23.02.2015

# Field Safety Notice

## Urgent Medical Device Correction - 2955842-01-26-2015-002-C

*Intuitive Surgical EndoWrist® One Vessel Sealer, insufficient energy delivery to thin vascular tissue used with both da Vinci Si™ and Xi™ Models*

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| **Introduction and Reason For Field Action** | Dear *da Vinci* Customer,<br><br>The purpose of this letter is to advise you that Intuitive Surgical, Inc. (ISI) is voluntarily taking corrective action for the ***da Vinci* Si *EndoWrist®* One Vessel Sealer** and ***da Vinci* Xi *EndoWrist®* Vessel Sealer**. The potential for insufficient energy delivery has been identified on a small population of Vessel Sealers only when used on thin, vascular tissue. This letter outlines the issue as well as the details to support continued safe use of the Vessel Sealer.<br><br>The Vessel Sealer is a single-use disposable instrument used for sealing and transecting vessels and tissue bundles up to 7mm. Intuitive Surgical has identified the potential for a certain, small portion of Vessel Sealers to exhibit interference in the proximal end (near the joint) of the instrument grips. This interference is due to manufacturing variability in some jaws. The interference can lead to contact between the instrument electrodes at the back of the jaws and subsequent shorting of the electrosurgical energy. The shorting behavior can lead to extended activation times and insufficient energy delivery to thin, vascular tissue bundles, leading to bleeding if transected. There has been no impact identified to sealing performance on larger vessels or tissue bundles.<br><br>There have been no patient injuries reported to ISI related to this issue. |
| **Risk to Health** | Scenarios in which the jaw interference can produce incomplete seals are limited to thin tissues (<2mm). If the surgeon cuts after an inadequate seal, it is anticipated that this could cause either oozing or free bleeding of the transected vessels. The bleeding is likely to be immediately observed and locally controllable. Users can attain hemostasis by reapplying the Vessel Sealer as a bipolar instrument or with a secondary electrocautery instrument. In some conditions where the vessels are short and therefore hard to grasp, such as with short gastric vessels, control of bleeding may be difficult and may result in further organ injury, such as a splenic laceration.<br><br>Extended free bleeding of small vessels may lead to significant patient blood loss, potentially leading to hypotension, and/or requiring transfusion. Conversion to open surgery to control bleeding may be necessary. However, this issue has not been shown to impact sealing of large vessels which would carry a greater risk of significant blood loss.<br><br>There have been complaints of insufficient energy delivery and extended sealing times at a rate of 0.4% in all Vessel Sealer procedures completed with the affected instruments. Since thin tissue, such as mesentery and short gastric vessels, are specific to general surgery, the complaint rate for general surgery was assessed independently at 0.9% of all general surgery procedures and 1.5% specifically in foregut procedures. |

**Affected Regions and Products**

The following is a list of affected part numbers:

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| 410322-05 | Vessel Sealer (da Vinci Si) |
| 480322-04 | Vessel Sealer (da Vinci Xi) |

**Affected Countries:**
Australia, Belgium, China, Cyprus, Denmark, Ecuador, Finland, France, Germany, Italy, Netherlands, Norway, Puerto Rico, Saudi Arabia, South Korea, Spain, Sweden, Switzerland, Turkey, United Kingdom, United States of America

**Affected product:** Only lots manufactured between 30 July 2014 and 1 December 2014 of the following da Vinci Si and Xi vessel sealer part numbers are affected:

**410322-05 *EndoWrist® One Vessel Sealer* for *da Vinci Si™***

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|---|---|---|---|---|---|
| M10140807 | M10140926 | M10141028 | M10141119 | M11140917 | M11141119 |
| M10140812 | M10141001 | M10141029 | M10141125 | M11140922 | M11141125 |
| M10140814 | M10141004 | M10141031 | M10141126 | M11140926 | M11141126 |
| M10140818 | M10141006 | M10141104 | M10141128 | M11141001 | M11141201 |
| M10140826 | M10141009 | M10141105 | M10141201 | M11141004 | |
| M10140828 | M10141015 | M10141107 | M11140808 | M11141006 | |
| M10140902 | M10141020 | M10141111 | M11140818 | M11141009 | |
| M10140905 | M10141022 | M10141113 | M11140826 | M11141015 | |
| M10140917 | M10141023 | M10141114 | M11140828 | M11141020 | |
| M10140922 | M10141024 | M10141117 | M11140904 | M11141024 | |

**480322-04 *EndoWrist® Vessel Sealer* for *da Vinci Xi™***

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|---|---|---|---|
| S10140730 | S10140904 | S10141007 | S10141103 |
| S10140805 | S10140912 | S10141009 | S10141111 |
| S10140814 | S10140916 | S10141015 | S10141118 |
| S10140824 | S10140923 | S10141020 | S10141125 |
| S10140827 | S10141001 | S10141028 | |

**Actions to be taken by the Customer/ User**

Please take the following actions to ensure all affected personnel are fully informed of this Notification.

