

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	Pipetas para Micromanipulación
NO. IDENTIFICACIÓN RISARH	R1407-275
REFERENCIAS DEL DISPOSITIVO MEDICO	PP-5.75-90, PP-9-90, PP-5.75-90PL, PP-9-90PL con fechas de expiración 02 de mayo de 2015 o posteriores
REGISTRO SANITARIO	2013DM-0010658
INDICACIONES Y USO ESTABLECIDOS	Estas pipetas son usadas para procedimientos de Micromanipulación y remoción de células, ovocito o blastocito
NOMBRE DEL FABRICANTE	Origio Inc
DESCRIPCION DEL PROBLEMA	El fabricante informa sobre el posible compromiso de la barrera estéril del dispositivo, conllevando a que se presenten potencialmente eventos adversos sobre el paciente..
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	07 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

www.ecri.org • Printed from *Health Devices Alerts* on Monday, July 07, 2014 Page 1

A22639 - High Priority Medical Device Alert

Medical Device Ongoing Action

Updated: July 3, 2014

UMDNS Terms:

- Pipettes [15166]

Suggested Distribution:

- Materials Management
- Clinical Laboratory/Pathology
- Infection Control
- Obstetrics/Gynecology /Labor and Delivery

Geographic Regions:

- Australia
- Barbados
- Brazil
- Canada
- Chile
- China
- Colombia
- Denmark
- Ecuador
- France
- Germany
- Greece
- Guatemala
- Haiti
- Honduras
- India
- Israel
- Italy
- Japan
- Jordan
- Korea
- Kuwait
- Lebanon
- Malaysia
- Mexico
- The Netherlands
- Peru
- Russia
- Singapore
- South Africa
- Spain
- Taiwan
- Thailand
- Turkey
- U.K.
- Ukraine
- United Arab Emirates
- U.S.
- Venezuela

ORIGIO—Pasteur Pipets: Packaging Sterile Barrier May Be Breached

Product Identifier:

Pasteur Pipets 3-Packs [Consumable]

Model Nos.: PP-5.75-90, PP-9-90, PP-5.75-90PL, PP-9-90PL

Expiration Dates: MAY 2 2015 or later

Manufacturer:

- ORIGIO Inc.2400 Hunters Way, Charlottesville, VA 22911-7930, United States

Problem: FDA's Center for Devices and Radiological Health (CDRH) states that the nylon pouch sterile barrier for the packaging of the above pipettes may have been breached. FDA's CDRH also states that ORIGIO initiated a recall by Field Safety Corrective Action Urgent Product Recall letter dated June 2014.

Action Needed:

Identify, isolate, discontinue use of any affected product in your inventory. If you have affected product, verify that you have received the June 2014 Field Safety Corrective Action Urgent Product Recall letter from ORIGIO. Return affected product to ORIGIO to obtain credit or replacement product.

For Further Information:

ORIGIO

Website: [Click here](#)

References:

- United States. Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall Pasteur pipets [online]. 2014 Jun 30 [cited 2014 Jul 1]. 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 Jul 1. FDA CDRH Database. Class II. Z-1946-2014
- 2014 Jul 2. Manufacturer. Manufacturer confirmed the information provided in the source material.