DEVICE TECHNOLOGIES

MALAYSIA OFFICE
3A-03, Wisma Mont Kiara,
1, Jalan Kiara, 50480 Kuala Lumpur, Malaysia

Toll-Free Number 1800 812 011
P +60 3 2779 2586
E customers.my@devicetechnologies.asia

Incorporated in Malaysia as DTG Medical Sdn. Bhd.
(Reg No.: 201901028676 / 1338005-A)

Date: July 20, 2025

Field Safety Notice

Urgent Medical Device Correction – Potential for Loose Universal Surgical Manipulators on da Vinci X and Xi Systems (ISIFA2022-14-C)

This notice provides updated information regarding the Universal Surgical Manipulators (USMs) affected by this Field Action:

- In early 2023, Intuitive notified customers of a potential issue with certain USMs and implemented corrective actions; only two complaints have been reported, with no adverse events.
- A recent investigation, while indicating low likelihood, suggests that additional USMs may be affected in the field.
- As a precaution, Intuitive will inspect the USMs listed in Appendix B; there is no increased risk, and the device remains safe for use.

Please refer to the below original communication and follow its instructions, as it remains applicable to the USMs selected for inspection.

1- Introduction and Reason for Field Action	Dear Intuitive Customer, This letter is to inform you that a population of the da Vinci X and Xi system instrument arms (USMs) have Instrument Carriages that may separate from the Insertion Axis Linear Rail during shipping, handling, or repositioning of the arms when the system is powered down. The Instrument Carriage would remain attached to the drive motor which prevents free-fall motion or complete detachment from the USM. However, the Instrument Carriage may feel like it is not tightly connected to the rail. This condition may also lead to increased friction along the insertion axis. Therefore, Intuitive would like to schedule a visit to perform inspection of the affected USM and conduct replacement of the USM if necessary. **Instrument Carriages that are intact will function as intended and are expected to remain firmly attached throughout a surgical procedure.**

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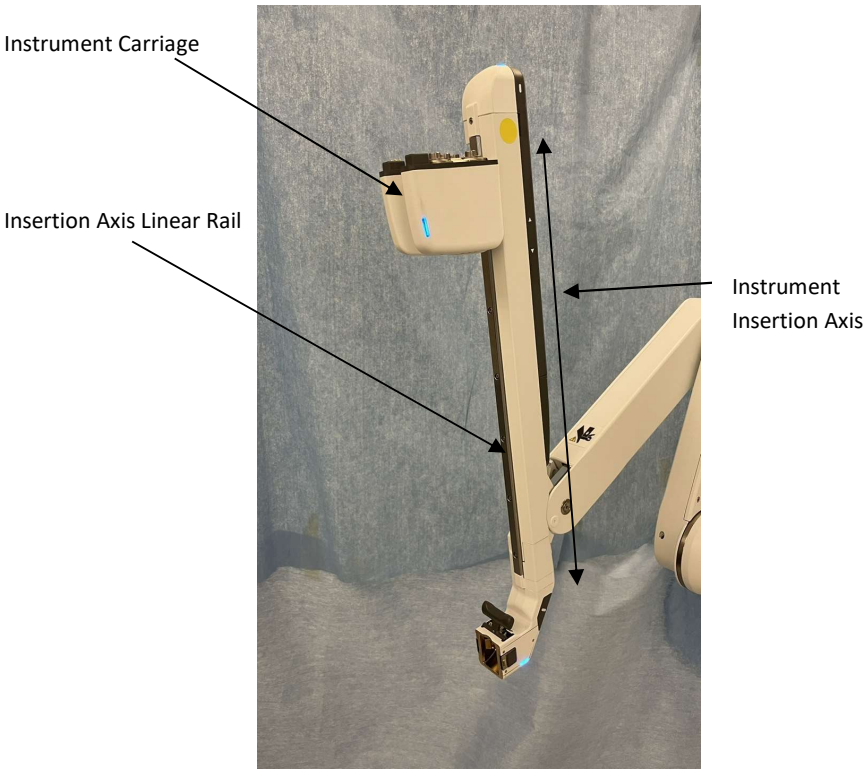

