URGENT Field Safety Notice: RA2020-2329946

URGENT MEDICAL DEVICE SAFETY NOTICE & CORRECTION

ACTION REQUIRED

Infant Child Reduced Energy Electrodes for Physio-Control LIFEPAK® Defibrillators

Product No.: 11101-000016 and 11101-000017

Please bring this letter to the immediate attention of the person(s) responsible for maintaining/monitoring your **Infant Child Reduced Energy Electrodes**.

April 24, 2020

Dear Valued Customer,

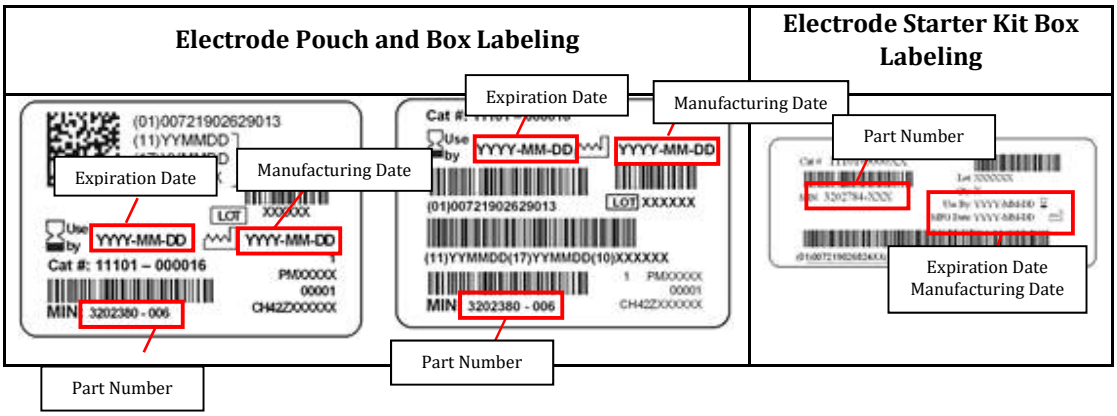
Stryker is conducting a voluntary correction for specific **Infant Child Reduced Energy Electrodes** that were manufactured by the electrode manufacturer, Cardinal Health, Inc. Affected electrodes were enclosed in packaging that may have compromised packaging seals. This recall affects Infant Child Reduced Energy Electrodes manufactured between August 2017 through October 2019. These electrodes are designed for use with the LIFEPAK 1000 defibrillator, LIFEPAK 500 defibrillator, and LIFEPAK CR Plus/EXPRESS defibrillator.

Description of issue

Stryker has become aware that certain packages of Infant Child Reduced Energy Electrodes produced by Cardinal Health, Inc. may have compromised packaging seals. The compromised packaging seal has the potential to result in the electrodes becoming dried out. This could result in inadequate adhesion to patient, failure of the defibrillator to detect patient connection, ineffective or no energy delivered to patient, or patient burns. Stryker estimates that only 1% to 2% of potentially affected product may exhibit packaging that has visible openings (compromised seals) as shown in the bottom figure. There have been no patient-related events associated with this issue.

Identification of impacted product

This correction affects Infant Child Reduced Energy Electrodes (PN 3202380-006) manufactured between August 2017 through October 2019 that have not yet reached their expiration date. This includes Infant Child Reduced Energy Electrodes that are included in the Infant Child Electrode Starter Kit (PN 3202784-009).

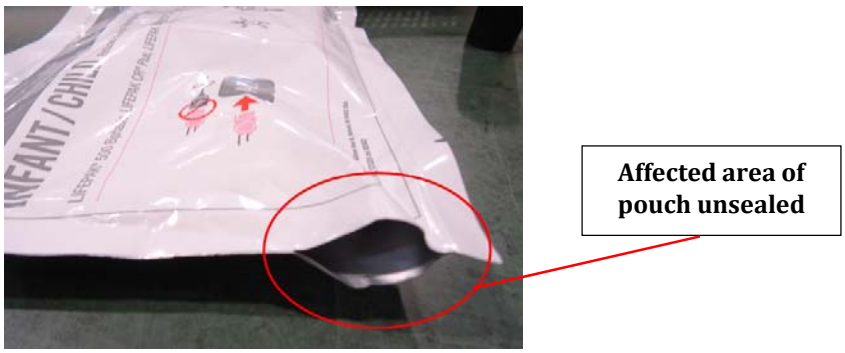


Stryker's planned actions

The company is notifying all customers that have received potentially affected Infant Child Reduced Energy Electrodes. Replacement electrodes will be provided for any that are identified to have a compromised packaging seal at no charge.

Required customer actions

1. Inspect your Infant Child Electrode inventory to identify any electrode packages that have a compromised packaging seal as shown in the figure below and destroy any product suspected to exhibit this condition. Note: only inventory manufactured between August 2017 and October 2019 are affected and will need to be inspected.
2. Complete the attached acknowledgement form and return it as directed to confirm your receipt and understanding of this information. Upon receipt of this form, you will be provided the replacement electrodes. If you do not have any impacted product, it is still required that you complete and return the form with the box checked indicating "No inventory."



We request that you respond to this notice within 7 calendar days from the date of receipt.

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:
Telephone:	E-mail:

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 support in completing this action within the target date and regret any inconvenience that may be cause. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remaining on the market.

Sincerely,

Medical Device Correction
URGENT Field Safety Notice: RA2020-2329946

Acknowledgment and receipt form—response is required

Infant Child Reduced Energy Electrodes (**Product No.: 11101-000016 and 11101-000017)**

Customers must complete the form even if you do not have inventory.

Customer information

Customer name _____

Name of person completing this form _____ Title _____

Direct phone # _____ Email _____

Address _____ City _____ State ____ Zip code _____

Country _____

If affected inventory, please provide information below. **Attach additional sheet if needed.**

Part number	Quantity destroyed (each)

No affected product in inventory (please check) ☐

I have read and understand the instructions provided and acknowledge receipt of the Medical Device Correction notification regarding the Infant Child Reduced Energy Electrodes by signing below.
I also agree to further distribute and communicate this important information from this letter to those whom I have distributed any of the Infant Child Reduced Energy Electrodes noted in this letter.

Name (print) _____ Signature _____ Date _____

Please return this acknowledgement via email to: XXXX or fax to: XXXX

Attachment 1

FSCA No: RA2020-2329946

Product No.	Lot/Serial No.	
11101-000016	728262	731049
	732441	801633
	804722	807535
	808209	808878
	810640	811328
	812021	812185
	813812	814511
	816218	816938
	819730	821913
	822645	823550
	824255	825013
	825708	826405
	827429	830953
	832310	833141
	833848	903559
	904227	912658
	915258	916854
	917517	920320
	824255	
11101-000017	825708	827429
	828853	830953
	833141	916855
	920320	824255