

El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con un Retiro de Producto del Mercado asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Balones de Extracción COOK
NO. IDENTIFICACIÓN RISARH	R1407-284
REFERENCIAS DEL DISPOSITIVO MEDICO	G50695-TXR-ME, lotes específicos.
REGISTRO SANITARIO	2011DM-0007454
INDICACIONES Y USO ESTABLECIDOS	Se utiliza para la extracción endoscópica de cálculos del sistema biliar y para la inyección del contraste.
NOMBRE DEL FABRICANTE	Wilson Cook Medical / Cook Endoscopy
DESCRIPCION DEL PROBLEMA	El fabricante informa que ha detectado en dichas referencias que a pesar de estar etiquetados para su uso con endoscopio de 2,8 mm, el dispositivo no logra pasar a través de estos canales, conllevando a que se presente retrasos en los procedimientos efectuados y posibles eventos adversos en los pacientes derivados de esta situación.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	18 de Julio de 2014

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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A22732 - High Priority Medical Device Alert

Medical Device Ongoing Action

Updated: July 18, 2014

UMDNS Terms:

- Catheters, Biliary, Strictureplasty, Endoscopic, Balloon [18713]

Suggested Distribution:

- Materials Management
- OR/Surgery
- Gastroenterology

Geographic Regions:

- Australia
- Belgium
- Canada
- Czech Republic
- Columbia
- Finland
- Germany
- Italy
- Monaco
- New Zealand
- The Netherlands
- Norway
- Poland
- Saudia Arabia
- Spain
- Sweden
- Switzerland
- U.K.
- U.S.

Cook—Tri-Ex Extraction Balloons with Multiple Sizing: May Not Fit through Endoscopes with 2.8 mm Channel

Product Identifier:

275 cm Tri-Ex Extraction Balloons with Multiple Sizing [Consumable]

Reorder No. G50695-TXR-ME; Lot Nos.: W3306823, W3308765, W3306822, W3307290, W3310327, W3314903, W33313508, W3315918, W3316200, W3317899, W3318601, W3320914, W3318363, W3324035, W3326083, W3326019, W3324760, W3326081, W3324761, W3327652, W3329126, W3332198, W3333823, W3333058, W3334395, W3334391, W3333053, W3334398, W3335043, W3335044, W3338990, W3339989, W3339988, W3342312, W3342321, W3340802, W3342313, W3346362, W3348543, W3346891, W3351100, W3352969, W3354256, W3353493, W3355987, W3355986, W3356062, W3360650, W3363301, W3369291, W3372237, W3373933, W3374409, W3372236, W3376517, W3376932, W3374821, W3378140, W3378783, W3378785, W3379750, W3379749, W3376524, W3378784, W3380510, W3382213, W3380922, W3382214, W3387285, W3387284, W3387903, W3388883, W3387904, W3393847, W3397902, W3399315, W3402514, W3402507, W3403170, W3403191, W3403190, W3402743, W3403192, W3403168, W3407177, W3406080, W3406675, W3407178, W3415262, W3415261, W3415263, W3414478, W3418222, W3418622, W3421782, W3425049, W3425571, W3427509, W3431690, W3431684, W3427219, W3433148, W3435810, W3438091, W3439508, W3442647, W3442042, W3443211

Manufacturer:

- Cook Group CosPO Box 1608, Bloomington, IN 47402-1608, United States

Problem: In a July 15, 2014, Urgent Product Recall letter submitted by ECRI Institute member hospitals, Cook states that the above extraction balloons are labeled for use with a 2.8 mm endoscope; however, the device may not fit through endoscopes with a 2.8 mm channel.

Action Needed:

Identify and isolate any affected product in your inventory. If you have affected product, verify that you have received the July 15, 2014, Urgent Product Recall letter from Cook. Complete the form at the bottom of the letter, and return it to Cook by fax at (812) 339-7316 or by e-mail at CustomerRelationsNA@cookmedical.com. To receive credit, return affected product to Cook by mail, Attn: Return Goods Department—044R, at 400 Daniel's Way, Bloomington, IN 47404.

For Further Information:

Cook customer relations department
Tel.: (800) 457-4500 (select option 4 then ext. 2146)
E-mail: CustomerRelationsNA@cookmedical.com
Website: [Click here](#)

Comment:

- 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):

- 2014 Jul 17. Member Hospital. Cordis letter submitted by ECRI Institute member hospital (includes reply form)
- 2014 Jul 18. Manufacturer. Manufacturer confirmed information