

August 13, 2018

URGENT: MEDICAL DEVICE RECALL

Product Name	Catalog No.	Lot No.
Gibco™ MEM Non-Essential Amino Solution (100X)	11140050	1986670 & 1995631
Gibco™ GlutaMAX™ Supplement	35050061	1967691
Gibco™ Sodium Pyruvate (100 mM)	11360070	1967697
Gibco™ DPBS, calcium, magnesium	14040141	1994520

Dear Customer:

Our records indicate that you purchased the products listed above. We are notifying you of the potential for leaking bottles, which through investigation has been isolated to the bottle cap. Our bottle cap supplier has confirmed an issue with the molding of the bottle caps which may cause a defect. As a result of this bottle cap defect, there is the potential for leakage, which could compromise the sterility and performance of the product.

RISK TO HEALTH:

We believe the risk to health is low as product leakage is easily recognized by the user. The products are contained in clear plastic bottles and are tamper- and puncture-resistant which would indicate whether the bottles have leaked, and/or been exposed to air and potential contamination. A leaking bottle would be easily detectable by the user. Visual indicators of leaking are liquid or dried media around the container closure area.

Leaked product may be exposed to environmental contaminants which slow/prevent cell growth or viability. If the leaked product is used to determine a treatment or diagnosis, the slow/no cell growth may cause no test results to be reported.

ACTIONS TO BE TAKEN BY THE CUSTOMER:

We ask that you return any remaining inventory of the lots listed above or discard the material per local and state requirements. We request that you complete the attached **Customer Response Form** – Appendix 1 and return the form to ts.productinfo@thermofisher.com for proper credit and regulatory reporting.

You should review results and laboratory reporting associated with use of the listed lots for further action. Please notify any personnel who need to be aware of the potential for failure of performance for this product. Please keep this notification on file.

We appreciate your assistance and apologize for any inconvenience. Thermo Fisher Scientific is committed to providing high quality products. We are working closely with our supplier to implement corrective and preventive actions to ensure such an event does not occur again.

If you have any questions, please contact our Technical Services Department at 800-955-6288 Option 2.

Sincerely,





Sarah Jennings
Director, Quality

cc Chairman Medical Board and Relevant Head of Departments

CUSTOMER RESPONSE SHEET

Appendix 1

Customer Mailing Name>

<Customer Ship To: Number>

Customer PO#	TFS Order#	Ship Date	Product	Catalog#	Lot#	Quantity Returned or Discarded (Circle One)

We will provide replacement for the material you return or have discarded.

I have read and understand the attached customer letter and field action instructions: _____ (initials)

I understand that this applies to all inventory of the affected product that I have received: _____ (initials)

Has the recalled product caused and/or contributed to any deaths or serious injuries? _____ Yes _____ No (circle)
If yes, please explain:

If you have any questions regarding return of material or destruction of material – Please contact: Technical Support at 1-800-955-6288 Option 2 or ts.productinfo@thermofisher.com.

I have shipped this lot to other facilities:	<input type="checkbox"/> YES <input type="checkbox"/> NO
If YES, I have notified those facilities of this recall:	<input type="checkbox"/> YES <input type="checkbox"/> NO
If YES: Describe method of notification:	
Number of customers/facilities notified:	
Date notified:	

Customer Signature/Date:	
Phone No.	
Email:	

For any questions or comments please contact Technical Support:

North American customers: Please complete the Customer Response Sheet and email a scanned copy of the response sheet to ts.productinfo@thermofisher.com. If you have any questions, please call Technical Support at 1-800-955-6288 Option 2.