URGENT MEDICAL DEVICE SAFETY NOTICE AND CORRECTION

ACTION REQUIRED

LIFEPAK® CR2 Defibrillator

Please bring this letter to the immediate attention of the person(s) responsible for maintaining/monitoring your **LIFEPAK® CR2 Defibrillator**.

January 22, 2021

Dear Valued Customer,

Stryker is conducting a voluntary action to notify customers with certain LIFEPAK CR2 devices manufactured with lids identified to have a manufacturing discrepancy that may cause the lid magnet to dislodge from the lid. Please forward this notice to all your sites, trainers and users.

Description of issue

Stryker has received complaints that the LIFEPAK CR2 lid magnet has dislodged from the device, which may result in premature battery depletion. This issue has the potential to result in the inability for the device to turn on if the user does not use the on/off button or if the battery has fully depleted. There have been two adverse events associated with this issue where the patients ultimately expired.

The lid magnet is the primary means by which the device will turn on and off when the lid is opened or closed. If the lid magnet is missing, the device battery can deplete prematurely, even if the device is not powered on.

When the magnet is missing, the user can still use the power button to turn the device on and off. The device will automatically turn off within five minutes after being powered on if no patient is detected by the device.

If you identify that your device has a missing lid magnet, you may continue to use your LIFEPAK CR2 device according to the operating instructions and the supplemental labeling attached to this letter until replacement product is received.

Stryker's planned actions

The company is notifying all LIFEPAK CR2 customers of this potential safety issue. We are requesting that all LIFEPAK CR2 devices be inspected according to the instructions provided in this letter to ensure the lid magnet is present. A replacement lid and battery will be provided at no charge for any device identified to have a missing magnet which may have begun prematurely depleting the battery. In addition, replacement lids will be provided at no charge for affected devices with lids identified to have a manufacturing discrepancy.

Required customer actions

1. Inspect all LIFEPAK CR2 devices to verify Green Readiness Indicator on device flashes every 6 seconds and the lid magnet is present according to the lid magnet inspection instructions at the end of this notification letter. If any devices are found with Readiness Indicator not flashing or the lid magnet missing, contact Customer Service at 1 800 787 9537 option 2 or by email at medtechsup@stryker.com.

2. Review and complete the attached LIFEPAK CR2 Affected Device List and Acknowledgement Form attached to this notification for the devices related to the lid dimension issue.

3. Return the completed LIFEPAK CR2 Affected Device List and Acknowledgement Form by Fax at 1 866 448 9567 or by email RSRecall@stryker.com to confirm your receipt of this safety notification.

4. Review the LIFEPAK CR2 Supplemental Instructions attached to this notification letter and retain this document as supplemental labeling for your device(s).

5. Continue to check device readiness **at least monthly** in accordance with the LIFEPAK CR2 Operating Instructions, Maintaining a State of Readiness (pp. 77-78) and the instructions provided herein.

   Device readiness is indicated by:
   - All Devices: Green Readiness Indicator on device flashes every 6 seconds. If device is not ready, the Readiness Indicator will not flash.
   - Devices with Wireless Connectivity: In addition to the green flashing Readiness Indicator on the device, the LIFELINKcentral AED Program Manager or LIFENET System will generate a monthly status report that the device is READY.

   Please see LIFEPAK CR2 Operating Instructions, Maintaining a State of Readiness (pp. 77-78) for complete instructions.

If you have any questions about this matter contact Stryker at 1 800 787 9537, option 2, 8:00 A.M. to 7:00 P.M. (Eastern Time), Monday – Friday or by email at medtechsup@stryker.com.

In addition to contacting Stryker, any potential quality problems or adverse reactions or events associated with the use of a product from Stryker may be reported to the U.S. Food and Drug Administration's MedWatch Safety Information and Adverse Event Reporting Program online at https://www.fda.gov/safety/medwatch/, by phone 1 800 332 1088 or fax 1 800 FDA 0178.

Sincerely,

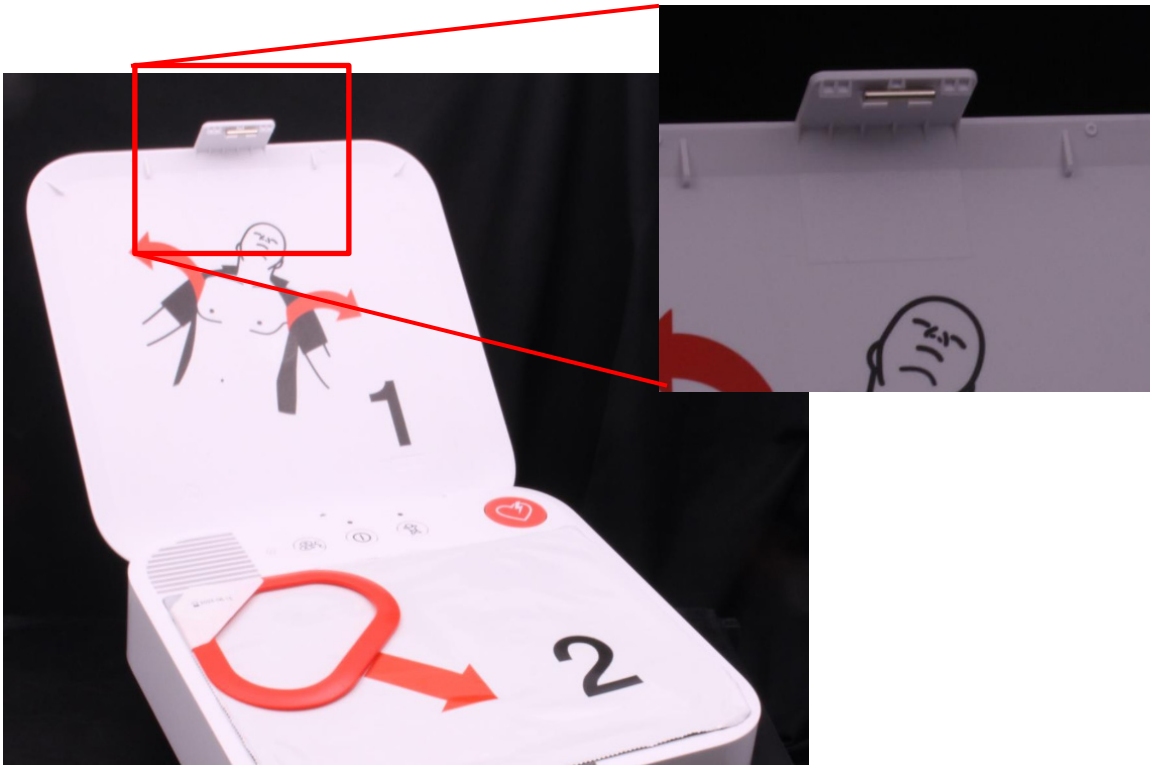
Todd Bandy

Todd Bandy
Director, Customer Quality Engineering
Stryker
Emergency Care

Attachments:
- LIFEPAK CR2 Affected Device List and Acknowledgment Form
- LIFEPAK CR2 Supplemental Instructions

Lid Magnet Inspection Instructions

1. Open the LIFEPAK CR2 lid
2. Inspect lid magnet clip for presence of magnet as shown in figure below



Emergency Care
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