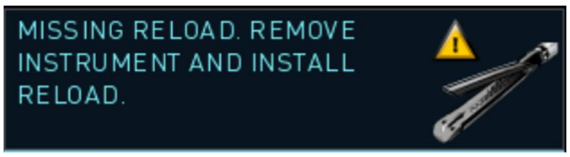
03.07.2015

Field Safety Notice

Urgent Medical Device Correction- 2955842-05-21-2015-007-C

da Vinci® Xi™ Surgical System Draping

Introduction and Reason for Field Action	Dear *da Vinci* Customer, The purpose of this Field Safety Notification is to advise you of an issue that may occur involving the combination of the *da Vinci® Xi™* Drapes and *Xi* instruments. During the draping of the *da Vinci Xi* Surgical System, the drape pouch attached to the sterile adapter may inadvertently get pinched between the sterile adapter and instrument carriage (Figure 1).  Figure 1. Pinched Drape Pouch (left) vs. Smooth Drape Pouch (right) Though the pinched drape pouch may occur with the use of all Xi instruments, the occurrence of an error has been identified only with the use of the da Vinci Xi EndoWrist Stapler instrument. In some cases, when the EndoWrist Stapler is installed on the system, the error message shown in Figure 2 may appear on the Vision Cart touchscreen. In addition, the LEDs on the arm where the Stapler is installed will flash amber (brownish yellow). The purpose of this message is to ensure that a Reload is installed. If the Reload is installed correctly and the message persists, it may be caused by a pinched drape pouch.  Figure 2. Example: Missing Reload message To resolve this issue, hospital staff should verify that the drape pouch around the sterile adapter is smooth by removing the sterile adapter, straightening the drape pouch, and reseating the sterile adapter.
Risk to Health	There have been no reported patient injuries or adverse health consequences due to this issue.

	However, a potential delay may occur due to troubleshooting the issue.
Affected Regions and Products	**Affected Countries:** Australia, Austria, Belgium, China, Cyprus, Czech Republic, France, Germany, India, Israel, Italy, Japan, Netherlands, Norway, Puerto Rico, Qatar, Romania, Saudi Arabia, Singapore, South Korea, Spain, Sweden, Switzerland, Turkey, United Kingdom and the United States. **Affected Product:** **Part Number(s)** / **Product Name** 470015-05 / INSTRUMENT ARM DRAPE,IS4000,20 PACK 470015-06 / INSTRUMENT ARM DRAPE,IS4000,20 PACK
Actions to be taken by the Customer/ User	**Please Take the Following Actions:** 1. Ensure that all affected personnel are fully informed of this notice. Forward this notice to your Risk Manager, OR Director, Purchasing Manager, Biomedical Engineering staff and members of your medical staff who perform *da Vinci* Surgery procedures. 2. **Complete and return the attached Acknowledgment Form** to Intuitive Surgical using the instructions provided. 3. Please retain a copy of this notice with your system. 4. Refer to the *da Vinci Xi* System User Manual for more information on draping the system.
Actions to be taken by Intuitive Surgical	Intuitive Surgical will update the labeling to address this issue in the form of an addendum to the system user manual. Intuitive Surgical representatives will be available by phone to answer any questions related to this Medical Device Correction.
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 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 • South Korea: 02-3271-3200 (9 AM to 6 PM KSTJ) • Japan: 0120-56-5635 or 003-5575-1362 (9 AM to 6 PM JST)

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

Sincerely,

Intuitive Surgical Sàrl
Chemin des Mûriers 1
CH-1170 Aubonne, Switzerland
+41 21 821 2020

03.07.2015

ACKNOWLEDGEMENT FORM

Field Safety Notice

Urgent Medical Device Correction- 2955842-05-21-2015-007-C

da Vinci® Xi™ Surgical System Draping

Hospital Name: <mail merge>
Address: <mail merge>
City, Postal Code: <mail merge>
NSID : <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):_____

Signature: _____

Hospital Name: _____

Phone Number:_____

Email: _____

Date: _____

Position:

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

Customer Service:

- North America and South America: 800-876-1310 Option 3 (6 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) or ics@intusurg.com

PLEASE FAX OR EMAIL THIS ACKNOWLEDGEMENT FORM TO Intuitive Surgical, Inc.
ATTN: REGULATORY COMPLIANCE
Subject line for email: *da Vinci Xi* Surgical System Draping
U.S. Fax +1 (408) 716-3040, or Scan and Email: isi.compliance@intusurg.com or eu.fsca@intusurg.com