Insert Date of Mailer

New Field Safety Notice

Urgent Medical Device Correction - Instrument Arm Broken Insertion Ballscrew (ISIFA2022-13-C)

1- Introduction and Reason for Field Action

Dear Intuitive Customer,

This Field Safety Notice is to notify you that Intuitive is initiating a voluntary field action related to specific Instrument Arms (Universal Surgical Manipulators (USMs)) that are part of the da Vinci Xi and X Surgical systems. The Instrument Arms allow the surgeon to control up to three instruments and an endoscope to perform surgical tasks in a variety of procedures.

Intuitive has become aware, via a single complaint, that an unexpected movement of the instrument carriage occurred along the insertion axis of the Instrument Arm. This Instrument Arm had a failed insertion ballscrew component due to damage of the Cannula Mount (see Figures 1 and 2), which allowed for uncontrolled movement of the carriage along the insertion axis.

Figure 1: Insertion Ballscrew location on USM

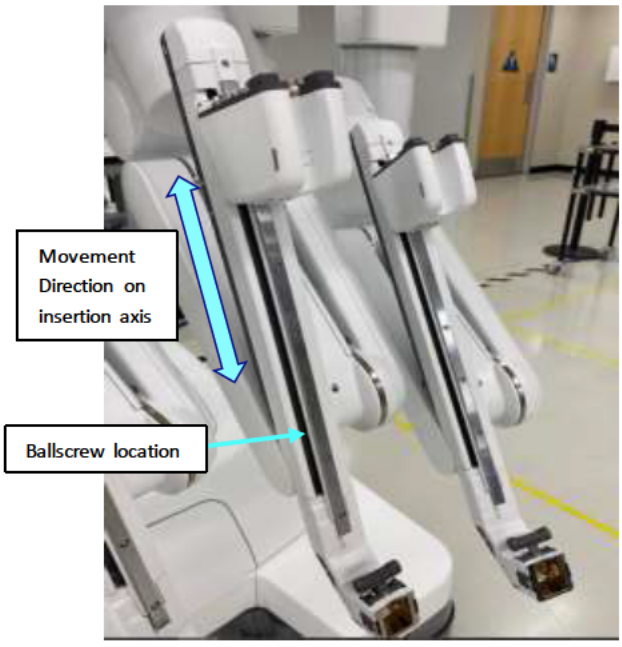
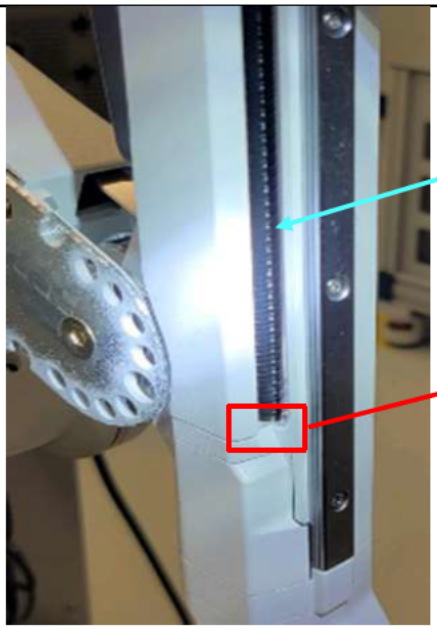


Figure 2: Ballscrew breakage location



Based on further engineering analysis, it has been determined that the Instrument Arms identified in the affected product section may be at risk of exhibiting uncontrolled movement of the carriage along the insertion axis; and therefore, Intuitive will replace the potentially affected product.

2- Hazard/Harm associated with the issue

Intuitive has not received any reports of adverse events*/serious Incidents**associated with this issue.

Uncontrolled motion due to insertion ballscrew failure may result in harms ranging from tissue injuries requiring little to no intervention, minor interventions like placement of suture or clips or moderate interventions such as extensive reconstruction of tissue or blood transfusion. In rare cases, if the unexpected movement resulted in injury to a critical blood vessel and/or a severe injury to a solid organ, harm could result in conversion to open surgery, permanent impairment, or death of the patient.

3- Affected Products

Affected System Serial Number	Affected Instrument Arm Serial Number(s)
SK0744	547953
SK0991	557322
SK1402	575093
SK2332	663393
SL0069	372054
SL0379	668080

Patient Side Cart Number (PSC)	Patient Side Cart UDI
380652 (da Vinci Xi PSC)	00886874110720
380620 (da Vinci X PSC)	00886874115404

4- Actions to be taken by the Customer/User	Based on our assessment, you may continue use your affected system until an Intuitive Representative schedules a site visit to provide a replacement system arm. **Please take the following actions:** 1. Review this Field Safety Notification with all users of da Vinci Xi and X surgical systems and place a copy of it with Instructions for use (IFU) of the system. 2. Complete the attached acknowledgement form promptly and return it via fax or email to Intuitive as instructed on the form. 3. Please retain a copy of this letter and the acknowledgement form for your files. 4. Please inform Intuitive of any adverse events*/serious incidents** or quality problems concerning the use of the subject devices via the standard complaint process. 5. Additionally, if adverse events*/serious incidents** or quality problems are experienced, please follow your standard reporting process to your health authority, if applicable.
5- Actions to be taken by Intuitive	An Intuitive Representative will schedule site visit to replace the affected Instrument Arm.
6- Further Information & Support	If you need further information or support concerning this Field Safety Notice, 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 Field Safety Corrective Action.

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, users, or other person's state of health,
c. a serious public health threat"

INTUITIVE

ACKNOWLEDGMENT FORM

Urgent Medical Device Correction – Instrument Arm Broken Insertion Ballscrew (ISIFA2022-13-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 Field Safety Notice.
2. I have ensured all appropriate personnel are fully informed of the contents of this Field Safety 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**
- ☐ **Physician**
- ☐ **Other:** _____

PLEASE FAX OR EMAIL THIS ACKNOWLEDGEMENT FORM TO Intuitive
ATTN: REGULATORY COMPLIANCE FIELD ACTIONS
Subject line for email: ISIFA2022-13-C
Instrument Arm Broken Insertion Ballscrew
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) or EUCS@intusurg.com