on your smart phone to check for changes to your battery level.
- Seek immediate medical care if you feel lightheaded, dizzy, chest pain, severe shortness of breath or if you are caring for someone who has lost consciousness. These may be signs your device’s battery has had a sudden drop or has drained.
- Talk to your health care provider about whether your device is affected, how best to manage your medical condition and what actions to take with your device.
- Contact Medtronic Technical Services Monday through Friday at 1-800-505-4636 if you have any questions.


FDA Actions:

The FDA will continue to work with Medtronic to monitor affected pacemakers and CRT-Ps for any adverse events related to premature battery depletion. The FDA will keep the public informed as new information becomes available.

Reporting Problems to the FDA:

Prompt reporting of adverse events can help the FDA identify and better understand the risks related to the use of medical devices. If you suspect or experience a problem with these devices, we encourage you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>). Health care personnel employed by facilities that are subject to the FDA’s user facility reporting requirements should follow the reporting procedures established by their facilities.

Additional Resources:

- Medtronic Performance Note (http://wwwp.medtronic.com/productperformance/document.html;JSESSIONID_productperformance=LotRcRlWJLg2CYmw1pjw6KpzKQTtB2RrpttVt9GWghKsFW3tVKg1-id=1125278)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)

Contact Information:

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV), 800-638-2041 or 301-796-7100.