



Hollister Incorporated  
2000 Hollister Drive  
Libertyville, IL 60048

October 21, 2022

**URGENT – Field Safety Notice**  
**Onli Hydrophilic Intermittent Catheter**  
**FSCA identifier – PMRA-04050**

Dear Valued Business Partner/Customer,

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

Product	Description	Lot number
82124	Onli Hydrophilic IC Ch12 40cm	2I103

**Device Use**

This intermittent catheter is a flexible tubular device that is inserted through the urethra by male, female, and pediatric patients who need to drain urine from the bladder.

**Reason for Recall**

There is a potential that some product may have a leak in the sterile packaging seal. If a leak is present, this may cause a breach in the sterile packaging seal. A breach in the sterile packaging seal has the potential to contribute to contaminated intermittent catheters, which could subsequently lead to a patient infection. Hollister initiated this action to prevent the use of potentially affected intermittent catheters that may impact patients. To date there have been 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.

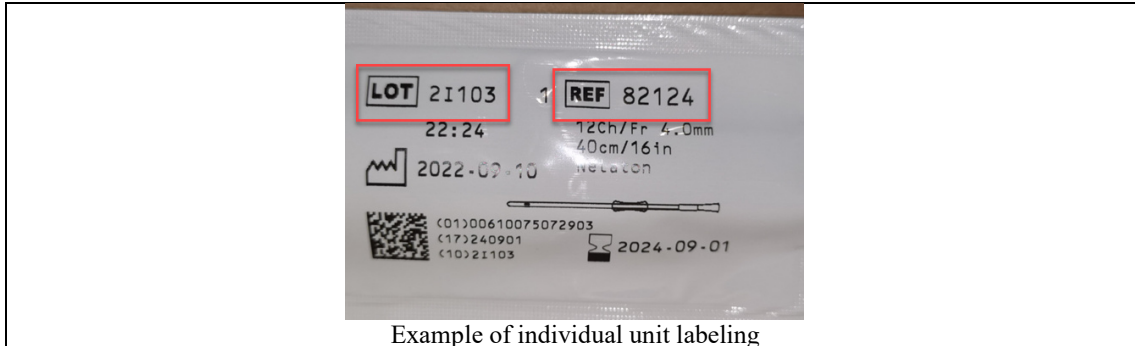
**Required Actions to be taken**

**You are receiving this notice because our records indicate that you received impacted products that are part of this action. Please take the following actions:**

1. Immediately identify and quarantine all impacted products.
  - a. The product number and lot number are found on the box of product or on the individual catheter packaging. Note red squares in images below.



Example of Control Label on Box



2. Destroy all impacted product in your inventory per your local procedures. Do not use these devices.
3. Please complete the attached Response Form, **even if you have no inventory** and send to [ComplaintCommunication@Hollister.com](mailto:ComplaintCommunication@Hollister.com) **within 3 business days of receipt of this letter.**
4. Pass on this notice to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
5. If you have further distributed this product, please identify your customers and notify them at once of this product recall. Date(s) distributed: October 2022
6. Response form directions:

Where to send completed form		Customer with inventory	Customer with zero inventory
Purchased directly from Hollister Incorporated	Email the completed form to <a href="mailto:ComplaintCommunication@Hollister.com">ComplaintCommunication@Hollister.com</a>	Please complete the attached Customer Response Form in its entirety. Document how many boxes/units are in your inventory	Complete form and check the box indicating "no inventory"
Purchased from a different source	Email the completed form to <a href="mailto:ComplaintCommunication@Hollister.com">ComplaintCommunication@Hollister.com</a> <u>AND</u> copy your distributor.		

**Product Replacement or Credit requests**

7. If you are a direct customer of Hollister, contact Hollister Incorporated Customer Service for product replacement or credit, as applicable.
8. If you purchase product from a distributor, please contact your distributor for product replacement or credit.

**Corrective Action being taken by manufacturer Hollister Incorporated:**

We have reviewed our processes and implemented actions to prevent any reoccurrence of this issue.

Hollister has notified the relevant Competent Authority of your country of this action.

We deeply regret and apologize for the inconvenience which this recall will undoubtedly cause. We are committed to patient safety and appreciate your prompt attention to this matter. Thank you again for being our valued business partner and for your understanding regarding this matter.

Sincerely,

Kristina Scheppa  
Global Post-Market Surveillance Supervisor



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**Response Form**

Please return completed response form, **even if you have no affected product** in your possession, to [ComplaintCommunication@Hollister.com](mailto:ComplaintCommunication@Hollister.com)

Product	Lot number	Quantity boxes in stock		Purchase order number
82124 Onli Hydrophilic IC Ch12 40cm	2I103		Boxes <input type="checkbox"/>	
			Units <input type="checkbox"/>	

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.

**\*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 code</b>		
<b>Country</b>		



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### Customer Frequently Asked Questions (FAQ)

**1. What lot number and products are impacted for this recall?**

Product	Description	Lot number
82124	Onli Hydrophilic IC Ch12 40cm	21103

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

The product 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.

**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 notification, it means that you have received the impacted product. 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 local procedures. Please complete and return your response form to [ComplaintCommunication@Hollister.com](mailto:ComplaintCommunication@Hollister.com)

**7. What if I don't have impacted product or I have already disposed of it?**

Even if you don't have impacted product, please complete and return the response form. This will allow us to quickly and easily confirm that there is no impacted product in your possession. Return response form to [ComplaintCommunication@Hollister.com](mailto:ComplaintCommunication@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 impacted by this recall.