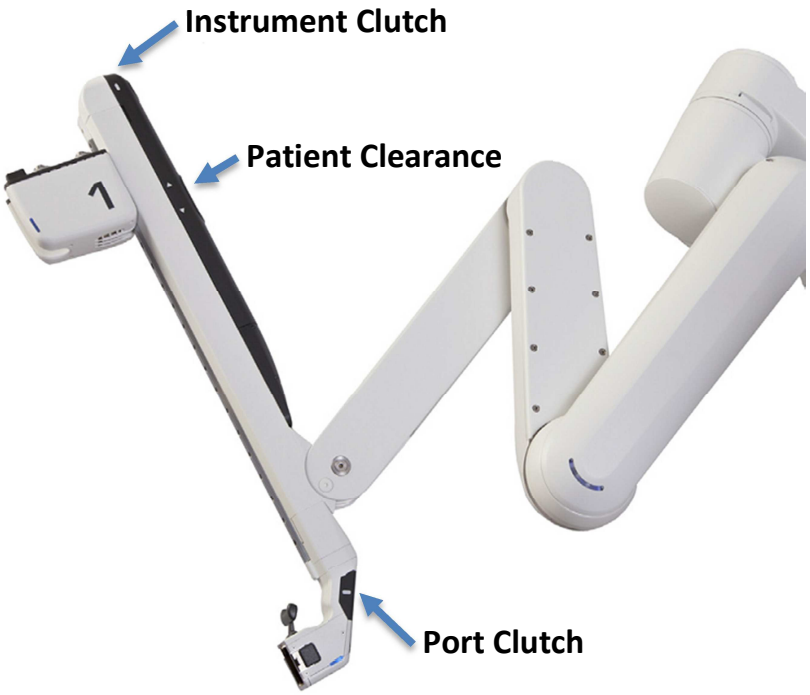
Date : 20.10.2016

Field Safety Notice
Urgent Medical Device Correction – 2955842-10/05/16-011-C

da Vinci® Xi™ Surgical System P5 Software

1- Introduction and Reason for Field Action	Dear *da Vinci* Customer, The purpose of this letter is to advise you that Intuitive Surgical is initiating a voluntary correction related to the *da Vinci Xi* Surgical System P5 Software. During an internal test, the left hand control (master) on the surgeon console moved unexpectedly upon the first entry into following mode. The system is in following mode when the surgeon is controlling the instruments at the surgeon console. This behavior was determined to be associated with a software anomaly in the *da Vinci Xi* Surgical System P5 software that can result in unexpected master movement and potential instrument tip movement under certain circumstances. A software update will be released to address this anomaly. Intuitive Surgical has received a small number of complaints related to this type of event, however, all clinical cases involving these complaints were completed with the *da Vinci Xi* Surgical System and without patient injury. To prevent this event from occurring, follow the **instructions** below during every *da Vinci Xi* procedure: 1. During **Single-Site** surgery, **after installing** each **instrument** on the sterile adapter, ensure **instrument clutch** is **not activated** and press the **port clutch*** button for that arm. This is only necessary at the beginning of the procedure, directly after docking. 2. During **Multi-Port** surgery, a. Immediately **after docking** to a cannula, press the corresponding **port clutch*** button for that arm, and b. If adjusting **patient clearance** mid-procedure, ensure instrument clutch is not activated and press the corresponding **port clutch*** button for that arm after the adjustment *Please refer to the following caution related to port clutch from the *da Vinci Xi* System User Manual 552000-04 Rev A: ⚠ CAUTION: Hold the port clutch button with one hand and support the cannula with the other.

