



Cardiac Arrhythmias and Heart Failure
15900 Valley View Court
Sylmar, CA 91342
USA

URGENT MEDICAL DEVICE RECALL

Ellipse ICD models CD1411-36Q, CD2411-36Q, CD2411-36C

UDI: 05414734507738, 05414734507615, 05414734507585

June 21, 2019

Dear Physician,

On June 20, 2019 Abbott began voluntarily recalling a small number (204 devices globally) of Ellipse implantable cardioverter defibrillators (ICDs) from our customers and hospitals to prevent implant of devices that may have a latent vulnerability in the electronics circuitry. We have currently received zero (0) product performance complaints related to this issue.

Description of the Issue

Abbott Ellipse ICDs utilize aluminum wires to connect the high voltage components of the device, and the electronics are then encapsulated in epoxy. During final manufacturing testing, two electrical failures were identified in a limited lot of manufactured devices due to damaged aluminum wires. Based on our investigation, we have decided to retrieve all non-implanted devices from this manufacturing lot and ensure that you have all requisite information to care for patients implanted with an impacted device.

Safety Impact

We have currently received zero (0) product performance complaints related to this issue. While the number of impacted devices is small, our investigation shows a total of thirty-six (36) implanted devices are from this population. Though we are aware of no adverse patient events as a result of this issue, the potential patient impact could be the inability to deliver high voltage therapy. Analysis has estimated the probability of device failure to be very low, but there remains a potential for compromised high voltage therapy. There is no available option to verify the vulnerability status for implanted devices.

Patient Management Recommendations and Action Requested

To support your patients implanted with an impacted device, Abbott recommends the following:

- Review the device model and serial numbers in the appendix of this letter to identify the impacted patients and return the acknowledgement form to your sales representative.
- **Device explant and replacement are recommended.** Abbott will work with you to provide an Abbott replacement device.

A copy of this letter is available on <https://www.cardiovascular.abbott/us/en/hcp/resources/product/advisories.html>. Should you have questions about patient management or this issue, please contact your local Abbott Representative or Abbott Support at **1-800-722-3774 (U.S.)**, 8:30am - 5:30pm Central Time Monday thru Friday.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. To submit your report:

- Complete the voluntary Form FDA 3500 online
- Call 1-800-FDA-1088 to report by telephone
- [Download form](#) from FDA.gov or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178 (Send only page 1 plus any continuation pages - do not send instruction pages).

Abbott is committed to providing the highest quality products and support. We apologize for any inconvenience this action may cause you, and we appreciate your understanding as we act to ensure patient safety and customer satisfaction.

Thank you for your continued support
Sincerely,

Robert Blunt
Divisional Vice President, Quality
Cardiac Rhythm Management