URGENT: Field Safety Notice

Strykeflow 2 Suction Irrigator (Part 1 of 2)

Attn: Materials Manager, OR Director, Risk Manager

Recall Number: RA2025- 4025396

August, 2025

Purpose: The purpose of this letter is to inform you that Stryker has initiated a field action due to an issue with the StrykeFlow 2 devices. This field action will be conducted in two parts, and this letter will provide you with instructions to ensure the safe use of the product until part 2 of the field action which involves a device recall.

Affected Product:

Catalog Number	GTIN	Product Description	Manufacturing Dates	Affected Lot Numbers
0250070500	07613327061390	STRYKEFLOW2 WITHOUT TIP (6BX)	September 15, 2024 – April 10, 2025	Please see Attachment B
0250070520	07613327061369	STRYKEFLOW2 WITH DISPOSABLE TIP (6BX)		

Product Description: The Strykeflow 2 Suction Irrigator is designed to be used with a laparoscopic probe to allow for controlled irrigation and suction during laparoscopic surgical procedures. It is a sterile, single-use, and disposable battery-powered unit. Some StrykeFlow 2 units (REF 250-070-520) are supplied with a disposable suction/ irrigator tip (applied part).

Reason for Recall: It has been identified that due to a change in design in 2024, irrigation solution is able to travel to the handpiece and battery pack during use of the Strykeflow 2 Suction Irrigator.

Potential Risks: This design change has caused some devices to leak and/or emit vaporized saline (which can resemble smoke) during use. The impacted devices can have the following failures: fluid leakage from the handpiece and battery pack that can pool on the floor, vaporized saline emitting from the device (which can resemble smoke), the handpiece buttons are unable to function and the device cannot be shut off, heated handpieces and/or battery packs, loud noise from the motor/battery pack, and particles observed in the saline flow. The impact can range from user dissatisfaction to potential user injury such as thermal injury, skin irritation or healthcare provider may slip and fall. As of June 9th 2025, there have been 933 complaints, with one adverse health event to the user.

Mitigations: When using these devices during surgery ensure the following:

1. Ensure that additional devices are readily available.
2. If fluid leaks are observed at the handpiece or battery pack, or vapor/smoke is observed from the handpiece, discontinue use and replace with a new device.
3. If particles are observed in the fluid flow, discontinue use and replace with a new device.
4. If the user is unable to control the fluid flow/suction, follow the steps listed:
    a. Discontinue use of the device.
    b. Remove spike from irrigation solution to stop the flow of fluid
    c. Remove the batteries to stop the activation of the device
    ***Caution**: batteries/battery pack may be hot.*
    d. Replace with a new device.
5. Per standard sterile processes and operating room procedure(s), ensure the battery pack is not hung over the sterile field.
6. Ensure standard universal precautions are utilized when handling device(s).

Actions taken by Stryker:

Stryker has investigated and identified the design change which contributed to the issues noted with the Strykeflow2 Suction Irrigators. A corrective manufacturing change has been implemented. Currently, there is a limited inventory of devices incorporating this change, and replacement devices may not be immediately available.

Requested Customer Actions:

1. Inform individuals within your organization who need to be aware of this device recall.
2. Review and implement the above mitigation strategies to address any potential hazards presented by the use of these products.
3. Please complete Attachment A, Business Reply Form (page 3), as an acknowledgement of this notice and return the completed form via email to **xxx@Stryker.com** Response is required.
4. If you have further distributed product, please complete the table in Attachment A, Business Reply Form (page 3) and return the completed form via email to **xxx@Stryker.com**
5. Maintain awareness of this communication internally until part 2 of 2 of this field action is conducted.

Adverse reactions or quality problems experienced with the use of this product should be reported to:

- Your Stryker Endoscopy Sales Representative and/or Customer Service.
- http://www.stryker.com/productexperience

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: Position: email:

In line with the recommendations of the Medical Device Coordination Group Guidance document Ref MDCG 2023-3 and EU MDR 2017/745, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country

On behalf of Stryker, we thank you sincerely for your help and support in completing this action and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards and your expectations, remain on the market.

