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	Equipo de Radiocirugía ELEKTA
NO. IDENTIFICACIÓN RISARH	I1410-412
REFERENCIAS DEL DISPOSITIVO MEDICO	LEKSELL GAMMA KNIFE, seriales FV001 hasta FV376
REGISTRO SANITARIO	2009EBC-0005038
INDICACIONES Y USO ESTABLECIDOS	Sistema de radiocirugía para el uso en la radiación estereotáctica de estructuras intracraneales. La cirugía se consigue al proporcionar una dosis prescrita en forma de uno o más disparos de radiación ionizante dirigidos al lugar exacto del blanco. Durante la radiación no hay partes móviles dentro de la unidad y por lo tanto, la seguridad, estabilidad y precisión son características inherentes
NOMBRE DEL FABRICANTE	Elekta Instrument AB
DESCRIPCION DEL PROBLEMA	El fabricante establece que el sistema de coordenadas al ser alineado con el marco adaptador de los sistemas anteriores puede experimentar un movimiento del objetivo hasta de 0,5 mm desde la posición prevista, pues las bridas de bloqueo pueden causar que la trama este mal cerrada evitando que el marco de coordenadas se fije adecuadamente, ocasionando un pequeño desajuste mecánico entre el sistema de coordenadas y el adaptador del bastidor en la dirección Z, lo que puede conllevar a posibles eventos adversos sobre los pacientes.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	17 de Octubre 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

A23131 - High Priority Medical Device Alert

Medical Device Ongoing Action

Updated: October 15, 2014

UMDNS Terms:
- Stereotactic Systems, Frame-Guided, Radiosurgical, Gamma [17641]

Suggested Distribution:
- Clinical/Biomedical Engineering
- Radiation Oncology/Medical Physics

Geographic Regions:
- Australia
- Austria
- Belgium
- Brazil
- Canada
- China
- Colombia
- Czech Republic
- Egypt
- France
- Germany
- Greece
- Hong Kong
- India
- Indonesia
- Italy
- Japan
- Mexico
- Morocco
- The Netherlands
- Norway
- Poland
- Portugal
- Russia
- Saudi Arabia
- South Korea
- Spain
- Sweden
- Switzerland
- Taiwan
- Turkey
- U.K.
- U.S.

Elekta—Leksell Gamma Knife Perfexion Systems: Coordinate Frame May Be Misaligned with Frame Adapter

Product Identifier:
Leksell Gamma Knife Perfexion Systems *[Capital Equipment]*
Serial Nos.: FV001 through FV376

Manufacturer:
- Elekta ABBox 7593, Stockholm, SE-103 93, Sweden

Problem: In an Urgent Important Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) and by the German Federal Institute for Drugs and Medical Devices (BfArM), Elekta states that the coordinate frame may be misaligned with the frame adapter of the above systems, potentially resulting in movement of the target up to 0.5 mm from the planned position. The coordinate frame is fixed to the patient positioning system before treatment using a frame adapter. The coordinate frame is locked to the frame adapter with latches. The latches are turned 90° and then locked. Elekta states that it received a report of the latches locking before they have been fully turned, which may cause the frame to be poorly locked and the adapter latches to become stuck just above the coordinate frame surface. This prevents the coordinate frame from being fixed properly, and may result in a small play between the coordinate frame and the frame adapter in the Leksell Z-direction. A small "shelf" can be created if the latch has been forced into position when at a small angle. Refer to detail Figure 3 in the Urgent Important Field Safety Notice letter. If the latch locks to that shelf, there will be a play between the frame and the latch.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the Urgent Important Field Safety Notice letter and Important Field Safety Notice Acknowledgment form from Elekta. The firm states that it will check and/or replace affected frame adapters in the field, and recommends that you ensure the following:
- That the plastic lever (black piece on figure 1 and 2 in the letter) is only operated when at a right angle with the frame adapter.
- That you do not force the plastic lever in place if it meets significant resistance when turned.
- That the plastic lever is completely flush with the frame adapter and that no angulations are present.

Complete the Important Field Safety Notice Acknowledgment form, and return it to Elekta using the instructions on the form.

For Further Information:
Elekta
Website: Click here

References:

- Germany. Federal Institute for Drugs and Medical Devices. Important safety notice for Leksell Gamma Knife Perfexion-stereotactic surgery system, Elekta [online]. 2014 Oct 2 [cited 2014 Oct 8]. Available from Internet: Click here.
- Great Britain. Medicines and Healthcare Products Regulatory Agency. Elekta Instruments. Radiotherapy gamma knife. Leksell gamma knife Perfexion [online]. London: Department of Health; 2014 Oct 6 [cited 2014 Oct 8]. (Field safety notice; reference no. 2014/010/001/081/022). 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 Oct 9. BfArM (Germany). 6366/14
- 2014 Oct 9. BfArM (Germany).
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- 100-01-202-027; FCA-EIAB-0001 (includes reply form)
- 2014 Oct 9. MHRA FSN.
- 2014/010/001/081/022
- 2014 Oct 9. MHRA FSN.
- 100-01-202-027; FCA-EIAB-0001 (includes reply form)
- 2014 Oct 15. Manufacturer. Manufacturer confirmed information confirmed in source material