

## Urgent Field Safety Notice

Kremsmünster, January 13, 2025

**Subject:** Urgent Field Safety Notice - Recall R002\_24

Dear valued customer,

Greiner Bio-One has been informed, that the devices (HOLDEX® Single-Use Holder PP single-packed, sterile) mentioned below show deviations regarding the reset of the rubber sleeve after puncturing.

Therefore Greiner Bio-One has decided to initiate a recall for the below mentioned devices.

**For product compliance and safety reason, the products need to be recalled.**

We kindly ask you to **isolate** your inventory, including any of this item on site and ensure that the affected lot is withdrawn from circulation at your customers' facilities.

Item Number	Lot Number
450263	A24063UG
450263	A240838N
450263	A24083G9
450263	A24083GD
450263	A240347W

Attached are two templates for you to complete. Your provided information will confirm to us that you have notified your customers and will also provide us with the total quantity that is isolated in your warehouse, as well as any stock that is isolated in the warehouse of your customers.

**Please complete the attached template and return it to our attention as soon as possible, but not later than within 10 working days.**

As soon as we have received the above requested information from you, we will provide you with further instructions.


Kindly accept our sincerest apologies for any inconvenience this matter may cause.

If you have any additional questions, please get in touch with your respective Greiner Bio-One Sales Representative or Assistant.

Best regards,



Daniel Stocker  
Project Manager Quality Management

	<b>F_REPLY DOCUMENT "CONFIRMATION"</b> <b>[ENGLISH]</b>	D5691600 Rev. 0 Page: 1/ 1
	Responsible: Site GBO AT: QM GBO AT-L	
Editor	Andreas Schinker 2024-07-24 11:04 (UTC+02:00)	
Review	Review not required	
Approval	Georg Sams (2024-07-24)	
Valid from	2024-10-10 08:05 (UTC+02:00)	

*This document is GxP-relevant. The usage is only permitted after completion of the required training.*

## RETURN to:

Greiner Bio-One GmbH  
Bad Haller Straße 32  
4550 Kremsmünster  
Tel: +43 7583 6791  
Fax: +43 7583 6318  
office@at.gbo.com

## Confirmation

We,  
Name of company:

Address of company:

herewith confirm to Greiner Bio-One GmbH, that we have acknowledged the information regarding

FSCA Number:

R002\_24

We have already informed our customers which have received the concerned products of the product recall and its related risks.

Details:

Item No.	LOT No.	No. of customers informed	Delivered quantity	Usage			
				Quantity used (with no reported problems)	Still held by customers	Still held in own stock	Total
450263	A24063UG						
450263	A240838N						
450263	A24083G9						
450263	A24083GD						
450263	A240347W						

Name (please PRINT):

Position in company:


Signature:

Date:

**Company stamp to be placed here:**

### Attention:

This confirmation has to be returned within 10 working days after receipt.  
Once Greiner Bio-One has received this confirmation regarding quantities remaining at your premises or with your customers, further instructions will be provided.  
Buyer is aware of the fact that seller is obliged to trace back each individual item to the customer and/or end user according to seller's Good Manufacturing Practice (GMP).

	<b>F_REPLY DOCUMENT "GOODS DISPOSAL TO R" [ENGLISH]</b>	D5691300 Rev. 0 Page: 1/ 1
	Responsible: Site GBO AT: QM GBO AT-L	
Editor	Andreas Schinker 2024-07-24 11:05 (UTC+02:00)	
Review	Review not required	
Approval	Georg Sams (2024-07-24)	
Valid from	2024-10-03 08:36 (UTC+02:00)	

*This document is GxP-relevant. The usage is only permitted after completion of the required training.*

## RETURN to:

Greiner Bio-One GmbH  
Bad Haller Straße 32  
4550 Kremsmünster  
Tel: +43 7583 6791  
Fax: +43 7583 6318  
office@at.gbo.com

## Goods Disposal to R002/24

We,  
Name of company:

Address of company:

Herewith confirm to Greiner Bio-One GmbH that we have disposed of the following listed item number(s), lot number(s), and quantities.

<i>Item number(s)</i>	<i>Lot number(s)</i>	<i>Quantity</i>
450263	A24063UG	
450263	A240838N	
450263	A24083G9	
450263	A24083GD	
450263	A240347W	

Name:

Position in company:

Signature:

Date:

**Company stamp to be placed here:**

Buyer is aware of the fact that seller is obliged to trace back each individual item to the Customer and/or end user according to seller's Good Manufacturing Practice (GMP).