75 Corporate Drive
Trumbull, CT, US 06611
T: +1 203 601 5200
www.coopersurgical.com

March 27, 2023

URGENT: MEDIA FIELD SAFETY CORRECTIVE ACTION

SAGE™ Vitrification Media Kit

Dear Valued CooperSurgical Customer,

CooperSurgical, Inc. is issuing a Field Safety Corrective Action (FSCA) for one (1) lot number of its SAGE Vitrification Media Kit (Reference Number ART-8026, **LOT 211112-002333)** (referred to in this letter as the "Product").

Per the Product Instructions for Use, these Products are intended for the vitrification and containment of human oocytes and embryos (pronuclear zygotes through day three cleavage stage embryos and blastocyst stage embryos) in Assisted Reproductive Technology (ART) procedures. This Product is designed to be used in conjunction with the SAGE™ Warming Kit (ART-8031) for warming and recovery of specimens.

Reason for Recall:

It has come to CooperSurgical's attention that certain SAGE Vitrification Media Kits within **LOT 211112-002333** may contain mislabeled vials. Specifically, the impacted kits may contain vials labeled as Vitrification Solution (VS) but actually contain Equilibration Solution (ES).

Risk to Health:

Use of an impacted SAGE Vitrification Media Kit from **LOT 211112-002333** may impact the viability of oocytes/embryos.

Actions to be Taken:

For CUSTOMERS and DISTRIBUTORS:

- Inspect your inventory for Product from this lot. Note the lot's labeled expiration date is November 12, 2022. Lot information can be found on the box and bottle labeling.
  - **If found, discontinue use / distribution of the Product immediately and quarantine.**
- Please complete the appropriate included **Acknowledgment Form** and send it via email to **Recall@coopersurgical.com**.

For CUSTOMERS:

- Check your records to determine whether you utilized SAGE Vitrification Media Kits from **LOT 211112-002333**. If so, follow up with your local sales representative for more information regarding implications of its use.

75 Corporate Drive
Trumbull, CT, US 06611
T: +1 203 601 5200
www.coopersurgical.com

For DISTRIBUTORS:

- If the Product has been distributed to your customers, send a copy of this letter and the Customer Acknowledgement Form to each of these customers.

***

We regret any inconvenience caused by this FSCA. CooperSurgical is committed to high quality, safe and effective Products.

Where appropriate, Regulatory Agencies will be notified of this issue.

You may reach us at **+1-203-601-5200** during normal operating hours of 09:00 – 17:00 M-F EST**.** Follow the phone prompt to enter extension **3300.** Our email address is **Recall@coopersurgical.com**.

Sincerely,

Karen Gienau
Sr. Post Market Surveillance Manager

75 Corporate Drive
Trumbull, CT, US 06611
T: +1 203 601 5200
www.coopersurgical.com

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: Product Surveillance**.

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

I have read and understand the notice instructions provided in the letter dated March 27, 2023. ☐ Yes ☐ No

SAGE Vitrification Media Kit (part number: ART-8026, LOT 211112-002333)
Please check the appropriate boxes below and complete the table if applicable.

- ☐ We have NO record of use for this lot at our facility.
- ☐ We have records of use for this lot at our facility and will contact / have contacted our local sales representative for more information regarding implications of its use.
- ☐ 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 kits to be Returned
ART-8026	**211112-002333**	

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

If yes, please explain: _____

If you have additional questions, please contact a CooperSurgical Product Surveillance representative at **+1.203.601.5200** Ext. **3300** or email us at Recall@coopersurgical.com.

75 Corporate Drive
Trumbull, CT, US 06611
T: +1 203 601 5200
www.coopersurgical.com

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: Product Surveillance.**

FOR DISTRIBUTORS ONLY:

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

I have read and understand the notice instructions provided in the letter dated March 27, 2023. ☐ Yes ☐ No

SAGE Vitrification Media Kit (part number: ART-8026, LOT 211112-002333)

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

☐ We have **NO** kits of the affected lot at our facility.

☐ We have the following affected Product at our facility and will discontinue its distribution and quarantine the affected Product for return to CooperSurgical.

Kommenteerinud [DH1]: Again, they would not be using, but rather distributing the product.

Product/Part Number	Lot Numbers	Quantity of kits to be Returned
ART-8026	**211112-002333**	

Quantity of devices shipped to customers: _____

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

☐ 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 _____