

New Field Safety Notice

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

<p>1- Introduction and Reason for Field Action</p>	<p>Dear Intuitive Customer,</p> <p>This Field Safety Notice follows up on the communication on March 4th, 2024, to locate and quarantine the affected products listed below.</p> <p>Intuitive has become aware that specific lots have been shipped past their labelled expiration dates.</p> <p>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.</p> <p>Note: All product labels carry the correct expiry date.</p>																																		
<p>2 - Risk to Health</p>	<p>To date, 0 serious incidents associated with this issue have been reported.</p> <p>The hazard of using a product past its labelled expiration date may be detected prior to a surgery or remain undetected.</p> <p>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.</p>																																		
<p>3- Affected Products</p>	<table border="1"> <thead> <tr> <th>Part Number</th> <th>Material Name</th> <th>Batch/Lot</th> <th>Expiration Date</th> <th>UDI</th> </tr> </thead> <tbody> <tr> <td>420023-03</td> <td>8 mm Bladeless Obturator (Box of 24)</td> <td>73J2100936</td> <td>9/30/2023</td> <td>14026704629586</td> </tr> <tr> <td>470015-07</td> <td>Arm Drape (Box of 20)</td> <td>DM2214502</td> <td>11/30/2023</td> <td>00886874112199</td> </tr> <tr> <td>470361-08</td> <td>5 mm - 8 mm Cannula Seal (Box of 10)</td> <td>M10211113</td> <td>11/30/2023</td> <td>00886874112540</td> </tr> <tr> <td>480445-04</td> <td>SureForm Stapler 45 (Box of 6)</td> <td>T91220125</td> <td>1/31/2024</td> <td>00886874117583</td> </tr> <tr> <td>480460-09</td> <td>SureForm Stapler 60 (Box of 6)</td> <td>T90220121</td> <td>1/31/2024</td> <td>00886874115640</td> </tr> </tbody> </table>	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				
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<p>4- Actions to be taken by the Customer/User</p>	<p>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.</p> <p>Please take the following Actions:</p> <ol style="list-style-type: none"> 1. Read and understand the contents of the letter. 2. If not yet done, locate and segregate the affected products to return 																																		

	<ol style="list-style-type: none"> 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.
5- Actions to be taken by Intuitive	Credit will be issued on returning the affected product(s).

6- Further Information & Support	<p>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:</p> <p>+800 0821 2020 (international toll-free) or use a local / local toll-free number:</p> <table border="0" style="width: 100%;"> <tr> <td style="vertical-align: top;"> Austria 0126 752 25 0800 298 890 Support.AT@intusurg.com </td> <td style="vertical-align: top;"> France 05 37 10 02 26 0800 905 720 Support.FR@intusurg.com </td> <td style="vertical-align: top;"> Sweden 08 580 987 81 020 127 661 Support.SE@intusurg.com </td> </tr> <tr> <td style="vertical-align: top;"> Belgium 02 888 17 49 0800 716 96 Support.BE@intusurg.com </td> <td style="vertical-align: top;"> Germany 0761 488 8962 0800 1825 068 Support.DE@intusurg.com </td> <td style="vertical-align: top;"> Switzerland 021 821 2020 0800 821 200 Support.CH@intusurg.com </td> </tr> <tr> <td style="vertical-align: top;"> Denmark 89 872 907 808 31158 Support.DK@intusurg.com </td> <td style="vertical-align: top;"> Ireland 019 131 227 1800 851 011 Support.IE@intusurg.com </td> <td style="vertical-align: top;"> The Netherlands 020 8081 348 0800 0249 547 Support.NL@intusurg.com </td> </tr> <tr> <td style="vertical-align: top;"> Finland 0800 415 729 0800 416 321 Support.FI@intusurg.com </td> <td style="vertical-align: top;"> Norway 21 98 41 47 Support.NO@intusurg.com </td> <td style="vertical-align: top;"> United Kingdom 01865 521 820 0800 066 8902 Support.UK@intusurg.com </td> </tr> </table>	Austria 0126 752 25 0800 298 890 Support.AT@intusurg.com	France 05 37 10 02 26 0800 905 720 Support.FR@intusurg.com	Sweden 08 580 987 81 020 127 661 Support.SE@intusurg.com	Belgium 02 888 17 49 0800 716 96 Support.BE@intusurg.com	Germany 0761 488 8962 0800 1825 068 Support.DE@intusurg.com	Switzerland 021 821 2020 0800 821 200 Support.CH@intusurg.com	Denmark 89 872 907 808 31158 Support.DK@intusurg.com	Ireland 019 131 227 1800 851 011 Support.IE@intusurg.com	The Netherlands 020 8081 348 0800 0249 547 Support.NL@intusurg.com	Finland 0800 415 729 0800 416 321 Support.FI@intusurg.com	Norway 21 98 41 47 Support.NO@intusurg.com	United Kingdom 01865 521 820 0800 066 8902 Support.UK@intusurg.com
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Intuitive has notified the appropriate Regulatory Authority for your region.

Sincerely,

Intuitive Surgical Ltd
 The Schrödinger Building
 Oxford Science Park
 Oxford, OX4 4GE

ACKNOWLEDGMENT FORM

New Field Safety Notice

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

Ship-to:

Hospital Name:

Address:

City, State, Zip:

SFID: 11

ATTENTION:

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: _____

Position:

Name (print): _____

Robotics Coordinator

Signature: _____

Operating Room Director

Phone Number: _____

Risk Manager

Surgeon

Other: _____

Email: _____

Date: _____

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