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 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.

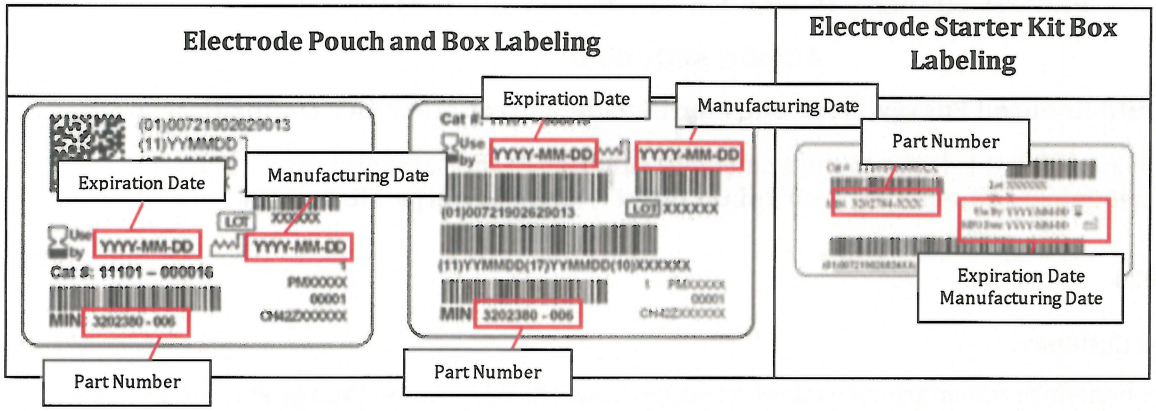
Description of issue

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).

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

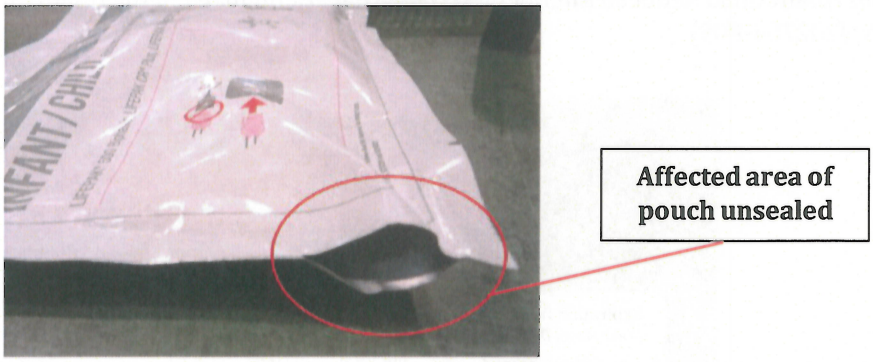


Stryker's planned actions

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."



If you have any questions about this matter contact Stryker at 1 800 787 9537, option 2, 8:00 A.M. to 6:00 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,

Kathryn E. Janecke

Kathryn E. Janecke
Senior Director, Regulatory, Quality, and Clinical Affairs
Stryker
Emergency Care