Date : July 14,2016

Field Safety Notice

Urgent Medical Device Correction and Removal – 2955842-07/08/16-009-R

da Vinci® Xi™ EndoWrist Stapler - Partial Fires

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 "Stapler Firing Failed" message on the *da Vinci Xi EndoWrist* Stapler. The "Stapler Firing Failed" message, as shown in Fig. 1 below, interrupts the Stapler firing prior to completion of the full staple line. When this error occurs, the transection of tissue may be incomplete. In all cases formed staples precede the cut line however; there may be unformed staples at the end of the staple line. Also note that the knife blade could be exposed.

Figure 1. "Stapler Firing Failed" message

Intuitive Surgical has seen a small increase in the number of complaints regarding the "Stapler Firing Failed" message (Figure 1) for the *Xi* Stapler. All clinical cases involving these complaints were completed minimally invasively.

The *Xi* Stapler is designed to monitor the instrument performance during firing. The "Stapler Firing Failed" message is triggered as intended, when firing forces exceed their prescribed limits. These limits are set to prevent an undesirable staple line or damage to the Stapler instrument.

Many factors can contribute to Stapler firing forces exceeding the prescribed limit, including firing across hard objects (e.g., metal clips), certain tissue conditions (e.g. disease state, density) and/or damage to the instrument from handling. This communication serves to:

- Announce an upcoming software update to optimize the firing performance in order to reduce the overall rate of incomplete fires
- Reinforce the need to follow instructions for proper instrument handling to prevent damage that can lead to incomplete fires; and
- Communicate actions for surgeons to take intraoperatively should a partial fire occur.
- Request specific instruments that have experienced a "Stapler Firing Failed" message to be returned to Intuitive Surgical as a precautionary measure. These instruments, identified in Attachment B, are a small subset of the overall Xi Stapler population.

Risk to Health	The "Stapler Firing Failed" message that may occur during use of the *Xi* Stapler is an intentional message, in which the *da Vinci Xi* Surgical System informs the user that the Stapler firing was interrupted prior to the completion of the full staple line, and that they should unclamp with the blue pedal, remove the Stapler, and discard the reload, as instructed in Figure 1. While this message can occur with gray, white, blue, or green reloads, the greatest concern is with gray and white reloads, where a partial fire could potentially occur while transecting critical vascular structures such as Pulmonary, Renal or Splenic Vessels. Of the small number of complaints received for "Stapler Firing Failed" message, there has only been one adverse event reported related to minor bleeding that the surgeon was able to control with a suture and clip. The procedure was completed robotically with no patient consequence. In the event of the "Stapler Firing Failed" message, please note the following: 1. While the Stapler remains in the clamped state, it provides compression and tamponades the vasculature. 2. Surgeons should ensure hemostatic and leak control, particularly when around critical vessels with the gray or white reload, before releasing the Stapler from the structure. 3. After unclamping, a blade may be exposed; hence, surgeons should not manipulate tissue with the Stapler after the "Stapler Firing Failed" message occurs. 4. Bedside assistants should take care when removing the fired reload, as sharps hazards, such as potentially exposed knife and unformed staples, may be present.
Affected Countries and Products	**Affected Countries:** Australia, Austria, Belgium, Chile, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Hong Kong, Ireland, Italy, Monaco, Netherlands, Norway, Portugal, Puerto Rico, Singapore, South Korea, Spain, Sweden, Switzerland, Taiwan, Turkey, United Kingdom, United States, Venezuela **Affected Product:** **Model Number** / **Product Name** 470298 / IS4000 EndoWrist® Stapler 45 470430 / IS4000 EndoWrist® Stapler 30 470530 / IS4000 EndoWrist® Stapler 30 Curved-Tip
Actions to be taken by the Customer/ User	Please take the following actions to ensure all affected personnel are fully informed of this Notification. Forward this letter to your Risk Manager, OR Director, Purchasing and Biomedical Engineering staff, as well as members of your medical staff who perform da Vinci procedures. 1. Ensure all surgeons using the *EndoWrist* Stapler for the *da Vinci Xi* Surgical System read and understand the contents of this letter. 2. Ensure all OR and Sterilization/Cleaning personnel who handle *da Vinci Xi* Staplers are aware of proper handling instructions, per the device User Manual/Reprocessing Instructions, also excerpted in Attachment A of this Field Safety Notice. Improper handling can cause instrument damage that may impact the performance of the device. 3. Review Attachment B of affected Xi Stapler 45 and 30 instrument lot numbers, identify any that are located at your site and return those identified to Intuitive Surgical by July 31st, 2016. Attachment B identifies all Xi Stapler instruments that have experienced a

