stryker

URGENT FIELD SAFETY NOTICE
Medical Device Recall

StrykeFlow PS and AHTO Tube Set Leaking

REF / RA2026- 4374105

Attn: Material Manager
Facility Name
Street Address
City, State Zip
Account #

August XX, 2026

Purpose: The purpose of this letter is to inform you that Stryker Endoscopy is conducting a voluntary, lot-specific product removal on StrykeFlow PS and AHTO tube sets.

Catalog Number	UDI DI	Product Description	Affected Lot Numbers
0250070530	07613327061352	PKG., SINGLE SPIKE TUBE SET	Please see **Attachment B**
0250070540	07613327061468	PKG., STRYKEFLOW SUCTION/IRRIGATOR PS	
0250070600	07613327061499	STRYKER AHTO TUBE SET PACKAGING	
0250070620	07613327061659	STRYKER AHTO TUBE SET WITH TIP PACKAGING	
0250070640	07613327061475	STRYKER AHTO DUAL SPIKE TUBE SET PACKAGING	

Product Description:

StrykeFlow PS: StrykeFlow™ PS suction irrigator is an irrigation suction device which is provided sterile for single use disposable applications. It accepts a variety of tips for laparoscopic and open general surgery, laparoscopic and open obstetric surgery, laparoscopic and open urologic surgery, endoscopic and open nasal surgery, open otolaryncologic surgery, and open plastic surgery. The tips may be sterile packaged and disposable (single use only) or non-sterile package for reusable purposes.

AHTO: The AHTO tube set and AHTO Dual Spike tube set are designed to be used with the AHTO Irrigation Pump (REF 0250070601) and a laparoscopic probe or tip to allow for controlled irrigation and suction during laparoscopic surgical procedures. It is a sterile, single use, and disposable unit that is easy to set up and use.

Reason for Recall:

There has been an increased amount in reported complaints consistently describing leaking from the handpiece during use.

Potential Risks:

StrykeFlow PS: The leaking may cause devices to leak during use. The impacted devices can have the following failures: fluid leakage from the handpiece that can pool on the floor. The impact can range from user dissatisfaction to the potential for the user of slip and fall. As of June 10th, 2026 Stryker has received 203 complaints pertaining to this issue. Stryker has not received reports of patient or user injury associated with this issue.

AHTO: The leaking may cause devices to leak during use. The impacted devices can have the following failures: fluid leakage from the handpiece that can pool on the floor, saline leakage into the handpiece, which may result in the sodium chloride reacting with the copper wire resulting in a leaked yellowish/green tinged saline containing copper II chloride (cupric chloride), particulate generation, and vaporized saline emitting from the device (which can resemble smoke). The vaporized saline and the handpiece do not heat up significantly, and there is no risk of thermal injury. The impact can range from user dissatisfaction to the potential of irritation or slip and fall. As of June 10th, 2026 Stryker has received 489 complaints pertaining to this issue. Stryker has not received reports of patient or user injury

Actions needed:

1. Inform individuals within your organization who need to be aware of this action.
2. Check your internal inventory to locate the affected product using Attachment B.
3. If affected product is found
    a. Quarantine, stop use and initiate the return process for affected units.
    b. Please complete Business Reply Form
    c. Stryker will contact your account to initiate the product return process for a replacement device.
4. If affected product is NOT found:
    a. Please complete Business Reply Form on Attachment A.
5. Maintain awareness of this communication internally until all required actions have been completed within your facility.
6. If you have further distributed the affected product, please notify the applicable parties at once about this recall. You may copy and distribute this notification letter.
    a. If possible, inform us if any of the subject devices have been distributed to other organizations, including contact details.
    b. If you are a distributor, note that you are responsible for notifying your affected customers

Please inform us of any adverse events and/or report them to the Health/Competent Authorities in accordance with current regulations.
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 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,

stryker

Business Reply Form

StrykeFlow PS and AHTO Tube Set Leaking

REF / RA2026- 4374105

August XX , 2026

Please choose the most appropriate box below and fill out the corresponding table(s):

- ☐ I am returning the following unused devices from Attachment B.
  - *Stryker will contact your account to initiate the product return process for a replacement device.*
- ☐ I have further distributed product(s). Please use, "For further distributed product" box below.
- ☐ I no longer have any affected product listed on Attachment B.

