New Urgent Field Safety Notice

Medical Device Notification – Incorrect Expiration Date on Brown/Outer Shipping Box of da Vinci Xi/X Instrument Arm Drapes (470015-07) – (ISIFA2023-05-C)

1- Introduction and Reason for Field Action

Dear Intuitive Customer,

This Field Safety Notice is to notify you that Intuitive has been made aware that a specific lot **(DM3223602)** of da Vinci Xi/X Instrument Arm Drapes (Part 470015-07) has an incorrect expiration date listed on the brown outer shipping box.
Please see table below for the incorrect and correct expiration dates.

Incorrect Expiration Date (On Brown Shipping box)	Correct Expiration Date (On Inner carton and pouch labels)
2044-09-30	2024-09-30

This issue **only impacts** the expiration dates on the **brown outer shipping boxes (as seen in Figure 2).** The **inner carton label** and **pouch label** have the **correct expiration date** listed. As a result, return of affected product is not required. You may continue to use affected product, as long as you follow guidelines per the Xi/X System User Manual (Part 551400-13). Always inspect the product, including drape packaging, prior to procedure.

This does not impact functionality or sterilization of affected product.

Figure 1: Example of Incorrect expiration date on the brown shipping box label.

	Figure 2: Example of location of Label on brown shipping box 
2 - Risk to Health	To date, no Adverse Events*/Serious Incidents** associated with this issue have been reported. This issue only poses a health risk for procedures occurring **after** 2024/09/30, the correct expiration date of the drapes. If a drape from lot DM3223602 were used prior to 2024/09/30, there would be no risk to patient. Incorrect expiration date labeling may lead to unintentional use of the drape past the actual expiration which could result in a potential breach in sterility. The theoretical outcomes of a breach in sterility range from no harm, as patients are given prophylactic antibiotics, to a life-threatening infection. However, the more severe scenario is unlikely to occur.
3- Affected Products	Part Number: 470015-07(Xi/X Instrument Arm Drape) Lot: DM3223602 UDI: 00886874112199 No other lot numbers are affected.
4- Actions to be taken by the Customer/User	**<u>Please take the following Actions:</u>** 1. Read and understand the contents of this letter. 2. For the affected lot of drapes **(DM3223602) follow the expiration date listed on inner cartons and pouches**. **Correct Expiration date for this lot is '2024-09-30.'** 3. If you have this lot number in stock, stored in the brown/outer shipper box, remove the inner cartons containing the pouches of drapes and store the inner cartons. Dispose of the brown/other shipping box. If this is not possible, take

	appropriate measures to ensure the correct expiry date listed on inner cartons and pouches are referenced. 4. Return of product is not deemed necessary as the correct expiration date is referenced on inner carton and pouches. However, if you prefer to return affected product, then Intuitive will provide credit for number of boxes returned. Please send an email with quantities to the EU Customer Service: Support.UK@intusurg.com. 5. Complete the attached Acknowledgment Form immediately and return it via fax or email to Intuitive as instructed on the form. 6. Please retain a copy of this letter and acknowledgment form for your files. 7. Inform Intuitive of any Adverse Events*/Serious Incidents** or quality problems concerning the use of the subject device via the standard complaint process.
5- Actions to be taken by Intuitive	Return of the affected product is not deemed necessary. However, if the customer prefers to return the affected product, credit will be issued for number of boxes returned. Intuitive has ceased further shipments of the affected lot.
6- Further Information & Support	If you need further information or support concerning this Medical Device Field Safety Notification, please contact your Clinical Sales Representative or contact Intuitive Customer Service at the numbers listed below: • Europe: +800 0821 2020 or +41 21 821 2020 (8 AM to 6 PM CET) or EUCS@intusurg.com.

Please be informed that the appropriate Regulatory Authority for your region has been notified (if applicable) as per local regulation requirement of this Medical Device Field Safety Notification.

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

Definitions:
* Adverse Event is defined as “an event or incident that led to a death, serious injury, or serious deterioration in the state of health of a patient, user, or other person; if the event or incident was wholly or partially caused by the device or by shortcomings in the information supplied with the device.“
**Serious Incident (EUMDR 2017/745) is defined as “any incident that directly or indirectly led, might have led or might lead to any of the following:

a. the death of a patient, user or other person
b. the temporary or permanent serious deterioration of a patient’s, user’s, or other person’s state of health,
c. a serious public health threat”

ACKNOWLEDGMENT FORM
New Urgent Field Safety Notice
Medical Device Notification – Incorrect Expiration Date on Brown/Outer shipping box of da Vinci Xi/X Instrument Arm Drapes – ISIFA2023-05-C

Ship-to:
Hospital Name:
Address:
City, State, Zip:
SFID:
ATTENTION:

PLEASE COMPLETE ALL REQUESTED INFORMATION AND RETURN IMMEDIATELY

1. I have received and read this notice.
2. I confirm, if this lot number is in my inventory and still in the brown shipper box, I have removed the inner cartons containing the pouches of drapes and disposed of the shipper box. If this is not possible, I have taken appropriate measures to ensure the correct expiration date listed on inner cartons and pouches are referenced.
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.

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: ISIFA2023-05-C Xi/X Instrument Arm Drape Incorrect Expiration Date
Email: EU.FSCA@intusurg.com

Customer Service:

- Europe: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm CET)