El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con un Retiro de Producto del Mercado asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Electrodos de Descarga Adulto y Pediátrico Utilizados con Desfibrilador Externo Automatizado Samaritan PAD.
NO. IDENTIFICACIÓN RISARH	R1408-332
REFERENCIAS DEL DISPOSITIVO MEDICO	Referencia Pad – Pak y Pediatric – Pak, lotes A1785 hasta A1805 y P433 hasta P445 respectivamente, distribuidos desde el 15 de mayo de 2014 con equipos nuevos o como sustitución de consumibles
REGISTRO SANITARIO	2010EBC-0005940
INDICACIONES Y USO ESTABLECIDOS	Se usa para realizar descargas eléctricas en casos de paro cardio-respiratorio y fibrilación.
NOMBRE DEL FABRICANTE	Heartsine Technologies Limited
DESCRIPCION DEL PROBLEMA	El fabricante determinó que las bolsas de aluminio que contiene los electrodos son de difícil apertura lo cual puede ocasionar el retraso de la terapia de desfibrilación o cardioversión, conllevando a que se generen posibles eventos adversos sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	08 de Agosto de 2014

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

A22775 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: August 7, 2014
UMDNS Terms:
- Defibrillators, External, Automated [17116]

Suggested Distribution:
- Cardiology/Cardiac Catheterization Laboratory
- Critical Care
- Emergency/Outpatient Services
- EMS/Transport
- Home Care
- Materials Management
- Pediatrics

Geographic Regions:
- Canada
- Europe
- Latin America
- Mexico
- U.S.

HeartSine—samaritan PAD AED Pad-Pak and Pediatric-Pak Accessories: Pouches May Be Difficult to Open, Potentially Delaying Therapy

Product Identifier:

Accessories used with HeartSine samaritan PAD 300, 350P, and 500P Automated External Defibrillators (AEDs):	Lot Nos.:
Pad-Pak (Pad-Pak 01)	A1785 through A1805
Pediatric-Pak (Ped-Pak 02)	P433 through P445

[Consumable]
Fewer than 900 units distributed to end users since May 15, 2014, either with new HeartSine samaritan PAD devices or as replacement consumables

Manufacturer:
- HeartSine Technologies Inc121 Friends Ln Suite 400, Newtown, PA 18940, United States

Problem: In a July 11, 2014, Urgent Field Safety Notice letter posted by the German Federal Institute for Drugs and Medical Devices (BfArM), HeartSine states that the foil pouches containing the above electrode/battery cartridges used with the above HeartSine AEDs may be difficult to open, potentially delaying therapy. FDA's Center for Devices and Radiological Health (CDRH) states that the manufacturer initiated a recall by letter on June 12, 2014.
Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the July 11, 2014, Urgent Field Safety Notice letter from HeartSine or been contacted by your distributor. The firm recommends that you contact your distributor for advice and to arrange for return and replacement of affected Pad-Paks or Pediatric-Paks, or contact HeartSine by e-mail at support@heartsine.co.uk. HeartSine also recommends that you do not take your device out of service.
For Further Information:

HeartSine Quality manager
Tel.: 44 (28) 90939419 or 44 (28) 90939404
E-mail: support@heartsine.co.uk
Website: Click here

References:

- United States. Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall PadPak and PediPak accessories for the HeartSine SamaritanPAD 300P and 350P device [online]. 2014 Jul 24 [cited 2014 Jul 28]. Available from Internet: Click here.
- Germany. Federal Institute for Drugs and Medical Devices. Corrective action concerning the HeartSine® samaritan® PAD (public access defibrillators), HeartSine Technologies [online]. 2014 Jul 30 [cited 2014 Aug 5]. Available from Internet: Click here.

Comment:

- 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):

- 2014 Jul 28. FDA CDRH Database. Class II. Reference No. Z-2115-2014
- 2014 Aug 1. Manufacturer. The manufacturer confirmed the information in the source material.
- 2014 Aug 5. BfArM (Germany). Reference No. 4022/14
- 2014 Aug 5. BfArM (Germany). Reference No. H007-003-003