INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

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	Instrumental para Cistoscopia OLYMPUS
NO. IDENTIFICACIÓN RISARH	I1708-381
REFERENCIAS DEL DISPOSITIVO MEDICO	Concerniente a los PUENTES E INSERTO CON RAMPA, referencias A20976A, A20977A, A20975A, lotes específicos.
REGISTRO SANITARIO	2008DM-0001428
INDICACIONES Y USO ESTABLECIDOS	Estos instrumentos han sido diseñados para el diagnóstico endoscópico y el tratamiento en operaciones urológicas.
NOMBRE DEL FABRICANTE	Olympus Winter & Ibe Gmbh Olympus Medical Systems Corporation
DESCRIPCION DEL PROBLEMA	El fabricante informa que ha detectado durante el uso previsto de los dispositivos referenciados, el desprendimiento de fragmentos de adhesivo del canal de trabajo, conllevando a que se presenten potenciales eventos adversos sobre los pacientes y retrasos en el tiempo del procedimiento.
FUENTE	ANEXO
FECHA DE NOTIFICACION	30 de Agosto de 2017

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

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ANEXO

[High Priority] - A29133 : Olympus—Cystoscopy Bridges and Working Inserts: Adhesive Fragments May Detach
Medical Device Ongoing Action

Published: Thursday, August 24, 2017

UMDNS Terms:

- Cystoscopes [11112]
- Surgical Retractor Kits, Urinary Tract [33236]

Product Identifier:

Products:	Model Nos.:	Lot Nos.:
Bridge, One Way	A20976A	146W through 172W
Bridge, Two Way	A20977A	146W through 174W
Working Insert with Ramp, One Way	A20975A	13ZW through 172W

[Consumable]

Geographic Regions: Worldwide

Manufacturer(s): Olympus Winter & Ibe GmbHKuehnstrasse 61, Hamburg, D-22045, Germany

Suggested Distribution: OR/Surgery, Urology, Materials Management

Problem: In an August 18, 2017, Urgent Medical Device Removal and Corrective Action letter submitted by an ECRI Institute member hospital, Olympus states that it has received reports of incidents in which fragments of adhesive detached from inside the working channel of the above bridges. Olympus also states that it has received reports of cracking, chipping, missing pieces, and delamination of the adhesive. If adhesive detaches during the intended use of the above bridges or working inserts (e.g., when inserting an instrument through the working channel), a fragment of adhesive may fall inside the patient's bladder or urethra, necessitating retrieval. Although they are typically flushed out with irrigation fluid or passed naturally, the retrieval of large fragments of adhesive could prolong the procedure or require additional surgical treatment. Olympus further states that it has received no reports of patient injury related to this problem.

Action Needed:
Identify and discontinue use of any affected product in your inventory. If you have affected product, verify that you have received the August 18, 2017, Urgent Medical Device Removal and Corrective Action letter and Reply Form from Olympus. To arrange for product return, bridge rework, and working insert replacement, contact the Olympus customer solutions department using the information below. Olympus states that, based on its investigation results and risk assessment, affected product is safe to use until reworked or replaced. Complete the Reply Form and return it to Olympus using the instructions on the form. Forward a copy of the letter to any facility to which you have further distributed affected product, and notify Olympus of the transfer.

For Further Information:
Olympus customer solutions department
Tel.: (800) 848- 9024 (select option 3)
Website: Click here

Comments:

- 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):

- 2017 Aug 23. Member Hospital. Olympus letter submitted by ECRI Institute member hospital (includes reply form) Download
- 2017 Aug 24. Manufacturer. Manufacturer confirmed information