

URGENT - Medical Device Recall Gel-E Donut and Squishon 2

Possibility of Mold

Dear Customer,

Mold has been detected on some Gel-E Donut and Squishon 2 gel-filled products. This Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur,
- the actions that should be taken by the customer/user in order to prevent risks to patients, and
- the actions planned by Philips/Children's Medical Ventures to correct the problem.

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

You may have been notified of a previous action taken by Philips/Children's Medical Ventures related to this issue. However, we are now taking action to request that you discontinue use of all of the Gel-E Donut and Squishon 2 products since additional complaints have been received regarding the presence of visible mold on these product lines. We are requesting that you discontinue use of these products, even if mold is not visible.

Our records indicate that you have purchased the Gel-E Donut and Squishon 2 gel-filled products. The following page provides additional instructions and actions to be taken; refer to the "ACTION TO BE TAKEN BY CUSTOMER / USER" section for more information.

This action has been reported to the appropriate regulatory agencies.

If you need any further information or support concerning this problem, please contact your Philips/Children's Medical Ventures representative or the UK Philips Customer Care Service Centre on 0870 532 9741.

Philips/Children's Medical Ventures apologizes for any inconveniences caused by this problem.


Sincerely,



Rusty Kelly
Quality and Regulatory Senior Manager

URGENT - Medical Device Recall Gel-E Donut and Squishon 2

Possibility of Mold

AFFECTED PRODUCTS	Any of the following part numbers are subject to this action: 92025-A, 92025-B, 92025-C (Gel-E Donut) and 91033-2 (Squishon 2).
PROBLEM DESCRIPTION	<p>Mold has been found on some Gel-E Donut and Squishon 2 gel-filled products.</p> <p>Philips/Children's Medical Ventures previously implemented a process to reduce the presence of viable mold on the products prior to shipment. The process has been determined to be insufficiently effective at eliminating the potential for mold growth. Therefore, Philips/Children's Medical Ventures cannot guarantee that mold growth will not occur on the product over time.</p>
HAZARD INVOLVED	The mold detected on the product has been <i>Cladosporium</i> and <i>Penicillium Fungi</i> , which are commonly found molds. NICU and PICU patients are much more sensitive to molds and there is potential for the mold to be transferred to these environments once the outer pack is opened.
HOW TO IDENTIFY AFFECTED PRODUCTS	<div style="text-align: center;">  </div> <p>Product can be identified by the part number located on the product itself (see area circled in red in the pictures above). Any of the following part numbers are subject to this action: 92025-A, 92025-B, 92025-C (Gel-E Donut) and 91033-2 (Squishon 2).</p>
ACTION TO BE TAKEN BY CUSTOMER / USER	<ol style="list-style-type: none"> 1.) Discontinue use of all Gel-E Donut and Squishon 2 products, even if mold is not visible. 2.) Take an inventory of all Gel-E Donut and Squishon 2 products in your possession and complete the reply form provided on the last page of this letter. 3.) Email the completed reply form to gelrecall@philips.com or fax it to +1 404-855-4900. 4.) Dispose of all Gel-E Donut and Squishon 2 products in your inventory, even if mold is not visible. Please do not return any product to Philips/Children's Medical Ventures. <p>Please return the reply form, even if you do not have any inventory of the Gel-E Donut or Squishon 2 products or if you responded to the previous action taken by Philips/Children's Medical Ventures related to this issue.</p>

**URGENT - Medical Device Recall
Gel-E Donut and Squishon 2****Possibility of Mold**

ACTIONS PLANNED BY PHILIPS/CHILDREN'S MEDICAL VENTURES	Once the reply form is received by Philips/Children's Medical Ventures, credit for any disposed product will be applied to your facility's account. <i>NOTE: The Gel-E Donut and Squishon 2 products are packaged as 12 units per case. Therefore, credit for an entire case will be given even in cases where there are not 12 total products. For example, if you possess 3 Gel-E Donut Extra Small, you will be credited for one case of Gel-E Donut Extra Small.</i>
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this problem, please contact your Philips/Children's Medical Ventures representative or the UK Philips Customer Care Service Centre on 0870 532 9741.

**URGENT - Medical Device Recall
Gel-E Donut and Squishon 2**

Possibility of Mold

Reply Form

Once this reply form is received by Philips/Children's Medical Ventures, credit for disposed product will be applied to the facility's account.

Contact Name:	
Telephone Number:	
Email Address:	
Facility Name:	
Account Number: <i>(if credit is to be given)</i>	
Street Address City, State Zip:	

Please check one option below:

- Our facility did not have any inventory of these products.** *(Please sign below.)*
- Our facility has inventory of these products.** *(Please complete the table and sign below.)*

	92025-A	92025-B	92025-C	91033-2
	Gel-E Donut Extra Small	Gel-E Donut Small	Gel-E Donut Medium	Squishon 2
Total Number of Each Product in Inventory/Scrapped*				

****Please count individual products and not cases. Also, please do not include any products for which you have already requested credit under the previous action taken by Philips/Children's Medical Ventures related to this issue.**

I certify that our facility did not have any inventory of the Gel-E Donut and Squishon 2 products –or– that our facility has disposed of all Gel-E Donut and Squishon 2 products in our inventory.

Signature: _____ Date: _____

Please email the completed reply form to gelrecall@philips.com or fax it to 01483 298831.

If you experience difficulty in carrying out the instructions contained in this communication, please contact your Philips/Children's Medical Ventures representative or the UK Philips Customer Care Service Centre on 0870 532 9741.