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:

NOMBRE DEL DISPOSITIVO MÉDICO	Incubadora para Manejo de Embriones COOK MEDICAL
NO. IDENTIFICACIÓN RISARH	I1803-149
REFERENCIAS DEL DISPOSITIVO MEDICO	K-MINC-1000-US, K-MINC-1000, todos los lotes.
REGISTRO SANITARIO	2010DM-0006339
INDICACIONES Y USO ESTABLECIDOS	Suministrar condiciones adecuadas de humedad, temperatura y PH durante el cultivo de células para fertilización in vitro (IVF).
NOMBRE DEL FABRICANTE	William A. Cook Australia Pty Ltd
DESCRIPCION DEL PROBLEMA	El fabricante ha detectado que la temperatura de las tapas de la cámara de incubación los dispositivos médicos referenciados, puede ser demasiado alta o demasiado baja para una adecuada incubación de gametos / embriones debido a falla por fatiga de los cables del calentador de tapa plana y flexible, lo anterior podría conllevar a que se presenten fallas en el proceso.
FUENTE	Anexo
FECHA DE NOTIFICACION	09 de marzo de 2018

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

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ANEXO

[High Priority] - A30149 : Cook—MINC Benchtop Incubators: Temperature of Incubation Chamber Lids May Become Too High or Too Low
Medical Device Ongoing Action

Published: Thursday, March 8, 2018

UMDNS Terms:

- Incubators, Laboratory, Aerobic [15151]

Product Identifier:
[Capital Equipment]

Product	Cook Medical Model	Catalog No.	Part No.	Lot No.
Incubators	MINC Benchtop (Mini-Incubator)	K-MINC-1000-US	G46022	All
	MINC Benchtop (Mini-Incubator)	K-MINC-1000	G20079	All

Geographic Regions: Albania, Algeria, Argentina, Australia, Austria, Bahrain, Bangladesh, Belarus, Belgium, Bolivia, Brazil, Brunei Darussalam, Bulgaria, Canada, Chile, China, Colombia, Costa Rica, Croatia, Czech Republic, Dominican Republic, Ecuador, Egypt, El Salvador, Finland, France, Germany, Greece, Guatemala, Honduras, Hong Kong, Hungary, India, Iran, Iraq, Ireland, Italy, Japan, Jordan, Kazakhstan, Korea, Kuwait, Lebanon, Malaysia, Mexico, New Caledonia, New Zealand, Nicaragua, Nigeria, Norway, Pakistan, Palestinian Territory, Panama, Peru, Philippines, Poland, Portugal, Puerto Rico, Qatar, Romania, Russian Federation, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, South Africa, Spain, Sri Lanka, Switzerland, Syrian Arab Republic, Taiwan, Thailand, Turkey, Ukraine, United Arab Emirates, U.K., U.S., Venezuela, Vietnam

Manufacturer(s): Cook Medical 700 Daniels Way, PO Box 489, Bloomington, IN 47402-1608, United States

Suggested Distribution: Clinical/Biomedical Engineering, Clinical Laboratory/Pathology, Obstetrics/Gynecology/Labor and Delivery

Problem:
In a January 16, 2018, Urgent Medical Device Correction letter submitted by an ECRI Institute member hospital, Cook states that the temperature of the incubation chamber lids on the above incubators may become too high or too low for proper gamete/embryo incubation because of fatigue failure of the flat flex lid heater cables.

Action Needed:
Identifyany affected product in your inventory. If you have affectedproduct, verify that you have received the January 16, 2018, Urgent Medical Device Correction letter and Acknowledgment and Receipt Form from Cook. Regardless of whether you have affected product, complete the Acknowledgment and Receipt Form and return it to Cook using the information in the letter. Cook will replace the flat flex lid heater cable on affected product. The firm also states that it will replace the lid heater cables every year during your annual preventive maintenance. A Cook representative will contact your facility to arrange for service or to reschedule your annual preventive maintenance. Cook recommends that you continue to perform biannual functionality testing, in accordance with the K-MINC-1000(-US) user manual. Report any adverse events related to use of affected product to the Cook Medical capital equipment service department by telephone at (855) 207-7214. Inform 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 affected product. U.S. customers should report adverse events or product quality problems relating to the use of affected product to FDA's MedWatch Adverse Event Reporting program by telephone at (800) 332-1088

; by fax at (800) 332-0178

; by mail (using postage-paid FDA Form 3500, available here) at Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20852-9787; or online at the MedWatch website .
For Further Information:
Cook Medical customer relations department
Tel.: (800) 457-4500 or (812) 339-2235
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):

- 2018 Mar 7. Member Hospital. Cook letter submitted by ECRI Institute member hospital (includes reply form) Download
- 2018 Mar 8. Manufacturer. Manufacturer confirmed information