Safety Communication رسالة سلامة

Premature Battery Depletion in Certain Medtronic Pacemakers

Device/ Product Description:	Pacemakers and Accompanying leads
Brand:	➢ Azure ➢ Astra ➢ Percepta ➢ Serena ➢ Solara
Affected product:	• 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
Manufacturer:	Medtronic Inc.
Problem:	The SFDA is aware of 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.
Recommendation /Actions:	**Recommendations for Health Care Providers:** • Prophylactic removal and replacement of affected devices is **NOT** recommended, but 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 if you have any questions.

SFDA Actions:
The SFDA has done a risk analysis study on Medtronic's affected devices to monitor their pacemakers and CRT-Ps. SFDA has gathered all market data share with the help of the manufacturer/AR in relevance to premature battery depletion. The SFDA will conduct a coordinated survey with the healthcare providers where the affected devices exist and will keep the public informed as new information becomes available.

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<tr><td></td><td>If you think you had a problem with your device or a device your patient uses, please do not hesitate to report the problem to SFDA through:
NCMDR
Vigilance system
19999 unified call center</td></tr>
<tr><td>Devices/Products photo:</td><td>  </td></tr>
<tr><td>Authorized Representative Details</td><td>
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<tr><td>AR name:</td><td>Medtronic SA</td></tr>
<tr><td>Assigned Contact Person:</td><td>Faisal Matbuli</td></tr>
<tr><td>Mobile/Phone:</td><td>0555066900</td></tr>
<tr><td>Email:</td><td>faisal.matbuli@medtronic.com;
KSA.RA@medtronic.com</td></tr>
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