INTUITIVE SURGICAL®

July 16, 2018

Field Safety Notice

Urgent Medical Device Correction – ISIFA2018-05-C

da Vinci® Si, Xi, and X Miswiring of Redundant Medical Grade Power Supply

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1- Introduction and Reason for Field Action	Dear *da Vinci®* Customer, Cc: Chairman Medical Board and relevant Head of Departments This Field Safety Notice is to inform you that Intuitive Surgical has become aware of certain Redundant Medical Grade Power Supply (RMGPS) units in specific *da Vinci Si®*, Xi®, and *X®* Surgeon Consoles and *da Vinci Si®* Patient Side Carts that have been shipped with a manufacturing defect. The RMGPS is the primary power supply to the console and is designed with redundancy so that if one power supply module fails, the power load is shifted to the functioning power supply module. This defect results in a lack of redundancy for the RMGPS in the rare occurrence of when one power supply module fails, leading to the Surgeon Console and/or Patient Cart not powering on prior to a procedure, or to the loss of power during a procedure. Please note that solely having the affected power supply module does not mean the system will encounter a power loss event. To encounter the related power loss scenario above, **both of the following two (2) conditions must be met**. 1. The system contains the affected power supply. 2. A failure of one of the power supply modules is experienced. Please follow your specific system user manuals for guidance on how to proceed in the scenario where a loss of power is experienced on a console or cart. If the failure occurs to the Surgeon Console and your site has a dual console set up, you may continue with the planned surgery robotically with one console. To correct this issue, an Intuitive Surgical Representative will schedule a site visit to provide a replacement at the earliest convenience.
2 - Risk to Health	There have been no adverse events related to this issue. This Field Safety Notice and the corresponding Field Action are precautionary measures only. There is no risk to the patient if the failure occurs prior to starting a *da Vinci* procedure, as it is standard clinical practice to turn on the system prior to a surgery to confirm the system is operational. This mitigates any risk of the patient already being under anesthesia, and the next course of action would be at the discretion of the Surgeon and

<table>
<tr><td></td><td>Hospital.

If the failure occurs during a da Vinci procedure, the surgeon may be required to convert to another surgical approach, resulting in a marginal risk to the patient. Please refer to the da Vinci System User Manuals for guidance of how to convert to another surgical approach.</td></tr>
<tr><td>3- Affected Products</td><td>
<table>
<tr><th>Part Name</th><th>Product Number</th><th>Affected Serial Numbers</th></tr>
<tr><td>Redundant MGPS's found in certain da Vinci Si, Xi, and X Surgeon Consoles and da Vinci Si Patient Side Carts</td><td>380610
380614
380649
380677
186610-02</td><td>See Appendix A</td></tr>
</table>
</td></tr>
<tr><td>4- Actions to be taken by the Customer/User</td><td>Please take the following actions to ensure all affected personnel are fully informed of this Field Safety Notice. Forward this letter to your Risk Manager, OR Director, Purchasing, Biomedical Engineering staff, and other members of your medical staff who perform da Vinci procedures.

1. You may continue using the system until the Intuitive Surgical representative replaces the unit. Please follow your specific system user manuals for guidance on how to proceed in the scenario where a loss of power is experienced on a console or cart.
2. Ensure surgeons and patient side assistants using the da Vinci Si, Xi, and X Surgical System read and understand the contents of this letter.
3. Inform affected personnel when corrective action has been completed.
4. Complete the attached Acknowledgement Form and return it via fax or email to Intuitive Surgical per the instructions contained in the Acknowledgement Form.
5. Please retain a copy of this letter and the Acknowledgement Form for your files.</td></tr>
<tr><td>5- Actions to be taken by Intuitive Surgical</td><td>1. A copy of this Field Safety Notice will be provided to customers with affected da Vinci Si, Xi, and X Surgical Systems.
2. An Intuitive Surgical representative will contact customers with affected da Vinci Si, Xi, and X Surgical Systems to schedule a site visit to provide the correction to impacted systems.
3. Intuitive Surgical representatives will be available by phone to answer any questions related to this Field Safety Notice.</td></tr>
<tr><td>6- Further Information & Support</td><td>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:</td></tr>
</table>

	• North and South America: (800) 876-1310, Option 3 (4 AM to 5 PM PST) or mail: customerservice@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 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 Field Notice.

Sincerely,

Intuitive Surgical, Inc.
950 Kifer Road
Sunnyvale, CA 94086-5304 USA
800-876-1310

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ACKNOWLEDGMENT FORM

Field Safety Notice

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Ship-to:
Hospital Name:
Address:
City, State, Zip:
SFID:
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 Surgical if I have any questions.

Hospital name: _____

Name (print): _____

Signature: _____

Phone Number: _____

Email: _____

Date: _____

Position:

- ☐ **Robotics Coordinator**
- ☐ **Operating Room Director**
- ☐ **Risk Manager**
- ☐ **Surgeon**
- ☐ **Other:** _____

PLEASE FAX OR EMAIL THIS ACKNOWLEDGEMENT FORM TO Intuitive Surgical, Inc.
ATTN: REGULATORY POST MARKET FIELD ACTIONS
Subject line for email: MISWIRING RMGPS
U.S. Fax +1(408) 523-0619, or Scan and Email: Recalls@intusurg.com or EU.fsca@intusurg.com

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)
- South Korea: 02-3271-3200 (9 am to 6 pm KSTJ)
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Appendix A

System Identification		
da Vinci Si	**da Vinci Xi**	**da Vinci X**
RSHXXXX	SKXXXX	SLXXXX
SCXXXX	SDXXXX	
SHXXXX		

[redacted]