Medtronic Recalls Evera, Viva, Brava, Claria, Amplia, Compia, and Visia Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy (CRT-Ds) Due to Risk of Shortened Battery Life

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- Medtronic Evera, Viva, Brava, Claria, Amplia, Compia, and Visia Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy (CRT-Ds)
- Models: Full List of Affected Devices below
- Serial Numbers: Full List of Affected Devices below
- Distribution Dates: August 31, 2012 to May 9, 2018
- Devices Recalled in the U.S.: 239,171
- Date Initiated by Firm: February 3, 2021

Device Use

Medtronic's Evera, Viva, Brava, Claria, Amplia, Compia, and Visia Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy (CRT-Ds) are devices that provide pacing for slow heart rhythms, and electrical shock or pacing to stop dangerously fast heart rhythms.

ICDs and CRT-Ds are both implanted under the skin in the upper chest area with connecting insulated wires called "leads" that go into the heart. A person may need an ICD or CRT-D if their heartbeat is too slow (bradycardia), too fast (tachycardia), or needs coordination to treat heart failure.

Reason for Recall

Medtronic is recalling the specified ICDs and CRT-Ds due to an unexpected and rapid decrease in battery life. The decrease in battery life is caused by a short circuit and will cause some devices to produce a "Recommended Replacement Time" (first warning that the battery is low) earlier than expected. Some devices may progress from "Recommended Replacement Time" to full battery depletion within as little as one day.

If the user does not respond to the first warning, the device may stop functioning. The likelihood that this issue will occur is constant after approximately three years after device use.

There have been 444 complaints regarding these devices. There are 264 Medical Device Reports, with 18 injuries including people experiencing bradycardia (slow heart rhythm) or heart failure symptoms. Zero deaths have been reported.

Who May be Affected

- Health care providers using the affected Evera and Visia family ICDs, Viva, Claria, Amplia, and Compia Family CRT-Ds
- Patients who require care using he affected Evera and Visia family ICDs, Viva, Claria, Amplia, and Compia Family CRT-Ds

What to Do

On February 3, 2021, Medtronic sent an Urgent Medical Device Correction letter to all affected health care professionals. The letter gave the following information:

Patient Management Guidance

- Continue normal follow-up per local clinical protocol.
    - Data suggests that battery failure is less common in patients who use the battery most, such as for frequent pacing support and higher voltage therapy.
    - Where possible, take advantage of the CareLink™ home monitoring system and the wireless low battery voltage CareAlert.
    - The low battery voltage audible alert is shipped 'On' with high-urgency tones; Remind patients to contact their clinic if they hear an audible alert, particularly since they may be opting to delay clinic visits due to COVID-19 guidance.
    - Inform a Medtronic Representative of any unexpected device behaviors.
    - Be aware that the inability to operate the device, or transmit data, may be an indicator that the device has experienced this issue.
- If unexpected Recommended Replacement Time (RRT) is observed, prompt replacement of the device should occur with the underlying clinical situation of the patient:
    - For non-pacing dependent patients or for primary prevention ICD patients, replacement within one week of an unexpected RRT notification is recommended.
    - For pacing dependent patients, immediate replacement is recommended following an unexpected RRT notification. Note: For all patients, this issue can also manifest

as an unexpected change in the remaining longevity estimate cannot be attributed to programming changes, or changes in use conditions.

The letter also stated:

- Medtronic medical staff in consultation with the Independent Physician Quality Panel recommends against replacing the device due to the low rate of occurrence and the low risk for permanent harm if immediate replacement occurs in response to an unexpected RRT.
- Patients and clinicians may determine if a specific device is affected by looking up the serial number on Medtronic's Product Performance website: http://wwwp.medtronic.com/productperformance/ (http://wwwp.medtronic.com/productperformance/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).
- Clinicians should also:
  - Complete a Clinician Confirmation Certificate (included with the correction letter) and return via email to RS.CFQFCA@medtronic.com (mailto:RS.CFQFCA@medtronic.com).
  - Notify Medtronic of any adverse events or quality problems associated with your use of this product.

Contact Information

Customers with questions should contact their local Medtronic Representative or Medtronic Technical Services at:
Tachycardia Devices
800-723-4636
tshelp@medtronic.com (mailto:tshelp@medtronic.com)

Full List of Affected Devices

- **Evera and Visia** (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=185641)
- **Viva, Claria, Amplia, Compia, and Brava** (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=185642)

Additional Resources:

- Recall Database Entry: Viva, Claria, Amplia, Compia, and Brava CRT-D (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=185642)

- Recall Database Entry: Evera and Visia ICD (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=185641)
- Medtronic Urgent Medical Device Correction (https://www.medtronic.com/content/dam/medtronic-com/global/HCP/Documents/icds-crtds-device-correction-february-2021.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program using an online form, regular mail, or FAX.