Karine Cardoso

From: Recalls
Sent: Thursday, April 7, 2022 8:40 PM
To: Recalls
Subject: Field Action Launch: ISIFA2022-02-C da Vinci Xi X SureForm Harms
Attachments: ISIFA2022-02-C Distributor Notification.pdf; ISIFA2022-02-C Distributor Report.pdf; HHE2022-001_Rev A_SureForm Harms Review.pdf; 5556015-01 Rev B SureForm Harms Customer Letter.pdf

Importance: High

Tracking:

Recipient	Delivery
Recalls	Delivered: 4/7/2022 8:40 PM

Hello Distributors,

I would like to inform you that Intuitive has launched a field action related to SureForm instruments.

To help you execute this issue in your regions, please see the attached files:

1. Distributor Letter
2. Distributor Report
3. Health Hazard Evaluation
4. Intuitive Customer Letter
    a. Adjust formatting for your letter if needed

Please note that this is an FDA class II field action, meaning that the FDA is required to be notified. FDA was notified on March 3, 2022.

Additionally, please note that post launch of this field action and until updated user documentation is available, all newly or existing customers acquiring for the first time a da Vinci X or Xi Surgical System will have to be notified with the customer letter upon installation of the system, as they might potentially use the da Vinci X/Xi SureForm instruments in the future.

Please review and complete all actions as soon as possible. Let me know if you have any questions or concerns.

Thank you!

Regulatory Compliance Field Actions
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