



Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048

December 20, 2024

URGENT – MEDICAL DEVICE RECALL
AnchorFast Oral Endotracheal Tube Fastener devices

Dear Valued Business Partner/Customer,

In order to best serve the needs of our customers, Hollister Incorporated is voluntarily recalling the following products:

Product	Lot number
9799/9799Q AnchorFast Oral Endotracheal Tube Fastener	See attached table for exact lots
9800/9800Q AnchorFast Guard Oral Endotracheal Tube Fastener	See attached table for exact lots
9700/9700Q AnchorFast Guard Select Oral Endotracheal Tube Fastener	See attached table for exact lots
9787/9787Q AnchorFast SlimFit Oral Endotracheal Tube Fastener	4L172, 4L182

Device Use

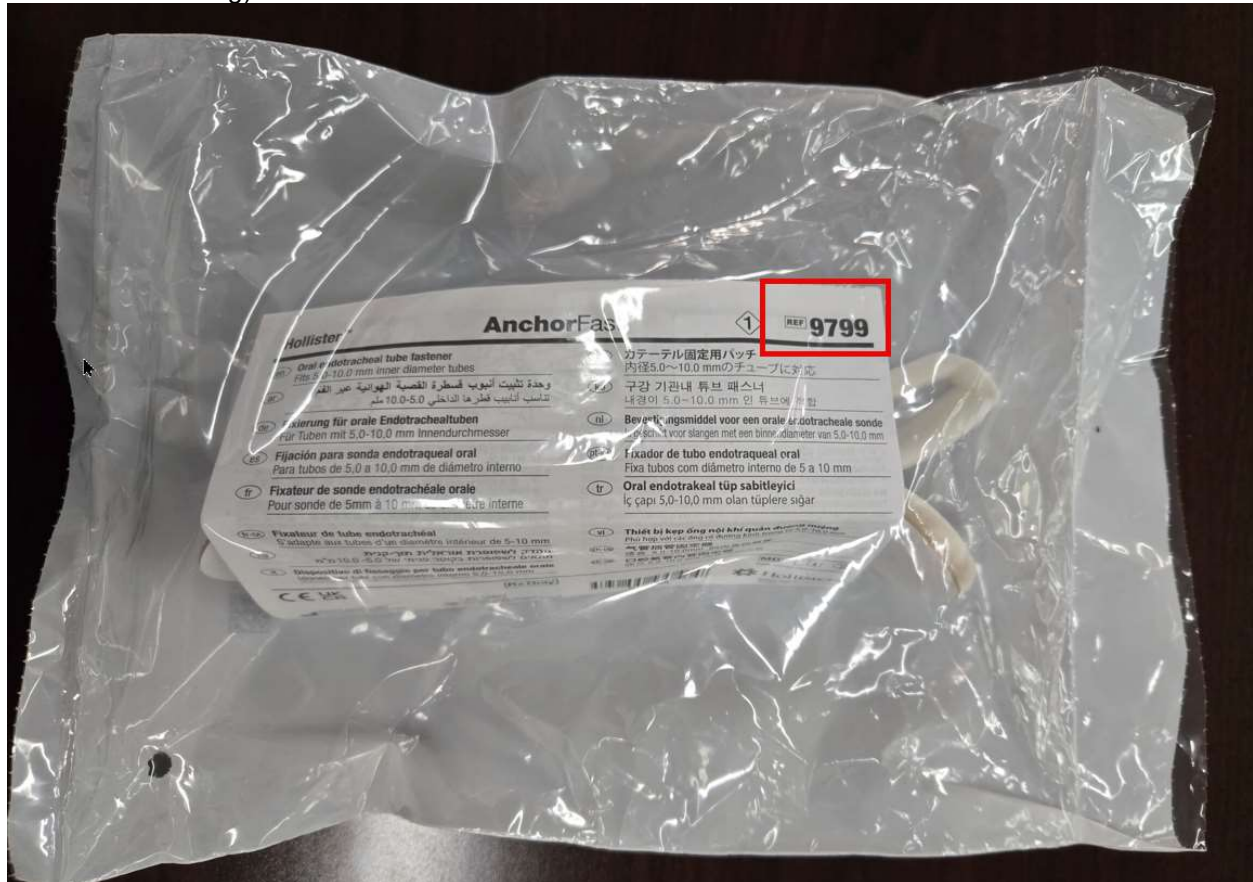
These devices provide a convenient means to hold an oral endotracheal tube securely in place without the use of adhesive tape. The oral endotracheal tube fastener allows repositioning of the tube in either direction along the track without removal of the device.

