MALAYSIA OFFICE

Unit 27-8, Menara One Mont Kiara, Jalan Kiara, Mont Kiara,
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March 24, 2022

New Field Safety Notice

Urgent Medical Device Correction – Tissue Pushout Events Associated with da Vinci X/Xi SureForm Staplers (PNs 480445, 480545, 480460)

(ISIFA2022-02-C)

1- Introduction and Reason for Field Action	Dear Intuitive Customer, This Field Safety Notice is to notify you of the potential for injury associated with the SureForm stapler instruments if the target tissue fails to remain in place within the jaws of the stapler during the stapler firing sequence. This phenomenon, where some or all the target tissue is pushed forward before the staples engage the tissue, is referred to as a "tissue pushout event". As the staple firing sequence progresses, the target tissue is transected but the target tissue is not approximated due the lack of staple engagement with the tissue. This type of event may result in un-approximated tissue. "Tissue pushout events" typically occur when attempting to cross over existing staple lines in the creation of a continuous staple line. Users are advised to use caution when unable to avoid crossing over existing staple lines and continue to **adhere to all existing warnings** and **cautions** found in the SureForm Instruments and Accessories User Manual Addendum. If a "tissue pushout event" is occurring, users may limit unapproximated tissue by pressing the emergency stop button (on Surgeon Console or Patient Cart helm), after which the SureForm stapler can be safely unclamped from the tissue using the Manual Release Knob.
2 - Risk to Health	16 SureForm Adverse Events*/Serious Incidents** due to "tissue pushout events" were reported between October 1, 2019 and September 30, 2021, with harms ranging up to patient extended hospitalization. This represents a rate of less than 0.01%. If any length of tissue is pushed forward, staples cannot effectively deploy into moving tissue, resulting in un-approximated transected tissue. Surgical repair of the un-approximated tissue, either through placement of sutures or the use of surgical stapling, is typically required to complete the procedure. "Tissue pushout events" that are not observed during the procedure, may result in harms ranging from infection and/or additional surgical procedures to resolve the infection and repair the un-approximated tissue. "Tissue pushout events" that are observed during a procedure may result in harms ranging from increased surgical procedure duration, possible resection of additional tissue to conversion to open surgery.

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3- Affected Products

Affected Product:

Part Number	Product Name	Affected Lot Number	Unique Device Identifier
480445	Sureform 45	All Lots	00886874117583
480545	Sureform 45 Curved-Tip	All Lots	00886874117590
480460	Sureform 60	All Lots	00886874115640

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 review and understand contents of this letter and reacquaint themselves by
    a. Reading the instructions, warnings, and cautions provided in the SureForm Instruments and Accessories User Manual Addendum
    b. Contacting their DTG Medical Sdn. Bhd. Sales Representatives for clarification of queries.
3. Complete the attached Acknowledgement Form immediately and return it via fax or email to DTG Medical Sdn. Bhd. as instructed on the form.
4. Please retain a copy of this letter and the acknowledgement form for your files.
5. Please inform DTG Medical Sdn. Bhd. 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.

You may continue the use of SureForm instruments by following instructions provided in Section 1 of this notice and instructions, warnings, and cautions provided in the SureForm Instruments and Accessories User Manual Addendum

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 Notification , please contact your Clinical Sales Representative or contact DTG Medical RAQA Team at email: regulatory@dtgmedical.com.sg

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Please be informed that the Medical Device Authority will be notified of this Field Safety Action.

Sincerely,

DTG Medical Sdn.Bhd.

Definitions:
* Adverse Event 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”

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ACKNOWLEDGMENT FORM

New Field Safety Notice

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(ISI2022-02-C)

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 DTG Medical Sdn. Bhd. if I have any questions.

Hospital name: _____

Name (print): _____

Signature and stamp: _____

Phone Number: _____

Email: _____

Date: _____

Position:

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

PLEASE FAX OR EMAIL THIS ACKNOWLEDGEMENT FORM TO
ATTN: REGULATORY COMPLIANCE FIELD ACTIONS
Subject line for email: ISIFA2022-02-C Xi SureForm Harms
Scan and Email: <regulatory@dtgmedical.com.sg>