October 24, 2013

Urgent Medical Device Correction – 2955842-10/21/2013-010-C

Replacement of "Metal-finish" Lamp Modules on the da Vinci® Si™ (IS3000) System Illuminator

Introduction/ Summary of Action

Intuitive Surgical is voluntarily implementing an Urgent Medical Device Corrective Action regarding the *da Vinci* Si (IS3000) endoscopic illumination system ("illuminator"), which is part of the Vision Cart System (VCS). This correction only applies to IS3000 HD Lamp Modules with a metal-finish that may be installed in the illuminator. The illuminator has a single light source integrated into the VCS and attached to the endoscope assembly by the light guide cable. It provides illumination inside the body for vision of the surgical field.

Summary of actions to be taken by the customer:

- Open the illuminator and replace any metal-finish lamp modules with plastic-finish lamp modules
- If you do not have a replacement plastic-finish lamp module available, you may continue to use the metal-finish lamp module until you receive a replacement
- If the message "Illuminator lamp module error: Please reseat or replace lamp module" is displayed on the patient side monitor and the surgeon console, contact Intuitive Surgical Customer Service
- Examine any remaining or spare inventory to identify any metal-finish lamp modules and return them to Intuitive Surgical for credit
- Firefly™ (i.e. Fluorescence Imaging) illuminators are not affected because they do not use a lamp module

Affected Regions and Products

The following is a list of affected regions. Not all customers in a region are affected.

United States	France	Qatar
Australia	Germany	Romania
Austria	Great Britain	Russian Fed.
Belgium	India	Saudi Arabia
Brazil	Israel	Singapore
Bulgaria	Italy	South Korea
Canada	Mexico	Sweden
Chile	Monaco	Switzerland
China	Netherlands	Taiwan
Czech Republic	Norway	Turkey
Denmark	Pakistan	
Finland	Panama	

Affected Product:

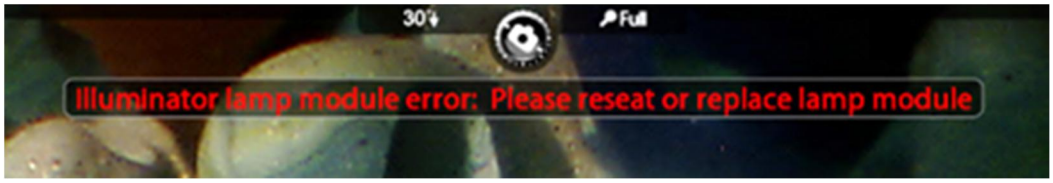
IS3000 HD Lamp Module – PN 950093-05

This field action affects 396 total customers (338 in the U.S. and 58 outside the U.S.).

Note: Firefly (i.e. Fluorescence Imaging) Illuminators are not affected by the lamp module.

Reason for the Voluntary Correction

1. Intuitive Surgical has identified that the metalized coating on the IS3000 HD Lamp Module (PN 950093-05) may be incompatible with the illuminator (PN 951183-06)

