URGENT FIELD SAFETY NOTICE: RA2021-2600240

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**.

February, 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 your designed Stryker Representative.

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 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.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name:

Position:

E-mail:

Phone:

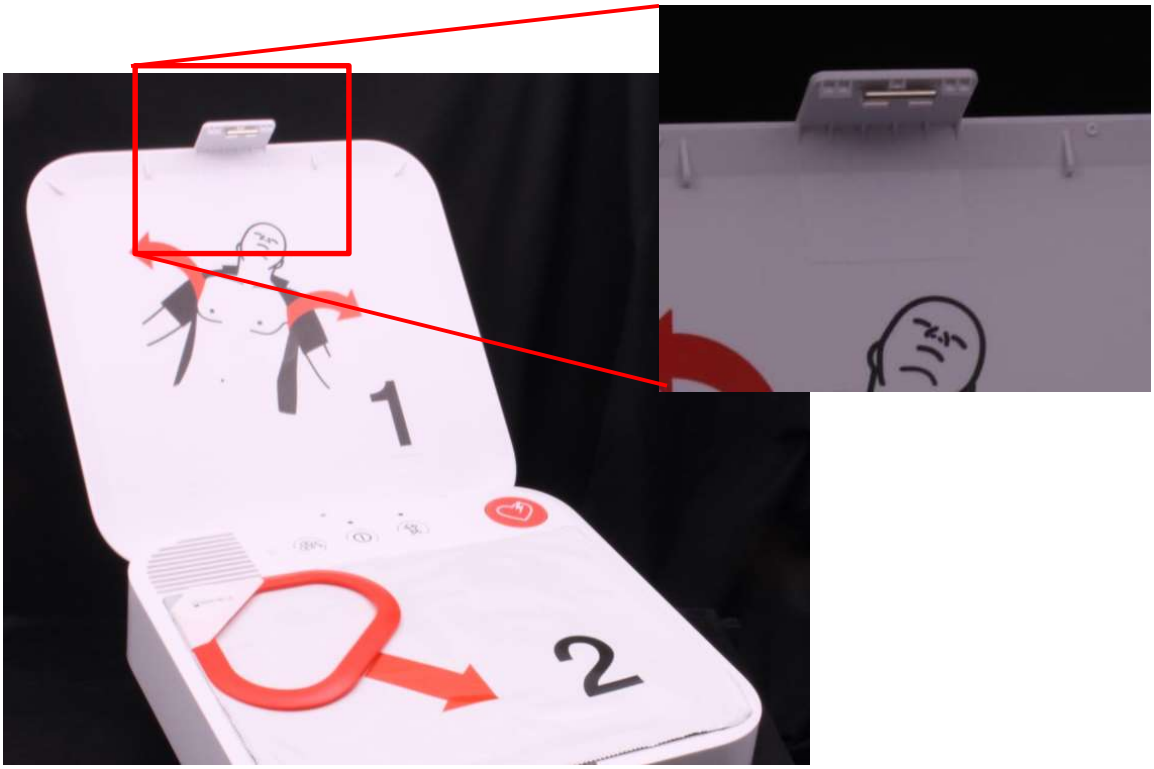
In line with the recommendations of the Meddev Vigilance Guidance document Ref.2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards and your expectations, remain on the market.

Sincerely,

Lid Magnet Inspection Instructions

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



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LIFEPAK ® CR2 Automated External Defibrillator (AED) Device List

Place Label here with:
Account Number
Account Name
Address
Cty State Zip

Completed by:
_____

Sign and date:
_____

Phone Number:
_____

Email:
_____

INSTRUCTIONS FOR IMPACTED DEVICES

1. **Please review the list below indicating device(s) affected by this field action:**
   - **Serial number(s) can be located on the back of your device.**
   - **Verify the status of your affected device(s) using selections provided in the table below.**
   - **If any device(s) with a serial number listed below is not in your possession, please provide the new address and contact information, if you have it.**
   - **If any device(s) has a lid missing a magnet, please reference the customer letter for instructions to have replacement lid kit and battery sent at no cost.**

Return completed form by Fax to Stryker at <insert fax number>, email to <enter email address>, or mail to Stryker <enter local address>.

Serial Number	Device in Possession		Lid has Magnet Intact		*Please provide the new address and new contact information
	Yes	No	Yes	No	
	☐	☐	☐	☐	
	☐	☐	☐	☐	
	☐	☐	☐	☐	
	☐	☐	☐	☐	
	☐	☐	☐	☐	
	☐	☐	☐	☐	
	☐	☐	☐	☐	

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	☐	☐	☐	☐	
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	☐	☐	☐	☐	
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	☐	☐	☐	☐	
	☐	☐	☐	☐	
	☐	☐	☐	☐	
	☐	☐	☐	☐	
	☐	☐	☐	☐	

We have further distributed subject devices to the following organizations:			
Facility Name			
Facility Address			
Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organization		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

PLEASE COMPLETE THIS FORM WITHIN 7 CALENDAR DAYS AND RETURN IT BY USING THE EMAIL, XX OR FAX, XX,