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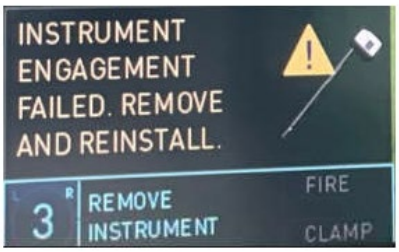
October 25, 2022

New Customer Communication

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, The purpose of this notification is to inform you that 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. In addition to the potential for installation engagement failure, an increase in roll axis friction may lead to: • A decrease in the Stapler's roll rate along the roll axis. • Controlled distal instrument to master controller offset motion that would occur immediately upon taking control of the instrument after installation. All SureForm 45 and 60 Stapler lots manufactured between the dates listed in Section 3 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")

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	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. If the distal instrument movement is offset from the master controllers upon taking control immediately after installation, remove and reinstall the SureForm Stapler. If the situation persists, please remove the SureForm Stapler and use a backup stapling instrument. Users are advised to adhere to all existing warnings and cautions found in the SureForm 45, 60 Instruments and Accessories User Manual Addendum.
2 - Risk to Health	None of the complaints received to date led to an adverse event*/serious incident**. **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. **Decreased roll rate along the roll axis** A decreased roll rate along the roll axis, if perceived by the user, may result in a minor delay in the procedure due to the time needed to troubleshoot. **Controlled offset 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	<table><tr><th>Part Number</th><th>Product Name</th><th>Affected Lot Number Manufactured Date Range</th><th>Unique Device Identifier</th></tr><tr><td>480445- 04</td><td>Da Vinci Xi/X SureForm 45</td><td>May 3, 2022 to Sept 8, 2022</td><td>00886874117583</td></tr><tr><td>480545-04</td><td>Da Vinci Xi/X SureForm 45 Curved-Tip</td><td>May 4, 2022 to Sept 12, 2022</td><td>00886874117590</td></tr><tr><td>480460-09</td><td>Da Vinci Xi/X SureForm 60</td><td>April 26, 2022 to Sept 16, 2022</td><td>00886874115640</td></tr></table> To help you identify affected lots for the da Vinci Xi/X Sureform Staplers please see **Figure 2** and reference **Table 1** to find the manufacturing date.

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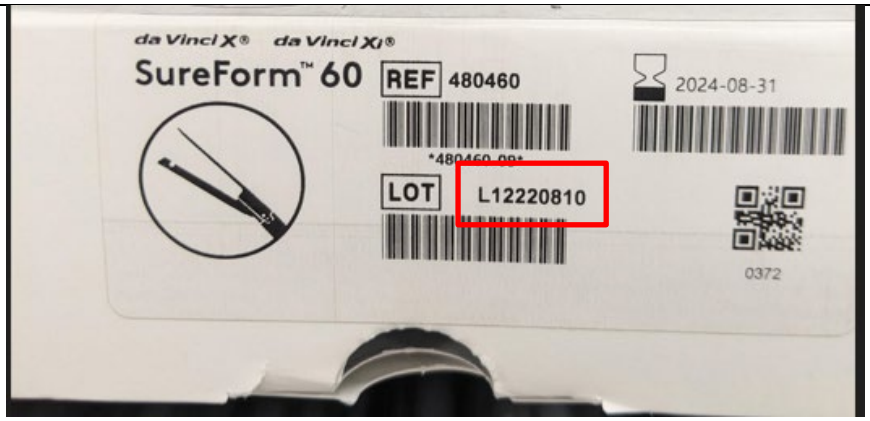

Figure 2: Picture of lot number location on affected SureForm Stapler instrument carton box

Table 1. Lot number break down for L12220810 (2022, August 10).

Lot#	L12	22	08	10
Meaning	N/A	Year (2022)	Month (August)	Day (10th)

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 DTG Medical Sdn. Bhd., as instructed on the form.
4. Retain a copy of this letter and the acknowledgement form for your files.
5. Inform DTG Medical Sdn. Bhd. 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.

6- Further Information & Support

If you need further information or support concerning this Medical Device Notification, please contact your Clinical Sales Representative or contact DTG Medical customer service at customers.my@devicetechnologies.asia or DTG RAQA team at regulatory@dtgmedical.com.sg

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Please be informed that the Medical Device Authority will be notified on this Field Safety Notice.

Sincerely,

DTG Medical Sdn. Bhd.

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:
Address:
City, State, Zip:
SFID:
ATTENTION:

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 and stamp: _____

Phone Number: _____

Email: _____

Date: _____

Position:

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

PLEASE FAX OR EMAIL THIS ACKNOWLEDGEMENT FORM TO DTG Medical
ATTN: REGULATORY COMPLIANCE FIELD ACTIONS
Subject line for email: ISIFA2022-09-C SureForm Stapler Engagement Failures
Scan and Email: regulatory@dtgmedical.com.sg

Customer Service:

- customers.my@devicetechnologies.asia