23.03.2015

Field Safety Notice
Urgent Medical Device Correction - 2955842-03-03-2015-004-C
Faults on the *da Vinci*® *Xi*™ Surgical System Patient Cart Arms

Introduction and Reason for Field Action	Dear *da Vinci* Customer, This Medical Device Correction is to advise you that Intuitive Surgical is initiating a voluntary correction related to a fault that occurs on some *da Vinci Xi* Surgical Systems. The system reports a "23008" system software fault that indicates a mismatch between the positions reported by the redundant position sensors on one of the patient cart arm joints. The system may fault during startup tests or during use. The system fault is an arm-specific recoverable fault, which leaves the system in a safe state. A fault message will be displayed and the affected arm LED color will change to yellow. It has been determined that the source of the fault is the premature failure of a position sensor located within the faulting joint. These sensors are secondary sensors that track each joint's position to compare against the primary sensors' reading. Intuitive Surgical's investigation has isolated the affected device population to a specific manufactured lot of sensors.
Risk to Health	If the error persists (i.e. the fault cannot be recovered), the affected arm should be disabled and the user should decide to continue the procedure with 3 arms, abort the procedure, or convert to an alternate surgical technique. There have been no reported injuries as a result of this issue. In a scenario in which the decision is made to convert a procedure to an alternate surgical method due to the error, the patient may be at higher risk of surgical complications because of the historically higher rate of complications in open surgery.
Affected Countries and Products	**Affected Countries:** Australia, Belgium, France, Germany, Hong Kong, India, Israel, Italy, New Zealand, Norway, South Korea, Spain, Sweden, Switzerland, Turkey, United Kingdom, and USA. **Affected Product:** *da Vinci Xi* Patient Side Cart composed of

Intuitive Surgical Part Number/Model Number	Product Name
380662-20, 380662-21	Inner Arm
380663-20, 380663-21	Outer Arm
380647-20, 380647-22	Universal Surgical Manipulator

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23.03.2015

Actions to be taken by the Customer/ User	**Please Take the Following Actions:** 1. Ensure that all affected personnel are fully informed of this notice. Forward this notice to your Risk Manager, OR Director, Purchasing Manager, Biomedical Engineering staff and members of your medical staff who perform *da Vinci* Surgery procedures. 2. Identify systems containing affected product at your site. 3. If you encounter this error during a procedure and the fault cannot be recovered, disable the affected arm and contact dVStat. One of the following actions may be taken: • Continue the procedure with 3 arms. • Abort the procedure. • Convert to an alternate surgical technique. 4. **Complete and return the attached Acknowledgment Form** to Intuitive Surgical using the instructions provided. 5. Please retain a copy of this notice for your records.
Actions to be taken by Intuitive Surgical	An Intuitive Surgical representative will contact you to schedule a remote assessment to determine the health of your system and to schedule an appointment to replace the affected arm. Intuitive Surgical representatives will be available by phone to answer any questions related to this Medical Device Correction.
Further Information & Support	If you need further information or support concerning this Medical Device Correction, please contact your Clinical Sales Representative or Intuitive Surgical Customer Service at the numbers listed below: • North America and South America: 800-876-1310, Option 3 (6 AM to 5 PM PST) • South Korea: 02-3271-3200 (9 AM to 6 PM KST) • Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 AM to 6 PM CET) or ics@intusurg.com

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

Sincerely,

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

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ACKNOWLEDGEMENT FORM

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Hospital Name: <mail merge>
Address: <mail merge>
City, Postal Code: <mail merge>
NSID : <mail merge>
ATTENTION: <mail merge>

1. I have received and read this Correction 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):_____

Signature: _____

Hospital Name: _____

Phone Number:_____

Email: _____

Date: _____

Position:

☐ **Robotics Coordinator**

☐ **Operating Room Director**

☐ **Risk Manager**

☐ **Recall Coordinator**

☐ **Other:** _____

PLEASE FAX OR EMAIL THIS ACKNOWLEDGEMENT FORM TO Intuitive Surgical, Inc.
ATTN: REGULATORY COMPLIANCE
Subject line for email: Pot to Encoder
U.S. Fax +1 (408) 716-3040, or Scan and Email: isi.compliance@intusurg.com

Customer Service:

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