

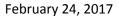
Field Safety Notice

Urgent Medical Device Recall - ISIFA2017-01-R

da Vinci[®] Si and Xi Surgeon Side Console Circuit Board

	Dear da Vinci Customer,		
Introduction and Reason for Field	This Field Safety Notice is to advise you that Intuitive Surgical is initiating a voluntary correction relating to specific <i>da Vinci Si®</i> and <i>da Vinci Xi®</i> Surgical Systems. Intuitive Surgical has found that one of the circuit boards on certain <i>da Vinci Si</i> and <i>da Vinci Xi</i> Surgeon Side Console has the potential to fail, leaving the surgeon console inoperable (console may not power on) and/or resulting in a non-recoverable message (System Error 90).		
Action	Only the following some second of the following second of the followin	erial	
Risk to Health	There have been no reported injuries or deaths as a result of this issue. In the worst case scenario, the <i>da Vinci</i> Surgeon Side Console will fail to power up or encounter a non-recoverable fault, preventing use of the Surgeon Side Console.		
Affected Countries and Products	Affected Countries: Japan and United St Affected Product: Part Number 380610-21 380677-10	= '	

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	Please take the following Actions:		
Actions to be taken by the Customer/ User	 Distribute a copy of this letter to all da Vinci Surgical System users at your facility. Complete the attached Acknowledgement Form and return it to Intuitive Surgical as instructed. Please retain a copy of this letter and the acknowledgement form for your files. Please log into the daVinci Online Community Field Action resource to read or complete any requested actions related to this issue. 		
Actions to be taken by Intuitive Surgical	An Intuitive Surgical Field Service representative will schedule a site visit to address this issue shortly.		
	If you need further information or support concerning this Notification, please contact Intuitive Surgical Customer Service at the numbers listed below:		
Further Information & Support	 North and South America: (800) 876-1310, Option 3 (4 AM to 5 PM PST) or mail: customersupport-servicesupport@intusurg.com Japan: 0120-56-5635 or 03-5575-1362 (9 AM to 6 PM JST) 		

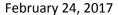
Please be informed that the appropriate Regulatory Authority for your region has been notified of this notification.

Sincerely,

Intuitive Surgical

1266 Kifer Rd. Sunnyvale, CA 94086-5304 USA 800-876-1310

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ACKNOWLEDGMENT FORM

Field Safety Notice

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da Vinci® Si and Xi Surgeon Side Console Circuit Board

Hospital Name:	
Address: City, State, Zip: SFID: ATTENTION: 1. I have received and read this notice. 2. I have ensured all appropriate personnel are fully informed 3. I will contact Intuitive Surgical if I have any questions.	I of the contents of this notice.
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: POST MARKET FIELD	ACTIONS
Subject line for email: Si ar	nd Xi GCC

Customer Service:

- North and South America: 800-876-1310 Option 3 (4 AM to 5 PM PST)
- Japan: 0120-56-5635 or 03-5575-1362 (9 AM to 6 PM JST)

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U.S. Fax +1(408) 523-0619, or Scan and Email: ISI.compliance@intusurg.com