INTUITIVE

January 16, 2019

Field Safety Notice

Urgent Medical Device Recall – ISIFA2018-21-R

da Vinci® S/Si Harmonic Ace Insert Sterility

1- Introduction and Reason for Field Action	Dear *da Vinci* Customer, *Cc: Chairman Medical Board and relevant Head of Departments* This letter serves as formal communication to the Urgent Product Safety Notice sent on December 19, 2018 to advise you that Intuitive is initiating a voluntary recall of the da Vinci S/Si Harmonic ACE Insert and immediate stop use. During an internal inspection, Intuitive found that the sterile packaging of the da Vinci S/Si Harmonic ACE Inserts may become damaged during transit. The potential damage includes pinholes and /or small openings (less than a few millimeters) on the pouch leading to a potential breach in sterility. Please consult with your Intuitive Clinical Sales Representative to determine which alternative da Vinci instruments may offer suitable features. Please note that this communication is only for the da Vinci S/Si Harmonic ACE Insert and does not affect any other instrument including X/Xi Harmonic ACE instruments.
2 - Risk to Health	There have been no reported adverse events related to this issue. Health risk for any potential breach in sterility includes risk of infection. Specifically, patients who are severely immunocompromised would be most at risk for infections that would require medical treatment. Patients with normal immune systems would have a remote possibility of an infection.
3- Affected Products	<table><tr><th>Part Number</th><th>Product Name</th><th>Affected Lot Number</th></tr><tr><td>400272-02</td><td>da Vinci S/Si Harmonic Ace Insert</td><td>All Lots</td></tr></table>
4- Actions to be taken by the Customer/User	**Please take the following Actions:** 1. Stop use and return all da Vinci S/Si Harmonic ACE Inserts to Intuitive. 2. Additionally, 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. 3. Inform affected personnel when the return has been completed. Note: Replacement product will be provided once available. 4. If available, please log into the *da Vinci* Online Community Field Action resource to read or complete any requested actions related to this issue, at this link: https://www.davincisurgerycommunity.com/ 5. In the case where the *da Vinci* online resource cannot be used, complete the attached Acknowledgement Form and return it via fax to Intuitive as instructed on the form. 6. Please retain a copy of this letter and the acknowledgement form for your files.

5- Actions to be taken by Intuitive Surgical	1. Intuitive representatives will be available by phone to answer any questions related to this Medical Device Recall and advise on alternatives where appropriate. 2. Credit will be provided for all returned affected product, and replacements will be provided to customers once product is available.
6- Further Information & Support	If you need further information or support concerning this Medical Device Recall, 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) or mail: customerservice@intusurg.com. • Europe, Middle East, Asia, Africa and South America: +800 0821 2020 or +41 21 821 2020 (8 AM to 6 PM CET) or ics@intusurg.com • South Korea: 02-3271-3200 (9 AM to 6 PM KSTJ) • Japan: 0120-56-5635 or 03-5575-1362 (9 AM to 6 PM JST)

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

Sincerely,

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

INTUITIVE

January 16, 2019

ACKNOWLEDGMENT FORM

Field Safety Notice

Urgent Medical Device Recall – ISIFA2018-21-R

da Vinci® S/Si Harmonic Ace Insert Sterility

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

PLEASE COMPLETE ALL REQUESTED INFORMATION AND RETURN IMMEDIATELY

1. I have received and read this notice.
2. I have returned all da Vinci S/Si Harmonic Ace Inserts with the affected part number and lots to Intuitive Surgical.
3. I have ensured all appropriate personnel are fully informed of the contents of this notice.
4. I will contact Intuitive Surgical if I have any questions.

Hospital name: _____

Name (print): _____

Signature: _____

Phone Number: _____

Email: _____

Date: _____

Position:

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

PLEASE FAX OR EMAIL THIS ACKNOWLEDGEMENT FORM TO Intuitive Surgical, Inc.
ATTN: REGULATORY POST MARKET FIELD ACTIONS
Subject line for email: HARMONIC ACE STERILITY
U.S. Fax +1(408) 523-0619, or Scan and Email: Recalls@intusurg.com or EU.fsca@intusurg.com

Customer Service:

- North America: 800-876-1310 Option 3 (4 am to 5 pm PST)
- Japan: 0120-56-5635 or 03-5575-1362 (9 am to 6 pm JST)
- South Korea: 02-3271-3200 (9 am to 6 pm KSTJ)
- Europe, Middle East, Asia, Africa and South America: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm CET)