April 4, 2017

Field Safety Notice

Urgent Medical Device Recall – ISIFA2017-03-R

da Vinci® Si and da Vinci Xi Vessel Sealer Expiration Date Discrepancy

1- Introduction and Reason for Field Action

Dear *da Vinci* Customer,

Intuitive Surgical is initiating a voluntary recall related to specific *da Vinci Si*® and *da Vinci Xi*® Vessel Sealer Instruments.

Intuitive Surgical has become aware that specific lots of the *da Vinci Si* and the *da Vinci Xi* Vessel Sealer Instruments may have an incorrect expiration date on the inner tray and carton of the packaging. This is an issue with the packaging label only, only the inner tray and inner carton are prone to the incorrect expiration date.

The short-dated product expiration dates on the product packaging do not have an impact on the functionality or sterility of the instrument.

Affected Product	Incorrect Label Date	Correct Label Date
da Vinci Si Vessel Sealer	**2016**-10-31	**2018**-10-31
da Vinci Xi Vessel Sealer	**2016**-11-30	**2018**-11-30

2- Risk to Health

There is no impact to the sterility or health risk to a patient. This is a label issue only.
The *da Vinci Si* and *da Vinci Xi* Vessel Sealers instruments are working as intended.

3- Affected Countries and Products

Affected Countries:
United States

Affected Product:

Affected Part Names	Affected Part Numbers	Affected Lots
da Vinci Si Vessel Sealer	410322-05	M10161003
da Vinci Xi Vessel Sealer	480322-07	M10161129

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4- Actions to be taken by the Customer/ User	Please take the following actions to ensure all affected personnel are fully informed of this Notification. Forward this letter to your Risk Manager, OR Director, Purchasing, Biomedical Engineering staff, and other members of your medical staff who perform *da Vinci* procedures. 1. If you have the affected lots, regardless of the expiration date listed above, please return the affected devices per the standard RMA process. Credit will be provided for the return of any unused and affected instruments. 2. Inform affected personnel when the device removal has been completed. 3. Please log into the *da Vinci* Online Community Field Action resource to read or complete any requested actions related to this issue. a. https://www.davincisurgerycommunity.com/ 4. In the case where the *da Vinci* online resource cannot be used, complete the attached Acknowledgement Form and return it via fax to Intuitive Surgical as instructed on the form. 5. Please retain a copy of this letter and the acknowledgement form for your files.
5- Action taken by Intuitive Surgical	1. A copy of this letter will be provided to customers who have instruments from the affected lots. 2. Intuitive Surgical representatives will be available by phone to answer any questions related to this Medical Device Recall.
6- Further Information & Support	If you need further information or support concerning this issue, please contact your Clinical Sales Representative or contact Intuitive Surgical Customer Service at the numbers listed below: • North America: 800-876-1310 Option 3 (4 am to 5 pm PST)

Sincerely,

Intuitive Surgical, Inc.
950 Kifer Road
Sunnyvale, CA 94086-5304 USA
800-876-1310

April 4, 2017

ACKNOWLEDGEMENT FORM

Urgent Medical Device Recall – ISIFA2017-03-R

da Vinci Si and da Vinci Xi Vessel Sealer Expiration Date Discrepancy

Ship-to
Hospital Name:
Address:
City, State, Zip:
SFID:
ATTENTION Robotics Coordinator:

PLEASE COMPLETE ALL REQUESTED INFORMATION AND RETURN IMMEDIATELY

I have received and read the attached Field Safety Notice- Urgent Medical Device Recall regarding the *da Vinci Si* and *da Vinci Xi* Vessel Sealer Expiration Date Label Discrepancy. I have completed all the actions to be taken by the customer/user as listed on the customer letter.

I acknowledge that I have informed all necessary parties at my facility of this Field Safety Notification. I will contact Intuitive Surgical if I have any questions.

Hospital name: _____

Name (print): _____

Signature: _____

Phone Number: _____

Date: _____

Position:

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

Customer Service:

- North America: 800-876-1310 Option 3 (4 am to 5 pm PST)

PLEASE FAX THIS ACKNOWLEDGEMENT FORM TO
Intuitive Surgical, Inc.
ATTN: POST MARKET FIELD ACTIONS
Subject line for email: VS Expiration Date
U.S. Fax +1 (408) 523-0619, or scan and email to ISI.compliance@intusurg.com