

May 3, 2018

Field Safety Notice Medical Device Correction - ISIFA2017-02-C Phase II

Proper use of da Vinci® Xi EndoWrist Stapler Release Kit

Introduction and Reason for Field Action

Dear *da Vinci*® Customer,

In March 2017, Intuitive Surgical initiated a voluntary field action (ISIFA2017-02-C) highlighting proper use of the *da Vinci Xi*® *EndoWrist*® Stapler Release Kit (SRK) tool and providing additional information regarding the use of the Instrument Release Kit (IRK) tool as a backup if a SRK tool is not available. A copy of this voluntary field action is provided for you convenience as Appendix A of this communication.

This notification is to inform *da Vinci* customers that Intuitive Surgical has developed an improved *da Vinci Xi* and *da Vinci X*® SRK tool. The new SRK tool design:

- Reduces the likelihood of SRK tool breakage
- Does not change the instructions for use

Intuitive Surgical will be providing you with replacement SRK tool(s) of the new design. Two new SRK tools will be provided for each *da Vinci X* or *da Vinci Xi* system. Place all new SRK tools with your system and discard any previous versions in your inventory. Additional SRK tools may be ordered via the standard ordering process.



Figure 1: New SRK tool design (1) and Previous SRK tool design (2)

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Risk to Health	<p>The Risk to Health due to SRK tool breakage can range from a minor delay in surgery due to the need to locate a backup SRK tool or IRK tool, to needing to extract clamped tissue from the stapler jaws, to the worst case scenario of needing to excise clamped tissue using an alternative stapling device or other surgical intervention.</p>																																		
Replacement Products you will receive	<p>The following Part Numbers refer to the new SRK tools:</p> <table border="1"> <thead> <tr> <th>Part Numbers</th><th>Description</th></tr> </thead> <tbody> <tr><td>381215-03</td><td>da Vinci Xi SRK – English</td></tr> <tr><td>381381-02</td><td>da Vinci Xi SRK – Czech</td></tr> <tr><td>381382-02</td><td>da Vinci Xi SRK – Danish</td></tr> <tr><td>381383-02</td><td>da Vinci Xi SRK – Dutch</td></tr> <tr><td>381384-02</td><td>da Vinci Xi SRK – Finnish</td></tr> <tr><td>381385-02</td><td>da Vinci Xi SRK – French</td></tr> <tr><td>381386-02</td><td>da Vinci Xi SRK – German</td></tr> <tr><td>381387-02</td><td>da Vinci Xi SRK – Greek</td></tr> <tr><td>381389-02</td><td>da Vinci Xi SRK – Italian</td></tr> <tr><td>381390-03</td><td>da Vinci Xi SRK – Japanese</td></tr> <tr><td>381391-02</td><td>da Vinci Xi SRK – Korean</td></tr> <tr><td>381393-02</td><td>da Vinci Xi SRK – Norwegian</td></tr> <tr><td>381395-02</td><td>da Vinci Xi SRK – Portuguese</td></tr> <tr><td>381401-02</td><td>da Vinci Xi SRK – Spanish</td></tr> <tr><td>381402-02</td><td>da Vinci Xi SRK – Swedish</td></tr> <tr><td>381403-02</td><td>da Vinci Xi SRK – Turkish</td></tr> </tbody> </table>	Part Numbers	Description	381215-03	da Vinci Xi SRK – English	381381-02	da Vinci Xi SRK – Czech	381382-02	da Vinci Xi SRK – Danish	381383-02	da Vinci Xi SRK – Dutch	381384-02	da Vinci Xi SRK – Finnish	381385-02	da Vinci Xi SRK – French	381386-02	da Vinci Xi SRK – German	381387-02	da Vinci Xi SRK – Greek	381389-02	da Vinci Xi SRK – Italian	381390-03	da Vinci Xi SRK – Japanese	381391-02	da Vinci Xi SRK – Korean	381393-02	da Vinci Xi SRK – Norwegian	381395-02	da Vinci Xi SRK – Portuguese	381401-02	da Vinci Xi SRK – Spanish	381402-02	da Vinci Xi SRK – Swedish	381403-02	da Vinci Xi SRK – Turkish
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Actions to be taken by the Customer/ User	<ol style="list-style-type: none"> 1. Receive your replacement SRK tools (new design) and once individually wrapped and sterilized, place them with your <i>da Vinci</i> Surgical Systems. 2. Discard your previous SRK tools upon receipt of your replacement SRK tools. 3. Distribute a copy of this letter to all individuals at your facility who use a <i>da Vinci</i> Surgical System. 4. Complete the attached Acknowledgement Form and return it to Intuitive Surgical. 5. Please retain a copy of this Field Safety Notice with your Stapler User Manual and a copy of any completed Acknowledgement Form for your files. If you have a previous notification relating to this issue in your manuals, please replace that letter with this notification. 																																		

