


Field Safety Notice

Urgent Medical Device Correction - ISIFA2017-02-C

Proper use of da Vinci® Xi EndoWrist Stapler Release Kit

<p>Introduction and Reason for Field Action</p>	<p>Dear <i>da Vinci</i> Customer,</p> <p>This Field Safety Notice is to advise you that Intuitive Surgical is initiating a voluntary correction relating to the <i>da Vinci Xi</i>® <i>EndoWrist</i>® Stapler Release Kit (SRK). Intuitive Surgical has received complaints where the tool has broken during use. The purpose of this communication is to reinforce proper use of the SRK and to provide additional instructions in the scenario of SRK tool damage (See Appendix A).</p> <div style="text-align: center;">  </div> <p style="text-align: center;">Figure 1: <i>da Vinci Xi EndoWrist Stapler Release Kit (SRK)</i></p>
<p>Risk to Health</p>	<p>The Risk to Health due to the SRK tool breaking can range from the minor delay in surgery in order to locate and use a backup SRK or Instrument Release Kit (IRK) tool, to extracting the clamped tissue from the stapler jaws, to the worst case scenario of the clamped tissue needing to be excised using an alternative stapling device or other surgical intervention. While most incidences were able to be resolved without issue, there have been three clinical cases where the <i>EndoWrist</i> Stapler jaws would not open while clamped on tissue, the SRK tool broke, and the stapler was excised using an alternative stapling device or other surgical intervention.</p> <p>In all three incidences, the surgical procedure was completed successfully.</p>
<p>Affected Countries and Products</p>	<p><u>Affected Countries:</u></p> <p>Australia, Austria, Belgium, Canada, Chile, Colombia, Czech Republic, Denmark, Finland, France, Germany, Hong Kong, Ireland, Italy, Japan, Luxembourg, Monaco, Netherlands, Norway, Portugal, Puerto Rico, Singapore, South Korea, Spain, Sweden, Switzerland, Taiwan, Turkey, United Kingdom, USA, and Venezuela.</p>

	Affected Product:				
	Product Name		Part Number(s)		
	<i>da Vinci Xi</i> English SRK		381215-02		
	<i>da Vinci Xi</i> Danish SRK		381382-01		
	<i>da Vinci Xi</i> Czech SRK		381381-01		
	<i>da Vinci Xi</i> Dutch SRK		381383-01		
	<i>da Vinci Xi</i> Finnish SRK		381384-01		
	<i>da Vinci Xi</i> French SRK		381385-01		
	<i>da Vinci Xi</i> Norwegian SRK		381393-01		
	<i>da Vinci Xi</i> German SRK		381386-01		
		Product Name		Part Number(s)	
		<i>da Vinci Xi</i> Greek SRK		381387-01	
		<i>da Vinci Xi</i> Japanese SRK		381390-01	
		<i>da Vinci Xi</i> Italian SRK		381389-01	
		<i>da Vinci Xi</i> Korean SRK		381391-01	
		<i>da Vinci Xi</i> Portuguese SRK		381395-01	
		<i>da Vinci Xi</i> Swedish SRK		381402-01	
		<i>da Vinci Xi</i> Spanish SRK		381401-01	
		<i>da Vinci Xi</i> Turkish SRK		381403-01	
Actions to be taken by the Customer/ User	<ol style="list-style-type: none"> 1. Distribute a copy of this letter to all <i>da Vinci Surgical System</i> users at your facility. 2. In the scenario where the SRK needs to be used, follow all instructions as provided in the <i>da Vinci Xi EndoWrist Stapler Instruments and Accessories User Manual Addendum</i> and reiterated in this letter (See Appendix A). 3. If the SRK tool breaks, proceed with the instructions using the Instrument Release Kit (IRK) tool to finish manually unclamping the stapler and return the SRK to Intuitive Surgical through the Returned Material Authorization (RMA) process. 4. Complete the attached Acknowledgement Form and return it via fax to Intuitive Surgical as instructed on the form. 5. Please retain a copy of this letter with your Stapler User Manual and the acknowledgement form for your files. 				
Actions to be taken by Intuitive Surgical	<ol style="list-style-type: none"> 1. A copy of this letter will be provided to all <i>da Vinci Xi</i> users where the <i>da Vinci EndoWrist Stapler</i> is available. 2. Intuitive Surgical representatives will be available by phone to answer any questions related to this Medical Device Correction. 3. Intuitive Surgical will distribute an addendum with additional instructions to all new users of the <i>da Vinci Xi Surgical System</i>. 				
Further Information & Support	<p>If you need further information or support concerning this notification , please contact Intuitive Surgical Customer Service at the numbers listed below:</p> <ul style="list-style-type: none"> • North and South America: (800) 876-1310, Option 3 (4 AM to 5 PM PST) or mail: customersupport-servicesupport@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 				

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

Sincerely,

Intuitive Surgical, Sàrl

Chemin des Mûriers 1

CH-1170 Aubonne, Switzerland

+41 21 821 20 20

ACKNOWLEDGMENT FORM
Field Safety Notice
Urgent Medical Device Correction - ISIFA2017-02-C
Proper use of da Vinci Xi EndoWrist Stapler Release Kit

Hospital Name: <mail merge>

Address: <mail merge>

City, State, Zip: <mail merge>

SFID: <mail merge>

ATTENTION: <mail merge>

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

Fax +41 21 821 20 21, or Scan and Email: EU.FSCA@intusurg.com

Customer Service:

- North and South America: (800) 876-1310, Option 3 (4 AM to 5 PM PST) or mail: customersupport-servicesupport@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

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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.

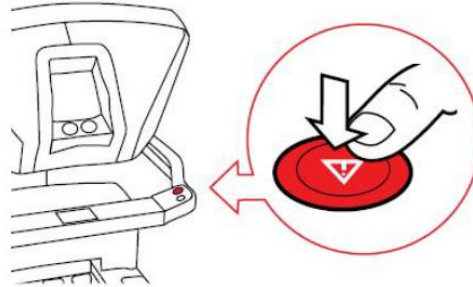


Figure 3: If necessary, press emergency stop button

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.

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.