

## Field Safety Notice

### Urgent Medical Device Correction – ISIFA2018-10-C

*System Software A70\_P8\_B622 and da Vinci® Xi Vessel Sealer Instrument Cutting Functionality*

<p><b>1- Introduction and Reason for Field Action</b></p>	<p>Dear <i>da Vinci Xi</i>® Customer,</p> <p>This Field Safety Notice is to inform you that Intuitive Surgical is initiating a voluntary correction related to the <i>da Vinci Xi A70_P8_B622</i> system software (upgraded May 30, 2018 to June 1, 2018) due to an issue that may prevent a <i>da Vinci Xi Vessel Sealer (VS)</i> Instrument or a <i>da Vinci Xi Vessel Sealer Extend (VSE)</i> Instrument from transecting tissue when the cut function is activated.</p> <p>This issue occurs when moving the VS/VSE between arms that are controlled by the same hand control (master). Please be aware that this issue does not affect sealing functionality or result in a partial cutting of tissue.</p> <p>To correct this issue, an Intuitive Surgical Representative will schedule a site visit to provide a software update at the earliest convenience.</p>				
<p><b>2 - Risk to Health</b></p>	<p>There have been no adverse events related to this issue.</p> <p>In most cases of VS/VSE usage, the tissue being sealed and cut is likely visible to the surgeon. Therefore, the surgeon is able to see the seal in the tissue, and use the seal as a guide to transect the tissue using another instrument.</p> <p>There may be a minor operative delay associated with using another instrument to transect the tissue, or restarting the system, each of which would result in no adverse health consequences.</p>				
<p><b>3- Affected Products</b></p>	<table border="1"> <thead> <tr> <th data-bbox="451 1402 781 1451">Product Name</th> <th data-bbox="781 1402 1198 1451">Affected System Serial Numbers</th> </tr> </thead> <tbody> <tr> <td data-bbox="451 1451 781 1566"><i>da Vinci Xi Surgical Systems</i> with A70_P8_B622 system software</td> <td data-bbox="781 1451 1198 1566">SK0204 SK0232 SK0248</td> </tr> </tbody> </table>	Product Name	Affected System Serial Numbers	<i>da Vinci Xi Surgical Systems</i> with A70_P8_B622 system software	SK0204 SK0232 SK0248
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<p>4- Actions to be taken by the Customer/User</p>	<p>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 <i>da Vinci</i> procedures.</p> <ol style="list-style-type: none"> <li>1. Ensure surgeons and patient side assistants using the <i>da Vinci Xi</i> Surgical System read and understand the contents of this letter.</li> <li>2. Inform affected personnel when corrective action has been completed.</li> <li>3. Complete the attached Acknowledgement Form and return it via fax or email to Intuitive Surgical per the instructions contained in the Acknowledgement Form.</li> <li>4. Please retain a copy of this letter and the Acknowledgement Form for your files.</li> </ol>
<p>5- Actions to be taken by Intuitive Surgical</p>	<ol style="list-style-type: none"> <li>1. A copy of this Field Safety Notice will be provided to customers with affected <i>da Vinci Xi</i> Surgical Systems.</li> <li>2. An Intuitive Surgical representative will contact customers with affected <i>da Vinci Xi</i> Surgical Systems to schedule a site visit to provide the correction to impacted systems.</li> <li>3. Intuitive Surgical representatives will be available by phone to answer any questions related to this Field Safety Notice.</li> </ol>
<p>6- Further Information &amp; 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"> <li>• Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 AM to 6 PM CET) or ics@intusurg.com</li> </ul>

Sincerely,

**Intuitive Surgical, Sàrl**  
 Chemin des Mûriers 1  
 CH-1170 Aubonne, Switzerland  
 +41.21.821.20.20

## ACKNOWLEDGMENT FORM

### Field Safety Notice

### Urgent Medical Device Correction – ISIFA2018-10-C

System Software A70\_P8\_B622 and da Vinci Xi Vessel Sealer Instrument Cutting Functionality

Ship-to:

Hospital Name: <mail merge>

Address: <mail merge>

City, State, Zip: <mail merge>

SFID: <mail merge>

ATTENTION: <mail merge>

**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: \_\_\_\_\_

**Position:**

Name (print): \_\_\_\_\_

Robotics Coordinator

Operating Room Director

Signature: \_\_\_\_\_

Risk Manager

Surgeon

Phone Number: \_\_\_\_\_

Other: \_\_\_\_\_

Email: \_\_\_\_\_

Date: \_\_\_\_\_

**PLEASE FAX OR EMAIL THIS ACKNOWLEDGEMENT FORM TO Intuitive Surgical, Inc.**

**ATTN: REGULATORY POST MARKET FIELD ACTIONS**

**Subject line for email: P8B VESSEL SEALER**

Scan and Email to: [EU.fsca@intusurg.com](mailto:EU.fsca@intusurg.com) or Fax +41.21.821.2021

**Customer Service:**

- Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm CET)