RECALL

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 Retiro de Producto del Mercado asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Dispositivo de Atomizaciòn Mucosal Intranasal – MAD NASAL
NO. IDENTIFICACIÓN RISARH	R1612-571
REFERENCIAS DEL DISPOSITIVO MEDICO	MAD100, MAD100OS, MAD110, MAD110OS, MAD130, MAD1130OS, MAD140, MAD140OS, MAD300, lotes específicos.
REGISTRO SANITARIO	2016DM-0014759
INDICACIONES Y USO ESTABLECIDOS	Para atomizar soluciones de uso tópico a través de las membranas mucosas naso y orofaríngeas.
NOMBRE DEL FABRICANTE	Wolfe Tory Medical Inc.
DESCRIPCION DEL PROBLEMA	El fabricante afirma que el dispositivo medico puede no ofrecer un penacho totalmente atomizado a la medicación, poniendo en peligro la eficacia de la medicación con la que se utiliza, conllevando a que se presenten posibles eventos adversos sobre los pacientes.
FUENTE	Anexo 1
FECHA DE NOTIFICACION	13 de Diciembre de 2016

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

RECALL

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

ANEXO 1

[High Priority] - A27488 03 : *Teleflex—LMA MAD Nasal Intranasal Mucosal Atomization Devices: May Not Deliver Fully Atomized Plume of Medication [Update]
Medical Device Ongoing Action

Published: Tuesday, November 29, 2016

UMDNS Terms:

- Atomizers [10226]

Product Identifier:
LMA MAD Nasal Intranasal Mucosal Atomization Devices *[Consumable]*

Product Nos.:	Batch/Lot Nos.:
MAD100	160105, 160137, 160302, 160321, 160402, 160435, 160506, 160523, 160609, 160620, 160707, 160802, 160813
MAD100OS	160322, 160524, 160630
MAD110	160217, 160507
MAD110OS	160240, 160312
MAD130	160107, 160138, 160517
MAD130OS	160436, 160803
MAD140	160125, 160218, 160437, 160610, 160801
MAD140OS	160226, 160438, 160727
MAD300	160108, 160117, 160126, 160145, 160146, 160200, 160219, 160225, 160231, 160300, 160313, 160327, 160400, 160409, 160422, 160432, 160440, 160500, 160518, 160602, 160611, 160621, 160631, 160701, 160708, 160718, 160728, 160800, 160804, 160814, 160816, 160823

MAD300B	160410

Geographic Regions: Argentina, Australia, Austria, Belgium, Canada, Chile, Colombia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Iceland, Iran, Ireland, Israel, Italy, Japan, Kuwait,   Latvia, Luxembourg, Malta, The Netherlands, Philippines, Portugal, Reunion, Saudi Arabia, Slovenia, South Africa, Spain, Switzerland, United Arab Emirates, U.K., U.S.

Manufacturer(s): Teleflex Medical2917 Weck Drive Research Triangle Park, NC 27709, United States

Suggested Distribution: Critical Care, Emergency/Outpatient Services, Nursing, Pulmonology/Respiratory Therapy, Diabetes Education/Coordination, Neurology, Pain Clinic, EMS/Transport, Pharmacy, Materials Management

Summary:
This Alert provides additional information based on a November 22, 2016, Amended Urgent Medical Device Recall Notification letter submitted by ECRI Institute member hospitals regarding Alert Accession No. A27488 . Additional information is provided in the Problem and Action Needed fields.

Problem:
[November 29, 2016]
In a November 22, 2016, Amended Urgent Medical Device Recall Notification letter submitted by ECRI Institute member hospitals, Teleflex states that in response to the October 27, 2016, Urgent Medical Device Recall Notification letter and the problem described below, some customers have indicated that, due to medical necessity, they plan to continue using the above devices rather than return them. Teleflex also states that it is advising all such customers to follow supplemental instructions for use (IFU) (attachment B of the letter), which allow nondestructive testing of each unit before a procedure to determine if it is defective.
[October 28, 2016]
In an October 27, 2016, Urgent Medical Device Recall Notification letter submitted by an ECRI Institute member hospital, Teleflex states that the above devices may not deliver a fully atomized plume of medication. Teleflex also states that it has received reports of the above devices producing a straight stream instead of an atomized stream. Teleflex further states that failure of the device to deliver an atomized plume may impair the effectiveness of the medication with which it is used, potentially leading to serious injury or death in certain emergency situations, such as when the device is used in an off-label manner for needle-free delivery of drugs for reversal of life-threatening narcotic overdose, reversal of life-threatening hypoglycemia, or treatment of epileptic seizures.

Action Needed:
Identify, isolate, and discontinue use of any affected devices in your inventory (if possible). If you have affected devices, verify that you have received the November 22, 2016, Amended Urgent Medical Device Recall Notification letter, supplemental IFU (attachment B), and Amended Recall Acknowledgment Form from Teleflex. Teleflex states that you should return affected devices for refund according to the instructions in the October 27, 2016, letter (for details, see the Action Needed field of Alert Accession No. A27488). If you intend to continue using affected devices because of medical necessity, ensure that replacement devices are available and perform the following steps to nondestructively test each unit before use in a procedure, as instructed in the supplemental IFU attached to the letter :

- Attach a syringe containing 1 mL of either sterile water or sterile saline to the device.
- Briskly compress the plunger on the syringe so as to deliver the liquid through the device and observe how the liquid comes out at the (distal) end.
- If the liquid sprays in a fine mist then the device is atomizing as intended.
- If the device demonstrates streaming, select another MAD device for testing and use.

If your institution intends to continue using affected devices with the supplemental testing, complete the Amended Recall Acknowledgment Form and return it to Teleflex using the instructions on the form. Teleflex states that you may choose to follow either or both pathways (i.e., return for refund and/or continue to use with supplemental testing). For example, you may return lots 1 and 2 to Teleflex and notify the firm that you are retaining lot 3 and applying the supplemental instructions).

For Further Information:
Teleflex local representative or Teleflex customer service department
Tel.: (866) 246-6990

Comments:

- For information on a similar and potentially related action initiated by Teleflex regarding LMA mucosal atomization devices, see Alert Accession No. A27489 .
- 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):

- 2016 Nov 28. Member Hospital. November 22, 2016, Teleflex letter submitted by an ECRI Institute member hospital (includes reply form) Download
- 2016 Nov 28. Member Hospital. October 27, 2016, Teleflex letter submitted by ECRI Institute member hospitals Download
- 2016 Nov 28. Manufacturer. Teleflex confirmed the information provided in the source material.