	control board, leading to a red Preventive Maintenance Advisory (PMA) that shows up on all monitors and cannot be dismissed by the user. This PMA is detected during the required pre-operative power on and set-up procedures. There is the rare occurrence that a -05 version metal-finish lamp module can damage an illuminator in such a way as to prevent the illuminator from communicating with lamp modules. This damage does not prevent the illuminator from properly controlling the light output of the lamp module; however, the damage is detected by the *da Vinci* Si Surgical System and the message "Illuminator lamp module error: Please reseat or replace lamp module" is displayed on both the patient side monitor and the surgeon console. This error does not affect the lighting of lamp module in the normal fashion, and there are no reports of lamp failure that have been associated with this issue. 2. There is a potential that, in very rare instances, the lamp module may not illuminate. This is a theoretical failure mode only in that there are no reports of lamp failure that have been associated with this issue. If this failure to illuminate were to occur, it would be detected upon system set-up prior to surgery.
Risk to Health	Risk associated with illuminator failures at power on and set-up is limited to non-use of the *da Vinci* Si Surgical System and such failures represent no direct risk to the patient or user. No adverse events or injuries have been reported as a result of a metal-finish lamp module being used in the illuminator. How to recognize that the illuminator has failed: • A message will appear on the patient side monitor and surgeon console view (Figure 1). ▪ "Illuminator lamp module error: Please reseat or replace lamp module" • The lamp module, in rare instances, may not turn on, which will prevent system use.  Figure 1. Error message
Actions to be taken by the Customer/ User	Please take the following actions: 1. Ensure all affected personnel are fully informed of this Urgent Medical Device Correction. Forward this letter to your Risk Manager, OR Director, Purchasing and Biomedical Engineering staff including members of your medical staff who perform *da Vinci* procedures. 2. **Complete the identification and replacement process outlined in Attachment A.** Contact your Intuitive Surgical Representative if you need assistance. 3. If you have an illuminator error message as shown in Figure 1, please contact Intuitive Surgical Customer Service. 4. **Complete the attached Acknowledgement Form** and return it to Intuitive Surgical as instructed. 5. Inform affected personnel when the correction has been completed. 6. Please retain a copy of this letter and the acknowledgement form for your files.
Product and Distribution Information	See **Attachment A** for information on how to identify which version of lamp module you have. **A total of 684 affected IS3000 HD Lamp Modules were distributed to 396 customers between**

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	February 4, 2012 and August 30, 2012. Distribution methods included the following: 1) Shipped as an individual lamp module (PN 950093-05), separate from the illuminator 2) Shipped in Vision Starter Kits (PN 380565-02 Rev B.) for new systems WITHOUT an illuminator 3) Shipped built into Vision Carts WITH an illuminator (PN 951183-06)
Action Taken by Intuitive Surgical	Intuitive Surgical will perform the following actions as part of this correction: • Help to assist customers to replace affected IS3000 HD Lamp Modules, PN 950093-05 ("metal-finish" lamp modules) with plastic-finish lamp modules, PN 950093-04 • Remove affected IS3000 HD Lamp Modules, PN 950093-05 ("metal-finish" lamp modules), from the field • Replace damaged illuminator, if any.
Further Information & Support	If you need further information or support concerning this issue, please contact your Intuitive Surgical 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) • Japan: 0120-56-5635 or 003-5575-1362 (9 a.m. to 6 p.m. 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)

The appropriate Regulatory Authority for your region has been notified of this correction.

Sincerely,

Richard Reeves
Vice President, Regulatory Affairs
Intuitive Surgical, Inc.
1266 Kifer Road, Building 101
Sunnyvale, CA 94086-5304

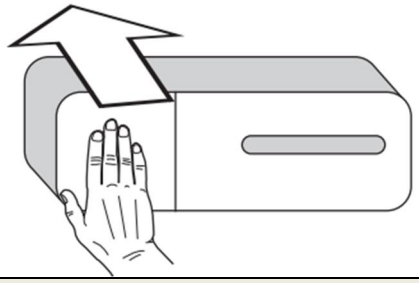
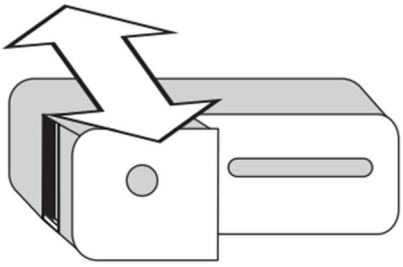
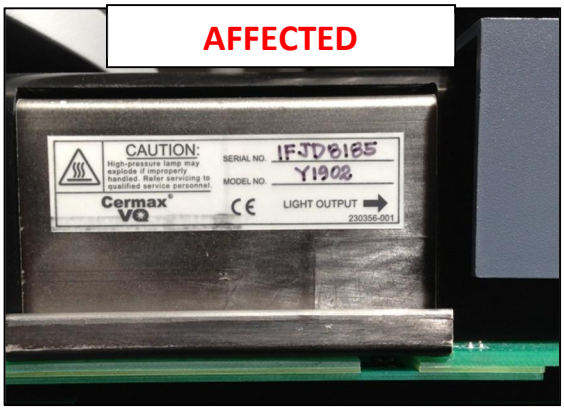
European Office
Intuitive Surgical, Sàrl
1 Chemin des Mûriers
1170 Aubonne, Switzerland

Attachment A

Lamp Module Identification and Replacement Process

Refer to the Cleaning and Maintenance section of the *da Vinci* Si User Manual for removal and replacement of the lamp module.

