September 19, 2017

Field Safety Notice

Urgent Medical Device Recall – ISIFA2017-09-R

da Vinci® Xi EndoWrist Stapler 45 Clutch Spindle

1- Introduction and Reason for Field Action	Dear *da Vinci* Customer, The purpose of this letter is to inform you that Intuitive Surgical is initiating a voluntary recall of certain lots of the *da Vinci Xi® EndoWrist®* Stapler 45 instrument. Intuitive Surgical has learned that specific *da Vinci Xi EndoWrist* Stapler 45 instruments are potentially impacted by a variation in the manufacturing process. In affected instruments, there is a possibility that the Stapler Release Kit (SRK) Wrench interface feature accessed through release hole 2 is manufactured to an incorrect dimension, which may prevent the SRK Wrench from being able to manually unclamp the instrument.  Figure 1. *da Vinci Xi EndoWrist* Stapler 45 Release Holes
2- Risk to Health	There have been no reported adverse events related to this issue. If the Stapler Release Kit is used on an affected instrument, the SRK Wrench may not be capable of successfully unclamping the *da Vinci Xi EndoWrist* Stapler 45 instrument. If the Stapler Release Kit tool is incapable of unclamping the *da Vinci Xi EndoWrist* Stapler 45 instrument, the clamped tissue may need to be excised using an alternate stapling device or another surgical intervention. The clinical consequences of excising the tissue could be of varying levels of severity, depending on the sufficiency of tissue immediately adjacent to the intended cut to accommodate a second resection.

INTUITIVE SURGICAL®

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3- Affected Products

Part Number	Product Name	Impacted Lots
470298-11	*da Vinci Xi EndoWrist* Stapler 45	S10170630 S11170705 S10170707 S10170731

4- 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 are involved with *da Vinci* procedures.

1. Using the lot numbers listed above, please locate and return all affected Staplers at your site via the standard RMA process.
    a. Credit will be provided for remaining uses on affected instruments returned to Intuitive Surgical.
2. Please log into the *da Vinci* Online Community field action resource to read and/or complete any requested actions related to this issue.
    a. https://www.davincisurgerycommunity.com/
3. If you cannot access the *da Vinci* Online Community field action resource, please complete the attached Acknowledgement Form and return it via fax or email to Intuitive Surgical per the instructions contained in the Acknowledgement Form.
4. Please retain a copy of this letter and a copy of the Acknowledgement Form for your files.

5- Action taken by Intuitive Surgical

1. A copy of this Field Safety Notice will be provided to customers with affected *da Vinci Xi EndoWrist* Staplers.
2. Credit for remaining uses will be provided for returned instruments.
3. Intuitive Surgical representatives will be available by phone to answer any questions related to this Field Safety Notice.

6- Further Information & Support

If you require further information or support concerning this Field Safety Notice, please contact your Clinical Sales Representative. You may also contact Intuitive Surgical Customer Service using information provided below:

- North and South America
    - Phone: (800) 876-1310, Option 3 (4 AM to 5 PM PST)
    - Email: customersupport-servicesupport@intusurg.com

Sincerely,

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

September 19, 2017

ACKNOWLEDGEMENT FORM

Urgent Medical Device Recall – ISIFA2017-09-R

da Vinci® Xi EndoWrist Stapler Clutch Spindle

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 Recall regarding the *da Vinci Xi EndoWrist* Stapler 45. 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 Notice. 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:** _____

Customer Service:

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  or email: customersupport-servicesupport@intusurg.com

PLEASE FAX THIS ACKNOWLEDGEMENT FORM TO
Intuitive Surgical, Inc.
ATTN: REGULATORY POST MARKET FIELD ACTIONS
Subject line for email: *Xi Stapler Clutch Spindle*
U.S. Fax +1 (408) 523-0619, or scan and email to ISI.compliance@intusurg.com