Sincerely,

Ashley Cupples
Regulatory Compliance Manager

Attachment A

Business Reply Form

Strykeflow 2 Suction Irrigator

RA2025-4025396

Catalog Number	Product Description	Affected Lot Numbers
0250070500	STRYKEFLOW2 WITHOUT TIP (6BX)	Please see Attachment B
0250070520	STRYKEFLOW2 WITH DISPOSABLE TIP (6BX)	

By signing this document, I am aware of and acknowledge the instructions listed above in the Customer Notification Letter.

Form Completed By:

Account Name			
Account Address			
Account Number (if known)			
Printed Name		**Title**	
Email		**Phone**	
Signature		**Date**	

Please note: You will need to sign an additional Business Reply Form when you receive Part 2 of 2 of this recall.

For Further Distributed Product:

Account Name			
Account Address			
Catalog Number		**Qty**	
Contact Name		**Phone**	

Return completed Business Reply Form to xxx@Stryker.com. RESPONSE IS REQUIRED.

☐ **I have read and understand the instructions provided and acknowledge receipt of the subjected FSN.**

☐ **I also agree to further distribute and communicate this important information from this letter to those whom I have distributed any of subjected devices noted in this letter.**

Name (print)_____ Signature _____ Date: _____.

Affected Lot Numbers

Catalog Numbers:

0250070500	STRYKEFLOW2 WITHOUT TIP (6BX)
0250070520	STRYKEFLOW2 WITH DISPOSABLE TIP (6BX)

Lot Numbers:

24260FG2	24284FG2	24308FG2	24341FG2	25010FG2	25035FG2	25064FG2
24261FG2	24285FG2	24309FG2	24342FG2	25012FG2	25036FG2	25065FG2
24262FG2	24286FG2	24311FG2	24343FG2	25013FG2	25037FG2	25066FG2
24263FG2	24287FG2	24312FG2	24344FG2	25014FG2	25038FG2	25069FG2
24264FG2	24288FG2	24313FG2	24345FG2	25015FG2	25039FG2	25070FG2
24265FG2	24289FG2	24316FG2	24346FG2	25016FG2	25040FG2	25071FG2
24266FG2	24290FG2	24317FG2	24347FG2	25017FG2	25041FG2	25072FG2
24267FG2	24291FG2	24318FG2	24348FG2	25018FG2	25042FG2	25073FG2
24268FG2	24292FG2	24319FG2	24349FG2	25019FG2	25043FG2	25076FG2
24269FG2	24293FG2	24320FG2	24350FG2	25020FG2	25044FG2	25077FG2
24270FG2	24294FG2	24321FG2	24351FG2	25021FG2	25045FG2	25078FG2
24271FG2	24295FG2	24322FG2	24352FG2	25022FG2	25048FG2	25079FG2
24272FG2	24296FG2	24323FG2	24353FG2	25023FG2	25049FG2	25080FG2
24273FG2	24297FG2	24324FG2	24354FG2	25024FG2	25050FG2	25083FG2
24275FG2	24298FG2	24325FG2	24355FG2	25025FG2	25051FG2	25084FG2
24276FG2	24299FG2	24326FG2	24356FG2	25026FG2	25052FG2	25085FG2
24277FG2	24300FG2	24327FG2	24357FG2	25027FG2	25055FG2	25086FG2
24278FG2	24302FG2	24335FG2	24358FG2	25028FG2	25056FG2	25087FG2
24279FG2	24303FG2	24336FG2	24361FG2	25029FG2	25057FG2	25090FG2
24280FG2	24304FG2	24337FG2	24362FG2	25030FG2	25058FG2	25091FG2
24281FG2	24305FG2	24338FG2	25007FG2	25032FG2	25059FG2	25092FG2
24282FG2	24306FG2	24339FG2	25008FG2	25033FG2	25062FG2	25093FG2
24283FG2	24307FG2	24340FG2	25009FG2	25034FG2	25063FG2	25094FG2