1. Forward this letter to any members of your medical staff who perform *da Vinci* procedures in addition to your Risk Manager, OR Director, Purchasing and Biomedical Engineering staff.
2. This field correction does not require you to quarantine or return the affected devices. Vessel Sealers can continue to be used safely by adhering to the following guidelines as provided in the Vessel Sealer User Manual:
    a. Only procedures that incorporate sealing and transection of thin tissue bundles and small diameter vessels are affected by this issue. Prior to the procedure, determine whether this issue may be a factor and choose whether

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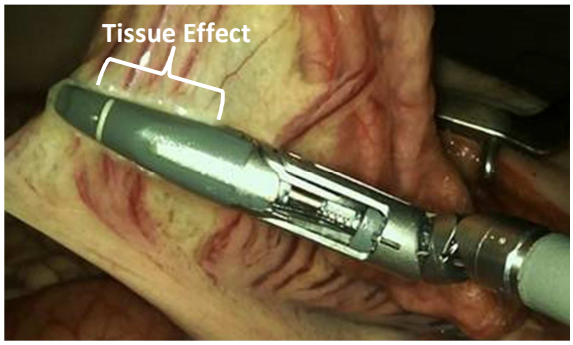
| | or not to use the device per the following instructions. Alternative methods of sealing and transection are described below.<br>b. During sealing, <u>always</u> inspect tissue for energy effect (i.e. blanching, steam, bubbling) along the entire jaw of the instrument. While audio tones designate seal cycle completion, tissue effect should always be seen prior to proceeding to cut.<br>  <br><br>c. If no tissue effect is seen, then DO NOT CUT. Re-grasp tissue and re-attempt sealing as described above.<br>d. If the issue persists, the instrument may be affected and an alternative means of sealing and transecting thin vascular tissue bundles should be used. These other methods include using another *da Vinci* Vessel Sealer, alternative da *Vinci* electrosurgical instruments, a *da Vinci* Harmonic instrument or hand-held laparoscopic sealing device.<br>3. Complete the attached Acknowledgement Form and return it to Intuitive Surgical as instructed.<br>4. Please retain a copy of this letter and the Acknowledgement Form for your files.<br>5. If you choose to not continue to use affected Vessel Sealer instruments, you may return them to Intuitive Surgical for full credit<br>a. Confirm that your vessel sealers are part of the affected lots<br>b. Contact Customer Service to initiate the standard Return Material Authorization (RMA) process by phone or email:<br>i. North and South America: (800) 876-1310 Option 3 (6 AM to 5 PM PST) or mail: customersupport-servicesupport@intusurg.com<br>ii. Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm CET) or ics@intusurg.com. |
| **Action taken by ISI** | Intuitive Surgical representatives will be available by phone to:<br>1. Create any Return Material Authorizations (RMAs) for affected product.<br>2. Issue credit for affected product.<br>3. Answer any questions related to this Medical Device Correction. |
| **Further Information & Support** | If you need further information or support concerning this issue, please contact your Clinical Sales Representative or contact ISI Customer Service at the numbers listed below:<br>• North and South America: 800-876-1310 Option 3 (6 am to 5pm PST) |

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| | • Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm CET) or ics@intusurg.com. |

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

Sincerely,

**Intuitive Surgical Sàrl**
Chemin des Mûriers 1
1170 Aubonne, Switzerland
+41 21 821 2020

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# ACKNOWLEDGEMENT FORM
## Field Safety Notice
## Urgent Medical Device Correction - 2955842-01-26-2015-002-C

*Intuitive Surgical EndoWrist® One Vessel Sealer, insufficient energy delivery to thin vascular tissue used with both da Vinci Si™ and Xi™ Models*

*Hospital Name*: <mail merge>
*Address*: <mail merge>
*City, Zip*: <mail merge>
*NSID:* <mail merge>
*ATTENTION*: <mail merge>

1. I have received and read this Correction 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.

**Name (print):**_____

**Signature:** _____

**Hospital Name:** _____

**Phone Number:**_____

**Email:** _____

**Date:** _____

**Position:**

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

**PLEASE FAX THIS ACKNOWLEDGEMENT FORM TO**
**Intuitive Surgical, Inc.**
**ATTN: REGULATORY Compliance**
**Subject line for email: Vessel Sealer Insufficient Energy Delivery**
**U.S. Fax +1 (408) 716-3040, or Scan and Email: isi.compliance@intusurg.com**

**Customer Service:**

- North and South America: 800-876-1310 Option 3 (6 am to 5 pm PST)
- Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm CET) or ics@intusurg.com