Catalog Number	GTIN	Product Description	Quantity on Hand	Affected Lot Numbers
0250070530	07613327061352	PKG., SINGLE SPIKE TUBE SET		
0250070540	07613327061468	PKG., STRYKEFLOW SUCTION/IRRIGATOR PS STRYKER AHTO TUBE SET WITH TIP PACKAGING		
0250070600	07613327061499	STRYKER AHTO TUBE SET PACKAGING		
0250070620	07613327061659	STRYKER AHTO TUBE SET WITH TIP PACKAGING		
0250070640	07613327061475	STRYKER AHTO DUAL SPIKE TUBE SET PACKAGING		

**Stryker assumes that you are sending all unused devices and other devices are deemed to be used or thrown away at your account.*

For further distributed product(s):

- ☐ I have identified and notified my customers that were shipped or may have been shipped this product.

Form Completed By:

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

****Your signature indicates that you have read and acknowledge the enclosed notification and that you have performed all actions requested.***

PLEASE COMPLETE THIS FORM WITHIN 5 BUSINESS DAYS AND RETURN IT BY USING THE EMAIL LISTED BELOW: xxxxxxxx@Stryker.com

Affected Lot Numbers

Catalog Numbers:
0250070530 - PKG., Single Spike Tube Set
0250070540 - PKG., Strykeflow Suction/Irrigator PS

Lot Numbers:

24260FG2	24302FG2	25007FG2	25024FG2	25063FG2	25092FG2	25153FG2	25183FG2
24261FG2	24306FG2	25008FG2	25034FG2	25064FG2	25093FG2	25154FG2	25216FG2
24297FG2	24340FG2	25009FG2	25034FG2	25065FG2	25121FG2	25167FG2	25217FG2
24298FG2	24341FG2	25010FG2	25035FG2	25084FG2	25134FG2	25168FG2	25245FG2
24299FG2	24344FG2	25011FG2	25052FG2	25091FG2	25135FG2	25182FG2	25274FG2

Catalog Numbers:
0250070600 - STRYKER AHTO TUBE SET PACKAGING
0250070620 - STRYKER AHTO TUBE SET WITH TIP PACKAGING
0250070640 - STRYKER AHTO DUAL SPIKE TUBE SET PACKAGING

Lot Numbers:

24262FG2	24297FG2	24327FG2	24361FG2	25038FG2	25071FG2	25101FG2	25135FG2
24263FG2	24298FG2	24337FG2	25007FG2	25041FG2	25072FG2	25104FG2	25137FG2
24264FG2	24299FG2	24338FG2	25008FG2	25042FG2	25073FG2	25105FG2	25139FG2
24265FG2	24302FG2	24339FG2	25009FG2	25043FG2	25076FG2	25106FG2	25140FG2
24266FG2	24303FG2	24340FG2	25010FG2	25044FG2	25077FG2	25107FG2	25141FG2
24267FG2	24304FG2	24341FG2	25011FG2	25045FG2	25078FG2	25111FG2	25142FG2
24268FG2	24305FG2	24342FG2	25013FG2	25048FG2	25079FG2	25112FG2	25143FG2
24269FG2	24306FG2	24343FG2	25014FG2	25049FG2	25080FG2	25113FG2	25144FG2
24270FG2	24309FG2	24344FG2	25015FG2	25050FG2	25083FG2	25114FG2	25147FG2
24271FG2	24311FG2	24345FG2	25016FG2	25051FG2	25084FG2	25115FG2	25148FG2
24283FG2	24312FG2	24346FG2	25017FG2	25052FG2	25085FG2	25118FG2	25149FG2
24284FG2	24313FG2	24347FG2	25020FG2	25055FG2	25086FG2	25119FG2	25150FG2
24286FG2	24316FG2	24348FG2	25021FG2	25056FG2	25087FG2	25120FG2	25151FG2
24287FG2	24317FG2	24349FG2	25022FG2	25057FG2	25090FG2	25121FG2	25153FG2
24288FG2	24318FG2	24350FG2	25023FG2	25058FG2	25091FG2	25122FG2	25154FG2
24289FG2	24319FG2	24351FG2	25024FG2	25059FG2	25092FG2	25125FG2	25155FG2
24290FG2	24320FG2	24352FG2	25027FG2	25062FG2	25093FG2	25126FG2	25156FG2
24291FG2	24321FG2	24353FG2	25028FG2	25063FG2	25094FG2	25127FG2	25157FG2
24292FG2	24322FG2	24354FG2	25029FG2	25064FG2	25097FG2	25128FG2	25160FG2
24293FG2	24323FG2	24355FG2	25030FG2	25065FG2	25098FG2	25129FG2	25161FG2
24294FG2	24324FG2	24356FG2	25035FG2	25066FG2	25098GF2	25132FG2	25162FG2
24295FG2	24325FG2	24357FG2	25036FG2	25069FG2	25099FG2	25133FG2	25163FG2
24296FG2	24326FG2	24358FG2	25037FG2	25070FG2	25100FG2	25134FG2	