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	Parche de Reparaciòn Dural
NO. IDENTIFICACIÓN RISARH	I1408-319
REFERENCIAS DEL DISPOSITIVO MEDICO	DURA GUARD, PERIGUARD, VASCU-GUARD
REGISTRO SANITARIO	2008DM-0001613
INDICACIONES Y USO ESTABLECIDOS	Se utiliza como sustituto dural para el cierre de la madre en intervenciones de neurocirugía
NOMBRE DEL FABRICANTE	Synovis Surgical Innovations
DESCRIPCION DEL PROBLEMA	El fabricante informa que ha recibido dos informes de la utilización incorrecta del dispositivo durante los procedimientos quirúrgicos y recuerda que el PERIGUARD y VASCU-GUARD no son sustitutos de duramadre, ya que no están indicados para este tipo de uso, esta práctica puede conllevar a que se presenten potencialmente eventos adversos serios sobre él paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	01 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

A22781 - Normal Priority Medical Device Alert

Medical Device Ongoing Action
Updated: July 29, 2014
UMDNS Terms:
- Pericardial Membrane Implants [17800]
- Cardiovascular Patch Implants [25708]
- Dura Mater Implants [23846]

Suggested Distribution:
- Cardiology/Cardiac Catheterization Laboratory
- Materials Management
- Neurology
- OR/Surgery
- Tissue Bank

Geographic Regions:
- Asia
- Australia
- Canada
- Europe
- Latin America
- New Zealand
- Saudi Arabia
- U.K.
- U.S.

Synovis—DURA-GUARD, PERI-GUARD, and VASCU-GUARD Products: Manufacturer Reminds Customers of Approved Indications

Product Identifier:
Implant Products: (1) DURA-GUARD Dural Repair Patch, (2), PERI-GUARD Pericardium, (3) VASCU-GUARD Peripheral Vascular Patch *[Consumable]*

Manufacturer:
- Synovis Life Technologies Inc, a Baxter company2575 University Ave W Suite 180, St Paul, MN 55114-1024, United States

Problem:
In an Important Product Information letter submitted by an ECRI Institute member hospital, Synovis states that in response to 2 recent reports involving use of the incorrect product during surgery, it is reminding customers of the approved indications for the above implants.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the Important Product Information letter from Synovis. Synovis states that only the above DURA-GUARD implants are indicated for use as a dura substitute; PERI-GUARD and VASCU-GUARD implants should not be used as a dura substitute because they are not indicated for this type of use. For additional information on the packaging and indications for affected product, see the Important Product Information letter. Synovis states that you should not return affected product and that you may continue to use affected product according to their Instructions for Use (IFU). Notify all relevant personnel at your facility of the information in the Important Product Information letter, and forward a copy of the letter to any facility to which you have further distributed affected product.

For Further Information:
Synovis customer service unit
Tel.: (800) 423-2090
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 Jul 25. Member Hospital. Synovis letter submitted by an ECRI Institute member hospital
- 2014 Jul 28. Manufacturer. Baxter/Synovis confirmed the information provided in the source material.