INTUITIVE

<Mailer Date>

Field Safety Notice

Urgent Medical Device Recall – ISIFA2019-05-R

da Vinci® Xi SureForm 60 Stapler Reload

1- Introduction and Reason for Field Action

Dear *da Vinci* Customer,

This Field Safety Notice is to inform you that Intuitive Surgical is conducting a voluntary recall of select da Vinci® Xi SureForm 60 Black and Green Reloads, due to a manufacturing variation which was identified during internal testing.

The likelihood of this manufacturing variation is extremely low and if it occurs, select black and green reloads may not deploy three individual adjacent staples, which could result in an incomplete staple line.

2 - Risk to Health

In the event a surgeon identifies any missing staples following the use of an affected black or green reload, there may be a minor delay in the case to reinforce the staple line with suture or an additional reload.

If an incomplete staple line is not identified and addressed immediately the risk is dependent on the type of tissue being stapled. In rare situations there is a theoretical possibility that this could potentially lead to an air leak or an anastomotic leak which may require an additional procedural intervention.

3- Affected Products

Part Number	Product Name	Affected Lots
48360G-08	da Vinci Xi SureForm 60 Green Reload	T10180511; T10180718; T10180821; T10180822; T10180906; T10180913; T10180925; T10181008; T10190204; T10190208; T10190213; T11180816; T11190219
48360T-08	da Vinci Xi SureForm 60 Black Reload	T10180615; T10180924; T10181003; T11181003; T10181010; T10181016; T10181029; T10181107; T10181109; T10181113

4- Actions to be taken by the Customer/User

<u>As a general reminder, Intuitive Surgical advises</u> that you continue to follow the guidelines found in the user manual to inspect surgical staple lines of each stapler firing.

Additionally, Intuitive Surgical requests that you locate the affected Stapler Reloads at your site and return them via the standard RMA process. Please note that only those lots identified in section 3 of this letter are impacted. The other lots do not need to be returned and you may continue to use them.

	In addition please take the following actions: 1. Inform necessary personnel when corrective action has been completed. 2. If you have distributed any affected product to other sites, please forward this notice to all related parties. 3. Complete and submit the attached Acknowledgement Form to Intuitive (page 3 of this letter). 4. Please retain a copy of this letter and the acknowledgement form for your files.
5- Actions to be taken by Intuitive Surgical	Intuitive Surgical will provide replacement for returned affected product. As stapler reloads are sold in boxes of 12, any partial returns will receive replacements up to the nearest full box.
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 Customer Service at the numbers listed below: • International Customer Service: +800 0821 2020 or +41 21 821 2020 (8 AM to 6 PM CET) or ics@intusurg.com

Please be aware that the appropriate Regulatory Authority for your region has been notified by Intuitive Surgical of this Field Safety Notice.

Sincerely,

Intuitive Surgical, Sàrl
Chemin des Mûriers 1
CH-1170 Aubonne, Switzerland
+41 21 821 20 20

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ACKNOWLEDGMENT FORM

Field Safety Notice

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da Vinci Xi SureForm 60 Stapler Reload

Ship-to:
Hospital Name: <mail merge>
Address: <mail merge>
City, State, Zip: <mail merge>
SFID: <mail merge>
ATTENTION: <mail merge>

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 have filled in Attachment 1 and I have returned all affected *da Vinci Xi* SureForm 60 Stapler Reloads.
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
ATTN: REGULATORY POST MARKET FIELD ACTIONS
Subject line for email: ISIFA2019-05-R
Scan and email to: EU.FSCA@intusurg.com or Fax +41.21.821.2021

Customer Service

International Customer Service: +800 0821 2020 or +41 21 821 2020 (8 AM to 6 PM CET) or ics@intusurg.com

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ATTACHMENT 1

Field Safety Notice

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da Vinci Xi SureForm 60 Stapler Reload

Affected Product Reconciliation:

Affected Part Number	Affected Lot	Remaining quantity in your inventory to be returned	
		Number of Boxes (unopened)	Number of Single Reloads
48360G-08	T10180511		
	T10180718		
	T10180821		
	T10180822		
	T10180906		
	T10180913		
	T10180925		
	T10181008		
	T10190204		
	T10190208		
	T10190213		
	T11180816		
	T11190219		
48360T-08	T10180615		
	T10180924		
	T10181003		
	T10181010		
	T10181016		
	T10181029		
	T10181107		
	T10181109		
	T10181113		
	T11181003		