Skintact DF29N Multi-function Defibrillation Electrodes by Leonhard Lang: Class I Recall - Connector Compatibility Issue

[Posted 10/14/2016]

AUDIENCE: Risk Manager, Emergency Medicine, Patient

ISSUE: The Leonhard Lang defibrillation electrode is being recalled due to a connector compatibility issue with the Welch Allyn AED model 10. The user may not be able to connect the electrodes to the defibrillator when a shock is needed. This may result in a delay in delivering the electrical therapy needed to revive a patient in cardiac arrest.

A delay in therapy could result in serious patient injury and/or death.

Recalled product details:

- 50028 Defibrillation Electrode SKINTACT DF29N

- Lot Numbers: 60602-0774, 60502-0779, 60308-0771,60114-0773, 51023-0775, 50904-0777, 50403-0778, 50130-0777, 41023-0771, 41008-0778 40730-0778, 40618-0778, 40130-0776
- Distribution Dates: February 14, 2014, to August 3, 2016

BACKGROUND: Automatic external defibrillators (AEDs) are used to deliver lifesaving electrical shocks to people with sudden cardiac arrest, a medical condition in which the heart suddenly and unexpectedly stops beating. Defibrillation electrodes are connected to the AED to help the device analyze a patient's heart rhythm and deliver an electrical shock to restore normal heart rhythm when needed.

RECOMMENDATION: On September 1, 2016, Leonhard Lang sent an "Important Safety Notice" letter to all affected customers. The letter asked customers to:

- Review the safety notice and ensure appropriate staff is aware of the notice.
- Make sure all unused defibrillation electrodes DF29N are secured and destroyed.
- Confirm the products were destroyed by completing the "Confirmation of Destruction / Consumption" form in the notice.
- Send the "Confirmation of Destruction / Consumption" form to their supplier no later than October 14, 2016.
- Keep the signed "Confirmation of Destruction / Consumption" form until their supplier informed them of the termination of this recall.

Health care professionals and consumers with questions are instructed to contact the Leonhard Lang sales staff at (800) 903-6199 with any questions related to this recall.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report (http://www.fda.gov/MedWatch/report)
- Download form (/Safety/MedWatch/HowToReport/DownloadForms/default.htm) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[10/14/2016 - Recall Notice (/MedicalDevices/Safety/ListofRecalls/ucm525244.htm) - FDA]

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