Figure 1: Instrument Carriage and Insertion Axis Rail on Instrument Arm

The Instrument Carriage slides on the Insertion Axis Linear Rail which ensures smooth motion along the Insertion Axis and maintains precise instrument alignment with the cannula. However, there is a population of USMs where the width of the insertion rail is below specification. This puts the Instrument Carriage at risk of becoming separated from the linear rail when a large external force is applied to the side of the Instrument Carriage.

Examples of when such forces may be generated include but are not limited to:

- Shipping and handling of the USM or System
- If the Instrument Carriage is grabbed to manually move the arm when the da Vinci X/Xi system is powered off
- Other high impact forces, such as collisions while moving or stowing the arm cart

The function and performance of an Instrument Carriage along the insertion axis of the affected population of rails is not altered if the instrument carriage is properly attached to the rail. Forces resulting from standard instrument exchanges and/or internal/external instrument collisions are not likely to be large enough to separate the instrument carriage from the linear rail. **It is highly unlikely for the Instrument Carriage**

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<table>
<tr><td></td><td>to separate from the linear rail during normal use of the affected USM in a surgical procedure.</td></tr>
<tr><td>2 - Risk to Health</td><td>To date, there have been no related Adverse Events*/Serious Incidents** for this issue.

Risk to health is possible when a separated Instrument Carriage is used during a procedure. Instrument collisions both internal and external on an Instrument Carriage, that is already separated from the linear rail, may result in lateral displacement of the instrument tip. This lateral motion may result in unintended tissue contact.

Additionally, unintended tissue interaction and/or injury may occur due to increased friction experienced while using an instrument installed on a separated Instrument Carriage. The degree of harm would depend on the tissue type and the degree of interaction, which could range from negligible to severe.

An instrument installed on a separated carriage may not present any functional deficiencies due to increased friction during clinical use. In this case, no patient harm will occur. The separated instrument carriage may be noticed as being not tightly connected during use or it may be noticed outside of clinical use.

During a procedure, instrument collisions both internal and external are not likely to separate the Instrument Carriage from the insertion linear rail.</td></tr>
<tr><td>3- Affected Products</td><td><table>
<tr><th>Part Number</th><th>Product Name (if applicable)</th><th>Unique Device Identifier</th><th>Affected Serial Number</th></tr>
<tr><td>380647</td><td>ASSY,USM,IS4000
da Vinci Xi Surgical System
da Vinci X Surgical System</td><td>00886874114216</td><td>See Appendix B</td></tr>
</table></td></tr>
<tr><td>4- Actions to be taken by the Customer/User</td><td>All affected systems remain safe for use if the following instructions are followed:
Prior to each use, inspect all the Instrument Carriages on your affected da Vinci X and Xi systems using the ‘Instrument Carriage Inspection Instructions’ outlined in Appendix A below. If an Instrument Carriage fails the inspection or if there is any concern, do not use the USM and notify Intuitive. If 3 of the 4 USM Instrument Carriages pass the inspection, the da Vinci X or Xi system may be used per instructions in section Three-Arm procedure of the da Vinci X and Xi systems user manual.
Please continue to adhere to instructions in the da Vinci X and Xi User Manual and hold the USM/arm by its gray handle during manual moving and positioning of the arm. Do not use the Instrument Carriage to manually reposition the USM when the system is powered off or in a fault condition. If this is unavoidable in the event of an emergency, please Stop Using that USM and notify Intuitive. An Intuitive representative will schedule a visit to perform inspection and necessary correction.
</td></tr>
</table>

