Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048

July 10, 2026

URGENT PRODUCT FIELD SAFETY NOTICE

Onli™ and Infyna™ Hydrophilic Urethral Intermittent Catheter

Dear Customer,

In order to best serve the needs of our customers, Hollister Incorporated, following agreement with the Health Products Regulatory Authority in Ireland (HPRA), is conducting a product alert on the following products:

SKU/REF	Description
82081	Ch08-17 Onli Hydrophilic Urethral Intermittent Catheter
82101	Ch10-17 Onli Hydrophilic Urethral Intermittent Catheter
82121	Ch12-17 Onli Hydrophilic Urethral Intermittent Catheter
82141	Ch14-17 Onli Hydrophilic Urethral Intermittent Catheter
82084	Ch08 40cm Onli Hydrophilic Urethral Intermittent Catheter
82104	Ch10 40cm Onli Hydrophilic Urethral Intermittent Catheter
82124	Ch12 40cm Onli Hydrophilic Urethral Intermittent Catheter
82144	Ch14-40cm Onli Hydrophilic Urethral Intermittent Catheter
82164	Ch16 40cm Onli Hydrophilic Urethral Intermittent Catheter
85124	CH12 40cm Onli Coude Hydrophilic Urethral Intermittent Catheter
85144	CH14 40cm Onli Coude Hydrophilic Urethral Intermittent Catheter
85164	CH16 40cm Onli Coude Hydrophilic Urethral Intermittent Catheter

The Competent (Regulatory) Authority of your country has been informed about this communication to customers

Device Use

This product 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 Product Field Safety Notice

The reason for this Product Field Safety Notice is Hollister has identified that select lots of the catheters identified in the above table may exhibit a protrusion caused by a manufacturing defect which might lead to genitourinary trauma or bleeding. This defect is approximately 2 centimeters from the funnel (refer to image #1 and #2 below). Defect highlighted in red circle.

Hollister is conducting a Product Field Safety Notice to make users aware that this protrusion may be present and as a precautionary measure to inspect catheters for this defect prior to use.

Image 1

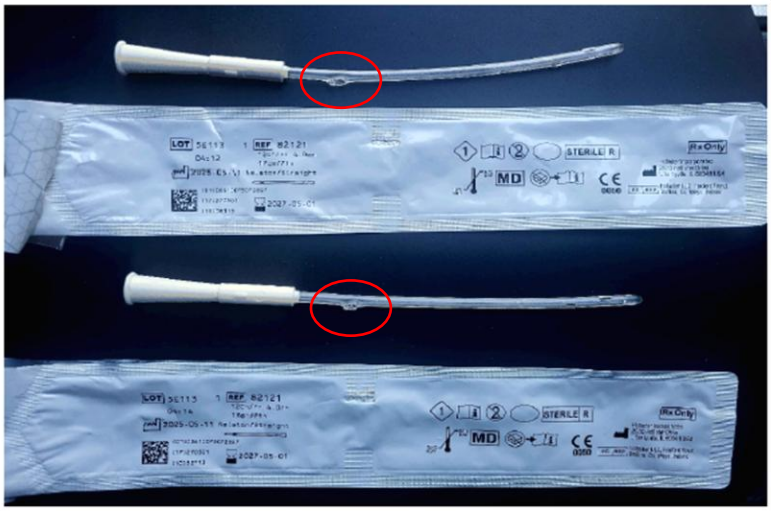
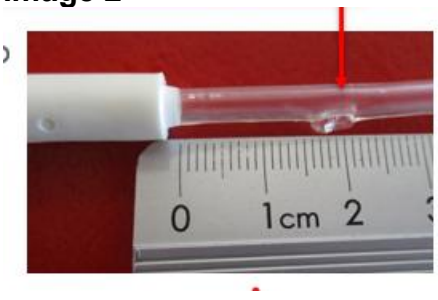


Image 2



Actions to be Taken by users

Step #1: Verify product lot number against list attached to this Product Field Safety Notice per image below.

Example of the product reference number (REF) and lot number, found on the individual package:

Example of product reference number (REF), found on the control label on the end of the box:

Step #2: If you are in possession of an affected lot, you may continue to use the device but **should inspect each catheter at the time of use for the potential presence of a protrusion located approximately 2 cm from the funnel** (as described in Images 1 and 2). **If a protrusion is identified, the catheter should not be used.** Users should also review and follow the Instructions for Use (IFU) and ensure that the device is opened, handled, and inserted in accordance with the IFU.

In case of serious injury (incident) in relation to your use of the product, please contact healthcare provider and / or your local distributor.

Please follow the steps below:

1. Please complete and return the response form attached as soon as possible, even if you do not have product in your possession and send the form to ComplaintCommunication@Hollister.com.
2. If you have supplied or transferred any potentially affected product to another facility or organization, provide that facility with a copy of this letter immediately.

For further information or to request replacement devices please contact us:

By phone –Please contact one of the following:

- If you are a consumer or healthcare professional, please call: 1.888.808.7456
- If you are a dealer, distributor, Institution, or pharmacy, please call: 1.800.323.4060 option 1

Thank you again for being our customer and for your understanding regarding this matter.

Sincerely,

Christine Ponka

Christine Ponka
Manager, Post Market Surveillance

URGENT PRODUCT FIELD SAFETY NOTICE

Onli™ and Infyna™ 17cm Hydrophilic Urethral Intermittent Catheter

Response is Required

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

Affected Products

SKU/REF	Description
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Response is Required

YES ☐		I have read and understood the instructions provided in the Product Field Safety Notice.
YES ☐	N/A ☐	I have inspected affected product and followed instructions provided in the Product Field Safety Notice.
YES ☐	N/A ☐	I have no affected product by this Field Safety Notice 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 at 1-800-323-4060 (prompt #1) and provide your purchase order number (PO number) at the time of your request.
*If you do not purchase product directly from Hollister, 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 ***(please use full facility name. Do not use abbreviations):***		
Address including city / town, state / county, post code, Country		

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Affected Products and Lots

Product	Lot
82081	5F273 5F283 5H293 5J153 6C313
82101	5F283 5G013 5K253 6A303
82121	5H283 5H293 5K183 5K193 5K213 6A253 6A263 6B053
82141	5E063 5E073 5E083 5F193 5F203 5F213 5F223 6B133

82084	5E293 5G213 5G223 6A223 6A213
82104	5E293 5E303 5G243 5G253 5J063 5J073 5L153 6D203 6E293
82124	5E303 5F033 5F063 5F043 5F053 5J223 5J283 5J243 5K143 6A163 6A153 6B173 6B183 5F073

82144	6A163 5F113 5F133 5I073 5G083 5E243 5E253 5E233 5F103 5I123 5F143 5E263 5E273 5I113 5E283 5F123 5F153 5G093 5G183 5G173 5I153 5I133 5I143 5I063 6A173 6B243 5I103 6B223 6B233 6B253 6B263 6B213 6C033 6C043 6B273 6C013 6C023 6C053 6B283

82164	6A223 6B183 5F153 5F163 5F183 5F173 5G103 5G143 5G113 5G153 6A233 6C253 6C243 6C223 6C233 6D303 6D293 6D283
85124	5K143 5K133 6B193

85144	6B263 6B273 6C253 5K133 5K123 5K113 5K053 5K043 5K063 5K073 6A113 6A133 5K103 6A123 6A093 6A103 6C283 6C263 6C273 6E013
85164	6D303 5K133 6B193 6A093 6C283 5L053 5L043 6A083 5L193 6A023 5L223 6A053 6C293