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March 3, 2022

New Field Safety Notice

Urgent Medical Device Correction– Potential for Insufficient Sealing with da Vinci X/Xi Vessel Sealer Extend (PN 480422) and SynchroSeal (PN 480440) Instruments (ISIFA2022-01-C)

1- Introduction and Reason for Field Action	Dear Intuitive Customer, This Field Safety Notice is to notify you that Intuitive has become aware that placing excessive tissue in the instrument jaws of the Vessel Sealer Extend or SynchroSeal instruments prior to sealing and transection can result in an insufficient seal resulting in either immediate or delayed bleeding. In addition to other factors, radio-frequency (RF) vessel sealing requires both adequate compression of and energy delivery to the intended target vessel to ensure reliable fusion of the vessel walls. Compression and/or energy delivery can potentially be affected by excessive tissue between the jaws, and the risk may be increased when a critical vessel is involved. To help mitigate the risk, please: 1) Ensure any critical vessels are within the boundaries of the electrode and sufficiently compressed and minimize tension. 2) Minimize tissue bundle size. 3) Skeletonize vessels (e.g. where vessel wall is visible) whenever possible. 4) Only transect tissue when both seal cycle completion tones are heard and adequate tissue effect is observed. Failure to follow these steps may lead to an insufficient seal resulting in either immediate or delayed bleeding. In addition, please **continue to adhere** to all **existing warnings and cautions** found in the Vessel Sealer Extend Instruments and Accessories User Manual Addendum and SynchroSeal User Manual. We are currently updating our user documentation with appropriate revisions to existing warnings/cautions.

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2 - Risk to Health	From March 1, 2017 through January 12, 2022, a total of 42 Vessel Sealer Extend Adverse Events*/Serious Incidents** have been reported due to insufficient vessel sealing with harms ranging from patient extended hospitalization to death. This represents a rate of 0.0058% (out of 723,340 procedures). From October 1, 2019 through September 30, 2021, Intuitive received 3 reports of Adverse Event*/Serious Incidents** due to insufficient vessel sealing relating to SynchroSeal, representing a rate of 0.0164% (out of 18,316 procedures). If insufficient sealing occurs, it is possible that the patient could experience bleeding from the targeted tissue. Halting the sealing cycle prior to completion of the cycle (indicated by audio tones from the generator) may cause insufficient sealing to occur. Severity of harm following an insufficient seal would vary dependent on the timing and detection of bleeding. If the bleed occurred during the procedure, harms may range from minimal or no intervention (bleed is self-resolved) up to a conversion to open surgery if bleeding cannot be resolved in a minimally invasive manner. If the bleed occurred postoperatively, harms may range from extended hospitalization up to patient death if the bleed goes undetected. Additionally, failure to follow the warnings and cautions may also cause insufficient sealing to occur such as halting the sealing cycle prior to completion of the cycle (indicated by audio tones from the generator) may cause insufficient sealing to occur.
3- Affected Products	See table below
4- Actions to be taken by the Customer/User	Place this customer communication with your da Vinci X/Xi User Manual. In addition, 1. Read and understand the contents of the letter. 2. Notify all surgeons and personnel using the da Vinci X/Xi Surgical System that they should reacquaint themselves by a. Reading the instructions, warnings, and cautions provided in • Vessel Sealer Extend Instruments and Accessories User Manual Addendum and • SynchroSeal User Manual b. Contacting their da Vinci Sales Representatives for clarification of queries. 3. Complete the attached Acknowledgement Form immediately and return it via fax or email to Intuitive as instructed on the form. 4. Please retain a copy of this letter and the acknowledgement form for your files. 5. Please inform Intuitive of any adverse events/serious incidents or quality problems concerning the use of the subject devices via the standard complaint process. 6. Additionally, if adverse events/serious incidents or quality problems are experienced, please follow your standard reporting process to your health authority, if applicable.

Part Number	Product Name	Lot Number	Unique Device Identifier (UDI)
480422	Vessel Sealer Extend	All lots	00886874115664
480440	SynchroSeal	All lots	00886874117309

	You may continue the use of Vessel Sealer Extend and SynchroSeal instruments by following instructions provided in Section 1 of this notice and warnings and cautions listed in the Vessel Sealer Extend Instruments and Accessories User Manual Addendum and SynchroSeal User Manual.
5- Actions to be taken by Intuitive Surgical	Intuitive will follow up with updated user documentation once available.
6- Further Information & Support	If you need further information or support concerning this Medical Device Correction, please contact your Clinical Sales Representative or contact Intuitive Customer Service at the numbers listed below: • US, Puerto Rico and Dominican Republic (800) 876-1310, Option 3 (4 AM to 5 PM PST) or mail: customerservice@intusurg.com • Europe, Middle East, Asia, South America and Africa: +800 0821 2020 or +41 21 821 2020 (8 AM to 6 PM CET) or EUCS@intusurg.com • South Korea: 02-3271-3200 (9 AM to 6 PM KSTJ) or support.korea@intusurg.com • Japan: 0120-56-5635 or 03-5575-1362 (9 AM to 6 PM JST) or csjapan@intusurg.com • Taiwan: 886-2-27008181 (7:30am to 5:30pm CT) or CS.Taiwan@intusurg.com

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

Sincerely,

Intuitive

Definitions:
* Adverse event (FDA) is defined as "an event or incident that led to a death, serious injury, or serious deterioration in the state of health of a patient, user, or other person; if the event or incident was wholly or partially caused by the device or by shortcomings in the information supplied with the device."
**Serious incident (EUMDR 2017/745) is defined as "any incident that directly or indirectly led, might have led or might lead to any of the following:

a. the death of a patient, user or other person
b. the temporary or permanent serious deterioration of a patient's, user's, or other person's state of health,
c. a serious public health threat"