

ORIGIO Inc 2400 Hunters Way Charlottesville, VA 22911

Tel: +1 434 979 4000 Fax: +1 434 295 5912

June 19, 2014

Subject:

**URGENT FIELD SAFETY NOTICE / URGENT PRODUCT RECALL** 

**PASTEUR PIPETTES** 

Product Codes PP-5.75-90, PP-9-90, PP-5.75-90L, PP-9-90PL Lot: Reference Pasteur Pipet-Product Code -Lot number listing

Dear Customer,

ORIGIO has identified a "pinhole" packaging breach on the 3-pack pouched version of the Pasteur Pipets. As a result, the sterility of the package cannot be guaranteed.

After an internal investigation, we have determined the best course of action is to conduct a removal of these product codes (all lots with a labeled expiry date of May 2, 2015 or later), which you may have in your inventories. Please return these Pasteur Pipets to your distributor as soon as possible for a credit or product replacement.

There are 4 codes which are impacted with this packaging issue.

- PP-5.75-90, Box of 90, 30 pouches of 3 pipets each , 5.75" (14.6cm) long
- PP-9-90, Box of 90, 30 pouches of 3 pipets each, 9" (22.9cm) long
- PP-5.75-90PL, Box of 90, cotton plugged, 30 pouches of 3 pipets each, 5.75" (14.6cm) long
- PP-9-90PL, box of 90, cotton plugged, 30 pouches of 3 pipets each, 9"
  (22.9cm) long

We are working on a solution for this packaging issue and we will inform you when we have the 3-pack product configuration available for shipment.

We sincerely apologize for the inconvenience this issue may cause in your laboratories. As ORIGIO, we want to provide only the best products for IVF.

Sincerely

John Clay

Director of Regulatory Affairs

ORIGIO Inc.

Contacts: