

Field Safety Notice

Urgent Medical Device Correction - 2955842-11/23/2015-011-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 <i>da Vinci</i> Xi I&A User Manual, in order to communicate proper use of the <i>da Vinci</i> Xi 8 mm Endoscopes in combination with the <i>da Vinci</i> 8 mm and 12 mm cannulae, cannula reducers, and monopolar energy instruments. This Field Safety Notice does not apply to <i>da Vinci</i> S or <i>da Vinci</i> Si 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 Customer Actions 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

Affected Countries:

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.

Affected Product:

Part Number	Product Name
470026-34	0 deg, 8mm Endoscope, IS4000
470026-40	
470026-41	
470027-34	30 deg, 8mm Endoscope, IS4000
470027-40	
470027-41	

Part Number	Xi I&A User Manual Language
551464	Czech
551465	Danish
551466	Dutch
551457	English
551706	OUS English
551468	Finnish
551469	French
551470	German
551471	Greek
551474	Italian
551475	Japanese
551476	Korean
551479	Norwegian
551481	Portuguese
551482	Romanian
551483	Russian
551461	Simplified Chinese
551487	Spanish
551488	Swedish
551462	Traditional Chinese
551489	Turkish

<p>Actions to be taken by the Customer/ User</p>	<p>Please take the following Actions:</p> <ol style="list-style-type: none"> 1. 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> 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 via the 12 mm <i>da Vinci</i> cannula. This is the case whether or not the <i>da Vinci</i> 12 mm to 8 mm cannula reducer is used. • 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 using monopolar energy during <i>da Vinci Xi</i> procedures in which contact between the endoscope cannula and the body wall is not assured. 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
950 Kifer Road
Sunnyvale, CA 94086-5304 USA
800-876-1310"

ACKNOWLEDGEMENT FORM

Field Safety Notice

Urgent Medical Device Correction - 2955842-11/23/2015-011-C

Updated warnings for da Vinci Xi endoscope and cannulae configurations

Hospital Name:

Address:

City, State, Zip:

NSID:

ATTENTION:

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): _____

Signature: _____

Hospital Name: _____

Phone Number: _____

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: isi.compliance@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)