16.06.2015

Field Safety Notice

Urgent Medical Device Correction - 2955842-05-18-2015-005-C

Breakage of input disks of EndoWrist instruments used with the da Vinci® Xi™ Surgical System

Introduction and Reason for Field Action	Dear *da Vinci* Customer, The purpose of this letter is to advise you that Intuitive Surgical is initiating a voluntary correction related to the *da Vinci Xi* Reprocessing Manuals for the EndoWrist instruments. The appendices in the reprocessing manuals incorrectly list the Getinge 88 Turbo Washer/Disinfector and the Getinge Clean MIS combination for reprocessing instruments. It has been determined that the use of the Getinge combination to reprocess instruments results in a higher chance of input disk breakage rendering the instrument inoperable. See Figure 1 for an example of a broken input disk. The Getinge combination of equipment and cleaning agents leaves a residual amount of detergent on the input disks resulting in disk breakage during sterilization. To reduce the potential for input disk breakage, please discontinue the use of the Getinge 88 Turbo Washer/Disinfector with Getinge Clean MIS for reprocessing *da Vinci Xi* instruments. Alternative reprocessing methods include the Manual Cleaning of Instruments (with Ultrasonic Bath) or another validated washer/ detergent per Reprocessing Manual for *da Vinci Xi* Instruments and Accessories. To ensure appropriate cleaning and sterilization, Intuitive Surgical encourages users to continue to follow the instructions for reprocessing and inspection of *da Vinci Xi* instruments provided in the User Manual.  **Figure 1: Broken input disk**
Risk to Health	The risk associated with this issue is a delay in the progress of surgery while the instrument is examined and replaced with a new one (As noted in the user manual it is advised to have a backup instrument available to complete the surgical procedure in case of instrument failure). This risk presents itself only if the input disk breaks during surgery. There have been no reported patient injuries or adverse health consequences as a result of this issue. Before use, all instruments should be inspected for damage or irregularities. The failure is able to be identified at three points during Endowrist Instruments interaction: 1. If the failure is identified during cleaning, the instrument should be returned to Intuitive Surgical via the standard RMA process.

2. If the failure is not identified during the cleaning process and the instrument is installed on the *da Vinci Xi* Surgical System, the instrument would fail engagement onto the Patient Cart instrument carriage; therefore, not allowing the user continue with the instrument
3. If the input disk breaks during the use of the EndoWrist Instrument, the surgeon will detect the instrument is not functioning properly, as the instrument would not follow the motions of the master controllers.

Affected Regions and Products

Affected Countries:

Australia, Austria, Belgium, China (Hong Kong), Cyprus, Czech Republic, France, Germany, India, Israel, Italy, Netherlands, Norway, Qatar, Romania, Saudi Arabia, Singapore, South Korea, Spain, Sweden, Switzerland, Turkey and United Kingdom.

Affected Product:

All EndoWrist instruments used with the *da Vinci Xi* Surgical System and covered by the following user manuals:

Document Language	IS4000 Reprocessing Instructions Appendices	IS4000 Cleaning Validations Summary QRG / IS4000 Automated Washer Disinfector Validations QRG
Czech	552286-01	553262-01
Dutch	552288-01	553265-01
English	551708-01	552898-01, 552628-01
French	552291-01	553267-01
German	552292-01	553268-01
Italian	552296-01	553269-01
Korean	552298-01	553270-01
Norwegian	552301-01	553271-01
Romanian	552304-01	553307-01
Spanish	552309-01	553273-01
Swedish	552310-01	553274-01
Traditional Chinese	552284-01	553263-01
Turkish	552311-01	553275-01

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, SPD/CSSD Manager, OR Director, Purchasing Manager, Biomedical Engineering staff and members of your medical staff who perform *da Vinci* Surgery procedures.

2. Discontinue the use of Getinge Turbo 88 Washer/Disinfector with Getinge Clean MIS detergent for reprocessing *da Vinci Xi* instruments.

3. Switch to an alternative reprocessing method such as Manual Cleaning of Instruments (with Ultrasonic Bath) or another validated washer/ detergent per Reprocessing

	Manual for *da Vinci Xi* instruments and Accessories. 4. If you have an instrument with a broken disk, please contact Customer Service to arrange for Return Material Authorization (RMA) to return your *da Vinci Xi* instrument. 5. **Complete and return the attached Acknowledgment Form** to Intuitive Surgical using the instructions provided. 6. Please retain a copy of this notice for your records and in your user manual.
Actions to be taken by Intuitive Surgical	Intuitive Surgical representatives will be available by phone to: 1. Create any Return Material Authorizations (RMAs) for instruments that exhibit a broken input disk. 2. Answer any questions related to this Medical Device Correction. In addition, Intuitive Surgical, will remove the reference to the use of Getinge 88 Turbo washer/disinfector with Getinge Clean MIS detergent from affected user manuals (listed above).
Further Information & Support	If you need further information or support concerning this issue, please contact your Clinical Sales Representative or contact ISI 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 of this notification.

Sincerely,

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

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ACKNOWLEDGEMENT FORM

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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 Correction 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:** _____

PLEASE FAX OR EMAIL THIS ACKNOWLEDGEMENT FORM TO Intuitive Surgical, Inc.
ATTN: REGULATORY COMPLIANCE
Subject line for email: Broken Input Disks
U.S. and Asia Fax +1 (408) 716-3040, or Scan and Email: isi.compliance@intusurg.com
Europe, Middle East, and Africa Email: EU.FSCA@intusurg.com

- 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