



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:

<b>Product</b>	<b>Lot number</b>
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**

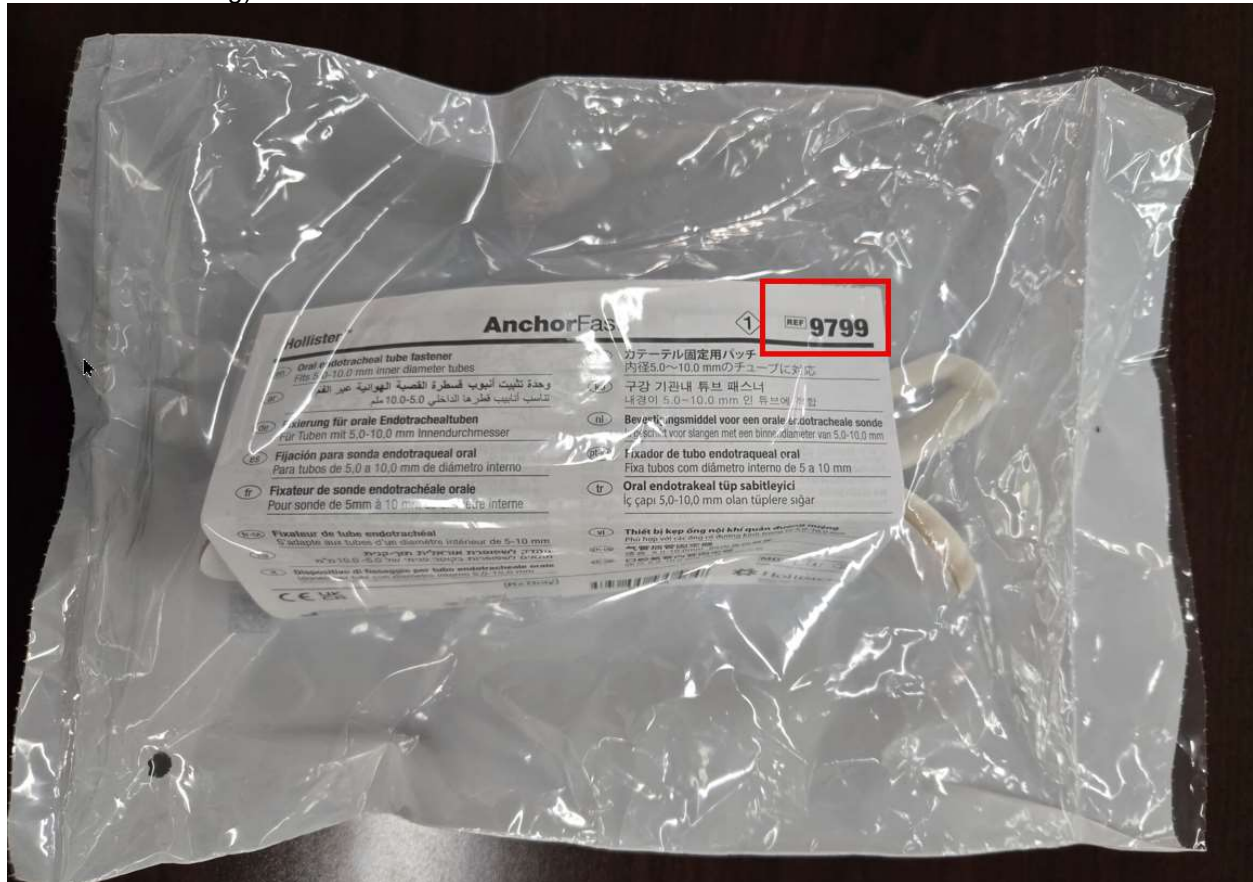
These devices provide a convenient means to hold an oral endotracheal tube securely in place without the use of adhesive tape. The oral endotracheal tube fastener allows repositioning of the tube in either direction along the track without removal of the device.

### **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 2023-09-10  
(17)290901  
(10)41192 **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**

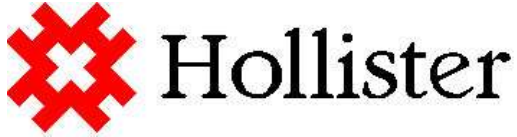
5. If you are a direct customer of Hollister, contact Hollister Incorporated Customer Service for product credit at: 1-800-323-4060 (prompt #1)
6. If you purchase product from a distributor, please contact your distributor for product credit.

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,



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](mailto:ComplaintCommunication@Hollister.com)

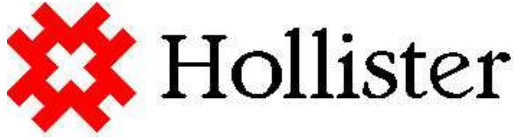
Product	Lot number	Quantity eaches in stock	Purchase order number
9799/9799Q AnchorFast Oral Endotracheal Tube Fastener			
9800/9800Q AnchorFast Guard Oral Endotracheal Tube Fastener			
9700/9700Q AnchorFast Guard Select Oral Endotracheal Tube Fastener			
9787/9787Q AnchorFast SlimFit Oral Endotracheal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

YES <input type="checkbox"/>	I have read and understood the Recall instructions provided in the Recall Communication letter.
YES <input type="checkbox"/>	N/A <input type="checkbox"/>
I have quarantined affected product and discarded per my local procedures for product destruction.	
YES <input type="checkbox"/>	N/A <input type="checkbox"/>
I have no affected product by this Recall in my possession.	
YES <input type="checkbox"/>	N/A <input type="checkbox"/>
<b>Distributors:</b> I have identified and notified my customers that were shipped or may have been shipped this product, if applicable.	
For <b>Credit Requests</b> 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:**

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



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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](mailto: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](mailto: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](mailto:ComplaintCommunication@Hollister.com)



**Table of SKUs and Lots Affected**

<b>Material Number</b>	<b>Lot Number</b>	<b>Material Number</b>	<b>Lot Number</b>	<b>Material Number</b>	<b>Lot Number</b>	<b>Material Number</b>	<b>Lot Number</b>
<b>9700</b>	4J162	<b>9799</b>	4J262	<b>9799</b>	4L032	<b>9799Q</b>	4K232
	4J172		4J272		4L042		4K242
	4J182		4J282		4L092		4K252
	4L172		4J292		4L112		4L052
	4L182		4J302		4L122		4L062
<b>9799</b>	4I192	4J312	4L132	4L072			
	4I202	4K012	4L142	4L082			
	4I212	4K022	4L152	4L092			
	4I222	4K032	4L162	4L102			
	4I232	4K042	4L172	4L112			
	4I242	4K052	4L182	<b>9800Q</b>	4J182		
	4I252	4K062	<b>9800</b>		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					