75 Corporate Drive
Trumbull, CT 06611
T: 203 601 5200
www.coopersurgical.com

December 5, 2023

URGENT MEDIA RECALL: FIELD SAFETY NOTICE

CooperSurgical LifeGlobal global® Media

Part Number: LGGG-100, LGGG-050, and LGGG-020

Dear Valued CooperSurgical Customer or Distributor,

CooperSurgical is hereby issuing a Medical Product Field Safety Notice (FSN) for its **global® Media**, Lot Numbers **231020-018741, 231020-018742,** and **231020-018743**.

Reason for Voluntary Field Safety Corrective Action (FSCA):

CooperSurgical has become aware of a sudden increase in complaints regarding the aforementioned lots of this product. While we do not know the cause of the performance concern, due to the high volume of customer complaints for the three associated lots, we wish to proactively address any possible issue with our products while we continue to investigate.

Risk to Health:

The risk to health is impaired embryo development prior to the blastocyst stage.

Actions to be Taken:

Our records indicate that you may have purchased the affected product from CooperSurgical. Please take the following steps to ensure proper quarantine and safe return of the affected product(s) for additional testing and CooperSurgical will issue credit for the return.

1) Inspect your inventory, identify, and quarantine **global® Media** (Part Numbers: **LGGG-100, LGGG-050**, and **LGGG-020,** Lots: **231020-018743, 231020-018742,** and **231020-018741)**

2) If you are a **Customer,** complete **page 3** of this communication, also labeled **Customer Acknowledgement Form** and return to Recall@coopersurgical.com or fax to +**1 203.601.9870, ATTN: Recall. Be sure to document information clearly** to prevent delays.

3) If you are a **Distributor,** complete **page 4** of this communication, also labeled **Distributor Acknowledgement Form** and return to Recall@coopersurgical.com or fax to **+1 203.601.9870, ATTN: Recall**. **Be sure to document information clearly** to prevent delays.

4) **As a regulatory requirement, even if you do not have any affected product in your inventory**, please complete and return the form so that we may document confirmation and receipt of this Field Safety Notice.

Once the completed form is received by CooperSurgical, arrangements will be made for the return of any affected product at no additional cost to you.

1) You will receive a CooperSurgical email with a Return Material Authorization (RMA) which is a prepaid shipping label along with any other necessary documentation required for shipping.

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2) Appropriate credit for product returns will be issued upon receipt of said product.
Note: All recalled Product returned *without* a Return Goods Authorization (RMA) label will delay the issuance of any credit until verification can be performed.

We regret any inconvenience caused by this Recall. CooperSurgical is committed to high quality products and is investigating to determine and address any identified root cause of these complaints.

This letter has been reported to the appropriate Regulatory Agencies. Adverse reactions or quality problems experienced with the use of this product may be reported to the Competent Authority Adverse Event Reporting program of your country via online, regular mail, or fax.

We sincerely apologize for the inconvenience caused by this notice. If you have additional questions, please email CooperSurgical Recall at **recall@coopersurgical.com**. Alternately, please contact a CooperSurgical Product Surveillance representative at **+1 203.601.5200** Ext. **3300.**

Sincerely,

[redacted]

Karen Gienau
Senior Manager of Post-Market Surveillance
CooperSurgical, Inc.

CooperSurgical®

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Customer Acknowledgement Form

IMMEDIATE RESPONSE REQUIRED – TIME-SENSITIVE ACTION NEEDED

Please complete this form and return it via email to **recall@coopersurgical.com** or via fax to **+1 203.601.9870, ATTN: Recall.**

Customer Account #:	**Account Name:**	
Street Address:		
Town, State, Country & Zip Code:		
Contact Name:	**Phone Number:**	**Email address:**

I have read and understand the notice instructions provided in the letter dated December 5, 2023. ☐ Yes ☐ No

global® Media (Part Numbers: **LGGG-100, LGGG-050**, and **LGGG-020,** Lots: **231020-018743, 231020-018742,** and **231020-018741)**

Please check the appropriate box below and complete the table if applicable.

☐ We have no inventory within the scope of this action.

☐ We have the following affected product at our facility and will discontinue use and quarantine the affected product for return to CooperSurgical:

Part Number	Lot Numbers	Quantity of Vials to be Returned
LGGG-100	231020-018743	
LGGG-050	231020-018742	
LGGG-020	231020-018741	

Have any adverse events been associated with affected product(s)? ☐ Yes ☐ No

If yes, please explain: _____

If you are responding on behalf of multiple locations, please indicate the locations here: _____

_____

_____ _____

Signature Printed Name

CooperSurgical®

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Distributor Acknowledgement Form

IMMEDIATE RESPONSE REQUIRED – TIME-SENSITIVE ACTION NEEDED

Please complete this form and return it via email to recall@coopersurgical.com or via fax to **+1 203.601.9870, ATTN: Recall.**

FOR DISTRIBUTORS ONLY:

Customer Account #:	**Account Name:**	
Street Address:		
Town, State, Country & Zip Code:		
Contact Name:	**Phone Number:**	**Email address:**

I have read and understand the notice instructions provided in the letter dated December 5, 2023. ☐ Yes ☐ No

global® Media (Part Numbers: **LGGG-100, LGGG-050**, and **LGGG-020,** Lots: **231020-018743, 231020-018742, and 231020-018741)**

Please check the appropriate line below and complete the table if applicable.

☐ We have no inventory within the scope of this action.

☐ We have the following affected product at our facility and will discontinue use and quarantine the affected product for return to CooperSurgical:

Part Number	Lot Numbers	Quantity of Vials to be Returned
LGGG-100	231020-018743	
LGGG-050	231020-018742	
LGGG-020	231020-018741	

Quantity of sales units shipped to customers: _____ (1 vial per sales unit)

If affected product has been distributed to customers, please select one of the following options:

☐ I have identified and notified all customers to whom the affected product may have been distributed.	**Date and Method of Notification:**
☐ I am providing a list of all customers to whom affected product may have been distributed along with their contact information.	

Signature _____ Printed Name _____