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	Cateter Intratecal Ascenda
NO. IDENTIFICACIÓN RISARH	I1408-318
REFERENCIAS DEL DISPOSITIVO MEDICO	8781,8780,8784
REGISTRO SANITARIO	2011DM-0008132
INDICACIONES Y USO ESTABLECIDOS	Se indica para uso cuando la terapia del paciente requiere la infusión cornica de medicamentos. El sistema está aprobado para uso con: solución estéril de clorhidrato de morfina/sulfato de morfina libre de preservativos en el tratamiento de dolor crónico intratable. Inyección intratecal de baclofen en el manejo de espasticidad severa. Solución estéril de ziconotide libre de preservativos para el manejo de dolor crónico severo. infusión intravascular crónica de floxuridine y metotrexate para el tratamiento de cáncer primario o metastasico (no para uso con el catéter intratecal de ascenda)
NOMBRE DEL FABRICANTE	Medtronic Neuromodulatiòn
DESCRIPCION DEL PROBLEMA	El fabricante informa que ha detectado que el componente del anillo de retención no cumple con las especificaciones de fabricación, conllevando a que se presenten potencialmente eventos adversos sobre el 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

A22716 01 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: July 31, 2014
UMDNS Terms:
- Catheters, Spinal, Intrathecal [18691]

Suggested Distribution:
- Anesthesia
- IV Therapy
- Materials Management
- Neurology
- OR/Surgery
- Pharmacy

Geographic Regions:
- Australia
- Austria
- Belgium
- Canada
- Chile
- Colombia
- Denmark
- France
- Germany
- Iraq
- Israel
- Italy
- Japan
- Lebanon
- Mexico
- The Netherlands
- Panama
- Puerto Rico
- Singapore
- South Africa
- Spain
- Sweden
- Switzerland
- U.K. U.S.
- Uruguay

Medtronic—Ascenda Intrathecal Catheters and Ascenda Revision Kits: Retainer Ring May Not Meet Specification Criteria

Product Identifier:

Ascenda Intrathecal Catheters:	Model Nos.:
66 cm Spinal Segment	8781
86 cm Spinal Segment	8780
Pump Segment Revision Kits with Sutureless Pump Connector	8784

[Consumable]
Serial Nos. beginning with the following letter/number combinations: N458522, N458524, N464184, N464200, N464206, N464254, N464257, N464258, N464262, N464263, N464264, N464271, N464693, N464703, N464708, N464725, N464727, N464730, N464734, N464736, N464738, N464742, N464746, N464750, N464752, N464841, N464924, N464930, N464995, N464995, N465020, N465038, N465063, N465065, N465073, N465082, N465088, N465091, N465094, N465111, N465125, N465129, N465131, N465136, N465138, N465144, N465145, N465146, N465148, N465150, N466065, N466067, N466067, N466068, N466069, N466071, N466072, N466075, N466134, N466167, N466177, N466196, N466201, N466240, N466244, N466259, N466289, N466290, N466291, N466306, N466368, N466390, N466392, N466394, N466398, N46639g, N466631, N466639, N466645, N466678, N466678, N466754, N466758, N466761, N466886, N466897, N466901, N466902, N466911, N466914, N467103, N467109, N467113, N467114, N467116, N467126, N467138, N467171, N467180, N467183, N467192, N467193, N467194, N467195, N467197, N467198, N467203, N467204, N467206, N467209, N467351, N467351, N467352, N467355, N467356, N467357, N467395, N467399, N467401, N467402, N467407, N467444, N467451, N467453, N467454, N467563, N467568, N467570, N467601, N467606, N467608, N467609, N467611, N467612, N467614, N467618, N467621, N467626, N468288, N468343, N468401, N468404, N468406, N468406, N468448, N468494, N468500, N468507, N468510, N468511, N468514, N468516, N468519, N468522, N468574, N468580, N468621, N468626, N468641, N469182, N469262, N469332, N469360, N469360, N469388, N469420, N469422, N469428, N469431, N469433, N469434, N469436, N469438, N469440, N469446, N469447, N469449, N469452, N469460, N469465, N469466, N469469, N469474, N469478, N469507, N469511, N469530, N469533, N469549, N469579, N469583, N469586, N469588, N470163, N470197, N470234, N470303, N470307, N470401, N470408, N470414, N470420, N470424, N470453, N470459, N470919, N470923, N470929, N470931, N470931, N470934, N470938, N470940, N470941, N470951, N470953, N470954,

N471442, N471443, N471446, N471447, N471448, N471449, N471487, N471488, N471490, N471490, N471491, N471764, N471791, N471840, N471853, N471856, N471860, N471863, N471864, N471865, N471866, N471870, N471871, N471875, N471880, N472310, N472326, N472333, N472336, N472342, N472345, N472347, N472857, N472861, N472866, N472868, N472873, N472875, N472876, N472878, N472882, N472885, N472886, N472890, N472894, N472900, N472905, N473140, N473144, N473148, N473154, N473156, N473176, N473178, N473180, N473202, N473207, N473211, N473221, N473222, N473223, N473228, N473230, N473311, N473311, N473323, N473377, N473401, N473426, N473438, N473492, N473493, N473989, N473996, N473999, N474001, N474005, N474006, N474007, N474010, N474018, N474019, N474023, N474027, N474037, N474038, N474047, N474047, N474421, N474423, N474427, N474431, N474433
Units distributed between May and July 2014

Manufacturer:
- Medtronic Neuromodulation7000 Central Ave NE, Fridley, MN 55432, United States

Summary: This Alert provides additional information based on manufacturer correspondance and a July 2014 Urgent Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) regarding Alert Accession No. A22716. Additional information is provided in the Geographic Regions field (see bolded information).

Problem:
[July 16, 2014]
In a July 11, 2014, Urgent Medical Device Removal letter submitted by an ECRI Institute member hospital, Medtronic states that the retainer ring component of the above catheters does not meet the firm's specification criteria. Medtronic states that it has received no reports related to this problem; however, the firm is investigating the possibility of unintentional disconnection of the catheter from the pump, or difficulty in disconnecting the catheter from the pump during a revision procedure.

Action Needed:
The following actions are those listed in Alert Accession No. A22716. Identify and isolate any affected product in your inventory. If you have affected product, verify that you have received the July 11, 2014, Urgent Medical Device Removal letter and reply form from Medtronic. A Medtronic representative will contact your facility to arrange for product return. Medtronic does not recommend the removal of catheters from patients; however, the firm does recommend that you monitor patients implanted with affected product for symptoms associated with drug withdrawal. Medtronic has not completed all of the testing to accurately characterize potential failure modes and/or potential frequencies of failures, if any. Medtronic states that it will provide additional information regarding the potential for impact to product performance as it becomes available. Complete the reply form, and return it to Medtronic using the information on the form.

For Further Information:
Medtronic local representative
(01923) 212213
Medtronic technical service department
Tel.: 31 (45) 5668844
Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Medtronic Inc. Implants, active, infusion pumps, implantable catheter. 8780, 8781, and 8784 [online]. London: Department of Health; 2014 Jul 24 [cited 2014 Jul 30]. (Field safety notice; reference no.

2014/007/016/121/004). 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 30. MHRA FSN. FA629
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- 2014 Jul 30. MHRA FSN. 2014/007/016/121/004