Hollister Limited
95 Eric T Smith Way
Aurora, ON L4G 0Z6

Phone: 1-800-263-7400
FAX: 1-800-432-8846

February 11, 2021

URGENT – MEDICAL DEVICE RECALL
Vertical Tube Attachment Device

Dear Valued Business Partner/Customer,

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

Product	Lot
SKU: 9782 Vertical Drain Tube Attachment Device	0K02

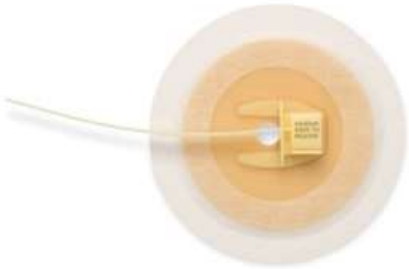
Device Use

The Hollister Vertical Drain Tube Attachment Device is designed to stabilize and secure a variety of catheters, surgical drains, and tubes from sizes 5-40 French.

The Hollister Vertical Drain Tube Attachment Device is used in hospitals, clinics, and by end users.

Reason for Recall

Hollister is recalling the Vertical Tube Attachment Device due to a manufacturing defect where the tube attachment device may separate from the barrier. There is a potential the tube attachment device can separate during use (See photo example below). This separation has the potential to subsequently lead to a catheter, drain, or tube migration and/or loss. There have been zero no reports of this leading to harm. We have initiated the recall to ensure that we continue to provide our customers with first class products they can rely on to meet their daily needs.



Vertical Tube Attachment Device

Example of separation

We are requesting that you follow the steps below:

1. Search inventory for SKU and lots affected from table above. The SKU and lot number information is printed on the control label which is located on one of the side labels on each box. The lot information can also be found on the individual packaging, see images below.

Example of Control Label

Example of Individual Product Packaging

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 December 31, 2020 to February 4, 2021
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 **Chantale.Laramee@hollister.com**.
    a. If you have any questions please reach out to Chantale Laramee Chantale.Laramee@Hollister.com

Product Replacement or Credit requests

5. If you are a direct customer of Hollister, contact Hollister Limited at 1-800-263-7400 for product replacement or credit as applicable.
6. If you purchase product from a distributor, please contact your distributor for product replacement or credit.

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

Sincerely,

Kristina Scheppa BSN, RN
Global Post Market Surveillance Supervisor
Hollister Incorporated
2000 Hollister Dr.
Libertyville, IL 60048

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MEDICAL DEVICE RECALL RESPONSE FORM
Response is Required

Vertical Tube Attachment Device

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

For **Credit or Replacement Requests** please contact Customer Service at 1-800-263-7400 and provide your purchase order number (PO number) at the time of your request.

Product	Lot	Quantity of boxes in your possession	Purchase Order (PO) number
SKU: 9782 Vertical Drain Tube Attachment Device	0K02		

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 Field Action in my possession.
YES ☐		I have read and understood the Recall instructions provided in the Recall Communication letter.
YES ☐	N/A ☐	Distributors: I have identified and notified my customers that were shipped or may have been shipped this product, if applicable.

Please Complete Contact Information for Person Completing Response:	
Name:	
Title:	
Telephone Number:	
Facility/Business name:	
Address:	
City, State, Zip:	
Date:	

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Customer Frequently Asked Questions (FAQ)
Vertical Drain Tube Attachment Device

1. **What lot number and product is impacted for this Field Action?**

Product	Lot
SKU: 9782 Vertical Drain Tube Attachment Device	0K02
	1A09
	1A10

2. **How do I identify the affected product?**

   The SKU and lot number information is printed on the control label which is located on one of the side labels of each box. Match this information to the table above to see if your product is affected. The SKU and lot information can also be found on the individual packaging

3. **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.

4. **What is the process to receive replacement product?**

   To receive credit or replacement product, 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.

5. **What if I bought product from a distributor and not directly from Hollister? Do I need to work with my distributor to get replacement product?**

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

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

   No, please destroy the product per your procedures.

7. **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 **Chantale.Laramee@hollister.com**.

8. **Was anyone injured using the affected product?**

   We have not received any complaints reporting an injury with the use of this product affected by this recall. There is a potential the tube attachment device can separate during use. This separation has the potential to subsequently lead to a catheter, drain, or tube migration and/or loss. There have been no reports of this leading to harm.

9. **Who do I contact for more assistance?**

   Please contact one of the following Hollister Limited departments:
   Hollister Customer Service: 1-800-263-7400
   Hollister Quality: **Chantale.Laramee@hollister.com**