	"Stapler Failed Firing" message. 4. If an instrument experiences the "Stapler Failed Firing" message that is not attributed to clinical conditions (such as tissue condition, hard objects, etc.), do not continue to use the instrument. Please return the instrument to Intuitive Surgical following the standard RMA procedure. 5. Complete the attached Acknowledgment Form and return it to Intuitive Surgical. 6. Inform affected personnel when the correction has been completed. 7. Please retain a copy of this letter and the acknowledgment form for your files.
Action taken by Intuitive Surgical	1. In order to optimize the firing performance of the Stapler instruments, a Field Service Engineer will schedule a software upgrade for your *da Vinci Xi* System. *Note:* Sites may continue to use the Stapler instruments on the *da Vinci Xi Surgical* System prior to the software upgrade once the above Actions are completed.
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)

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

Sincerely,

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

Date : July 14,2016

ACKNOWLEDGMENT FORM

Urgent Medical Device Correction and Removal – 2955842-07/08/16-009-R

da Vinci® Xi™ EndoWrist Stapler - Partial Fires

Ship-to
Hospital Name:
Address:
City, State, Zip:
SFID:
ATTENTION Robotics Coordinator:

PLEASE COMPLETE ALL REQUESTED INFORMATION AND RETURN IMMEDIATELY

I have received and read the attached Field Safety Notice - Urgent Medical Device Correction and Removal regarding the *da Vinci Xi EndoWrist* Stapler Partial Fires. 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:

- North and South America: 800-876-1310 Option 3 (6 am to 5 pm PST)
- Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm CET)

PLEASE FAX THIS ACKNOWLEDGEMENT FORM TO
Intuitive Surgical, Inc.
ATTN: REGULATORY Compliance
Subject line for email: *da Vinci Xi EndoWrist* Stapler Partial Fires
U.S. Fax +1 (408) 523-0619, or Scan and Email: ISI.compliance@intusurg.com
For EMEIA: eu.fsca@intusurg.com

Date : July 14,2016

ATTACHMENT A

Reminder on Instructions for Proper Handling

The *EndoWrist Stapler Instruments and Accessories User Manual Addendum* and the associated *Reprocessing Instructions* provide specific guidance on handling of the Staplers, as indicated below.

Remember: Do not lift or manipulate the Stapler by the jaws. Proper care and handling are essential for the satisfactory performance of surgical instruments.

Refer to the below sections from the User Manual and Reprocessing Instructions

Operating Room Considerations:

1. CAUTION: Handle the instruments with care. Avoid mechanical shock or stress that can cause damage to the instruments.
2. Handling in the OR:
    a. CAUTION: Do not lift the Stapler by the jaws when the Stapler is not installed on an instrument arm. Support the housing or the shaft of the Stapler instrument and do not manipulate it by the jaws, as this may damage the instrument.
    b. CAUTION: Keep the Stapler wrist straight when removing and loading reload or otherwise handling the instrument when it is not installed on an instrument arm.

Reprocessing Considerations:

1. In general
    a. CAUTION: Please handle the products with care and avoid mechanical shock or stress which can lead to damage.
2. Cleaning in SPD:
    a. CAUTION: During scrubbing and flushing do not push the Stapler jaws against the sink or other hard surfaces, as this may cause instrument damage.
    b. CAUTION: Do not lift the Stapler by the jaws. Support the housing or the shaft of the Stapler instrument and do not manipulate it by the jaws, as this may damage the instrument.
    c. CAUTION: Do not use excessive force when moving the Stapler through its range of motion.