Lamp Module Identification:

<table>
<tr><th colspan="2">To access the IS3000 HD Lamp Module:</th></tr>
<tr><td>1. Unplug the light guide cable and press on the lamp module panel
  </td><td>2. The panel will release, allowing access to the lamp module
  </td></tr>
<tr><th colspan="2">IS3000 HD Lamp Module Installed in the IS3000 HD Illuminator</th></tr>
<tr><td>Lamp module with a plastic finish
NOT AFFECTED
  </td><td>Lamp module with a metal finish
AFFECTED
  </td></tr>
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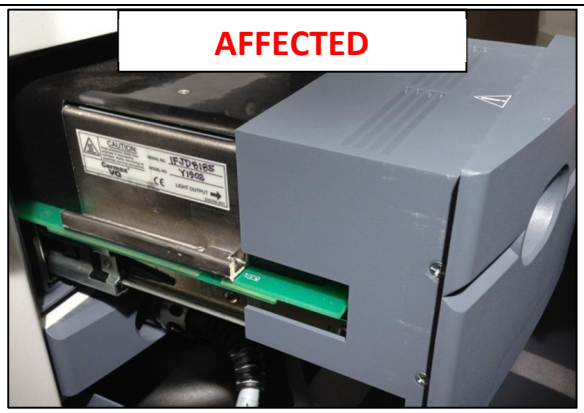
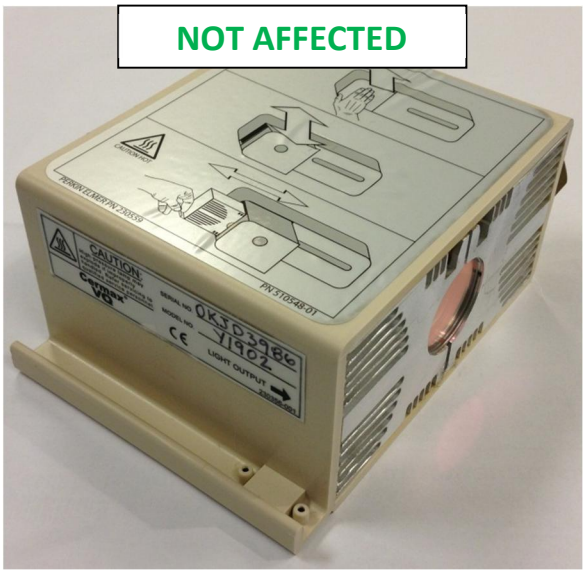
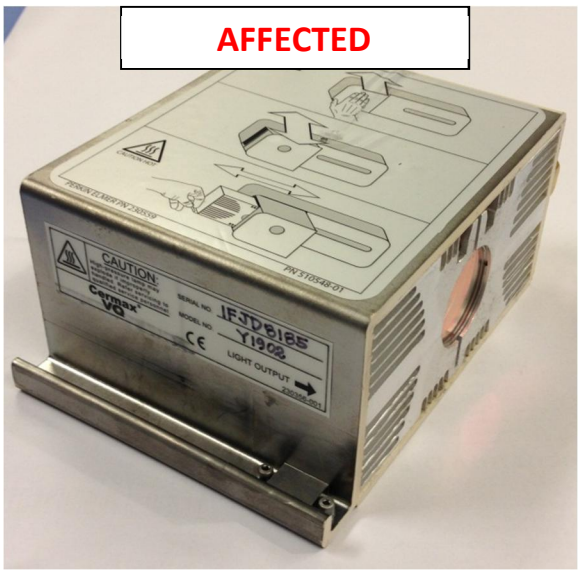


