URGENT Field Safety Notice: RA2020- 2329946

URGENT MEDICAL DEVICE SAFETY NOTICE & CORRECTION

ACTION REQUIRED

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

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,

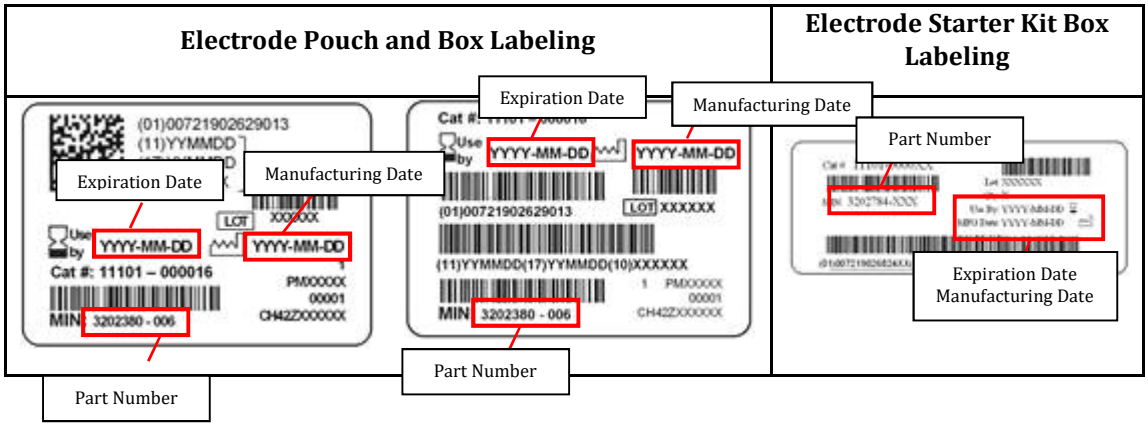
Stryker is conducting a voluntary correction for specific **Infant Child Reduced Energy Electrodes** that were manufactured by the electrode manufacturer, Cardinal Health, Inc. Affected electrodes were enclosed in packaging that may have compromised packaging seals. This recall affects Infant Child Reduced 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).

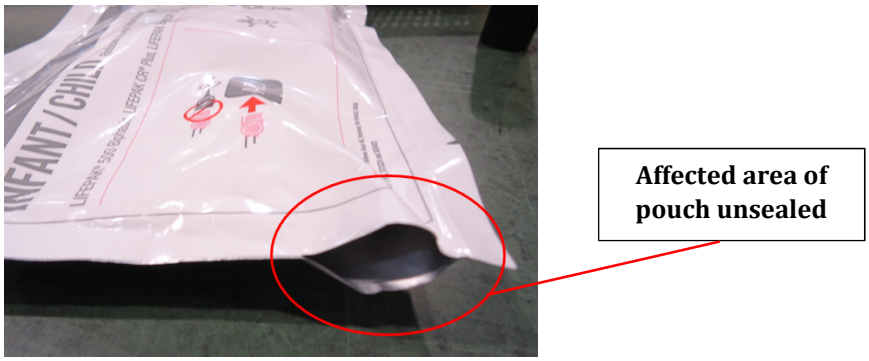


Stryker's planned actions

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,

Name:

Title:

Signature:

URGENT Field Safety Notice: RA2020- 2329946

URGENT MEDICAL DEVICE SAFETY NOTICE & CORRECTION

ACTION REQUIRED

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

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

May 12, 2020

Dear Valued Distributor,

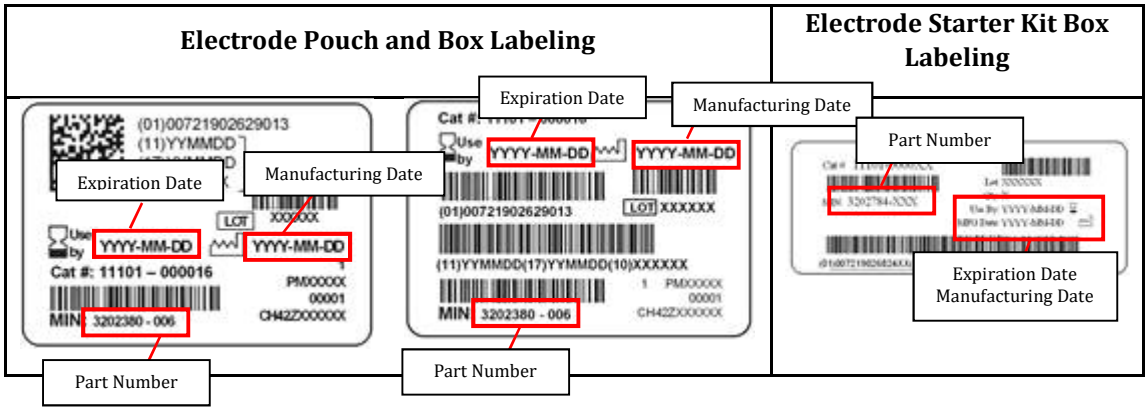
Stryker is conducting a voluntary correction for specific **Infant Child Reduced Energy Electrodes** that were manufactured by the electrode manufacturer, Cardinal Health, Inc. Affected electrodes were enclosed in packaging that may have compromised packaging seals. This recall affects Infant Child Reduced 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 direct customers and distributors 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.