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	 **Figure 2:** Image showing how to properly hold the USM during manual positioning • If instruments cannot be manipulated in a precise and controlled manner, contact Intuitive Technical Support immediately to prevent tissue injury. **<u>As part of this communication, please take the following standard actions:</u>** • This notice needs to be passed on to all those who need to be aware within your organization or functions where the potentially affected devices have been transferred. • **Complete the attached Acknowledgement Form immediately** and return it via fax or email to DTG Medical Sdn. Bhd. as instructed on the form. • Please **retain a copy of this letter, place a copy with your affected system, and keep the acknowledgement form for your files**. • Please 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. • 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 Surgical	An Intuitive Representative will schedule a site visit to inspect the insertion linear rail and replace the USM if necessary.
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 Sdn. Bhd. Customer Service at the numbers listed below: • 1800 812 011 or mail: customers.my@devicetechnologies.asia

Please be informed that the Medical Device Authority (MDA) will be notified of 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:

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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

Urgent Medical Device Correction – Potential for Loose Instrument Carriage on da Vinci X and Xi Systems (ISIFA2022-14-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 Sdn. Bhd.
ATTN: REGULATORY COMPLIANCE FIELD ACTIONS
Subject line for email: Potential Loose Instrument Carriage on da Vinci System (ISIFA2022-014-C)
Email: regulatory@dtgmedical.com.sg

Customer Service:

- 1800 812 011 or mail customers.my@devicetechnologies.asia

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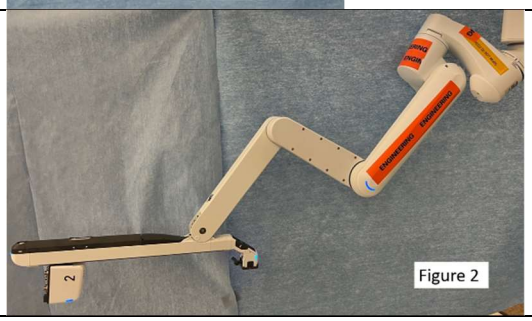
ISIFA2022-14-C Appendix A: Instrument Carriage Inspection Instructions

From stowed position, orient all Patient Cart arms such that the instrument arms are in the vertical position (Figure 1). When facing the Patient Cart column, identify the right-hand side of the Instrument Carriage as designated by the arrow in Figure 1.	 Figure 1
Position one Patient Cart arm such that it is pitched fully forward, and the instrument arm is parallel to the ground (Figure 2).	 Figure 2

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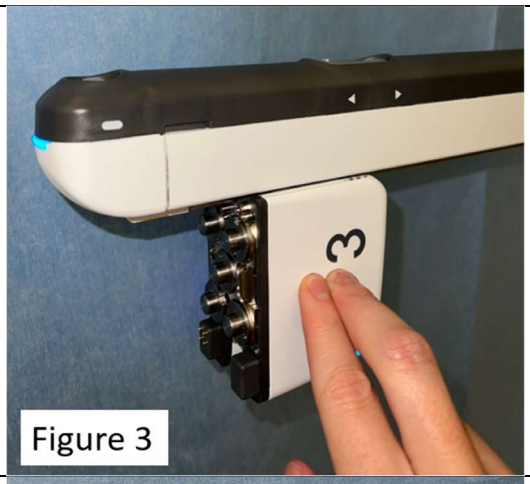
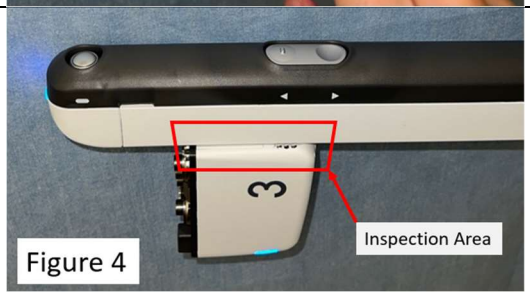
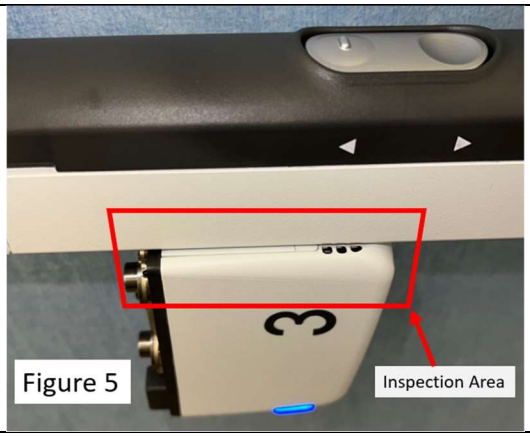
Using only two fingers, apply moderate pressure to the center of the Instrument Carriage on the right-hand side, as shown in Figure 3. **This must be done on the right-hand side of the Instrument Carriage, as defined in Figure 1.** The arm may move. If movement occurs, stabilize the arm to avoid collisions with user or other arms.	 Figure 3
Closely inspect from all angles the interface between the Instrument Carriage and arm (inspection area in red box, Figure 4) and evaluate the interface using the below Pass/Fail criteria. **This must be done on the right-hand side of the Instrument Carriage, as defined in Figure 1.** Repeat all steps for all remaining arms.	 Figure 4
PASS: Unable to see serial number **and** barcode (Figure 5). Acceptable to use system.	 Figure 5

