



## Field Safety Notice

### Urgent Medical Device Correction – ISIFA2018-07-C

*da Vinci® Xi/X Erbe Footswitch User Manual*

<b>1- Introduction and Reason for Field Action</b>	<p>Dear <i>da Vinci</i> Customer,</p> <p><i>Cc: Chairman Medical Board and relevant Head of Departments</i></p> <p>The purpose of this letter is to inform you that Intuitive Surgical, Inc. (ISI) is initiating a voluntary correction related to the <i>da Vinci Xi/X Erbe Footswitch User Manual</i>. Intuitive Surgical has learned that the user manual for the Erbe Footswitch contained within the Vision Cart was not provided when the system was installed. Therefore, ISI will be sending an Erbe Footswitch user manual to each <i>da Vinci Xi/X</i> customer in order to correct this issue.</p>
<b>2- Risk to Health</b>	<p>As the information within the missing Erbe Footswitch User Manual is already contained within the <i>da Vinci</i> manuals provided and is within the provisions of standard hospital practice, patient safety risk is low.</p>
<b>3- Actions to be taken by the Customer/User</b>	<p><b><u>Please take the following Actions:</u></b></p> <ol style="list-style-type: none"> <li>1. Once the Erbe Footswitch User Manual has been received, please store it with the <i>da Vinci Xi/X System User Manual</i>.</li> <li>2. Inform affected personnel when the Erbe Footswitch User Manual has been received.</li> <li>3. Please log into the <i>da Vinci</i> Online Community Field Action resource to read or complete any requested actions related to this issue, at this link: <a href="https://www.davincisurgerycommunity.com/">https://www.davincisurgerycommunity.com/</a></li> <li>4. In the case where the <i>da Vinci</i> online resource cannot be used, complete the attached Acknowledgement Form and return it via email or fax to Intuitive Surgical as instructed on the form.</li> <li>5. Please retain a copy of this letter and the acknowledgement form for your files.</li> </ol>
<b>4- Further Information &amp; Support</b>	<p>If you need further information or support concerning this Medical Device Notification, please contact your Clinical Sales Representative or contact Intuitive Surgical Customer Service at the numbers listed below:</p> <ul style="list-style-type: none"> <li>• North and South America: (800) 876-1310, Option 3 (4 AM to 5 PM PST) or mail: <a href="mailto:customerservice@intusurg.com">customerservice@intusurg.com</a>.</li> <li>• Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 AM to 6 PM CET) or <a href="mailto:ics@intusurg.com">ics@intusurg.com</a></li> <li>• South Korea: 02-3271-3200 (9 AM to 6 PM KSTJ)</li> <li>• Japan: 0120-56-5635 or 03-5575-1362 (9 AM to 6 PM JST)</li> </ul>

Sincerely,

**Intuitive Surgical, Inc.**

950 Kifer Road

Sunnyvale, CA 94086-5304 USA

800-876-1310

555095-01 Rev A

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## ACKNOWLEDGMENT FORM

### Field Safety Notice

### **Urgent Medical Device Correction – ISIFA2018-07-C**

*da Vinci Xi/X Erbe Footswitch User Manuals*

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 ensured all appropriate personnel are fully informed of the contents of this notice.
3. I will contact Intuitive Surgical if I have any questions.

Hospital name: \_\_\_\_\_

Position:

Name (print): \_\_\_\_\_

☐ Robotics Coordinator

☐ Operating Room Director

Signature: \_\_\_\_\_

☐ Risk Manager

☐ Surgeon

Phone Number: \_\_\_\_\_

☐ Other: \_\_\_\_\_

Email: \_\_\_\_\_

Date: \_\_\_\_\_

**PLEASE FAX OR EMAIL THIS ACKNOWLEDGEMENT FORM TO Intuitive Surgical, Inc.**

**ATTN: REGULATORY POST MARKET FIELD ACTIONS**

**Subject line for email: ERBE USER MANUAL**

**U.S. Fax +1(408) 523-0619, or Scan and Email: [Recalls@intusurg.com](mailto:Recalls@intusurg.com) or [EU.fsca@intusurg.com](mailto:EU.fsca@intusurg.com)**

#### Customer Service:

- North and South 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 and Africa: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm CET)