Reason for Recall

Hollister is recalling lots of the AnchorFast, AnchorFast Guard, AnchorFast Guard Select and AnchorFast SlimFit Oral Endotracheal Tube Fastener due to reports of decreased skin barrier wear time. See the attached table for the lots for each SKU. Decreased skin barrier wear time can lead to tube migration.

We are requesting that you follow the steps below:

1. Search inventory for SKUs and lots affected from table above. The SKU and lot number information is available within the product packaging.
 - a. Please refer to Image below and note the red box around the SKU (located on the clear side of the poly bag) and lot (located towards the bottom of the opaque side of the poly bag)





(01)0061007509590
(17)290901
(10)41192

2023-08-10

LOT 41192

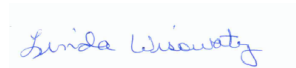
2. If you have further distributed this product, please identify your customers and notify them at once of this product recall. Date(s) distributed: Between September 19, 2024, to December 19, 2024
3. Quarantine affected inventory. Discard the product per your local procedures for product destruction.
4. Please complete and return the response form attached as soon as possible, even if you do not have affected product in your possession and send to **ComplaintCommunication@Hollister.com**.

Product Credit requests

5. If you are a direct customer of Hollister, contact Hollister Incorporated Customer Service for product credit at: 1-800-323-4060 (prompt #1)
6. If you purchase product from a distributor, please contact your distributor for product credit.

We deeply regret the inconvenience which this recall will cause. Thank you again for being our valued business partner and for your understanding regarding this matter.

Sincerely,

A handwritten signature in blue ink that reads "Linda Wisowaty".

Linda Wisowaty
Senior Post Market Surveillance Specialist



Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048

MEDICAL DEVICE RECALL RESPONSE FORM
Response is Required
AnchorFast Oral Endotracheal Tube Fastener devices

Please return completed response form, even if you do not have affected product in your possession, to ComplaintCommunication@Hollister.com

Product	Lot number	Quantity eaches in stock	Purchase order number
9799/9799Q AnchorFast Oral Endotracheal Tube Fastener			
9800/9800Q AnchorFast Guard Oral Endotracheal Tube Fastener			
9700/9700Q AnchorFast Guard Select Oral Endotracheal Tube Fastener			
9787/9787Q AnchorFast SlimFit Oral Endotracheal Tube Fastener			

YES ☐	I have read and understood the Recall instructions provided in the Recall Communication letter.	
YES ☐	N/A ☐	I have quarantined affected product and discarded per my local procedures for product destruction.
YES ☐	N/A ☐	I have no affected product by this Recall in my possession.
YES ☐	N/A ☐	Distributors: I have identified and notified my customers that were shipped or may have been shipped this product, if applicable. For Credit Requests please contact Hollister Customer Service and provide your purchase order number (PO number) at the time of your request.
*If you do not purchase product directly from Hollister Incorporated, please provide your supplier's name:		
Please Complete Contact Information for Person Completing Response Form:		

Name and title:		Date:
Telephone Number and/or email:		
Facility/Business name <i>(please use full facility name. Do not use abbreviations):</i>		
Address including city, state, zip, Country		



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Customer Frequently Asked Questions (FAQ)

1. What is the reason for this recall?

Hollister is recalling lots of the AnchorFast, AnchorFast Guard, AnchorFast Guard Select and AnchorFast SlimFit Oral Endotracheal Tube Fastener due to reports of decreased skin barrier wear time. See the attached table for the lots for each SKU. Decreased skin barrier wear time can lead to tube migration.