<table>
<tr><td></td><td> 
</td></tr>
<tr><td>1- Introduction and Reason for Field Action Continued</td><td>Once the software update is completed, you can resume standard workflow per the da Vinci Xi System User Manual.</td></tr>
<tr><td>2- Risk to Health</td><td>Certain interactions with the patient cart (during patient cart docking or, during Multi-port procedures, repositioning the instrument arm) can trigger this behavior upon entering following mode. The surgeon may receive a recoverable error, experience movement of the master controller and/or movement of the associated cannula*/instrument in any direction including potential lateral movement. However, the instrument does not insert further beyond the tip of the cannula than it was previously inserted.

In the case where an instrument or cannula contacts tissue, risk depends on the amount of contact or motion, the type of instrument (blunt vs sharp tip) and the type of tissue. Potential consequences range from delay in procedure to varying degrees of tissue injury/bleeding. The likelihood of a severe injury is remote.

*In all cases cannula movement is about the remote center.</td></tr>
<tr><td>3- Affected Countries and Products</td><td>Affected Countries:
Australia, Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Hong Kong, India, Ireland, Israel, Italy, Japan, Monaco, Netherlands, Norway, Portugal, Puerto Rico, Qatar, Romania, South Korea, Spain, Sweden, Switzerland, Taiwan, Turkey, United Kingdom, United States

Affected Product:
<table>
<tr><th>Model Number</th><th>Product Name</th></tr>
<tr><td>IS4000, P5x</td><td>da Vinci Xi Surgical System with P5 Software</td></tr>
</table></td></tr>
<tr><td>4- Actions to be taken by the Customer/</td><td>Follow the <u>instructions</u> in section 1 above, during every da Vinci Xi procedure.

Please take the following actions to ensure all affected personnel are fully informed of this</td></tr>
</table>

Date : 20.10.2016

User	Notification. Forward this letter to your Risk Manager, OR Director, Purchasing and Biomedical Engineering staff; including members of your medical staff who perform da Vinci procedures. 1. Ensure surgeons and patient side assistants using the *da Vinci Xi* Surgical System read and understand the contents of this letter. 2. Complete the attached Acknowledgement Form and return it to Intuitive Surgical. 3. Inform affected personnel when the correction has been completed. 4. Please retain a copy of this letter and the acknowledgement form for your files.
5- Action taken by Intuitive Surgical	An Intuitive Surgical Representative will schedule a software upgrade for your *da Vinci Xi* Surgical System by quarter 1 2017.
6- Further Information & Support	If you need further information or support concerning this issue, please contact your Clinical Sales Representative or contact Intuitive Surgical Customer Service at the numbers listed below: • North and South America: 800-876-1310 Option 3 (6 am to 5pm PST) • Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm CET) • 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 notification.

Sincerely,

Intuitive Surgical Sàrl
Chemin des Mûriers 1
CH-1170 Aubonne, Switzerland
+41 21 821 2020

Date : 20.10.2016

ACKNOWLEDGEMENT FORM

Urgent Medical Device Correction – 2955842-10/05/16-011-C

da Vinci® Xi™ Surgical System P5 Software

Ship-to
Hospital Name: <Mail Merge>
Address: <Mail Merge>
City, State, Zip: <Mail Merge>
SFID: <Mail Merge>
ATTENTION Robotics Coordinator: <Mail Merge>

PLEASE COMPLETE ALL REQUESTED INFORMATION AND RETURN IMMEDIATELY

I have received and read the attached Field Safety Notice- Urgent Medical Device Correction regarding the *da Vinci Xi* P5 System Software. I have completed all the actions to be taken by the customer/user as listed on the customer letter.

I acknowledge that I have informed all necessary parties at my facility of this Field Safety Notification. I will contact Intuitive Surgical if I have any questions.

Name (print): _____

Signature: _____

Phone Number: _____

Date: _____

Position:

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

Customer Service:

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PLEASE FAX THIS ACKNOWLEDGEMENT FORM TO
Intuitive Surgical, Inc.
ATTN: POST MARKET FIELD ACTIONS
Subject line for email: *da Vinci Xi* P5 Software
U.S. Fax +1 (408) 523-0619, or scan and email to eu.fsca@intusurg.com