

Field Safety Notice

Urgent Medical Device Correction - 2955842-11-23-15-011-C

Updated warnings for da Vinci® Xi™ endoscope and cannulae configurations

<p>Introduction and Reason for Field Action</p>	<p>Dear <i>da Vinci</i> Customer,</p> <p>This Field Safety Notice is to advise you that Intuitive Surgical is initiating a voluntary correction to the instructions for use of the <i>da Vinci</i> Xi 8mm endoscopes, in order to communicate proper use of the endoscopes in combination with the <i>da Vinci</i> 8 mm (PN 470002 and 470004) and 12 mm cannulae (PN 470375 and 470389), cannula reducers (PN 470381), and monopolar energy instruments. This Field Safety Notice does not apply to <i>da Vinci</i> S or <i>da Vinci</i> Si Surgical Systems and accessories.</p> <p>Upon becoming aware of publications identifying a risk of capacitive coupling from monopolar energy sources to endoscopes in laparoscopic surgery, Intuitive Surgical initiated an investigation to determine if this risk applies to existing <i>da Vinci</i> technologies. As a result of this investigation, Intuitive Surgical has identified specific configurations in which monopolar energy has the potential to be transmitted from the <i>da Vinci</i> Xi endoscope shaft to tissue it is contacting.</p> <p>Although there have been no reported complaints related to this issue, these configurations have the potential to result in unintended thermal injury. These potential injuries would only occur <u>when all three (3) of the following conditions are met simultaneously</u>:</p> <ol style="list-style-type: none"> 1) The cannula is not in direct contact with the patient's body wall or the endoscope shaft is not in direct contact with the cannula, and 2) Monopolar energy is being activated, and 3) There is pinpoint tissue contact with the endoscope shaft (approximately 1 mm² area of contact) <p>There is no risk of unintended thermal injury if the endoscope shaft is in contact with a larger area of tissue, or if the endoscope shaft does not make tissue contact.</p> <p>If users follow the instructions detailed below in the "Actions to be taken by the customer" section, the risk is effectively mitigated and the <i>da Vinci</i> Xi endoscope can continue to be used.</p>
<p>Risk to Health</p>	<p>Under the specific use conditions described above, the endoscope has the potential to deliver monopolar energy to tissue which could lead to thermal injury.</p> <p>There have been no reported complaints or injuries related to the transfer of thermal energy from the <i>da Vinci</i> Xi 8 mm endoscope to tissue in contact with the endoscope shaft.</p>

Affected Countries and Products	<p><u>Affected Countries:</u> Australia, Austria, Belgium, Cyprus, Czech Republic, Denmark, France, Germany, Hong Kong, India, Israel, Italy, Japan, Monaco, Netherlands, Norway, Puerto Rico, Qatar, Romania, Saudi Arabia, Singapore, South Korea, Spain, Sweden, Switzerland, Taiwan, Turkey, United Kingdom, United States, and Venezuela.</p> <p><u>Affected Product:</u></p> <table border="1"> <thead> <tr> <th>Part Number</th> <th>Product Name</th> </tr> </thead> <tbody> <tr> <td>470026-34</td> <td rowspan="3">8mm Endoscope, 0°</td> </tr> <tr> <td>470026-40</td> </tr> <tr> <td>470026-41</td> </tr> <tr> <td>470027-34</td> <td rowspan="3">8mm Endoscope, 30°</td> </tr> <tr> <td>470027-40</td> </tr> <tr> <td>470027-41</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th>Part Number</th> <th>da Vinci Xi I&A User Manual Language</th> </tr> </thead> <tbody> <tr><td>551464</td><td>Czech</td></tr> <tr><td>551465</td><td>Danish</td></tr> <tr><td>551466</td><td>Dutch</td></tr> <tr><td>551706</td><td>English</td></tr> <tr><td>551469</td><td>French</td></tr> <tr><td>551470</td><td>German</td></tr> <tr><td>551471</td><td>Greek</td></tr> <tr><td>551474</td><td>Italian</td></tr> <tr><td>551475</td><td>Japanese</td></tr> <tr><td>551476</td><td>Korean</td></tr> <tr><td>551479</td><td>Norwegian</td></tr> <tr><td>551482</td><td>Romanian</td></tr> <tr><td>551461</td><td>Simplified Chinese</td></tr> <tr><td>551487</td><td>Spanish</td></tr> <tr><td>551488</td><td>Swedish</td></tr> <tr><td>551462</td><td>Traditional Chinese</td></tr> <tr><td>551489</td><td>Turkish</td></tr> </tbody> </table>	Part Number	Product Name	470026-34	8mm Endoscope, 0°	470026-40	470026-41	470027-34	8mm Endoscope, 30°	470027-40	470027-41	Part Number	da Vinci Xi I&A User Manual Language	551464	Czech	551465	Danish	551466	Dutch	551706	English	551469	French	551470	German	551471	Greek	551474	Italian	551475	Japanese	551476	Korean	551479	Norwegian	551482	Romanian	551461	Simplified Chinese	551487	Spanish	551488	Swedish	551462	Traditional Chinese	551489	Turkish
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Actions to be taken by the Customer/ User	<p>Please take the following Actions:</p> <ol style="list-style-type: none"> The <i>da Vinci Xi</i> endoscope and cannula configurations that electrically isolate the endoscope shaft from the body wall have the potential to enable the transfer of monopolar energy to tissue in contact with the endoscope shaft. This tissue contact, if it occurs, happens outside the surgeon's field of view. Observe the following warnings and cautions to mitigate this risk during use of the <i>da Vinci Xi</i> Surgical System: <ul style="list-style-type: none"> Monopolar energy should not be used when the <i>da Vinci Xi</i> 8 mm endoscope is introduced through the 12 mm & Stapler cannula. 																																														