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Actions to be taken by Intuitive Surgical	Intuitive Surgical representatives will be available by phone to answer any questions related to this Field Notice.
Further Information & Support	<p>If you need further information or support concerning this notification, please contact Intuitive Surgical Customer Service using the information provided below:</p> <ul style="list-style-type: none"> • North and South America: (800) 876-1310, Option 3 (4 AM to 5 PM PST) or 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)

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

Sincerely,

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

Cc: Chairman Medical Board and Relevant Head of Departments

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ACKNOWLEDGMENT FORM
Field Safety Notice
Medical Device Correction - ISIFA2017-02-C Phase II

Proper use of da Vinci Xi EndoWrist Stapler Release Kit

Hospital Name: _____

Address: _____

City, State, Zip: _____

SFID: _____

ATTENTION:

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.

Name (print): _____

Position:

Signature: _____

☐ Robotics Coordinator

☐ Operating Room Director

Hospital Name: _____

☐ Risk Manager

☐ Surgeon

Phone Number: _____

☐ Other: _____

Email: _____

Date: _____

PLEASE FAX OR EMAIL THIS ACKNOWLEDGEMENT FORM TO: Intuitive Surgical, Inc.

ATTN: POST MARKET FIELD ACTIONS

Subject line for email: Xi SRK Phase II

U.S. Fax +1(408) 523-0619, or Scan and Email: Recalls@intusurg.com

For EMEA: EU.FSCA@intusurg.com

Customer Service:

- North and South America: (800) 876-1310, Option 3 (4 AM to 5 PM PST) or customerservice@intusurg.com
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Field Safety Notice

Urgent Medical Device Correction - ISIFA2017-02-C Phase II

Appendix A

This appendix is meant to provide emphasis on the proper use of the *da Vinci Xi EndoWrist* Stapler Release Kit (SRK). For the full instructions, please refer to the *da Vinci Xi EndoWrist* Stapler Instruments and Accessories User Manual. The SRK is intended to be used in situations when the *da Vinci Xi EndoWrist* Stapler instrument jaws will not open. Opening the stapler jaws with the SRK requires rotating the provided tool in up to three release holes per the instructions on the integrated SRK instruction tag.

In situations where release hole 2 is covered by a white flag (Figure 1) and is not accessible, the SRK tool must be rotated in release holes 1, 2 and 3.



Figure 1: Stapler instrument release hole 2 “closed” with white flag present

In situations where release hole 2 is not covered by the white flag (Figure 2), rotating the tool in release hole 1 is **not required**. Attempting to rotate the tool in release hole 1 may result in breaking and rendering the tool unusable.



Figure 2: Stapler instrument release hole 2 “open” without white flag

To avoid breaking the tool, users should follow the manual stapler release instructions found in the *EndoWrist Stapler Instruments & Accessories User Manual Addendum*:

1. Obtain the Stapler Release Kit and open its sterile wrapping.
2. If the system is not faulted, press the Emergency Stop button on the Surgeon Console. Do not recover the fault.

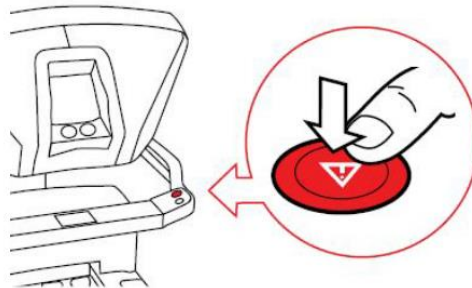


Figure 3: If necessary, press emergency stop button

NOTE: Examine release hole 2 on the instrument housing *before* using the SRK. If the white flag **is not** present, skip steps 3 and 4 and proceed to step 5.

3. Examine the release hole labeled with a 2 on the Stapler housing. If a white flag is not present, proceed to step 5 and begin with hole 2. If a white flag is present, insert the tool into the release hole labeled with a 1. Place your hand under the instrument carriage for support and turn the tool clockwise until the second release hole is completely exposed and the white flag is gone.
4. Remove the tool from hole 1.
5. Keeping your hand under the instrument carriage for support, insert the tool into the release hole labeled with a 2.

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6. Turn the tool counterclockwise until resistance is felt (approximately 12 full turns).

NOTE: Continuing to turn the tool after resistance is felt (approximately or up to 12 full turns) could lead to breaking the tool.

NOTE: If the tool breaks in either release hole 1 or release hole 2:

- Release holes 2 and/or 3 may also be rotated using the tool included in the **da Vinci Xi Instrument Release Kit (IRK)**.
- The release hole that the tool has broken in has been fully rotated and does not require further actuation with the tool.