Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: October 14, 2014

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Covidien - RECALL[Medical Device]

AFFECTED PRODUCT: **Medi-Trace™ Cadence and Kendall™ Multi-function Defibrillation Electrodes**

SUMMARY: **Class I Recall; The Field Safety Alert for certain Medi-Trace™ Cadence and Kendall™ Multi-function Defibrillation Electrodes is due to a connector compatibility issue with Philips FR3 and FRx Defibrillators.**

The following Covidien electrodes are affected:

- **22660R – Medi-Trace™ Cadence Adult Multi-Function Defibrillation Electrodes Radiotransparent**
- **22660PC - Medi-Trace™ Cadence Adult Multi-Function Defibrillation Electrodes Pre-connect**
- **20660 - Kendall™ Adult Multi-Function Defibrillation Electrodes**
- **40000006 - Kendall™ 1710H Multi-Function Defibrillation Electrodes**

In addition, similar private label electrodes produced by Covidien were also distributed under the following brands, and have the same connector compatibility issue:

- **MC1710H - MediChoice® Multifunction Electrode**
- **M3718A – Philips HEARTSTART Multifunction Electrode Pads**

The Field Safety Alert applies to all lot numbers distributed globally.

SUGGESTED ACTION: **For consumer inquiry only. For further information or to report a problem, please contact Covidien Quality Assurance at 1-800-962-9888, option 8, then extension 2500 between the hours of 8 a.m. and 5 p.m. (eastern) or email Mansfield.productmonitoring@covidien.com**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Covidien Initiates Voluntary Field Safety Alert for Medi-Trace™ Cadence and Kendall™ Multi-function Defibrillation Electrodes

Contact:
Consumer:
1-800-332-1088

FOR IMMEDIATE RELEASE - October 10, 2014 - Covidien today announced that it has notified customers of a voluntary Field Safety Alert for certain Medi-Trace™ Cadence and Kendall™ Multi-function Defibrillation Electrodes due to a connector compatibility issue with Philips FR3 and FRx Defibrillators.

These electrodes will not connect with Philips FR3 or FRx AED units, and in the case of the use of Covidien defibrillation electrodes with the Philips FR3 AED units, could result in a delay of therapy. The FRx AED unit requires the pads to be pre-connected, and will issue a continuous alarm chirp to alert the user that the proper pads are not connected to the unit prior to use. The FR3, however, does not require pre-connection and the user will not discover the compatibility issue until the AED must be used. This may result in a delay in therapy.

Philips FR3 and FRx AED units should only be used with the Philips brand electrodes specified in the equipment manual.

Covidien has received two reports where customers attempted to use a Covidien electrode with a Philips FR3 AED unit. The mismatch of these devices contributed to a delay in resuscitation and may have contributed to the subsequent death of one patient.

Covidien alerted customers to the this issue by letter on September 18, 2014, and has revised labeling to clarify that use of these electrodes is incompatible with Philips FR3 and FRx AED units.

The Field Safety Alert requests that customers review the use of Covidien defibrillation electrodes in their facility to assure that Covidien electrodes are not placed for use with Philips model FR3 or FRx AEDs.

There are a total of 644,460 electrodes affected by this safety alert.

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The Food and Drug Administration has classified this as a Class 1 Recall, the most serious recall where there is a reasonable risk of a serious adverse health consequences or death.

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Health care professionals and customers may report adverse events or quality problems experienced with the use of this product to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or by phone.

- **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail**: use postage-paid FDA form 3500 available at:
  www.fda.gov/MedWatch/getforms.htm.
  Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- **Fax**: 1-800-332-0178
- **Phone**: 1-800-332-1088

About Covidien

Covidien is a global health care leader that understands the challenges faced by providers and their patients and works to address them with innovative medical technology solutions and patient care products. Inspired by patients and caregivers, Covidien's team of dedicated professionals is privileged to help save and improve lives around the world. With more than 38,000 employees, Covidien operates in 150-plus countries and had 2013 revenue of $10.2 billion. To learn more about our business visit www.covidien.com or connect with us on Twitter.

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