INTUITIVE

Date : <Month Day, Year>

New Field Safety Notice

Urgent Medical Device Recall – Expired Products Shipped – *ISIFA2024-02-R*

1- Introduction and Reason for Field Action

Dear Intuitive Customer,

This Field Safety Notice follows up on the communication **on March 4th, 2024**, to locate and quarantine the affected products listed below.

Intuitive has become aware that specific lots have been shipped past their labelled expiration dates.

Please get in touch with Intuitive Customer Service to begin the RMA process for the expired products in your inventory. Credit will be provided for returned products.

Note: All product labels carry the correct expiry date.

2 - Risk to Health

To date, 0 serious incidents associated with this issue have been reported.

The hazard of using a product past its labelled expiration date may be detected prior to a surgery or remain undetected.

A user may detect that a product is past its labeled expiration date prior to the start of a procedure. If detected, the product would be replaced, which could potentially result in a minor procedure delay. If the product's expiration date is detected prior to the start of a procedure, the product would be replaced, potentially. However, this may result in a negligible procedure delay. If no replacement products are available at the time, the procedure may be rescheduled.

3- Affected Products

Part Number	Material Name	Batch/Lot	Expiration Date	UDI
420023-03	8 mm Bladeless Obturator (Box of 24)	73J2100936	9/30/2023	14026704629586
470015-07	Arm Drape (Box of 20)	DM2214502	11/30/2023	00886874112199
470361-08	5 mm - 8 mm Cannula Seal (Box of 10)	M10211113	11/30/2023	00886874112540
480445-04	SureForm Stapler 45 (Box of 6)	T91220125	1/31/2024	00886874117583
480460-09	SureForm Stapler 60 (Box of 6)	T90220121	1/31/2024	00886874115640

4- Actions to be taken by the Customer/User	Locate and **return all affected products in your inventory** as per the instructions provided below. If you have shared these products with other sites, please make sure appropriate notice/communication is made with the site recipient and that they understand this notification so they can locate and return their affected products**.** **Please take the following Actions:** 1. Read and understand the contents of the letter. 2. If not yet done, locate and segregate the affected products to return. 3. Notify all surgeons and personnel using the affected products that they should review and understand the content of this letter. 4. Complete the attached Acknowledgement Form immediately and scan it via email to Intuitive at eu.fsca@intusurg.com. 5. Contact your local Customer Service (listed below) to provide the details of the products to return (part numbers, lot numbers and quantities). Customer Service will issue an RMA number and organize the return of the affected products. 6. Please retain a copy of this letter and the acknowledgement form for your files. 7. Inform Intuitive of any Serious Incidents or quality problems concerning the use of the subject devices via the standard complaint process. 8. Additionally, if Serious Incidents or quality problems occur, please escalate the experienced issue to your local customer service and/or follow your standard reporting process to your health authority, if applicable. 9. For Customers in Switzerland: Serious incidents experienced with the use of affected products shall be reported to Swissmedic using the appropriate form, which must be submitted electronically and in machine-readable format to materiovigilance@swissmedic.ch.
5- Actions to be taken by Intuitive	Credit will be issued on returning the affected product(s).

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6- Further Information & Support	If you need further information or support concerning this Medical Device Notification, please contact your Clinical Sales Representative or contact Intuitive Customer Service at the numbers listed below: +800 0821 2020 (international toll-free) or use a local / local toll-free number: **Austria** 0126 752 25 0800 298 890 Support.AT@intusurg.com **Belgium** 02 888 17 49 0800 716 96 Support.BE@intusurg.com **Denmark** 89 872 907 808 31158 Support.DK@intusurg.com **Finland** 0800 415 729 0800 416 321 Support.FI@intusurg.com **France** 05 37 10 02 26 0800 905 720 Support.FR@intusurg.com **Germany** 0761 488 8962 0800 1825 068 Support.DE@intusurg.com **Ireland** 019 131 227 1800 851 011 Support.IE@intusurg.com **Norway** 21 98 41 47 Support.NO@intusurg.com **Sweden** 08 580 987 81 020 127 661 Support.SE@intusurg.com **Switzerland** 021 821 2020 0800 821 200 Support.CH@intusurg.com **The Netherlands** 020 8081 348 0800 0249 547 Support.NL@intusurg.com **United Kingdom** 01865 521 820 0800 066 8902 Support.UK@intusurg.com

Intuitive has notified the appropriate Regulatory Authority for your region.

Sincerely,

Intuitive
<mail merge local office address>

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ACKNOWLEDGMENT FORM

New Field Safety Notice

Urgent Medical Device Recall – Expired Products Shipped – *ISIFA2024-02-R*

Ship-to:

Hospital Name: <mail merge>

Address: <mail merge>

City, State, Zip: <mail merge>

SFID: <mail merge>

ATTENTION: <mail merge>

PLEASE COMPLETE ALL REQUESTED INFORMATION AND RETURN IMMEDIATELY

1. I have received and read this notice.
2. I have reviewed my inventory and will return all affected product found as noted in the table below.
3. I have ensured all appropriate personnel are fully informed of the contents of this notice.
4. I will contact Intuitive if I have any questions.

Part Number	Batch/Lot	Quantity of product found in inventory to be quarantined and returned
420023-03	73J2100936	
470015-07	DM2214502	
470361-08	M10211113	
480445-04	T91220125	
480460-09	T90220121	

All products that cannot be returned have been used and/or disposed: ☐ Yes ☐ No ☐ Do not know.

Any products that cannot be returned will be considered disposed at your establishment and therefore physically unavailable, unless otherwise noted.

Hospital name: _____

Name (print): _____

Signature: _____

Phone Number: _____

Email: _____

Date: _____

Position:

☐ **Robotics Coordinator**

☐ **Operating Room Director**

☐ **Risk Manager**

☐ **Surgeon**

☐ **Other:** _____

PLEASE EMAIL THIS ACKNOWLEDGEMENT FORM TO Intuitive
ATTN: REGULATORY COMPLIANCE FIELD ACTIONS
Subject line for email: ISIFA2024-02-R
Email: EU.FSCA@Intusurg.com