Urgent Product Defect Correction

April 01, 2021

To:
Attention: Recall Manager/Chief Biomedical Engineer

TGA Reference #:	**RC-2021-RN-00732-1**
ARTG #:	**282772**
Product Field Action #:	**RA 2600240**
Description:	**LIFEPAK® CR2 Defibrillator**
Affected Item & Serial Numbers:	**Please see Response Form attached**

Stryker has initiated a Product Defect Correction for the operating instructions of all LIFEPAK® CR2 devices. A further subset of LIFEPAK® CR2 have been identified to have a manufacturing discrepancy that may cause the lid magnet to dislodge from the lid.

The intent of this letter is to list all known hazards potentially associated with the noted issue and the risk mitigation factors. Our records indicate that you have been supplied with a LIFEPAK® CR2 Defibrillator. We therefore request that you read this notice carefully and complete the actions requested.

Product 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 labelling attached to this letter until you receive replacement parts.

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.

The Product Defect Correction Response Form attached includes the details of the affected devices sent to you and fall into two categories, A) Lid Non-Conforming and B) Lid Conforming, shown in Tables 1 and 2 respectively.

To confirm the serial number of your device, remove the battery from the battery compartment, the SN is shown as below

Category (A) Devices in Table 1: These devices have been identified as having received a non-conforming lid, due to the above-mentioned manufacturing discrepancy. Stryker will provide a replacement lid for these devices at no charge. Upon completion of the actions below, if your device does not pass the inspection and checks, Stryker will also provide a replacement battery at no charge.

Category (B) Devices in Table 2: These devices do not have a lid with a manufacturing discrepancy. However, if your device is not successful in the inspections and checks detailed below, Stryker will provide a replacement lid and/or battery, where required, at no charge.

Actions Required by Customers

1. Please inform any users of your LIFEPAK® CR2 of this Product Defect Correction and forward this notice to them.

2. Review the attached LIFEPAK® CR2 Affected Device Lists in the Product Defect Correction Response Form to determine whether your devices are in Category A and/or Category B. You may have devices from both categories.

   If any devices are found in your possession other than those listed in Tables 1 and 2, please list these in Table 3 attached and perform the required inspection and checks.

3. Review the LIFEPAK® CR2 Supplemental Instructions attached to this notification letter. Please retain this document as supplemental labelling for your device(s).

4. Perform the below on all LIFEPAK® CR2 Defibrillators:

   i. Inspect for the presence of magnet as per the instructions in Attachment 1.

   ii. Conduct Device Readiness check in accordance with the LIFEPAK® CR2 Operating Instructions, maintaining a State of Readiness (pp. 77-78) and the Supplemental Instructions provided with this notification.

   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.

5. Please confirm this inspection and check has been performed by completing Tables 1 and/or 2 in the provided Product Defect Correction Notification Response Form.

6. Please return this form Stryker by fax on (02) 9467 1325 or electronically via email to postmarketssp@stryker.com.

   This form can also be completed online at: https://www.jotform.com/strykerssp/RA2600240lifepakcr2.

   Note: Even if you do not have a LIFEPAK® CR2 Defibrillator, please confirm this by completing Tables 1 and/or 2 in the attached form, indicating that the device is not in your possession.

7. If your response indicates that you require a replacement lid and/or battery, a replacement will be provided at no charge. Customers are able to replace the lids and batteries themselves.

8. Continue to check Device Readiness (indicated as per point 4 above), **at least monthly** in accordance with the LIFEPAK® CR2 Operating Instructions, maintaining a State of Readiness (pp. 77-78) and the Supplemental Instructions provided herein.

9. If you have disposed, transferred or sold any LIFEPAK® CR2 Defibrillators, please immediately let them know of this recall and notify Stryker through email to postmarketssp@stryker.com.

10. Stryker is also required to report any serious injuries where a product has contributed or may have contributed to the event. Please keep Stryker informed of any adverse events associated with this product by emailing postmarketssp@stryker.com.

We request that you **respond to this notice within 7 calendar days** from the date of receipt. Thank you for your support on this important matter.

Additional Information: Please contact your local Stryker representative or Stryker's ProCare Service team on 1800 667 55 or at ssptechservices@stryker.com.

For any general enquiries, please contact Stryker's Post Market team on +61 427 540 168.

We are issuing this notice following consultation with the Therapeutic Goods Administration.

We regret any inconvenience this action may cause you and if you have any questions, feel free to contact Stryker using the details below.

