



Document Name:	Recall Letter to Customer	Revision Number:	1
Document Number:	IMI-303-FRM-75	Author:	[REDACTED]

URGENT: Field Safety Notice

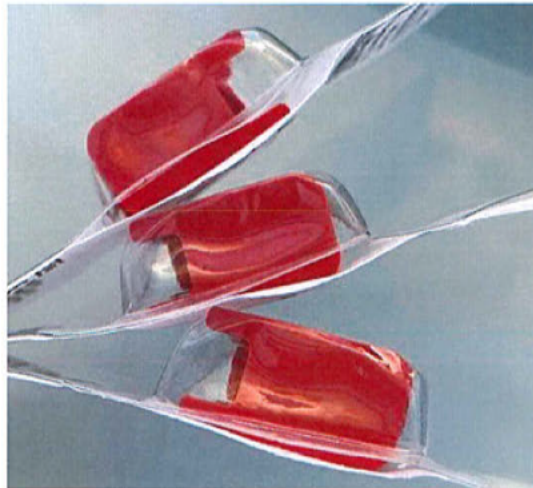
December 2, 2022

Dear Customer/Distributor,

The purpose of this letter is to advise you that International Medical Industries, Inc. is voluntarily recalling **Prep-Fill™ Guarded Luer Connector (GLC)**. The Guarded Luer Connector is a fluid transfer device used in the pharmacy to provide the fluid path for transferring large source container ingredients into a smaller container. Please refer to the attachment below for your affected lots.

Reason for the Field Safety Corrective Action:

Unsealed edge of blister packaged individual GLC devices. Device may not meet label claims for sterility.



Risk to Health:

If used, at the worst case the breach in sterile barrier might cause or contribute to a heightened level of bacterial, fungal, or viral contaminant in the delivered medication. This risk is remote however, as the product and packaging do not promote or support growth of those biological organisms. There were no adverse events associated with this recall.

Proprietary and Confidential:

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Product and Distribution Information Table					
<i>Prep-Fill™ Guarded Luer Connector (GLC)</i>					
Customer Questions					
Do you have any of these devices remaining within your facility?		<input type="checkbox"/> Yes <input type="checkbox"/> No		If you have used any devices from this lot, did you encounter any devices with open blister seals? (Check N/A if you did not inspect/use any product) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
If yes above, how many devices will be returned or destroyed?		<u>Total QTY</u>		If yes above, how many devices were observed with the defect? (If No or N/A please N/A this section) <u>Total QTY</u>	
Lot # (Please check lots that apply)	QTY Purchased	QTY To be Returned	QTY Used Up	Was product distributed to your customers?	QTY Distributed
45266 <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No	
45047 <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No	
44549 <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No	
44120 <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No	
43800 <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No	
43633 <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No	
43626 <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No	
42634 <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No	
42236 <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No	
39371 <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No	
39350 <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No	
37176 <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No	
37093 <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No	
37158 <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No	
37151 <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No	
37086 <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No	
37079 <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No	
36596 <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No	
33074 <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No	
39378 <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No	
39364 <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No	
39357 <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No	
36558 <input type="checkbox"/>				<input type="checkbox"/> Yes <input type="checkbox"/> No	

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Company Name:		
Completed by (Print)	Signature	Date

Actions to be taken by the Customer/User:

International Medical Industries, Inc. requests that you do not use the lots and have all identified product to be returned. Please identify the number of devices by lot, complete the table on page two, return this completed form via email. IMI will contact you to arrange for return or destruction of the product. Returned goods will be coordinated through IMI's Customer Service Department.

Product and Distribution Information:

Refer to page two above.

Type of Action by the Company:

International Medical Industries, Inc. is performing an investigation and Root Cause – Corrective Action.

Sincerely,

[REDACTED]

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