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: 15-Apr-2026

Field Safety Notice
Urgent Medical Device Correction
da Vinci X, Xi Systems Cannula Mount Screws Breakage
(ISIFA2026-01-C)

1- Introduction and Reason for Field Action

Dear Intuitive Customer,

This Urgent Medical Device notice is to advise you that Intuitive is initiating a voluntary correction involving the da Vinci X, Xi systems Universal Surgical Manipulator (USM). Our records indicate that your facility has received at least one of the affected USM units that is suspected of having screws located within the arm sub-assembly that may be susceptible to breaking.

The USM includes the cannula mount used to hold the cannula during surgery, as shown in Figure 1 below. Intuitive has identified that the screws on the cannula mount of the USM are from a specific population that are susceptible to breaking over time. When the cannula mount experiences a breakage of all six screws, the cannula mount can separate from the rest of the USM. Breakage of any fewer than six screws will not result in cannula mount separation, or impact to clinical performance.

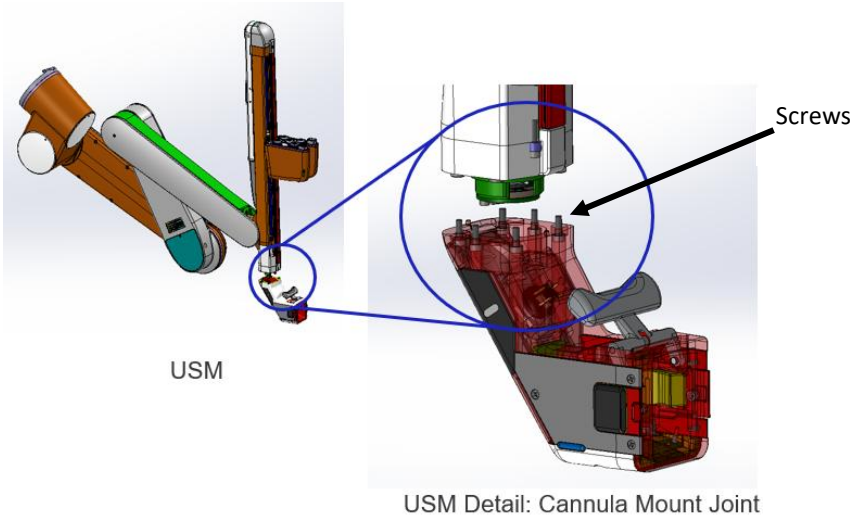

Figure 1. Cannula Mount on USM

2 - Risk to Health

Intra-operative cannula mount separation may result in unintended motion of the instrument tip. This unintended motion may lead to tissue injury or bleeding with severities ranging from negligible to catastrophic. The severity of injury would depend on the amount of motion, proximity to tissue, type of installed instrument, and type of injured tissue. To date, there has been one reported complaint related to six screws

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	breaking in the cannula mount which did not result in an adverse event/serious incidents. There have been no reports of *adverse events/serious incidents** or patient harm. **How to recognize that the device may fail**: Screw breakage or cannula mount loosening may be observable as visible or tactile separation of the cannula mount from the body of the USM. Prior to a procedure, closely inspect the joint between the cannula mount and insertion axis that is joined by the screws indicated in Figure 1 above. Manipulate the cannula mount joint by hand to ensure there is no movement or looseness. If looseness or separation is observed, discontinue use of the USM and contact your representative to schedule a site visit. If all six screws were to break intra-operatively, the user may also observe imprecise or unintended instrument tip motion. If you observe imprecise or unintended instrument tip motion, inspect the cannula mount for looseness or separation and if present, discontinue use of the USM and contact your representative to schedule a site visit.
3- Affected Products	<table><tr><th>Part Number</th><th>Product Name</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 A</td></tr></table>
4- Actions to be taken by the Customer/User	Users can continue to use the da Vinci X, Xi Systems. As indicated above, if a cannula mount becomes separated, the users may identify this separation and may also notice imprecise or unintended instrument movement. If this occurs, avoid using the affected da Vinci X or Xi USM for additional procedures until Intuitive personnel have serviced the system. **<u>Please take the following Actions:</u>** 1. 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. 2. Please retain a copy of this letter, place a copy with your affected system, and keep a copy of the acknowledgement form for your files. 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. 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. 5. Additionally, if Adverse Events*/Serious Incidents** or quality problems are experienced, please follow your standard reporting process to your health authority, if applicable.

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5- Actions to be taken by Intuitive	An Intuitive Representative will schedule a site visit to perform a repair of the affected system.
6- Further Information & Support	If you need further information or support concerning this Field Safety Notice, please contact your Clinical Sales Representative or contact DTG Medical 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:

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”

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ACKNOWLEDGMENT FORM

Field Safety Notice

Urgent Medical Device Correction

da Vinci X, Xi Systems Cannula Mount Screws Breakage (ISIFA2026-01-C)

Ship-to:
Hospital Name:
Address:
City, State, Zip:
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: ISIFA2026-01-C
Scan and Email: <regulatory@dtgmedical.com.sg>

Customer Service:

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

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Appendix A: Affected System and USM Serial Number

System Serial Number	USM Serial Number
SK7078	10695534
N/A	10738829