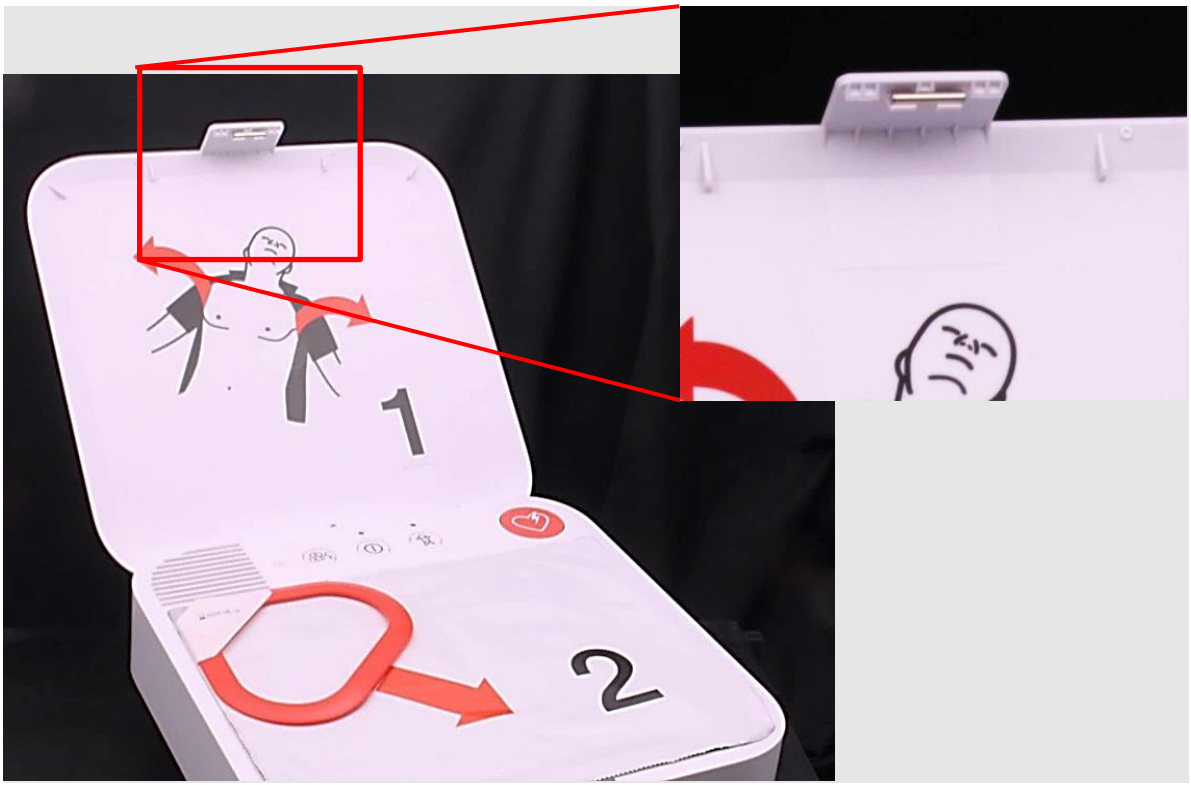
Sincerely,

Brigitte

Brigitte Rees
Post Market Associate
Stryker
South Pacific
8 Herbert Street
St Leonards, NSW 2065 Australia
E: postmarketssp@stryker.com
www.stryker.com.au

Attachment 1 – Lid Magnet Inspection Instructions

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



Product Defect Correction Customer Response Form

Please sign & return this form.

Please inspect your inventory for affected devices as described in the Product Defect Correction Letter and complete this form as acknowledgement of receipt.

Please note this form is also available online:
https://www.jotform.com/strykerssp/RA2600240lifepakcr2

For quick access, scan with your mobile phone or tablet camera over this QR code (compatible with iPhone & Android).

Account Details: Name:

Address:

Please complete the tables on the following pages to confirm the status and completion of inspections/checks on your LIFEPAK® CR2 Defibrillators device(s).

Please refer to Product Defect Correction Letter, Attachment 1 & the Operating Instruction provided herewith to complete inspections & tests.

By signing below and returning to Stryker, you have acknowledged that you have received the notification for the Product Defect Correction involving the LIFEPAK® CR2 Defibrillator and that it has been delivered to sites, trainers and users of the LIFEPAK® CR2 Defibrillators at your facility.

Name (Print): _____

Business/Facility Name (if applicable): _____

Email: _____

Phone: _____

Signature: _____ **Date:** _____

Please return a scanned copy via email at postmarketssp@stryker.com or return by fax to (02) 9467 1325

Product Defect Correction Customer Response Form

Table 1 – <u>Category A Devices (Non-Conforming)</u>

- Require inspection & check
- **Will** receive replacement lid
- **May** require replacement battery

Serial Number	Device in Possession?	Device readiness indicator is flashing?	Device lid magnet is present?
	YES NO	YES NO	YES NO
	YES NO	YES NO	YES NO
	YES NO	YES NO	YES NO
	YES NO	YES NO	YES NO
	YES NO	YES NO	YES NO
	YES NO	YES NO	YES NO

Table 2 – <u>Category B Devices (Conforming)</u>

- Require inspection & check
- **May** require replacement lid and/or battery

Serial Number	Device in Possession?	Device readiness indicator is flashing?	Device lid magnet is present?
	YES NO	YES NO	YES NO
	YES NO	YES NO	YES NO
	YES NO	YES NO	YES NO
	YES NO	YES NO	YES NO
	YES NO	YES NO	YES NO
	YES NO	YES NO	YES NO

Table 3 – <u>Additional Devices in your possession NOT listed in Table 1 or 2</u>

- Require inspection & check
- **May** require replacement lid and/or battery

Serial Number	Device in Possession?	Device readiness indicator is flashing?	Device lid magnet is present?
	YES NO	YES NO	YES NO
	YES NO	YES NO	YES NO
	YES NO	YES NO	YES NO
	YES NO	YES NO	YES NO
	YES NO	YES NO	YES NO
	YES NO	YES NO	YES NO
	YES NO	YES NO	YES NO
	YES NO	YES NO	YES NO
	YES NO	YES NO	YES NO
	YES NO	YES NO	YES NO
	YES NO	YES NO	YES NO
	YES NO	YES NO	YES NO