



Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048

July 06, 2026

URGENT PRODUCT FIELD SAFETY NOTICE

Onli™ and Infyna™ 17cm 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
88081	Ch08-17 Infyna Hydrophilic Urethral Intermittent Catheter
88101	Ch10-17 Infyna Hydrophilic Urethral Intermittent Catheter
88121	Ch12-17 Infyna Hydrophilic Urethral Intermittent Catheter
88141	Ch14-17 Infyna 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 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

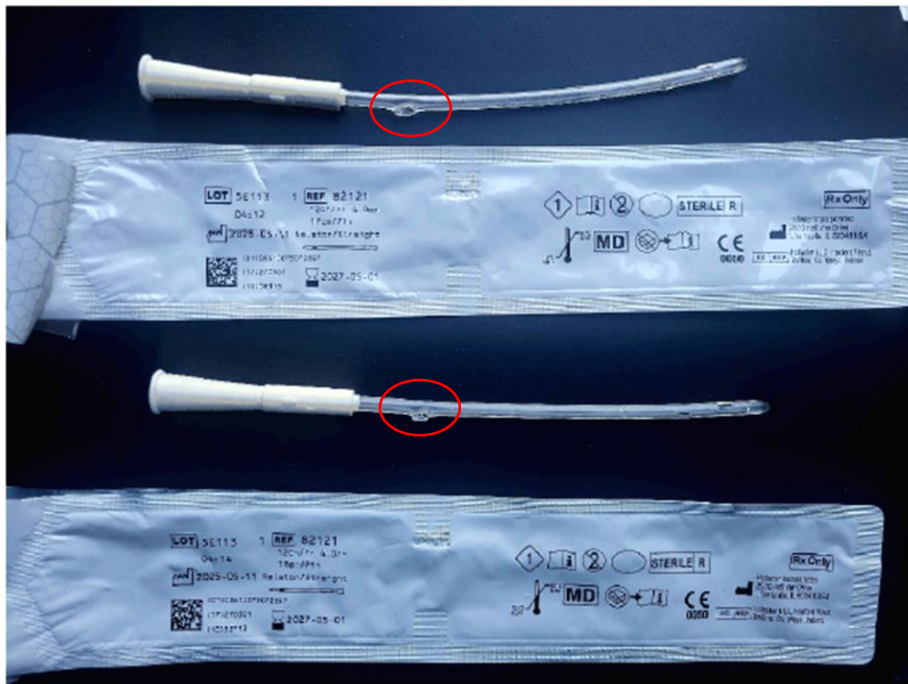


Image 2



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:
Tel no: +353 1 800 503 400
- If you are a dealer, distributor, Institution, or pharmacy, please call: Tel no:
+353 1 800 503 400

By Email - Contact Hollister at: customerservicesie@hollister.com

Address: Unit 4045 Kingswood Road Citywest Business Park D24 V06K Co.
Dublin

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
82081	Ch08-17 Onli Hydrophilic Urethral Intermittent Catheter
82101	Ch10-17 Onli Hydrophilic Urethral Intermittent Catheter
82121	Ch12-17 Onli Hydrophilic Urethral Intermittent Catheter
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88081	Ch08-17 Infyna Hydrophilic Urethral Intermittent Catheter
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88121	Ch12-17 Infyna Hydrophilic Urethral Intermittent Catheter
88141	Ch14-17 Infyna Hydrophilic Urethral Intermittent Catheter

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 customerservicesie@hollister.com 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		

Product Table with lots impacted

SKU	Lots
82081 Ch08-17 Onli	5E223 5F283 5F273 5H293 5J153 5J163 6B013 6C313
82101 Ch10-17 Onli	5E213 5E223 5F283 5F293 5F303 5G013 5J143 5K253 5K263 5K273 5K263 6A303 6A313 6B133 6B143 6D123 6D133
82121 Ch12-17 Onli	5E163 5E143 5E133 5E153 5F233 5F243 5H273 5H283 5J103 5J113 5K163 5K183

	6A263 6B033 6B043 6B013 5K173 6C313 6C303 5E093 5E113 5E123 5H293 5K193 5K213 6A253 6B053 6B073 6D123 6D113
82141 Ch14-17 Onli	5E063 5F223 5F233 6B133 5E073 5E083 5F213 5F203 5F193
88081 Ch08-17 Infyna	5G023 5H293 5J173 5J203 5K273 5K283 6D033
88101 Ch10-17 Infyna	5G033 5F273 5G073 5G023 5G043 5J133 5J123

	5K293 6D153 6A293 5J133
88121 Ch12-17 Infyna	5H313 5H303 6A283 6A273 6B103 5E203 5E193 5E213 5F263 5I013 5I043 5I023 5I053 5J123 5J113 5L013 5K233 5K213 5L023 5K303 5K243 5L033 6B083 6A293 6B093 6B073
88141 Ch14-17 Infyna	5F243 5L033 5E163 5E183 5E173 5E193 5F253 5I053 5K243 5K253 6B113 6D083