El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con una alerta asociada a:

NOMBRE DEL DISPOSITIVO MÉDICO	Marcapasos VICTORY
NO. IDENTIFICACIÓN RISARH	A1403-104
REFERENCIAS DEL DISPOSITIVO MEDICO	MARCAPASOS VICTORY
REGISTRO SANITARIO	2007DM-0000430
INDICACIONES Y USO ESTABLECIDOS	Tratamiento de arritmias cardiacas sintomáticas.
NOMBRE DEL FABRICANTE	St Jude Medical Puerto Rico B.V. St Jude Medical Operations Snd Bhd St. Jude Medical, Inc., Cardiac Rhythm Management Division
DESCRIPCION DEL PROBLEMA	Se informa que pueden experimentar un cambio temporal en su correcto funcionamiento cuando son expuestos a las corrientes emitidas por fuentes de electrocauterización, dicho cambio puede durar treinta (30) segundos o mas después de terminada la exposición, lo que puede conllevar a potenciales eventos adversos sobre el paciente.
FUENTE	Anexo
FECHA DE NOTIFICACION	10 de Marzo 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

A21896 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: March 6, 2014
UMDNS Terms:
- Pacemakers, Cardiac, Implantable [12913]
- Defibrillator/pacemaker/monitoring systems [33053]
- Defibrillator/Pacemakers, Implantable [17989]
- Pacemakers [18495]
- Pacemakers, Cardiac [12911]

Suggested Distribution:
- Cardiology/Cardiac Catheterization Laboratory
- Central Sterilization Reprocessing
- Materials Management
- Information Technology
- OR/Surgery

Geographic Regions:
- (Impact in specific regions has not been identified or ruled out at the time of this posting)
- Worldwide

St. Jude Medical—Various Pacemakers: May Exhibit Change in Function When Exposed to Electrocautery

Product Identifier:
Older Generation Pacemakers: (1) Affinity, (2) Entity, (3) Frontier, (4) Identity, (5) Integrity, (6) Sustain, (7) Victory, (8) Zephyr *[Consumable]*

Manufacturer:
- St Jude Medical Inc15900 Valley View Ct, Sylmar, CA 91342, United States

Problem:
In a January 29, 2014, letter submitted by an ECRI Institute member hospital, St. Jude Medical states that the above pacemakers may exhibit a temporary change in function when exposed to electrocautery or the PEAK PlasmaBlade. This change could last for 30 sec or longer after electrocautery exposure has been terminated. St. Jude states that the duration of the effect depends on the battery voltage of the device, the energy of the electrocautery output, and the distance from the electrocautery source to the implanted system. The firm also states that a loss of capture because of a transient reduction in the pacing output voltage may occur. Placing a magnet over the device or programming it to an asynchronous pacing mode will not prevent this temporary voltage reduction in pacing output. The firm also states that recent pacemakers (e.g., Accent, Anthem) and all St. Jude Medical implantable cardioverter defibrillators (ICDs) are not affected. The manufacturer has not confirmed the information provided in the source material.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the January 29, 2014, letter from St. Jude Medical. St. Jude Medical recommends that you evaluate an individual patient's dependence on cardiac implantable electronic devices before any procedure that would require electrocautery, especially a pacemaker procedure. If pacemaker dependency is identified, do not use electrocautery or use appropriate precautions to ensure that the patient heart rate will be supported in the presence of electrocautery. St. Jude Medical also recommends that you consider placing a temporary, transvenous pacemaker. All user manuals for St. Jude Medical pacemakers and ICDs provide warnings and precautions about the use of electrosurgical devices near an implanted device.
For Further Information:
St. Jude Medical technical services department
Tel.: (800) 722-3774
Website: 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 Feb 28. Member Hospital. St. Jude Medical letter submitted by ECRI Institute member hospital