April 27, 2018

Field Safety Notice

Urgent Medical Device Notification – ISIFA2018-04-C

da Vinci Xi® Stapler 45 Blue and Green Reloads Missing Knife Component

Introduction and Reason for Field Action	Dear *da Vinci®* Customer, Intuitive Surgical, Inc. (ISI) has recently become aware of an issue with the da Vinci Xi Stapler 45 Blue and Green Reloads that may be missing a component of the knife mechanism. Without this component, the reload knife will not move and cut tissue when the stapler is fired. As a result, the user may see a staple line that has all the staples formed, but no tissue transection. There will be no indication from the system that a transection has not occurred. There is no risk of partial fire or exposed blade associated with this missing component because the knife does not leave its home position. This is a notification of the issue only, and no product is required to be returned. In over 30,000 procedures, ISI has only seen one confirmed instance of this occurrence. Although there is a very low chance of no transection occurring, Intuitive Surgical advises to always visually inspect the tissue after firing. In the event of a lack of transection, please use another instrument to cut the tissue between the formed staple lines.
Risk to Health	There have been no adverse events related to this issue. In most cases, the surgeon should be able to immediately detect whether the tissue has been transected upon firing the reload. If the surgeon sees that the tissue has not been cut, there may be a minor operative delay associated with using another instrument to transect the tissue. In the event that a surgeon is unaware that a transection has not occurred during an intracorporeal anastomosis and the lumens of the anastomosed structures are not in continuity, there may be consequences of varying levels of severity depending on the modification made to the original surgical plan.

Affected Products

For your reference, lots that fall within the referenced lot ranges below may be affected by this issue. You can locate the affected lot number on the reload packaging by identifying only the last 6 digits. See Figure 1:

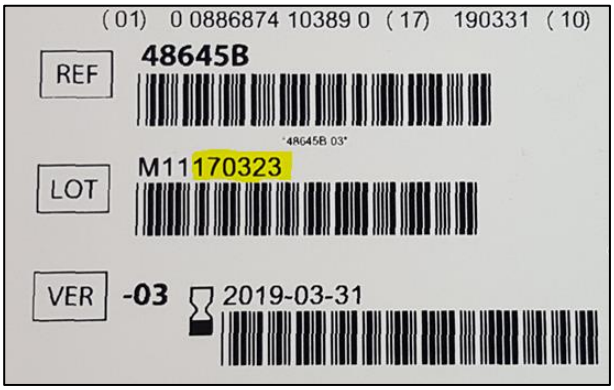

Figure 1: Affected Lot of Xi Stapler 45 Reloads

Part Number	Product Name	Potentially Affected Lot Number
48645B-03	Xi Stapler 45mm Blue Reload	XXX160202 – XXX180107
48445G-03	Xi Stapler 45mm Green Reload	XXX151014 and XXX160601 – XXX180221

Actions to be taken by the Customer/User

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 da Vinci procedures.

1. During the surgical procedure, check the tissue after firing. In the event of a lack of tissue transection, an alternative instrument (e.g., another EndoWrist instrument or laparoscopic instrument) may be used to transect the tissue along the staple line.
2. The return of product is not required, however if you would like to return affected product, please follow the standard RMA process. Credit will be provided for all returned affected product.
3. Ensure surgeons and patient side assistants using the *da Vinci Xi* Stapler read and understand the contents of this letter.
4. Please log into the *da Vinci* Online Community Field Action resource to read or complete any requested actions related to this issue, at this link: https://www.davincisurgerycommunity.com/
5. In the case where the *da Vinci* online resource cannot be used, complete the attached Acknowledgement Form and return it via fax to Intuitive Surgical as instructed on the form.
6. Please retain a copy of this letter and the acknowledgement form for your files.

Actions to be taken by Intuitive Surgical	1. A copy of this Field Safety Notice will be provided to customers with the affected lot of *da Vinci Xi* Stapler Reloads. 2. Intuitive Surgical representatives will be available by phone to answer any questions related to this Field Safety Notice.
Further Information & Support	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: • North and South America: (800) 876-1310, Option 3 (4 AM to 5 PM PST) or mail: customerservice@intusurg.com. • Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 AM to 6 PM CET) or ics@intusurg.com • 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)

Sincerely,

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

Cc: Chairman Medical Board and relevant Head of Departments

April 27, 2018

ACKNOWLEDGMENT FORM

Field Safety Notice

Urgent Medical Notification – ISIFA2018-04-C

da Vinci Xi® Stapler 45 Blue and Green Reloads Missing Knife Component

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

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: _____

Name (print): _____

Signature: _____

Phone Number: _____

Email: _____

Date: _____

Position:

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

PLEASE FAX OR EMAIL THIS ACKNOWLEDGEMENT FORM TO Intuitive Surgical, Inc.
ATTN: REGULATORY POST MARKET FIELD ACTIONS
Subject line for email: Xi Stapler Reloads Missing Knife Component
U.S. Fax +1(408) 523-0619, or Scan and Email: Recalls@intusurg.com or EU.fsca@intusurg.com

Customer Service:

- North and South America: 800-876-1310 Option 3 (4 am to 5 pm PST)
- Japan: 0120-56-5635 or 03-5575-1362 (9 am to 6 pm JST)
- South Korea: 02-3271-3200 (9 am to 6 pm KSTJ)
- Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm CET)