

# 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:**

<b>NOMBRE DEL DISPOSITIVO MÉDICO</b>	Video Nasofaringolaringoscopio Flexible PENTAX
<b>NO. IDENTIFICACIÓN RISARH</b>	I1707-315
<b>REFERENCIAS DEL DISPOSITIVO MEDICO</b>	EB-1170K, EB-1570, EB-1570AK, EB-1570K, EB-1970AK, EB-1970K, EB-1970TK, EB-1970UK y VNL-1570STK, seriales específicos.
<b>REGISTRO SANITARIO</b>	2008DM-0002551
<b>INDICACIONES Y USO ESTABLECIDOS</b>	Para visualización de órganos y cavidades corporales del sistema respiratorio y digestivo superior.
<b>NOMBRE DEL FABRICANTE</b>	Hoya Corporation Pentax Miyagi Factory Pentax Medical Company
<b>DESCRIPCION DEL PROBLEMA</b>	El fabricante ha identificado que el tornillo que conecta el brazo de succión al cuerpo de control de los dispositivos referenciados puede aflojarse con el tiempo, conduciendo potencialmente a la acumulación de desechos en el espacio entre la boquilla de succión y el cuerpo de control, además de una succión inadecuada causada por fugas de aire, conllevando a que se presenten potenciales eventos adversos sobre los pacientes.
<b>FUENTE</b>	ANEXO
<b>FECHA DE NOTIFICACION</b>	31 de Julio 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](mailto:tecnovigilancia@invima.gov.co)

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### ANEXO

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**[High Priority] - A29002 : PENTAX—Video/Ultrasound Bronchoscopes and Video Nasopharyngolaryngoscopes: Screw Connecting Suction Arm to Control Body May Become Loose Medical Device Ongoing Action**

Published: Tuesday, July 25, 2017

**UMDNS Terms:**

- Bronchoscopes, Flexible, Video/Ultrasound [25705]
- Nasopharyngoscopes [12709]

**Product Identifier:**

Endoscopes:	Model Nos.:	Purchase Dates:
Video Bronchoscope	EB-1170K	October 25, 2006, through January 26, 2011
Video Bronchoscope	EB-1570	August 23, 2003, through January 26, 2011
Video Bronchoscope	EB-1570AK	March, 30, 2009, through January 26, 2011
Video Bronchoscope	EB-1570K	October 24, 2002, through January 26, 2011
Video Bronchoscope	EB-1970AK	April 23, 2007, through January 26, 2011
Video Bronchoscope	EB-1970K	October 24, 2002, through January 26, 2011
Video Bronchoscope	EB-1970TK	December 3, 2008, through January 26, 2011
Video Bronchoscope	EB-1970UK	January 14, 2009, through January 26, 2011
Video Nasopharyngolaryngoscopes	VNL-1570STK	April 26, 2007, through January 26, 2011

**[Capital Equipment]**

Serial Nos.: A001122, A010001, A020005, A020006, A110003, A110004, A110006, A110015, A110016, A110017, A110018, A110019, A110022, A110023, A110025, A110028, A110033, A110035, A110036, A110036, A110037, A110039, A110042, A110042, A110043, A110044, A110045, A110046, A110046, A110052, A110053, A110053, A110060, A110064, A110066, A110067, A110068, A110069, A110070, A110072, A110075, A110076, A110079, A110082, A110084, A110089, A110090, A110090, A110091, A110091, A110094, A110100, A110103, A110103, A110104, A110105, A110108, A110115, A110116, A110116, A110119, A110127, A110127, A110130, A110132, A110135, A110137, A110138, A110144, A110145, A110145, A110146, A110148, A110152, A110152, A110153, A110154, A110159, A110160, A110160, A110161, A110161, A110162, A110163, A110164, A110165, A110166, A110167, A110168, A110170, A110175, A110176, A110177, A110178, A110180, A110183, A110186, A110189, A110190, A110204, A110205, A110216, A110222, A110224, A110226, A110233, A110234, A110242, A110243, 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G110209, G110212, G110214, G110215, G110217, G110218, G110219, G110236, G110237, G110242, G110243, G110247, G110248, G110252, G110253, G110254, G110257, G110258, G110267, G110276, G110277, G110278, G110280, G110281, G110282, G110283, G110284, G110286, G110288, G110290, G110293, G110294, G110295, G110296, G110299, G110300, G110311, G110312, G110320, G110322, G110323, G110324, G110325, G110330, G110332, G110333, G110336, G110339, G110341, G110342, G110344, G110351, G110352, G110357, G110358, G110360, G110361, G110361, G110362, G110365, G110366, G110368, G110374, G110376, G110378, G110381, G110381, G110382, G110383, G110384, G110385, G110385, G110386, G110387, G110391, G110391, G110393, G110393, G110394, G110394, G110395, G110396, G110396, G110397, G110398, G110398, G110399, G110399, G110400, G110401, G110402, G110403, G110403, G110404, G110405, G110405, G110406, G110410, G110411, G110413, G110414, G110416, G110416, G110417, G110418, G110418, G110419, G110420, G110420, G110421, G110423, 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G110967, G110982, G110984, G110990, G110997, G111022, G111023, G111026, G111033, G111036, G111037, G111038, G111039, G111045, G111047, G111050, G111051, G111052, G111056, G111057, G111060, G111063, G111067, G111072, G111073, G111080, G111082, G111084, G111104, G111109, G111112, G111114, G111117, G111119, G111120, G111123, G111125, G111136, G111139, G111140, G111142, G111143, G111150, G111151, G111152, G111153, G111157, G111159, G111164, G111165, G111166, G111167, G111170, G111172, G111174, G111176, G111177, G111178, G111179, G111180, G111181, G111182, G111185, G111186, G111188, G111189, G111190, G111191,

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G111193, G111194, G111195, G111200, G111224, G111231, G111234, G440419, VAL001A, VAL001N, VAL001S, VAL002N, VAL003N

**Geographic Regions:** Worldwide

**Manufacturer(s):** PENTAX Medical 3 Paragon Dr, Montvale, NJ 07645, United States

**Suggested Distribution:** Clinical/Biomedical Engineering, Oncology, OR/Surgery, Pulmonology/Respiratory Therapy, Otolaryngology

**Problem:**

In a July 19, 2017, Urgent Field Correction letter submitted by an ECRI Institute member hospital, PENTAX states that the screw connecting the suction arm to the control body of the above endoscopes may loosen over time, potentially leading to debris accumulating in the space between the suction nipple and the control body and inadequate suctioning caused by leakage of air. PENTAX also states that this problem may cause cross-contamination between patients.

**Action Needed:**

Identify any affected product in your inventory. PENTAX states that this problem does not affect endoscopes manufactured after January 26, 2011. If you have affected product, verify that you have received the July 19, 2017, Urgent Field Correction letter and field correction response form. Complete the field correction response form, and return it to PENTAX. Upon receipt of the form, PENTAX will contact your facility to arrange for product repair. Notify all relevant personnel at your facility of the information in the letter.

**For Further Information:**

PENTAX

Tel.: (800) 431-5880, 8:30 a.m. to 5 p.m. Eastern time, Monday through Friday

E-mail: [customeradviosories@pentaxmedical.com](mailto:customeradviosories@pentaxmedical.com)

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 Jul 24. Member Hospital. PENTAX Document No. MK-975 Rev. A [Download](#)
- 2017 Jul 24. Manufacturer. The manufacturer confirmed the information provided in the source material.