

Date: December 4, 2015

Field Safety Notice

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

 $\textit{Updated warnings for da Vinci}_{\circledcirc}\textit{Xi}^{\text{\tiny{IM}}} \ endoscope \ and \ cannulae \ configurations$

Dear da Vinci Customer, This Field Safety Notice is to advise you that Intuitive Surgical is initiating a voluntary correction to the da Vinci Xi I&A User Manual, in order to communicate proper use of the da Vinci Xi 8 mm Endoscopes in combination with the da Vinci 8 mm and 12 mm cannulae, cannula reducers, and monopolar energy instruments. This Field Safety Notice does not apply to da Vinci S or da Vinci Si systems and accessories. 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 da Vinci 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 da Vinci Xi endoscope shaft to tissue it is contacting. Introduction and Although there have been no reported complaints related to this issue, these **Reason for Field** configurations have the potential to result in unintended thermal injury. These potential Action injuries would only occur when all three (3) of the following conditions are met simultaneously: 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) 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. If users follow the instructions detailed below in the Customer Actions section, the risk is effectively mitigated and the da Vinci Xi endoscope can continue to be used. Under the specific use conditions described above, the endoscope has the potential to deliver monopolar energy to tissue which could lead to thermal injury. There have been no reported complaints or injuries related to the transfer of thermal Risk to Health energy from the da Vinci Xi 8 mm endoscope to tissue in contact with the endoscope shaft.



Affected Countries:

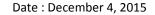
Australia, Austria, Belgium, Cyprus, Czech Republic, Denmark, France, Germany, Hong Kong, India, Israel, Italy, Japan, Monaco, Netherlands, Norway, Puerto Rico, Qatar, Romania, Saudi Arabia, Singapore, South Korea, Spain, Sweden, Switzerland, Taiwan, Turkey, United Kingdom, United States, and Venezuela.

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	

Affected Countries and Products

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		





	Please take the following Actions:					
	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</i> Xi system:					
Actions to be taken by the Customer/	 Monopolar energy should not be used when the da Vinci Xi 8 mm endoscope is introduced via the 12 mm da Vinci cannula. This is the case whether or not the da Vinci 12 mm to 8 mm cannula reducer is used. Never insert a da Vinci Xi cannula into another cannula placed in 					
User	the patient's body wall (i.e. double cannulation).					
	 Use caution when using monopolar energy during da Vinci Xi procedures in which contact between the endoscope cannula and 					
	the body wall is not assured.					
	 Distribute a copy of this letter to all <i>da Vinci</i> Xi users at your facility. Place a copy of this letter with your user manual. Complete the attached Acknowledgement Form and return it to Intuitive Surgical as instructed. Retain a copy of this letter and the Acknowledgement Form for your files. 					
Actions to be taken by Intuitive Surgical	Intuitive Surgical will provide a user manual addendum to incorporate the warnings and cautions related to this risk.					
	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:					
Further	North and South America: (800) 876-1310, Option 3 (6 AM to 5 PM PST) or					
Information &	mail: customersupport-servicesupport@intusurg.com					
Support	 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"



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ACKNOWLEDGEMENT FORM

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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)