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	Videolaringoscopios GLIDESCOPE
NO. IDENTIFICACIÓN RISARH	I1507-297
REFERENCIAS DEL DISPOSITIVO MEDICO	Concerniente a las hojas reutilizables referencias AVL2, AVL3, AVL4, AVL5, GVL3, GVL4, GVL5, seriales específicos.
REGISTRO SANITARIO	2010DM-0005379
INDICACIONES Y USO ESTABLECIDOS	Para entubación.
NOMBRE DEL FABRICANTE	Verathon Medical
DESCRIPCION DEL PROBLEMA	El fabricante afirma que ha detectado a través de pruebas simuladas limitaciones de compatibilidad de las hojas referenciadas cuando se utilizan ciertos agentes de limpieza (ASP de CIDEX OPA, Metrex MetriCide Plus 30 y STERIS Revital-Ox resert HLD), de igual forma a decidido excluir como agentes de limpieza el Hipoclorito de Sodio (Bleach), la solución de alcohol isopropilico y el peróxido de hidrogeno liquido al 7.5%, conllevando a que se presenten potencialmente desviaciones del proceso de limpieza y desinfección de las hojas, lo que puede conllevar a potenciales eventos adversos sobre el paciente.
FUENTE	Anexo 1
FECHA DE NOTIFICACION	21 de Julio de 2015

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

[High Priority] - A24251 01 : Verathon—GlideScope Reusable Video Laryngoscope Blades: Manufacturer Revises Operations and Maintenance Manuals

Medical Device Ongoing Action

Published: Wednesday, July 8, 2015

UMDNS Terms:

- Laryngoscope Blades [23534]

Product Identifier:

GlideScope Reusable Laryngoscope Blades:	Part Nos.:	Serial Nos. (located on side of handle):
AVL 2	0574-0118	AC131852 through AC151510
AVL 3	0574-0115	AD131589 through AD151506
AVL 4	0574-0116	AE131587 through AE151558
AVL 5	0574-0117	AF131504 through AF151500
GVL 3	0574-0007	MD131860 through MD151622
GVL 4	0574-0001	LG131995 through LG151773
GVL 5	0574-0030	XL131578 through XL151524

[Capital Equipment]

Geographic Regions: Worldwide

Manufacturer(s): Verathon Inc 20001 North Creek Pkwy, Bothell, WA 98011, United States

Suggested Distribution: Clinical/Biomedical Engineering, Infection Control, OR/Surgery, Otolaryngology, Central Sterilization Reprocessing, Materials Management

Summary:
This Alert provides additional information based on a June 19, 2015, Urgent Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Agency (MHRA) regarding Alert Accession No. A24251 . Additional information is provided in the Geographic Regions field (see bolded region).

Problem:
[April 22, 2015]
In an April 13, 2015, Urgent Medical Device Safety Alert letter submitted by an ECRI Institute member hospital, Verathon states that it is revising the Operations and Maintenance Manuals (OMMs; part numbers 0900-1204-08-60 and 0900-4200-02-60) for the above reusable video laryngoscope blades to specifically state compatibility limitations when the following cleaning and disinfection agents are used:

- ASP CIDEX OPA
- Metrex MetriCide Plus 30
- STERIS Revital-Ox Resert HLD

The new OMMs specifically state compatibility limitations of the reusable video laryngoscope validated through simulated use cycles, using cleaning and disinfection agents in the OMM. Verathon also states that the following chemicals for cleaning and disinfecting reusable blades have been removed from the OMMs:

- Bleach (sodium hypochlorite)
- Isopropyl alcohol solution
- Liquid hydrogen peroxide (7.5%)

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the April 13, 2015, Urgent Medical Device Safety Alert letter and Safety Alert Reply Form and/or the June 19, 2015, Urgent Field Safety Notice letter and Reply Form from Verathon. The following actions are those listed in Alert Accession No. A24251 . For detailed information on the revised cleaning and disinfection methods for affected product, refer to Table 1 in the letter . For a copy of the most recent OMMs, visit Verathon's website . Complete the Safety Alert Reply Form, and return it to Verathon using the instructions on the form.

For Further Information:
Verathon customer care
Tel.: (800) 331-2313 or (425) 867-1348
E-mail: customerservice@verathon.com
Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Verathon Medical: GlideScope video laryngoscope [online]. London: Department of Health; 2015 Jun 29 [cited 2015 Jul 2]. (Field safety notice; reference no. 2015/006/025/291/007). Available from Internet: 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):

- 2015 Jul 2. MHRA FSN. 2015/006/025/291/007 Download
- 2015 Jul 2. MHRA FSN. Verathon letter posted by MHRA (includes reply form) Download
- 2015 Jul 2. Member Hospital. April 13, 2015 Verathon letter submitted by ECRI Institute member hospital (includes reply form) Download
- 2015 Apr 23. Manufacturer. Manufacturer confirmed information in original alert.