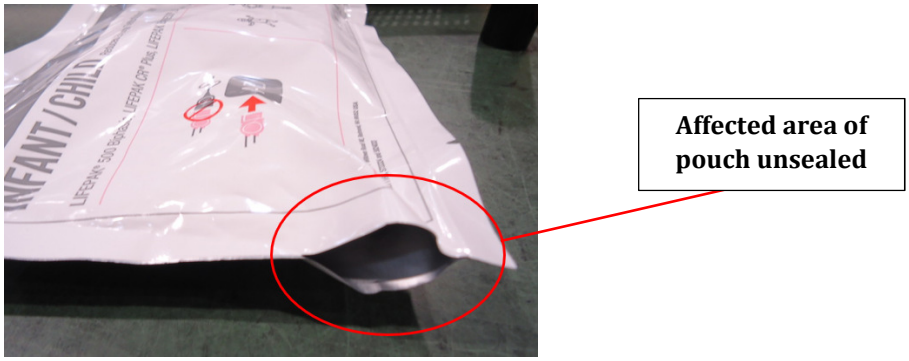
Required distributor actions

Product in distributor inventory

1. Inspect your own 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 enclosed "Acknowledgement and Receipt Form" on behalf of your organization and return it as directed to confirm your receipt and understanding of this information. Upon return 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."

Product shipped to customers

1. Use the editable "**Customer Communication Packet**" provided with this letter to communicate to your end customers who have purchased electrodes.
    - The "Customer Communication Packet – End Customer Acknowledgement Form" should be edited to include remittance information for your organization (recommend email address and/or fax number) in the editable fields at the bottom of the form so that the forms completed by your customers will be returned to you.
2. Upon receipt of "Customer Communication Packet – Acknowledgement Form" from end customers, consolidate information within a copy of the enclosed "Acknowledgement and Receipt Form" and return to Stryker as directed.
3. Stryker will ship replacement electrodes to distributor upon receipt for you to distribute to your end customers.



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,

Name:
Title:
Signature:

Customer Communication Packet

stryker

URGENT MEDICAL DEVICE SAFETY NOTICE & CORRECTION

ACTION REQUIRED

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

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

April xx, 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 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

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Emergency Care
11811 Willows Road NE, Redmond, WA 98052 USA | P +1 425 867 4000 | Toll-free +1 800 442 1142 | stryker.com

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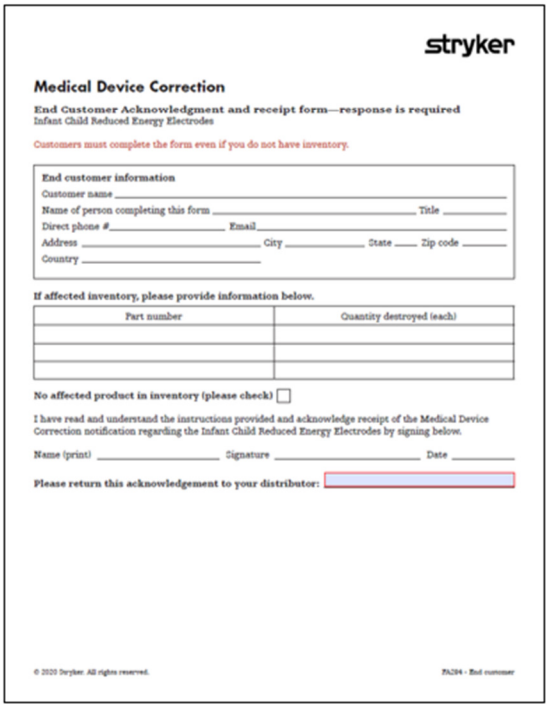
End Customer Letter



stryker

Medical Device Correction

End Customer Acknowledgment and receipt form—response is required
Infant Child Reduced Energy Electrodes

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

End 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.

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.

Name (print) _____ Signature _____ Date _____

Please return this acknowledgement to your distributor:

FA284 - End customer

End Customer Acknowledgment and Receipt Form