

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	Lámpara Quirúrgica - TRUMPF
NO. IDENTIFICACIÓN RISARH	I1509-436
REFERENCIAS DEL DISPOSITIVO MEDICO	lled 3 y lled 5
REGISTRO SANITARIO	2014DM-0011439
INDICACIONES Y USO ESTABLECIDOS	Este equipo sirve para iluminar localmente con una intensidad lumínica elevada una zona del paciente que se deba examinar u operar en hospitales o consultas médicas.
NOMBRE DEL FABRICANTE	Trumpf Medizin Systeme Gmbh + Co. Kg.
DESCRIPCION DEL PROBLEMA	El fabricante ha determinado que puede existir una posibilidad de que las soldaduras de los brazos elásticos anteriores puedan desarrollar fracturas por fatiga con el tiempo cuando se exponen a fuerzas extremas, lo que podría conllevar a que se presenten potencialmente eventos adversos sobre el paciente o los usuarios.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	19 de Septiembre 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

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[High Priority] - A24720 01 : TRUMPF— Various Medical Lighting, Camera, and Monitor Systems: Welds Require Biannual Inspection Medical Device Ongoing Action

Published: Thursday, September 10, 2015

UMDNS Terms:

- Lights, Surgical [12282]
- Cameras, Video, Surgical [26334]
- Monitors, Video, High Definition [28170]
- Facility Booms, Ceiling-Mounted [22613]

Product Identifier:

Surgical Lighting, Camera, and Monitor Systems: (1) iLED 3, (2) iLED 5, (3) Helion S, (4) Helion M, (5) Helion L, (6) TruLight 3000, (7) TruLight 5000, (8) TruVidia SD, (9) TruVidia HD, (10) VidiaPort, (11) Xenion S, (12) Xenion M, (13) Xenion L [Capital Equipment]

Geographic Regions: Algeria, Angola, Antilles, Argentina, Australia, Austria, Azerbaijan, Bahrain, Belarus, Belgium, Bosnia and Herzegovina, Brazil, British Virgin Islands, Bulgaria, Canada, Chile, China, Colombia, Croatia, Cyprus, Czech Republic, Denmark, Ecuador, Egypt, Estonia, Finland, France, Gabon, Georgia, Germany, Greece, Hong Kong, Hungary, Iceland, India, Indonesia, Iran, Iraq, Ireland, Israel, Italy, Japan, Jordan, Kazakhstan, Kenya, Kosovo, Kuwait, Latvia, Lebanon, Libya, Liechtenstein, Lithuania, Luxembourg, Macedonia, Malaysia, Malta, Mauritius, Mexico, Morocco, Myanmar, The Netherlands, New Zealand, Norway, Pakistan, Palestine, Peru, Philippines, Poland, Portugal, Puerto Rico, Qatar, Romania, Russia, San Marino, Saudi Arabia, Serbia, Singapore, Slovenia, Slovakia, South Africa, South Korea, Spain, Sudan, Sweden, Switzerland, Syria, Taiwan, Thailand, Tunisia, Turkey, Turkmenistan, U.K., Ukraine, United Arab Emirates, Uruguay, U.S., Venezuela, Vietnam

Manufacturer(s): TRUMPF Medical Systems Inc 1046 LeGrand Blvd, Charleston, SC 29492, United States

Suggested Distribution: Clinical/Biomedical Engineering, OR/Surgery, Facilities/Building Management

Summary:

This Alert provides additional information based on FDA Center for Devices and Radiological Health (CDRH) source material regarding [Alert Accession No. A24720](#). FDA's CDRH states that the manufacturer initiated a recall by letter on or about July 27, 2015. Additional information is provided in the Geographic Regions field (see bolded regions).

Problem:

[July 17, 2015]

In a July 6, 2015, Urgent Medical Device Correction letter submitted by an ECRI Institute member hospital, TRUMPF states that it was notified by its supplier that there is potential for the welds of the above spring arms to develop fatigue fractures over time when exposed to extreme forces. TRUMPF states that it has received no customer reports of this problem occurring.

Action Needed:

The following actions are those listed in [Alert Accession No. A24720](#). Identify any affected product in your inventory. If you have affected product, verify that you have received the July 6, 2015, Urgent Medical Device Correction letter, Confirmation of Receipt form, and Supplement to the User Manual from TRUMPF. Complete the Confirmation of Receipt form, and return it to TRUMPF using the instructions on the form. TRUMPF states that a visual inspection of the welded joints should be completed on a biannual basis as advised in the user manual. If you are not under contract for the affected product, contact the TRUMPF technical service department at (888) 474-9360 to schedule a visual inspection of the welds as part of your standard biannual maintenance, or have your authorized technician perform the inspection. Store a copy of the supplement with the user manual(s) for the affected product. Notify all relevant personnel at your facility of the information in the letter, and forward a copy of the letter to any facility to which you have further distributed product. U.S. customers should report serious adverse events or product quality problems relating to the use of affected product to FDA's MedWatch Adverse Event Reporting program by fax at (800) 332-0178; by mail (using postage-paid FDA Form 3500, available [here](#)) at MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787; or online at the [MedWatch website](#).

For Further Information:

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Website: [Click here](#)

References:

United States:

- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall Trumpf [online]. 2015 Aug 7 [cited 2015 Aug 10]. Available from Internet: [Click here](#).
- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall Trumpf [online]. 2015 Aug 7 [cited 2015 Aug 10]. Available from Internet: [Click here](#).
- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall Trumpf [online]. 2015 Aug 7 [cited 2015 Aug 10]. Available from Internet: [Click here](#).
- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall Trumpf [online]. 2015 Aug 7 [cited 2015 Aug 10]. Available from Internet: [Click here](#).

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- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall Trumpf [online]. 2015 Aug 7 [cited 2015 Aug 10]. Available from Internet: [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):

- 2015 Sep 10. FDA CDRH Database. Class II. Z-2353/2357-2015 [Download](#)