INTUITIVE SURGICAL®

URGENT: MEDICAL DEVICE CORRECTION

July 1, 2011

Gulf Medical: Assir Hospital Attn: Hazem Abdullah
Al-Youssifiah Building , Ali Bin Ab
Jeddah, # 21455
Saudi Arabia

Dear Customer:

This is to inform you of a medical device correction involving a component of your Intuitive Surgical® da Vinci® Si Surgical System (IS3000), **SH0565**. This field correction is being initiated due to failure of a retention component in the Master Tool Manipulator (MTM – commonly referred to as the "Master") spring counterbalance subsystem.

Intuitive Surgical recently received a report of a serious injury that occurred in Europe due to uncontrolled movement of the MTM when the surgeon released his grip on the handle of the MTM while his head was still in the stereo viewer and where the retention component had failed.

If the MTM is released while the surgeon's head is in the stereo viewer and in following mode, the MTM can move in an uncontrolled fashion. This can result in the associated surgical instrument contacting patient anatomy in an uncontrolled fashion.

Action To Be Taken
The surgeon should always assure that he/she does not release the grip of the masters while his/her head is in the stereo viewer. Please be reminded of the following excerpt from the product labeling:

WARNING: Once in following, the Surgeon Console operator must not remove his or her hands from the masters until removing his or her head from the Surgeon Console viewer—thereby taking the system out of following mode. Failure to do so may result in uncontrolled movement of the masters, resulting in serious harm to the patient.

Retrofit of Existing Systems
Intuitive Surgical has designed reinforcing caps for the retention component to correct the problem with the MTM subsystem. Please expect our customer support staff to contact you (without any further action by you) within the next two weeks to schedule a retrofit of this component.

Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, California 94086

Ph: 408.523.2100
Fax: 408.523.1390
www.intuitivesurgical.com

URGENT: MEDICAL DEVICE CORRECTION

In some cases, failure of the retention component can manifest in the sensation of increased weight or heaviness of the MTM when in following mode. This sensation may be more perceptible in the upper and lower regions of the MTM workspace.

If you have any questions, please contact Customer Service at 1-800-876-1310 or for Outside United States call + 41 21 821 2020.

The Food and Drug Administration is being made aware of this medical device correction.

Please complete and return the enclosed response form as soon as possible.

Sincerely,

William Nowlin, Ph.D.
Vice President, Product Quality
1266 Kifer Road
Sunnyvale, CA 94086

Enclosure: Device Correction Response Form

URGENT: MEDICAL DEVICE CORRECTION

RESPONSE FORM

I have read and understand the Medical Device Correction letter and information provided in the letter from Intuitive Surgical dated July 1, 2011. Please acknowledge receipt of this notice on or before July 20, 2011.

Name (print):

_____

Signature:

_____

Title:

_____

Telephone number:
__(____)_____

Customer Contact Name: Gulf Medical: Assir Hospital Attn: Hazem Abdullah, **SH0565**

Address: Al-Youssifiah Building , Ali Bin Ab Jeddah, # 21455

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

OR EMAIL TO: ISI.Compliance@Intusurg.com

Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, California 94086

Ph: 408.523.2100
Fax: 408.523.1390
www.intuitivesurgical.com