INTUITIVE

<Month Day Year>

New Field Safety Notice – Urgent Medical Device Removal

8 mm SureForm 30 Gray Reload Issue

(ISIFA2026-02-R)

1- Introduction and Reason for Field Action

Dear Intuitive Customer,

This Field Safety Notice (FSN) is to advise you that Intuitive is initiating a Field Safety Corrective Action (FSCA) involving the 8 mm SureForm 30 Gray Reload (PN: 48230M-05 and 48230M-06). Our records indicate that your facility has received one or more of the affected devices. Please identify, discontinue use, and quarantine any affected product(s) before contacting customer service to initiate a return.

The Intuitive Surgical 8 mm SureForm 30 Curved-Tip Stapler and 8 mm SureForm 30 Gray Reloads are intended to be used with a compatible da Vinci Surgical System for resection, transection of vasculature and tissue, and/or creation of anastomoses in General, Thoracic, Gynecologic, Urologic, and Pediatric Surgery. The root cause of the 8 mm SureForm 30 Gray Reload issue is currently under investigation.

2 - Risk to Health

As of February 23, 2026, there have been five reports of serious incidents* related to incomplete staple lines with Gray reloads on blood vessels, with five reports of bleeding including one report of death.

Incomplete staple line formation on blood vessels will result in bleeding with varying health consequences ranging from Marginal to Catastrophic. Beyond general surgical techniques to control the bleeding source, conversion to an open surgical technique may be required.

3- Affected Products

Part Number	Product Name	Unique Device Identifier	Affected Serial Number
48230M-05 48230M-06	8mm SureForm 30 Gray Reload	00886874121931	All serial numbers

4- Actions to be taken by the Customer /User

Please take the following Actions:

1. Please identify, discontinue use, and quarantine any affected product(s). Affected product(s) listed above may be returned by calling customer service with quantities and lot numbers to your regional customer service: Support.UK@intusurg.com **(Note: Please do not use the Customer Portal).**
2. Complete the attached Acknowledgement Form immediately and return it via email to Intuitive as instructed on the form.
3. Please ensure to include the FSCA number "ISIFA2026-02-R" in your return notes.
4. If you have shared or further distributed these products with other sites, please make sure appropriate staff at the site receive and understand this notification so they locate and return their affected product.
5. Please retain a copy of this letter and the acknowledgement form for your files.
6. Inform Intuitive of any Serious Incidents* or quality problems concerning the use of the subject devices via the standard complaint process.

Alternative reload consideration should be based on the clinical assessment made by the surgeon.

5- Actions to be taken by Intuitive	Once the returned product(s) is received via the RMA process, credit will be issued.
7- Further Information & Support	If you need further information or support concerning this Medical Device Correction, please contact your da Vinci Sales Representative or contact Intuitive Customer Service at the numbers listed below: • Europe: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm CET) or Support.UK@intusurg.com

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

Sincerely,

Intuitive Surgical SAS
11 avenue de Canteranne
33600 Pessac
France

Definitions:
*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, users, or other person's state of health,
c. a serious public health threat"

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ACKNOWLEDGMENT FORM

New Field Safety Notice – Urgent Medical Device Removal

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(ISIFA2026-02-R)

Ship-to:
Hospital Name: _____

Address: _____

City, State, Zip: _____

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 if I have any questions.

☐ I have reviewed my current inventory and will be contacting Intuitive to return the affected products.

☐ I confirm that I **do not have** any remaining affected product at my site.

Hospital name: _____

Name (print): _____

Signature: _____

Phone Number: _____

Email: _____

Date: _____

Position:

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

PLEASE EMAIL THIS ACKNOWLEDGEMENT FORM TO Intuitive
ATTN: REGULATORY COMPLIANCE FIELD ACTIONS
Subject line for email: ISIFA2026-02-R
Scan and Email: EU.FSCA@intusurg.com

Customer Service:

- Europe: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm CET) Support.UK@intusurg.com