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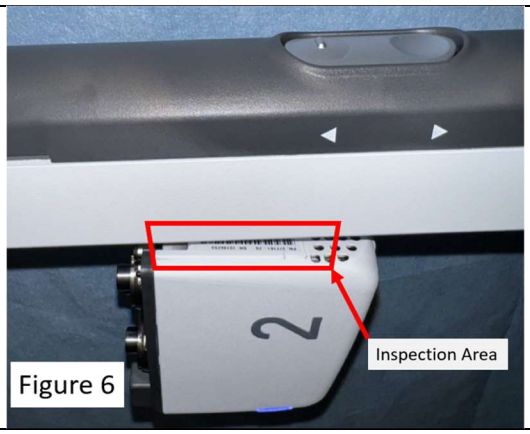
FAIL: Able to see serial number **and** any section of barcode (Figure 6). Do not use arm.	 Figure 6

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ISIFA2022-14-C Appendix B: Affected USM Serial Numbers

Country	System Serial #	USM Serial #
Malaysia	SK5870	10113518
Malaysia	SK5870	10114257
Malaysia	SK5870	10114849
Malaysia	SK5870	10117103
Malaysia	SK6090	10116367
Malaysia	SK6466	10272023
Malaysia	SK6466	10276813
Malaysia	SK6466	10276855
Malaysia	SK6466	10276875
Malaysia	SK6519	503344
Malaysia	SK6519	10296093
Malaysia	SK6519	10299539
Malaysia	SK6519	10407258
Malaysia	SK6088	10114869
Malaysia	SK6088	10116373
Malaysia	SK6088	10118347
Malaysia	SK6142	10273404
Malaysia	SK6142	10276843
Malaysia	SK6142	10276859
Malaysia	SK6142	10276884
Malaysia	SK6587	10275666
Malaysia	SK6587	10283341
Malaysia	SK6587	10289267
Malaysia	SK6587	10289273
Malaysia	SK7079	10340555
Malaysia	SK7079	10397284
Malaysia	SK7079	10397287
Malaysia	SK7079	10398009

Country	System Serial #	USM Serial #
Malaysia	SK7078	10374878
Malaysia	SK7078	10374882
Malaysia	SK7078	10375661
Malaysia	SK7372	10480387
Malaysia	SK7372	10495823
Malaysia	SK7372	10495827
Malaysia	SK7372	10496302
Malaysia	SK7070	10394726
Malaysia	SK7070	10395767
Malaysia	SK7070	10396424
Malaysia	SK7070	10396429
Malaysia	SK7113	10373431
Malaysia	SK7113	10378107
Malaysia	SK7113	10387766
Malaysia	SK7113	10388210