

URGENT MEDICAL DEVICE RECALL NOTIFICATION
Multiple Products Affected

November 17, 2017

Account Number: «CUSTOMER_NUMBER»

Attn: Risk Manager, OR Director, Materials Manager

«CUSTOMER_NAME»

«ADDRESS1»

«ADDRESS2»

«CITY», «STATE» «ZIP»

The purpose of this notification is to advise you that Stryker Endoscopy is conducting a voluntary recall. These products were distributed to customers from October 30 – November 9, 2017. Attachment A, on the back of this letter, includes a list of all products affected by this recall, and it may include products your account did not receive. Please refer below for Part and Lot Numbers that were identified as shipped to your account.

<u>Part Number(s) shipped</u>	<u>Lot Number(s) shipped</u>				
«Part_Number_1»	«PN1_Lot_1»	«PN1_Lot_2»	«PN1_Lot_3»	«PN1_Lot_4»	«PN1_Lot_5»
	«PN1_Lot_6»	«PN1_Lot_7»	«PN1_Lot_8»	«PN1_Lot_9»	«PN1_Lot_10»
	«PN1_Lot_11»				
«Part_Number_2»	«PN2_Lot_1»	«PN2_Lot_2»	«PN2_Lot_3»	«PN2_Lot_4»	«PN2_Lot_5»
«Part_number_3»	«PN3_lot_1»	«PN3_lot_2»	«PN3_lot_3»		
«Part_number_4»	«PN4_lot_1»				

Product Description:

Products are sterile devices intended for use in minimally invasive surgical procedures.

Reason for the Voluntary Recall:

During routine bioburden testing of certain lots, Stryker found that the levels of bioburden on tested product were higher than our internal acceptable rates. Therefore, we are initiating this voluntary recall for all products that may be potentially impacted as the sterility of the product cannot be confirmed.

Risk to Health:

In addition to the normal risk of infection that any procedure carries, there is an additional potential risk that if the product is used in a procedure, an infection may occur that may require medical treatment. To date, there have been no reports of any adverse events or serious injuries.

Actions to be taken by the Customer/User:

1. Inform individuals within your organization who need to be aware of this device recall.
2. Check all stock areas and/or operating room storage to determine if any devices from the affected product list are at your facility.
Response is required.
3. Quarantine and discontinue use of the recalled devices.
4. If no product is found, complete acknowledgement form located on the Stryker Endoscopy recall website endorecall.stryker.com. Log into the website by using the account number and zip code located at the top of this letter.
5. If affected product is found, segregate the product and call Stryker customer service at 1-800-624-4422 (Option 3) or email endocustomersupport@stryker.com to arrange for product return and issuance of credit or replacement (upon availability).

Please forward a copy of this letter to any other personnel within your facility that you deem appropriate.

We appreciate your cooperation and we recognize the inconvenience this may cause your facility. Thank you for your support on this important matter.

Sincerely,



Kimberly Lynch
Regulatory Compliance Manager, Stryker Endoscopy

Part Number: 234-010-056

Product Long Description: UNIVERSAL WEDGE SCREW, 9MM X 25MM

Lot Number: 17278AG2

Part Number: 234-020-280

Product Long Description: ACL DISPOSABLE PACK BONE-TENDON-BONE

Lot Number: 17299AG2

Part Number: 250-070-505

Product Long Description: PKG. DISPOSABLE STRYKEFLOW S/I TIP

Lot Number: 17294FG2

Part Number: 250-070-500

Product Long Description: PKG., ASSY., SUCTION / IRRIGATOR 2

Lot Numbers: Table Below

17275FG2	17280FG2	17289FG2	17294FG2
17276FG2	17283FG2	17290FG2	17297FG2
17277FG2	17284FG2	17291FG2	17299FG2
17278FG2	17285FG2	17292FG2	17301FG2
17279FG2	17286FG2	17293FG2	

Part Number: 250-070-520

Product Long Description: PKG., ASSY., STRYKEFLOW 2 WITH TIP

Lot Numbers: Table Below

17282FG2	17292FG2	17298FG2
17283FG2	17293FG2	17299FG2
17286FG2	17294FG2	17300FG2
17289FG2	17296FG2	17301FG2
17290FG2	17297FG2	17302FG2

Part Number: 250-070-600

Product Long Description: STRYKER AHTO TUBE SET PACKAGING

Lot Numbers: Table Below

17284FG2	17291FG2	17300FG2
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Part Number: 250-070-620

Product Long Description: STRYKER AHTO TUBE SET WITH TIP PACKAGING

Lot Numbers: Table Below

17275FG2	17284FG2	17292FG2
17279FG2	17285FG2	17293FG2
17280FG2	17286FG2	17297FG2
17282FG2	17289FG2	17298FG2
17283FG2	17291FG2	17299FG2