

El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con un Informe de Seguridad asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Desfibrilador ZOLL SERIE M
NO. IDENTIFICACIÓN RISARH	I1507-327
REFERENCIAS DEL DISPOSITIVO MEDICO	8900-3000-01 y 8900-3001-01, lote 1615, referente a los electrodos a paciente fabricados en abril de 2015.
REGISTRO SANITARIO	2009EBC-0003880
INDICACIONES Y USO ESTABLECIDOS	Este producto combina un desfibrilador con capacidades avanzadas de monitores ECG y ritmo transcutáneo no invasivo (NTP) con capacidades de comunicación, impresión de datos y grabación, diseñado como apoyo para reanimación cardiopulmonar.
NOMBRE DEL FABRICANTE	Zoll Medical Corporation
DESCRIPCION DEL PROBLEMA	El fabricante establece que los electrodos anteriores pudieron ser etiquetados con el número de referencia y fecha de vencimiento incorrecta, la fecha de caducidad correcta es 18 de abril de 2017, conllevando a que se presenten potencialmente confusiones con los dispositivos.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	29 de Julio de 2015

RECOMENDACIÓN:

En caso de identificar la existencia del producto mencionado anteriormente comuníquese con su proveedor quien determinara las acciones que se llevaran a cabo.

Es importante mantener un estado de alerta, realizando un seguimiento permanente a los productos que se fabrican y/o comercializan en el país, divulgando la información de seguridad respectiva entre los profesionales de la salud que realizan uso de estos recursos tecnológicos.

Para mayor información comuníquese al teléfono 2948700 extensión 3880 en Bogotá, ó al correo electrónico tecnovigilancia@invima.gov.co

ANEXO 1

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[Normal Priority] - A24683 : ZOLL—Pedi-padz Solid Gel Multifunction Electrodes: May Be Mislabeled

Medical Device Ongoing Action

Published: Monday, July 13, 2015

UMDNS Terms:

- Electrodes [15578]

Product Identifier:

Pedi-padz Solid Gel Multifunction Electrodes [Consumable]

Part Nos.: 8900-3000-01, 8900-3001-01; Lot No. 1615

Units manufactured in April 2015

Geographic Regions: Canada, Colombia, Czech Republic, Poland, U.S.

Manufacturer(s): ZOLL Medical Corp 269 Mill Rd, Chelmsford, MA 01824-4105, United States

Suggested Distribution: Cardiology/Cardiac Catheterization Laboratory, Critical Care, Emergency/Outpatient Services, OR/Surgery, Pediatrics, EMS/Transport, Materials Management

Problem:

In a July 1, 2015, Urgent Device Correction letter submitted by an ECRI Institute member hospital, ZOLL states that the above electrodes may be labeled with the incorrect part number and expiration date. The correct expiration date is APR 18 2017. ZOLL states that there is no risk of harm to the patient or caregiver associated with this error.

Action Needed:

Identify any affected product in your inventory. If you have affected product, verify that you have received the July 1, 2015, Urgent Device Correction letter and Response Return Form from ZOLL. Inspect the pouch label of affected product, and check that the expiration date is listed as "2017-04-18." Complete the Response Return Form, and return it to ZOLL using the instructions on the form. Notify all relevant personnel at your facility of the information in the letter. If you have product that is mislabeled, ZOLL will provide your facility with replacement product free of charge and contact your facility to arrange for product return.

For Further Information:

ZOLL technical support department

Tel.: (800) 348-9011 or (978) 421-9460

Website: [Click here](#)

Comments:

- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert. For additional information regarding the format of this alert, refer to our [HDA Format Guide](#).

Source(s):

- 2015 Jul 10. Member Hospital. (includes reply form) [Download](#)
- 2015 Jul 13. Manufacturer. The manufacturer confirmed the information in the source material and provided additional details.

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