2. What lot number and product are impacted for this recall?

Product	Lot number
9799/9799Q AnchorFast Oral Endotracheal Tube Fastener	See attached table for exact lots
9800/9800Q AnchorFast Guard Oral Endotracheal Tube Fastener	See attached table for exact lots
9700/9700Q AnchorFast Guard Select Oral Endotracheal Tube Fastener	See attached table for exact lots
9787/9787Q AnchorFast SlimFit Oral Endotracheal Tube Fastener	4L172, 4L182

3. How do I identify the affected product?

The SKU and lot number information are visible on the poly bag containing each device. One side of the poly bag shows the SKU, and the other side contains the lot number. Match this information to the table above to see if your product is affected.

4. What happens if I threw out the packaging and I don't know the lot number of my product?

If there is no packaging and you have received the customer notification, it means that you have received the affected SKU and lot combination. Please check your inventory for the affected product.

5. What is the process to receive replacement product?

We are working diligently to resume production of replacement product. Please work with your clinical resource specialist at your facility for an appropriate substitution. To receive credit, please contact Hollister Customer Service if you have purchased product directly from Hollister. If you know your purchase order number (PO number), please provide this at the time of your request. If you have purchased product from a distributor, please contact your distributor's customer service department.

6. What if I bought product from a distributor and not directly from Hollister? Do I need to work with my distributor to receive credit?

Please work with your distributor as they will have your purchase information and will be able to process your request quickly.

7. Do I need to send the affected product back to Hollister?

No, please destroy the product per your local procedures. Please complete and return your response form to ComplaintCommunication@Hollister.com

8. What if I don't have affected product or I have already disposed of it?

Even if you don't have affected product, please complete and return the response form. This will allow us to quickly and easily confirm that there is no affected product in your possession. Return response form to ComplaintCommunication@Hollister.com.

9. Was anyone injured using the affected product?

We have received reports of tube extubation. No patient injury was reported due to the tube extubation. We have also received reports of lip pressure injuries.

10. Who do I contact for more assistance?

Please contact one of the following Hollister Incorporated departments:
Hollister Customer Service: 1-800-323-4060 (prompt #1)
Hollister Quality: ComplaintCommunication@Hollister.com

Table of SKUs and Lots Affected

Material Number	Lot Number	Material Number	Lot Number	Material Number	Lot Number	Material Number	Lot Number
9700	4J162	9799	4J262	9799	4L032	9799Q	4K232
	4J172		4J272		4L042		4K242
	4J182		4J282		4L092		4K252
	4L172		4J292		4L112		4L052
	4L182		4J302		4L122		4L062
9799	4I192	9799	4J312		4L132		4L072
	4I202		4K012		4L142		4L082
	4I212		4K022		4L152		4L092
	4I222		4K032		4L162		4L102
	4I232		4K042		4L172		4L112
	4I242		4K052		4L182	9800Q	4J182
	4I252		4K062	9800	4K162		4J192
	4I262		4K072		4K172		4J202
	4I272		4K082		4K182		4J212
	4I282		4K092		4K192		4L152
	4I292		4K102		4K202		4L162
	4I302		4K112		4K212		4L172
	4J012		4K122		4K222		
	4J022		4K132		4K232		
	4J032		4K142		4K252		
	4J042		4K152		4K262		
	4J052		4K162		4L012		
	4J062		4K172		4L022		
	4J072		4K182		4L032		
	4J082		4K192		4L042		
	4J092		4K202		4L052		
	4J102		4K212		4L092		
	4J112		4K222		4L102		
	4J122		4K232		4L112		
	4J132		4K242		4L122		
	4J142		4K252		4L132		
	4J152		4K262		4L142		
	4J162		4K272				
	4J212		4K282				
	4J222		4K292				
	4J232		4K302				
	4J242		4L012				
	4J252		4L022				