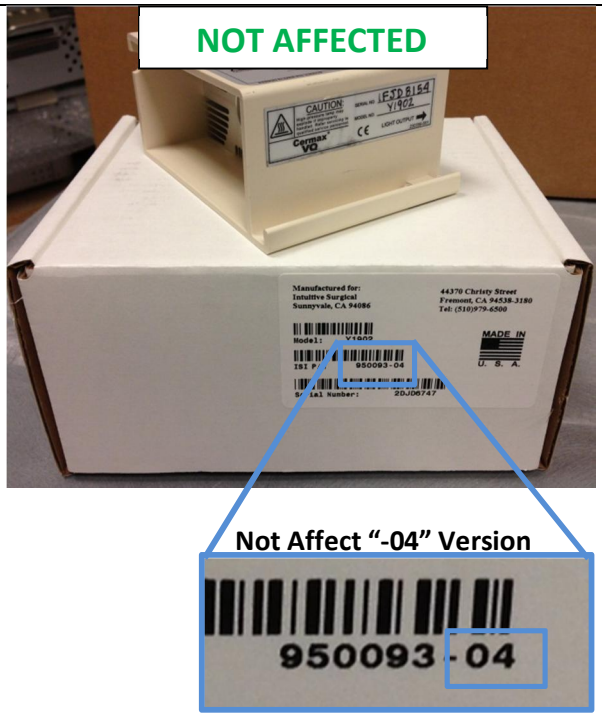
IS3000 HD Lamp Modules Not installed in the IS3000 HD Illuminator

Lamp module with a **plastic finish**



Lamp module with a **metal finish**




NOT AFFECTED
Not Affect "-04" Version
950093-04


AFFECTED
Affected "-05" Version
950093-05

Replacement Process

Identify whether you are in possession of the affected IS3000 HD Lamp Module:

- Examine the lamp module installed in the illuminator
- Examine your inventory of spare lamp modules

Step	IS3000 HD Lamp Module installed in IS3000 HD Illuminator
1.	**Metal finish**  Remove the installed metal-finish lamp module and install a plastic-finish lamp module. If you need to order the plastic-finish replacement lamp module, go to Step 2.
	Plastic finish  Continue to use the plastic-finish lamp module.
	Firefly (Fluorescence) Illuminator  Continue to Step 3.
2.	If needed, contact Intuitive Surgical Customer Service to order replacement (plastic-finish) lamp module(s). You may want to consider maintaining a replacement spare lamp module in your inventory.
3.	Return all metal-finish lamp module(s) in your possession via the Return Material Authorization (RMA) process to receive credit.
4.	Complete the Acknowledgment Form and return it to Intuitive Surgical as instructed.

INTUITIVE SURGICAL®

October 24, 2013

ACKNOWLEDGEMENT FORM

Urgent Medical Device Correction – 2955842-10/21/2013-010-C

Replacement of "Metal-finish" Lamp Modules on the da Vinci® Si™ (IS3000) System Illuminator

PLEASE COMPLETE ALL REQUESTED INFORMATION AND RETURN IMMEDIATELY

ATTENTION: da Vinci Robotics Coordinator, Risk Manager, Biomedical Engineers:

Select and check one option below:

☐ I have received and read the attached Urgent Medical Device Correction regarding the lamp module. I have examined our inventory; I **have** the affected product (metal-finish lamp modules) and will follow the replacement process outlined in Attachment A.

☐ I have received and read the attached Urgent Medical Device Correction regarding the lamp module. I have examined our inventory of lamp modules and I **do not have** any affected product.

I acknowledge that I have informed all necessary parties at my facility of this Urgent Medical Device Correction.

Hospital Name: _____

City & State: _____

Name (print): _____

Signature: _____

Phone Number: _____

Date: _____

Position:

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

Customer Service:

- North and South America: 800-876-1310 Option 3 (6 am to 5 pm PST)
- Japan: 0120-56-5635 or 003-5575-1362 (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)

PLEASE FAX THIS ACKNOWLEDGEMENT FORM TO
Intuitive Surgical, Inc.
ATTN: REGULATORY COMPLIANCE
U.S. (408) 716-3040, or Scan and Email: isi.compliance@intusurg.com