INTUITIVE.

Date

New Field Safety Notice

Urgent Medical Device Notification – Engagement Failures Associated with da Vinci X/Xi SureForm 45 and SureForm 60 Staplers (PNs 480445-04, 480545-04, 480460-09)

(ISIFA2022-09-C)

1- Introduction and Reason for Field Action	Dear Intuitive Customer, During standard post-market surveillance activities, Intuitive has observed an increase in complaints regarding engagement failures associated with da Vinci X/Xi SureForm 45 and 60 Stapler instruments. This is related to specific lots and as a precautionary measure, this notice is being sent to raise awareness that there may be increased occurrences of these instruments failing to engage to the system. Intuitive has determined that a friction increase in the roll axis of the SureForm 45 and 60 Staplers may result in instrument installation engagement failures. All SureForm 45 and 60 Stapler lots listed in Appendix A of this letter, will have varying degrees of roll axis friction. Origin of roll axis friction is assignable to a component of the device. Should you encounter any engagement or initialization issues—follow the on-screen instructions, as described in the existing instructions for use and built-in system alerts (Figure 1) to remove and reinstall the SureForm Stapler. This safety check ensures that the installed Stapler engages with the system correctly prior to use.  Figure 1 (On-screen message as displayed on Vision Side Cart Touchscreen, “Instrument Engagement Failed. Remove and Re-install”) If the issue with engagement failure persists, please remove the SureForm Stapler and use a backup stapling instrument or a laparoscopic stapler if no backup SureForm Stapler is available. Users are advised to adhere to all existing warnings and cautions found in the SureForm 45, 60 Instruments and Accessories User Manual Addendum.

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2 - Risk to Health

To date, there have been 2 incidents related to this issue that have been assessed as an adverse event*/serious incident**. Both events were assessed as an adverse event due to user frustration resulting in the conversion to laparoscopic surgery.

Repeated engagement failures
Repeated engagement failures may lead to a negligible delay in the procedure, due to time needed to troubleshoot. Persistent engagement failure may result in the use of a different stapling device.

Controlled Offset Motion
If there is additional friction in the roll axis and the stapler were to pass engagement, the one effect is imprecise motion, which presents as a controlled, offset motion. Reinstallation of the instrument may resolve the imprecise motion, as the inaccurate engagement identification is not persistent despite high roll friction in the instrument. While the stapler may exhibit slightly imprecise motion, the motion is controlled by the user and does not impact the performance of the stapler.

Non-Intuitive Motion
If offset distal instrument movement from the master controllers were to occur, it would be immediately noticeable by the surgeon upon taking control after instrument installation. This may result in minor procedure delay to remove and reinstall the SureForm Stapler. If the issue were to persist after initial troubleshooting, there may be an additional delay to obtain a different stapling instrument.

In the unlikely event that the offset distal instrument motion from the master controllers is not immediately detected by the surgeon, the distal end of the stapler may make contact with patient anatomy that could result in tissue damage.

3- Affected Products

Part Number	Product Name	Affected Lot Number	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

4- Actions to be taken by the Customer/ User

Place this customer communication with your da Vinci Xi SureForm 45 and 60 User Manual Addendum. In addition,

1. Read and understand the contents of the letter.
2. Notify all surgeons and personnel using SureForm Staplers that they should review and understand contents of this letter and;
    a. Read the instructions, warnings, and cautions provided in the SureForm Instruments and Accessories User Manual Addendum; and
    b. Contact their da Vinci Sales Representatives for clarification.
3. Complete the attached Acknowledgement Form immediately and return it via fax or email to Intuitive, as instructed on the form.
4. Retain a copy of this letter and the acknowledgement form for your files.
5. Inform Intuitive of any Adverse Events*/Serious Incidents** or quality problems concerning the use of the subject devices via the standard complaint process.

	6. Additionally, if Adverse Events*/Serious Incidents** or quality problems are experienced, please follow your standard reporting process to your health authority, if applicable. You may continue the use of SureForm Staplers by following instructions provided in Section 1 of this notice, and following the instructions, warnings, and cautions provided in the SureForm Instruments and Accessories User Manual Addendum.
5- Actions to be taken by Intuitive	Credit will be issued, via the standard RMA process, for instruments returned for this engagement failure issue. Please contact your Clinical Sales Representative or Intuitive Customer Service for inventory return policies for unboxed, unopened instruments.
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: • Europe, Middle East, Asia, South America and Africa: +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 as per local regulation requirement of this Medical Device Notification.

Sincerely,

Intuitive Surgical SAS
11 avenue de Canteranne
33600 Pessac, France
+800 0821 20 20

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"

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(ISIFA2022-09-C)

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.

Hospital name: _____

Name (print): _____

Signature: _____

Phone Number: _____

Email: _____

Date: _____

Position:

- ☐ **Robotics Coordinator**
- ☐ **Operating Room Director**
- ☐ **Risk Manager**
- ☐ **Surgeon**
- ☐ **Other:** _____

PLEASE FAX OR EMAIL THIS ACKNOWLEDGEMENT FORM TO Intuitive
ATTN: REGULATORY COMPLIANCE FIELD ACTIONS
Subject line for email: ISIFA2022-09-C SureForm Stapler Engagement Failures
Scan and Email: EU.FSCA@intusurg.com or Fax: +800 0821 2021 / +41 21 821 2021

Customer Service:

- Europe, Middle East, Asia, South America and Africa: +800 0821 2020 or +41 21 821 2020 (8 AM to 6 PM CET)