	<p>This applies whether or not the <i>da Vinci Xi 12 - 8 mm reducer</i> is used.</p> <ul style="list-style-type: none"> • Never insert a <i>da Vinci Xi</i> cannula into another cannula placed in the patient's body wall (i.e. double cannulation). • Use caution when activating monopolar energy during <i>da Vinci Xi</i> procedures in which contact between the endoscope cannula and the body wall is not assured. <ol style="list-style-type: none"> 2. Distribute a copy of this letter to all <i>da Vinci Xi</i> users at your facility. 3. Place a copy of this letter with your user manual. 4. Complete the attached Acknowledgement Form and return it to Intuitive Surgical as instructed. 5. Retain a copy of this letter and the Acknowledgement Form for your files.
<p>Actions to be taken by Intuitive Surgical</p>	<p>Intuitive Surgical will provide a user manual addendum to incorporate the warnings and cautions related to this risk.</p>
<p>Further Information & Support</p>	<p>If you need further information or support concerning this Medical Device Notification, please contact your Clinical Sales Representative or contact Intuitive Surgical Customer Service at the numbers listed below:</p> <ul style="list-style-type: none"> • North and South America: (800) 876-1310, Option 3 (6 AM to 5 PM PST) or mail: customersupport-servicesupport@intusurg.com • Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 AM to 6 PM CET) or ics@intusurg.com • South Korea: 02-3271-3200 (9 AM to 6 PM KSTJ) • Japan: 0120-56-5635 or 003-5575-1362 (9 AM to 6 PM JST)

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

Sincerely,

Intuitive Surgical
 Chemin des Mûriers 1
 CH-1170 Aubonne, Switzerland
 +41 21 821 2020

ACKNOWLEDGEMENT FORM

Field Safety Notice

Urgent Medical Device Correction - 2955842-11-23-15-011-C

Updated warnings for da Vinci Xi endoscope and cannulae configurations

Hospital Name: <mail merge>

Address: <mail merge>

City, Zip: <mail merge>

NSID: <mail merge>

ATTENTION: <mail merge>

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 Surgical if I have any questions.

Name (print): _____

Position:

Signature: _____

Robotics Coordinator

Operating Room Director

Hospital Name: _____

Risk Manager

Surgeon

Phone Number: _____

Other: _____

Email: _____

Date: _____

PLEASE FAX OR EMAIL THIS ACKNOWLEDGEMENT FORM TO Intuitive Surgical, Inc.

ATTN: REGULATORY COMPLIANCE

Subject line for email: Xi Endoscope Cannulae Configurations

U.S. Fax +1(408) 716-3040, or Scan and Email: eu.fsca@intusurg.com

Customer Service:

- North and South America: 800-876-1310 Option 3 (6 am to 5 pm PST)
- Japan: 0120-56-5635 or 003-5575-1362 (9 am to 6 pm JST)
- South Korea: 02-3271-3200 (9 am to 6 pm KSTJ)
- Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm CET)