INTUITIVE

Date of Mailer

Follow-up Regarding the Field Safety Notice
Urgent Medical Device Notification for Ireland – Engagement Failures Associated with da Vinci Xi/X SureForm 45 and SureForm 60 Staplers (PNs 480445-04, 480545-04, 480460-09)
(ISIFA2022-09-C)

Dear Intuitive Customer,

This letter is a follow-up to the Field Safety Notice, related to engagement failures associated with da Vinci Xi/X SureForm 45 and SureForm 60 Staplers, that was communicated in early 2023.

Although, to date there have been no patient harms resulting from the potential engagement issues with the affected lots of these da Vinci Xi/X SureForm 45 and SureForm 60 Staplers, it was agreed with the HPRA (Health Products Regulatory Authority) to remove any remaining affected product in Ireland.

While there remains minimal risk of harm from this issue, in order to minimize the potential customer impact from this engagement issue, we ask you to action the following:

Please locate and return all affected product(s) listed below in your inventory by sending an email with quantities and lot numbers to EU customer service: EUCS@intusurg.com

Affected Part Number	Product Name	Affected Lots	Unique Device Identifier
480445-04	Da Vinci Xi/X SureForm 45	See Appendix A	00886874117583
480545-04	Da Vinci Xi/X SureForm 45 Curved-Tip	See Appendix A	00886874117590
480460-09	Da Vinci Xi/X SureForm 60	See Appendix A	00886874115640

Please ensure to include the field action number "**ISIFA2022-09-C**" in your return notes. Credits will be provided to returned products.

If you need further information or support, please contact your Sales Representative. For any other concerns, contact Customer Service at the number listed below:

Europe: +800 0821 2020 or +41 21 821 2020 (8 AM to 6 PM CET) or EUCS@intusurg.com

Sincerely,

Intuitive

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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 ensured all appropriate personnel are fully informed of the contents of this notice.
3. I will contact Intuitive if I have any questions.

☐ I have contacted Intuitive and will be returning _____**Units** AND/OR _____**Boxes** of affected lots referencing RMA number_____

☐ I confirmed that I **do not have** any remaining affected products at my site.

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: Ireland Follow Up ISIFA2022-09-C
Email: EU.FSCA@intusurg.com

ISIFA2022-09-C Appendix A – Affected Lots

Da Vinci Xi/X SureForm 45 (Part Number: 480445-04)			
T10220614	T10220719	L11220620	L11220706

Da Vinci Xi/X SureForm 45 Curved-Tip (Part Number: 480545-04)
T91220518

Da Vinci Xi/X SureForm 60 (Part Number: 480460-09)				
L91220503	L11230209	L10221018	L11221006	L91220509