August 08, 2014

Field Safety Notice

Urgent Medical Device Correction – 2955842-06022014-004-C

Intuitive Surgical Battery Box of the da Vinci® S™, Si™ and Si-e™ Surgical Systems

Introduction and Reason for Field Action	Dear *da Vinci* Customer, This Field Safety Notice is to advise you that Intuitive Surgical is initiating a voluntary correction relating to the battery box contained in the Patient Side Cart of the ***da Vinci S, Si and Si-e*** Surgical Systems. The battery box provides a backup power source in case of power outage. Patient Side Cart battery boxes returned to Intuitive Surgical from the field have revealed that, in some rare charging conditions, the battery has been found to heat sufficiently to cause the battery case to bulge. A battery case that has bulged has the potential to release some of its internal gases to the surrounding air. The da Vinci S, Si and Si-e Surgical Systems are designed to detect overheating batteries and issue a system warning, Error Code 808 is displayed on the Surgeon Console and Patient Side Cart monitors. When this event is detected, the system disables the charging of the battery until it cools down.
Risk to Health	The gases that may be released from a bulging battery are mostly water vapor with trace amounts of hydrogen sulfide. The hydrogen sulfide creates a "rotten egg" or sulfur odor. For the patient and operating room staff, potential exposure to such low concentrations of hydrogen sulfide could cause irritation of the eyes, nose, and throat, with burning sensations or increased tearing of the eyes, coughing, or shortness of breath. In a scenario in which the decision is made to convert a procedure to an alternate surgical method due to Error Code 808, the patient is at a slightly higher risk of surgical complications because of the historically higher rate of complications in open surgery. Since March 2012, Intuitive Surgical has received a total of 26 complaints worldwide relating to Error Code 808 and the confirmed instance of the battery bulging of which: - Two (2) were reportable complaints (both outside of EU), due to a procedure outcome of convert to open and abort post anaesthesia respectively. - Twenty-four (24) non-reportable complaints (one in EU) related to either aborts before anaesthesia or sulfur odors emanating from the battery box. There have been no reports of long-term exposure to the gas, nor any report of patient or user injury. Currently, there is less than a 0.1% occurrence rate per procedure for Error Code 808, and less than a 0.03% occurrence rate per procedure for battery bulging detected in

	Failure Analysis.
Affected Countries and Products	**Affected Countries:** Argentina, Australia, Austria, Belgium, Brazil, Canada, Chile, China, Colombia, Czech Republic, Denmark, Egypt, Finland, France, Germany, Greece, India, Indonesia, Ireland, Israel, Italy, Japan, Kuwait, Lebanon, Malaysia, Mexico, Monaco, Netherlands, Norway, Pakistan, Philippines, Portugal, Puerto Rico, Qatar, Russian Federation, Romania, Saudi Arabia, Singapore, Slovakia, Slovenia, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, Turkey, United Kingdom, United States of America, Uruguay, Venezuela. **Affected Product**: All da Vinci S, Si and Si-e Patient Side Carts that contain battery box 371268-02, which was manufactured between 22 November 2005 and 09 July 2012.
Actions to be taken by the Customer/ User	**Please Take the Following Actions:** 1. Ensure all affected personnel are fully informed of this Notification. Forward this letter to Risk Manager, OR Director, Purchasing Manager, Biomedical Engineering staff and members of your medical staff who perform *da Vinci* surgery procedures. 2. You may continue to use your da Vinci S, Si and Si-e Patient Side Carts. However, if you receive an Error Code 808, or experience a sulfur odor while using your da Vinci® S, Si or Si-e Surgical System, please contact your Intuitive Surgical Representative, following the standard troubleshooting process. 3. Complete and return the attached Acknowledgement Form to Intuitive Surgical using the instructions provided. 4. Please retain a copy of this letter and the acknowledgement form for your files.
Actions to be taken by Intuitive Surgical	1. Intuitive Surgical representatives will be available by phone to answer questions related to this Medical Device Correction. 2. Since 2012 Intuitive Surgical has implemented changes for newly manufactured products to address the potential for batteries to overheat and bulge. For impacted product already in the field, Intuitive Surgical has been utilizing its standard repair and preventive maintenance programs to monitor battery performance and perform battery replacement as needed.
Further	If you need further information or support concerning this Correction Notice, please

Intuitive Surgical Part Number	Product Name
380430	*da Vinci S* System, Patient Side Cart
380614	*da Vinci Si* System, Patient Side Cart
380649	*da Vinci Si-e* System, Patient Side Cart

Information & Support	contact your Clinical Sales Representative or Intuitive Surgical Customer Service at the numbers listed below: • Europe: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm) or **ics@intusurg.com**

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

Sincerely,

Mark Johnson
Sr. Vice President, Regulatory Affairs and Quality

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1170 Aubonne, Switzerland

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ACKNOWLEDGEMENT FORM

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Hospital Name: <mail merge>
Address: <mail merge>
City, Postal Code: <mail merge>
Affected Systems: <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/Company Name: _____

Phone Number:_____

Email: _____

Date: _____

Position:

☐ **Robotics Coordinator**

☐ **Operating Room Director**

☐ **Risk Manager**

☐ **Recall Coordinator**

☐ **Other:** _____

PLEASE FAX THIS ACKNOWLEDGEMENT FORM TO Intuitive Surgical, Inc.
ATTN: REGULATORY COMPLIANCE
Subject line for email: Bulging Battery
U.S. Fax +1 (408) 716-3040, or Scan and Email: isi.compliance@intusurg.com

Customer Service:

- Europe: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm) or ics@intusurg.com