

URGENT: MEDICAL DEVICE CORRECTION

February 3, 2012

Subject: Possible passive uncontrolled motion by instrument arm on Patient Side Cart during power off state - *da Vinci*® S Surgical System (IS2000) and *da Vinci*® Si Surgical System (IS3000) and *Si-e* Surgical Systems (IS3000)

[HOSPITAL NAME for NET SUITE] Attn: [da VINCI COORDINATOR]
[HOSPITAL STREET ADDRESS]
[CITY] [STATE] [POSTAL CODE]
[COUNTRY]

Dear Customer:

This letter is to inform you of a medical device correction involving a component of the Intuitive Surgical® *da Vinci*® S Surgical System (IS2000) , *da Vinci*® Si Surgical System (IS3000) and *da Vinci*® *Si-e* Surgical Systems (IS3000).

Your affected system serial number is: [SYSTEM ID].

This medical device correction is being initiated based on observations made in our engineering facility related to the holding brake inside the three instrument arms on the Patient Side Cart. These brakes are automatically applied when there is no electrical power applied to the arms. These brakes are not required while the device is under electrical power. Under certain circumstances these brakes may allow passive uncontrolled motion due to gravity during power-off conditions as described below. **We have received no complaints, reportable incidents or reports of patient injury we could attribute to this issue.** This action is being taken proactively based on the results of our internal testing. The camera arm is not impacted by this brake issue.

The issue we have observed only arises when the system power is turned off during a procedure in order to restart the system. In our testing, we found that a small percentage of instrument arm holding brakes may not apply the required force to securely hold the instrument arm in a fixed position with an installed instrument when power is turned off during a procedure. This issue does not occur during normal operation when the system is in following mode because the brakes are not applied. This also does not occur during power failures while the Patient Side Cart is operating under internal battery backup. This brake force issue is only a concern under the following scenario:

- A non-recoverable fault occurs during a procedure and requires a system restart;
- An instrument is left installed on an instrument arm and inside the patient when the power is interrupted to restart the system; and
- The instrument arm is in certain unique positions where the combined weight of the arm and an instrument can exceed the brake's holding force.

"Taking surgery beyond the limits of the human hand."

URGENT: MEDICAL DEVICE CORRECTION

Although this scenario has only been observed in internal testing, and may occur on only a small fraction of all instrument arms, we are initiating the following actions for all sites:

1. We are revising the *da Vinci S* and *da Vinci Si* instructions for use and notifying customers that if a system restart is required during a procedure, **all instruments should be removed before the system restart is initiated.** After the restart is complete, the instruments can be reinstalled. If it is not clinically possible to remove an instrument, the instrument arm should be closely monitored during the restart to ensure that no motion occurs during the restart.

These new instructions will replace the current instructions for use in the *da Vinci S* and *da Vinci Si* user manuals:

da Vinci Si excerpt, updated, from page A-3

Restarting the System During a Procedure

If a non-recoverable fault occurs during a procedure, you must completely remove all instruments from the system. The endoscope does not need to be removed. Follow these steps to restart the system:



1. Completely remove all instruments from the system. The endoscope does not need to be removed.
2. Power off the system: Press the **Power** button on any system component.
The system takes several seconds to shut down. When complete, all system **Power** buttons will be lit amber, indicating standby mode, and readiness for restart.
3. Restart the system: Press the **Power** button on any system component.
4. After the system has restarted successfully, then the instruments can be reinserted.



Note: During system restart, video is temporarily unavailable at the Surgeon Console viewer and touchscreen monitor.



Note: If the fault cannot be cleared by a system restart, call *Intuitive Surgical* Technical Support.

da Vinci S excerpt, updated, from top of page A4

Restarting the System During a Procedure

If a non-recoverable fault occurs during a procedure, you must completely remove all instruments from the system. The endoscope does not need to be removed. Follow these steps to restart the system:

1. Completely remove all instruments from the system. The endoscope does not need to be removed.
2. Power off the system by pressing the POWER button on the right-side pod of the Surgeon Console.
3. Restart the system by pressing POWER on the right-side pod of the Surgeon Console.
4. Press HOME when the following message is displayed:

Prepare for homing. Instruments and camera will not move.
Press HOME when done.

5. After the system has homed successfully, then the instruments can be reinserted.
6. Select the appropriate scope angle and proceed with the case.



Note: During a system restart, video will be temporarily unavailable at the surgeon console viewer and touchscreen monitor.



Note: In the event where the fault cannot be cleared by a system restart, call ISI product support.

“Taking surgery beyond the limits of the human hand.”

URGENT: MEDICAL DEVICE CORRECTION

2. An Intuitive Surgical Field Engineer will be contacting your site to schedule an inspection of all instrument arm brakes to determine if an instrument arm brake is insufficient to prevent motion during power-off cycles. Instrument arms found to be outside of the required performance specification will be replaced with an arm that has been tested to ensure correct brake force is being applied.

Please inform and train your OR staff on the new instructions described above regarding the removal of instruments during a system restart during a procedure before further surgical procedures are performed using your *da Vinci* system.

We regret any inconvenience this may cause you. If you have any questions or concerns, please contact Intuitive Surgical Customer Service:

U.S: 1-800-876-1310

Outside U.S. : + 41 21 821 2020.

The Food and Drug Administration and other regulatory authorities are being made aware of this medical device correction.

Please complete and return the enclosed response form as soon as possible so we can be sure you have received this information.

Sincerely,



Richard Reeves
Vice President, Regulatory
1266 Kifer Road
Sunnyvale, CA 94086

Enclosure: Device Correction Response Form

"Taking surgery beyond the limits of the human hand."

URGENT: MEDICAL DEVICE CORRECTION

RESPONSE FORM

I have read and understand the information provided in Medical Device Correction letter from Intuitive Surgical dated February 3, 2012.

Please acknowledge receipt of this notice on or before February 17, 2012.

Name (print):

Signature:

Title:

Telephone number:

__ (____) _____

Customer Contact Name:

[HOSPITAL NAME for NET SUITE] Attn: [da VINCI COORDINATOR]
da Vinci Surgical System [SYSTEM ID]

Address:

[HOSPITAL STREET ADDRESS]
[CITY] [STATE] [POSTAL CODE]
[COUNTRY]

PLEASE FAX COMPLETED RESPONSE FORM TO 408-523- 1390
ATTN: REGULATORY COMPLIANCE

OR

EMAIL TO: ISI.Compliance@Intusurg.com

"Taking surgery beyond the limits of the human hand."