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	Instrumental quirúrgico SYMMETRY
NO. IDENTIFICACIÓN RISARH	R1401-42
REFERENCIAS DEL DISPOSITIVO MEDICO	QUAD – LOCK CONTAINERS
REGISTRO SANITARIO	2013DM-0009907
INDICACIONES Y USO ESTABLECIDOS	Instrumentos empleados para prestar apoyo en procedimientos quirúrgicos
NOMBRE DEL FABRICANTE	Symmetry Surgical, Inc. Specialty Surgical Instrumentation, Inc.
DESCRIPCION DEL PROBLEMA	Se manifestó por parte del fabricante que los dispositivos almacenados en los contenedores mencionados, pueden haber perdido su condición de estériles, debido a que no garantizan el mantenimiento de la barrera de esterilidad de una forma efectiva y segura, conllevando a que se generen posibles eventos adversos sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	31 de Enero 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

A21545 01 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: January 30, 2014
UMDNS Terms:
- Instrument Trays [12143]

Suggested Distribution:
- Materials Management
- Infection Control
- Central Sterilization Reprocessing

Geographic Regions:
- (Impact in additional regions has not been identified or ruled out at the time of this posting)
- Australia
- Canada
- Chile
- China
- Colombia
- Germany
- Italy
- Korea
- Puerto Rico
- Saudi Arabia
- U.K.
- U.S.

Symmetry Surgical/Codman—Quad-Lock Containers: May Not Maintain Effective Sterile Barrier

Product Identifier:

Quad-Lock Containers:	Product Nos.:	Height:	Color:
270 x 270 mm Small Base, Perforated, with Filter Retainer	50-8731	100 mm	None Listed
	50-8732	135 mm	
	50-8733	150 mm	
	50-8734	200 mm	
	50-8735	260 mm	
270 x 270 mm Small Base, Nonperforated	50-8744	100 mm	None Listed
	50-8745	135 mm	
	50-8746	150 mm	
	50-8747	200 mm	
	50-8748	260 mm	
280 x 276 mm Small Lid, 4 Latch, Perforated, with Filter Retainer	50-8950	None Listed	Gray
	50-8951	Yellow	
	50-8952	Green	
	50-8953	Blue	
	50-8954	Red	
	50-8955	Black	
440 x 270 mm Medium Base, Perforated, with Filter Retainer	50-8736	100 mm	None Listed
	50-8737	135 mm	
	50-8738	150 mm	
440 x 270 mm Medium Base, Nonperforated	50-8749	100 mm	None Listed
	50-8740	135 mm	
	50-8741	150 mm	
445 x 279 mm Medium Lid, 4 Latch Perforated, with Filter Retainer	50-8956	None Listed	Gray
	50-8957	Yellow	
	50-8958	Green	
	50-8959	Blue	
	50-8960	Red	
	50-8961	Black	
560 x 275 mm Large Base, Perforated with Filter Retainer	50-8726	100 mm	None Listed

50-8727		135 mm	
50-8728		150 mm	
50-8729		200 mm	
50-8730		260 mm	
560 x 275 mm Large Base, Nonperforated	50-8739	100 mm	None Listed
50-8740		135 mm	
50-8741		150 mm	
50-8742		200 mm	
50-8743		260 mm	
570 x 280 mm Large Lid, 4 Latch Perforated with Filter Retainer	50-8944	None Listed	Gray
50-8945		Yellow	
50-8946		Green	
50-8947		Blue	
50-8948		Red	
50-8949		Black	

[Consumable]

Units distributed since 2009

Manufacturer:
- Symmetry Medical Inc3724 N State Rd 15, Warsaw, IN 46582, United States

Summary: This Alert provides additional information based on FDA Center for Devices and Radiological Health (CDRH) source material regarding Alert Accession No. A21545. FDA's CDRH states that the manufacturer initiated a recall by letter on December 2, 2013. Additional information is provided in the Geographic Regions field (see bolded regions).

Problem:
[December 31, 2013]
In a December 2, 2013, Urgent Medical Device Recall letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Symmetry Surgical states that devices stored in the above containers may not be sterile because the container system may not maintain an effective sterile barrier. The manufacturer has not confirmed the information provided in the source material.

Action Needed:
The following actions are those listed in Alert Accession No. A21545. Identify, isolate, and discontinue use of any affected product in your inventory. If you have affected product, verify that you have received the December 2, 2013, Urgent Medical Device Recall letter and recall response form from Symmetry Surgical. Complete the recall response form, and return it to Symmetry Surgical using the instructions on the form.

For Further Information:
U.S.
Larry Knox, Symmetry Surgical customer service associate
Tel.: (615) 964-5546, or (800) 251-3000, 8 a.m. to 5 p.m. Eastern time, Monday through Friday
Outside U.S.
Mariska Hermes, Symmetry Surgical customer service associate
Tel.: 41 (52) 5575970 or 41 (52) 5575900, 8 a.m. to 5 p.m. Central European Time
E-mail: internationalorders@symmetrysurgical.com
Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Symmetry Surgical. Sterilization, healthcare sterilization process failure. Codman®—Quad-Lock™ sterilization container systems and/or Symmetry Surgical—Quad-Lock™ sterilization container system [online] London: Department of Health; 2013 Dec 20 [cited 2013 Dec 26]. (Field safety notice; reference no. 2013/012/012/601/015). Available from Internet: Click here.
- United States. Food and Drug Administration. Center for Device and Radiological Health. Medical device recalls: Class 2 recall—Symmetry and CODMAN(R) brands, QUADLOCK (TM) sterilization container [online]. 2014 Jan 27 [cited 2014 Jan 28]. Available from Internet: 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 Jan 30. FDA CDRH Database. Class II. Z-0833-2014
- 2013 Dec 31. MHRA FSN. 2013/012/012/601/015
- 2013 Dec 31. MHRA FSN.