



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 AnchorFast Oral Endotracheal Tube Fastener	4K272 4J062 4J042 4K052 4J052 4I272 4K062 4J092 4I252 4K182 4J112 4J102 4J072 4K272 4J062
9700 AnchorFast Guard Select Oral Endotracheal Tube Fastener	4J172 4J162

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 and AnchorFast Guard Select 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.



(01)0061007509590 2028-08-10
(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 canadacustomerservice@hollister.com

Product Credit requests

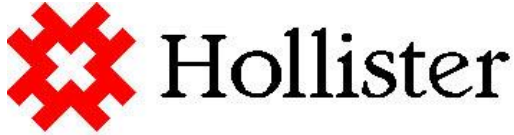
If you are a direct customer of Hollister, contact Hollister Customer Service for product credit at: 1-800-263-7400

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 canadacustomerservice@hollister.com

Product	Lot number	Quantity eaches in stock	Purchase order number
9799 AnchorFast Oral Endotracheal Tube Fastener			
9700 AnchorFast Guard Select 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"/>	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, province, postal code, 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 and AnchorFast Guard Select 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 AnchorFast Oral Endotracheal Tube Fastener	4K272 4J062 4J042
	4K052 4J052 4I272
	4K062 4J092 4I252
	4K182 4J112
	4J102 4J072
	4K272 4J062
9700 AnchorFast Guard Select Oral Endotracheal Tube Fastener	4J172
	4J162

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 canadacustomerservice@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 canadacustomerservice@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: 1-800-263-7400
Hollister Quality: canadacustomerservice@hollister.com