

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

<p>1- Introduction and Reason for Field Action</p>	<p>Dear Intuitive Customer,</p> <p>This Field Safety notice is to advise you that Intuitive is initiating a Field Safety Corrective Action (FSCA) 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 are suspected of having screws located within the arm sub-assembly that may be susceptible to breaking.</p> <p>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.</p> <div data-bbox="560 1050 1404 1564" data-label="Image"> </div> <p>Figure 1. Cannula Mount on USM</p>
<p>2 - Risk to Health</p>	<p>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 serious incident related to six screws breaking in the cannula mount.</p>

	<p>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.</p> <p>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.</p> <p>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.</p>								
<p>3- Affected Products</p>	<table border="1"> <thead> <tr> <th data-bbox="456 772 613 840">Part Number</th> <th data-bbox="613 772 886 835">Product Name</th> <th data-bbox="886 772 1135 840">Unique Device Identifier</th> <th data-bbox="1135 772 1390 840">Affected Serial Number</th> </tr> </thead> <tbody> <tr> <td data-bbox="456 840 613 1003">380647</td> <td data-bbox="613 840 886 1003">ASSY,USM,IS4000 da Vinci Xi Surgical System da Vinci X Surgical System</td> <td data-bbox="886 840 1135 1003">00886874114216</td> <td data-bbox="1135 840 1390 1003">See Appendix A</td> </tr> </tbody> </table>	Part Number	Product Name	Unique Device Identifier	Affected Serial Number	380647	ASSY,USM,IS4000 da Vinci Xi Surgical System da Vinci X Surgical System	00886874114216	See Appendix A
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380647	ASSY,USM,IS4000 da Vinci Xi Surgical System da Vinci X Surgical System	00886874114216	See Appendix A						
<p>4- Actions to be taken by the Customer/User</p>	<p>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.</p> <p>Please take the following Actions:</p> <ol style="list-style-type: none"> 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 Intuitive as instructed on the form. 4. Please inform Intuitive of any Serious Incidents* or quality problems concerning the use of the subject devices via the standard complaint process. 5. Additionally, if 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 a site visit to perform a repair of the affected system.
6- Further Information & Support	If you need further information or support concerning this Medical Device Correction, please contact your da Vinci X, Xi Sales Representative or contact Intuitive Customer Service at the numbers listed below: <ul style="list-style-type: none"> • Malta: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm CET) or Support.MT@intusurg.com

Please be informed that the appropriate Regulatory Authority for your region has been notified of this Field Safety Notice.

Sincerely,

Intuitive Surgical SAS
11 avenue de Canteranne
33600 Pessac
France

Definitions:

*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”

ACKNOWLEDGMENT FORM

New 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: _____

Customer ID: _____

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: _____

Position:

Name (print): _____

Robotics Coordinator

Signature: _____

Operating Room Director

Phone Number: _____

Risk Manager

Email: _____

Surgeon

Date: _____

Other: _____

PLEASE EMAIL THIS ACKNOWLEDGEMENT FORM TO Intuitive
ATTN: REGULATORY COMPLIANCE FIELD ACTIONS
Subject line for email: ISIFA2026-01-C
Scan and Email: EU.FSCA@intusurg.com

Customer Service:

- Malta: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm CET) or Support.MT@intusurg.com

Appendix A: USM Serial Numbers

Country	USM SN	System Serial Number
Malta	578115	SK8734