

**Field Safety Notice**  
**Urgent Medical Device Recall - ISIFA2017-01-R**  
*da Vinci® Si and Xi Surgeon Side Console Circuit Board*

<b>Introduction and Reason for Field Action</b>	<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 relating to specific <i>da Vinci Si</i>® and <i>da Vinci Xi</i>® Surgical Systems.</p> <p>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).</p> <p>Only the following systems are affected:</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th style="background-color: #D9E1F2;"><i>da Vinci</i> System Serial</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">RSH0136</td> </tr> <tr> <td style="text-align: center;">SH0625</td> </tr> <tr> <td style="text-align: center;">SK1054</td> </tr> <tr> <td style="text-align: center;">SK1107</td> </tr> </tbody> </table>	<i>da Vinci</i> System Serial	RSH0136	SH0625	SK1054	SK1107	
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RSH0136							
SH0625							
SK1054							
SK1107							
<b>Risk to Health</b>	<p>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.</p>						
<b>Affected Countries and Products</b>	<p><b><u>Affected Countries:</u></b> Japan and United States</p> <p><b><u>Affected Product:</u></b></p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th style="background-color: #D9E1F2;">Part Number</th> <th style="background-color: #D9E1F2;">Product Name</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">380610-21</td> <td style="text-align: center;"><i>da Vinci Si</i> Surgeon Side Console</td> </tr> <tr> <td style="text-align: center;">380677-10</td> <td style="text-align: center;"><i>da Vinci Xi</i> Surgeon Side Console</td> </tr> </tbody> </table>	Part Number	Product Name	380610-21	<i>da Vinci Si</i> Surgeon Side Console	380677-10	<i>da Vinci Xi</i> Surgeon Side Console
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February 24, 2017

<p><b>Actions to be taken by the Customer/ User</b></p>	<p><b><u>Please take the following Actions:</u></b></p> <ol style="list-style-type: none"> <li>1. Distribute a copy of this letter to all <i>da Vinci</i> Surgical System users at your facility.</li> <li>2. Complete the attached Acknowledgement Form and return it to Intuitive Surgical as instructed.</li> <li>3. Please retain a copy of this letter and the acknowledgement form for your files.</li> <li>4. Please log into the <i>daVinci</i> Online Community Field Action resource to read or complete any requested actions related to this issue.</li> </ol>
<p><b>Actions to be taken by Intuitive Surgical</b></p>	<p>An Intuitive Surgical Field Service representative will schedule a site visit to address this issue shortly.</p>
<p><b>Further Information &amp; Support</b></p>	<p>If you need further information or support concerning this Notification , please contact Intuitive Surgical Customer Service at the numbers listed below:</p> <ul style="list-style-type: none"> <li>• North and South America: (800) 876-1310, Option 3 (4 AM to 5 PM PST) or mail: customersupport-servicesupport@intusurg.com</li> <li>• Japan: 0120-56-5635 or 03-5575-1362 (9 AM to 6 PM JST)</li> </ul>

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

February 24, 2017

## ACKNOWLEDGMENT FORM

### Field Safety Notice

### Urgent Medical Device Recall - ISIFA2017-01-R

*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 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: POST MARKET FIELD ACTIONS

Subject line for email: Si and Xi GCC

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

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