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Field Safety Notice

Urgent Medical Device Notification – Expansion to 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, ***This is an update to the previous communication sent in early 2023 regarding Engagement Failures Associated with da Vinci X/Xi SureForm 45 and SureForm 60 Staplers. Based on further investigation, Intuitive has become aware of 7 additional lots that are susceptible to the related issue. Appendix A attached, highlights these additional lots.*** ***Note: If you are receiving this communication for the first time, kindly reference the information from this point forward which corresponds with the content of the communication sent in early 2023. No further adverse events*/serious incidents** have been recorded related to the issue than described below.*** 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. 

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	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.
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	**Affected Product:**

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 Surgical	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: +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 may be notified as per local regulation requirement of this Field Safety Corrective Action.

Sincerely,

<mail merge local office address>

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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ACKNOWLEDGMENT FORM

Field Safety Notice

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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
Email: EU.FSCA@intusurg.com

Customer Service:

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

ISIFA2022-09-C Appendix A

Hinweis: Dies ist eine Aktualisierung des Anhangs, der mit 5556023-04 Rev A übermittelt wurde

Zusätzlich betroffene Chargen sind farbig gekennzeichnet.

480445-04

T11230601	T10230531	T11230531

480460-09

L11230209	T12230313

480545-04

T10221214	T12221214

480445-04

T90220603	T10220719	T12220824	T10220708	T11220926	L12220620	T10220806	T11220829	T90220606	L10220721	L11220814	T12220713
T91220606	T11220726	T16220926	T14220908	T11220614	T10220609	L11220627	T11220624	L11220620	T10220824	L13220613	T10220722
T91220526	L10220805	T10220922	T10220908	T10220622	T13220921	T12220614	T10220921	L10220815	T10220802	T12220803	T12220719
T10220629	T12221014	T10220713	T11220908	T16220908	T12220921	T11220922	T10220920	L10220621	L10220706	T10220812	T90220602
T90220609	T12220606	T14220926	T10220628	T18221004	T10220912	T17221004	T11220919	T10220803	T11220629	T12220526	T10220624
L11220811	T10220707	L10220814	L10220729	T12220926	L11220706	T14220921	L10220627	T15220908	T11220824	T11220719	L11220613
T11220713	L11220721	T10220809	T10220829	T10220728	T15220926	T13220614	T90220526	T11220803	T11220802	L10220613	T90220525

480460-09

L11220629	L13220816	L10220801	L10221018	L10221013	L11221003	L13220718	L11220923	L11220803	L12220908	L11220906	L10220826	L11220615
L10220725	L12220827	L12221015	L91220601	L10221007	L11221010	L12220804	L11220924	L11220804	L12220909	L10220906	L11220831	L10220812
L10221110	L11220801	L13221009	L10220622	L11221006	L11221001	L13220905	L11220926	L10220918	L12220910	L10220909	L10220823	L10220810
L13221004	L11221002	L13221010	L10221012	L11221004	L11220809	L13220802	L11220927	L10220919	L10220910	L12220830	L11220902	L12220719
L90220426	L10220905	L10221019	L10221010	L11220919	L11221007	L11220925	L11220930	L10220926	L10220908	L12220819	L11220823	L10220809
L10221109	L10220927	L10221014	L11220729	L12220926	L11220608	L11220914	L10221001	L10220921	L12220810	L12220829	L11220828	L10220802
L11221107	L10221005	L10221009	L12221012	L11220928	L10220816	L10220808	L11220802	L10220928	L12220822	L12220828	L10220827	L10220803
L12221108	L10221102	L12221010	L11221009	L12220927	L12220809	L11220915	L12220627	L10220929	L11220822	L12220818	L10220825	L12220808
L12221031	L10221104	L10220811	L10221015	L12220925	L13220719	L10220915	L11220916	L10220930	L11220907	L12220825	L11220609	L10220630
L10220718	L10221023	L11221008	L90220419	L13220926	L13220620	L11220805	L11220917	L13220628	L13220811	L12220826	L12220817	L10220727
L11220720	L10221024	L90220503	L11221011	L13220927	L13220809	L10220914	L11220918	L12220905	L91220509	L11220830	L13220810	L13220726
L13220925	L10221026	L13221002	L12221005	L12221003	L10221008	L13220804	L11220920	L10220911	L12220831	L11220901	L90220504	L10220713
L10220728	L10220719	T10220520	L10220824	L10221006	L13220607	L13220728	L11220921	L12220823	L12220811	L12220816	L10220726	L92220509
L10220720	L13221013	L10220609	L10220925	L11221005	L11220929	L13220801	L11220810	L12220906	L10220907	L13220808	L10220712	L12220725
L12221110	L13221011	L10221011	L12221002	L13220814	L13220621	L11220922	L13220706	L12220907	L11220905	L13220815	L10220804	L11220726

L13220725	L12220712	L13220629	L11220718	L11220630	L10220711	L12220613	L91220516	L91220426
L11220727	L12220629	L93220530	L11220713	L11220628	L12220608	L93220516	L92220418	L90220418
L12220721	L13220712	L11220712	L91220410	L12220606	T90220505	T90220506	L91220504	L93220426
L12220726	L13220721	L13220627	L10220608	L12220609	L12220621	L93220503	L93220418	L90220425
L12220718	L13220711	L11220719	L12220628	L11220606	L91220418	L92220419	L93220425	L92220425
L12220728	L11220711	L13220614	L11220621	L10220629	L12220614	L90220516	L92220503	L92220426
L11220725	L91220503	L12220711	L11220622	L13220608	L93220531	L92220516	L92220504	L91220425

480545-04

T10220721	T10220928	T10220901	T11221004	T13221004	T91220520	T11220714	T10220714	T90220516	T10220610
T10220926	T10220919	L13220823	L10220828	T10220915	T10220623	T10220725	T10220726	T91220518	T90220504
T11220818	T10220614	T10221004	T13220908	T11220616	T11220701	T11220623	T10220617	T90220520	T91220514
L10220620	T11220901	T10220811	T13220926	T90220511	T11220707	T11220617	T10220616	T90220518	T90220509