ATTACHMENT B

INSTRUMENTS WITH KNOWN PARTIAL FIRES AND INSTRUCTIONS FOR RETURN

ACTION: Review the table of specific *Xi* Stapler lot numbers that have known incidences of the "Stapler Failed Firing" message to identify any instruments that are located at your site (system numbers provided for reference):

IS4000 EndoWrist® Stapler 45 (P/N) 470298				
System S/N	**Stapler ID**		**System S/N**	**Stapler ID**
United States			SK0263	S10160413 0009
SK0039	S10150923 0006		SK0275	S10150919 0019
SK0058	S10160121 0014		SK0288	S10160216 0015
SK0059	S10151009 0020		SK0294	S10160412 0008
SK0066	S10141203 0008		SK0298	S10160216 0001
SK0067	S10150428 0018		SK0316	S10160314 0007
SK0070	S10151009 0002		SK0348	S10150323 0011
SK0074	S10160321 0010		SK0356	S10160408 0002
SK0095	S10151013 0006		SK0358	S10160321 0002
SK0097	S10160427 0004		SK0358	S10160216 0004
SK0098	S10150116 0002		SK0358	S10160209 0001
SK0127	S10150406 0013		SK0358	S10160314 0014
SK0135	S10160511 0009		SK0382	S10150915 0029
SK0135	S10160216 0002		SK0385	S10150406 0029
SK0138	S10150513 0005		SK0385	S10150406 0001
SK0140	S10151202 0025		SK0400	S10160408 0012
SK0163	S10150406 0031		SK0417	S10150513 0021
SK0178	S10150203 0006		SK0434	S10160307 0013
SK0191	S10160107 0002		SK0440	S10160504 0001
SK0206	S10141203 0002		SK0486	S10150727 0018
SK0209	S10151204 0002		SK0487	S10150727 0016
SK0209	S10141205 0005		SK0541	S10151204 0016
SK0209	S10150123 0003		SK0573	S10150923 0016
SK0216	S10151202 0027		SK0599	S10151012 0009
SK0225	S10150212 0008		SK0608	S10151208 0009
SK0225	S10150203 0013		SK0616	S10160225 0004
SK0231	S10150203 0004		SK0616	S10160225 0003
SK0235	S10151202 0017		SK0621	S10160127 0020
SK0236	S10160401 0005		SK0638	S10150916 0013
SK0237	S10160310 0011		SK0653	S10151022 0012

IS4000 EndoWrist® Stapler 45 (P/N) 470298	
System S/N	**Stapler ID**
United States Cont.	
SK0653	S10151208 0001
SK0676	S10151125 0002
SK0682	S10160307 0011
SK0682	S10160310 0001
SK0697	S10160504 0002
SK0709	S10151229 0006
SK0764	S10151207 0018
SK0764	S10151215 0017
SK0807	S10150129 0002

International	
SK0319	S12151210 0017
SK0740	S12151210 0008
SK0226	S10150323 0002

IS4000 EndoWrist® Stapler 30 Curved-Tip (P/N) 470530	
System S/N	**Stapler ID**
SK0113	S10160523 0003
SK0225	S10160318 0003
SK0225	S10160318 0014

Please follow the instructions listed below and return all of the identified *Xi* Stapler 45 and 30 instruments, specified by the lot number, to Intuitive Surgical by July 31st, 2016.

NOTE: The lot number of the *Xi* Stapler 45 and 30 instruments can be found on the instrument housing, Figure 1.

Figure 1: Lot number location on *Xi* Staplers

- Contact Customer Service to initiate the standard Return Material Authorization (RMA) process by phone or email:
    - **North and South America: 800-876-1310 Option 3 (6 am to 5pm PST)**
        - **Phone:** Call Customer Service at (800) 876-1310 Option 3 (6 AM to 5 PM PST)
        - **Email:** customersupport-servicesupport@intusurg.com
    - **Europe, Middle East, Asia and Africa:**
        - **Phone:** 800 0821 2020 or +41 21 821 2020 (8 am to 6 pm CET)
        - **Email:** ics@intusurg.com

- **Note:** Please clean and sterilize all Staplers before returning.

- Please return Xi Staplers by **July 31st, 2016**