

## El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con una alerta asociada a:

<b>NOMBRE DEL DISPOSITIVO MÉDICO</b>	Sistema de Plataforma de Estabilización Quirúrgica ESTECH
<b>NO. IDENTIFICACIÓN RISARH</b>	A1501-34
<b>REFERENCIAS DEL DISPOSITIVO MEDICO</b>	HERCULES 3 / 001-401-161 y HERCULES 360 / 001-401-160, distribuidos desde mayo del 2011.
<b>REGISTRO SANITARIO</b>	2012DM-0009204
<b>INDICACIONES Y USO ESTABLECIDOS</b>	Instrumentos para intervenciones quirúrgicas cardiovasculares utilizados en cirugía de corazón. Están destinados específicamente para proporcionar estabilización, posicionamiento, aislamiento arterial y limpieza de tejidos o estructuras, mejorando la visibilidad durante la cirugía.
<b>NOMBRE DEL FABRICANTE</b>	Endoscopic Technologies, Inc.
<b>DESCRIPCION DEL PROBLEMA</b>	El fabricante afirma que si las instrucciones de uso ( <i>IFU</i> ) para los sistemas anteriores no son acatadas, el cable de acero inoxidable puede romperse durante su uso, situación que se puede presentar con el reposicionamiento del cable cuando ya se encuentra tensado, o cuando se realiza un ajuste excesivo, y por corrosión al utilizar una solución de limpieza inadecuada durante su descontaminación, lo cual puede conllevar a que se presenten potencialmente eventos adversos sobre el paciente.
<b>FUENTE</b>	ANEXO 1
<b>FECHA DE NOTIFICACION</b>	21 de Enero 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](mailto:tecnovigilancia@invima.gov.co)

## ANEXO 1

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### [High Priority] - A23666 : Terumo—Hercules 3 and Hercules 360 Universal Stabilizing Arms: Stainless Steel Cable May Break if Instructions for Use are Not Followed Medical Device Ongoing Action

**UMDNS Terms:**

- Surgical Retractor Kits, Sternum [33225]

**Product Identifier:**

Universal Stabilizing Arms, Reusable, Stainless Steel:	Catalog Nos.:	Distribution Dates:
Hercules 3, Top Mount, Low Profile	001-401-161	May 2011 to present
Hercules 360, Top Mount, 360-Degree Rotation	001-401-160	May 2011 to present

[Capital Equipment]

**Geographic Regions:** Worldwide

**Manufacturer(s):** Terumo Cardiovascular Systems Corp Div Terumo Corp 125 Blue Ball Road, Elkton, MD 21921, United States

**Suggested Distribution:** Cardiology/Cardiac Catheterization Laboratory, Clinical/Biomedical Engineering, OR/Surgery, Risk Management/Continuous Quality Improvement, Perfusion, Central Sterilization Reprocessing

**Problem:**

In a January 6, 2015, Urgent Safety Alert letter submitted by an ECRI Institute member hospital, Terumo states that if the instructions are use (IFU) for the above systems are not followed, the stainless steel cable may break during use. Terumo states that its investigation identified two causes of cable breakage:

- Over-tightening or repositioning when tensioned
- Using improper cleaning solution during decontamination.

If the cable breaks, the stainless steel links on the arm may fall off, potentially into the surgical site. Terumo states that if a component falls into a patient's body cavity, it is unlikely to cause patient injury; however, it may delay the procedure while the surgeon retrieves the component. Terumo further states that the components are made of stainless steel and have a relatively smooth surface with no sharp or pointed features and that the radiopaque nature of the components would aid in retrieval and mitigate patient risk. Terumo also states that tissue injury from a fractured cable end may occur. If cable failure occurs, it is likely that each end of the fractured cable will be held by the user's hands, thus mitigating risk. Terumo also states that it has received no reports of injury resulting from this problem.

**Action Needed:**

Identify any affected product in your inventory. If you have affected product, verify that you have received the January 6, 2015, Urgent Safety Alert letter and Customer Response Form from Terumo. Review the following information from the affected product IFU:

**Warnings:**

- Excessive torque might cause the cable to fray, snap, or break. If the arm does not hold position, it should not be used.
- Avoid repositioning the arm when the arm is tensioned. It will cause the cable in the flexible arm to fray and possibly break.

Strictly follow the manufacturer's instructions for concentration of the detergent solution and proper use to avoid high acidity or alkaline pH balances outside the validated pH range 7.8 to 8.8, which may cause corrosion and result in breakage.

**Precaution:**

- Cable fatigue and wear can be easily detected, and failure prevented, by examining the cable before each use. Before beginning each procedure, while the arm is fully loosened, look at the arm to determine whether the cable shows signs of fraying (see the [letter](#) for fraying example). If so, it should not be used. A cable will not suddenly fail during a procedure if inspection is done to verify cable integrity before use.

**Pre-inspection before use:**

- Before use, the unit should be fully loosened and visually inspected. The cable should be inspected by examining the spaces between links. No signs of wear or fraying of the cable should be present. If any wear is found, it is recommended the product be returned for replacement.

Notify all relevant personnel of the information in the letter. Complete the Customer Response Form, and return it to Terumo using the instructions on the form. U.S. customers should also report any adverse events 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 Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787; or online at the MedWatch website.

**For Further Information:**

Terumo customer service department  
Tel.: (888) 758-8000, 8 a.m. to 6 p.m. Eastern time, Monday through Friday  
Website: [Click here](#)

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**Background:**

**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 Jan 12. Member Hospital. Terumo letter submitted by ECRI Institute member hospital (includes reply form). Terumo reference no. MD-2015-001-C [Download](#)
- 2015 Jan 15. Manufacturer confirmed information