



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
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
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
88084	Ch08 40cm Infyna Hydrophilic Urethral Intermittent Catheter
88104	Ch10 40cm Infyna Hydrophilic Urethral Intermittent Catheter
88124	Ch12 40cm Infyna Hydrophilic Urethral Intermittent Catheter
88144	Ch14 40cm Infyna Hydrophilic Urethral Intermittent Catheter
88164	Ch16 40cm Infyna 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

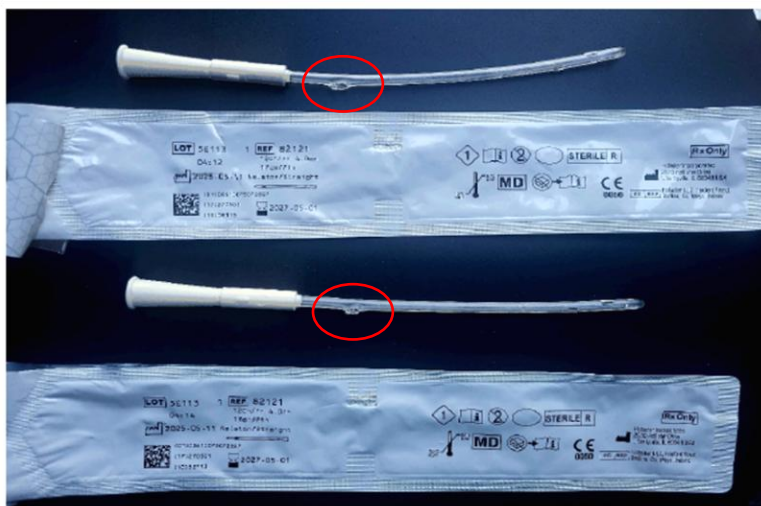


Image 2



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:
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
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
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
88084	Ch08 40cm Infyna Hydrophilic Urethral Intermittent Catheter
88104	Ch10 40cm Infyna Hydrophilic Urethral Intermittent Catheter
88124	Ch12 40cm Infyna Hydrophilic Urethral Intermittent Catheter
88144	Ch14 40cm Infyna Hydrophilic Urethral Intermittent Catheter
88164	Ch16 40cm Infyna 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

URGENT PRODUCT FIELD SAFETY NOTICE

Onli™ and Infyna™ 17cm Hydrophilic Urethral Intermittent Catheter 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 ☐	<i>Distributors:</i> 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		

URGENT PRODUCT FIELD SAFETY NOTICE

Onli™ and Infyna™ 17cm Hydrophilic Urethral Intermittent Catheter

Affected Products and Lots

SKU/REF	Lots
82081 Ch08-17 Onli	5E223 5F273 5F283 5H293 5J153 5J163 6B013 6C313
82101 Ch10-17 Onli	5E213 5E223 5F283 5F293 5F303 5G013 5J143 5K253 5K263 5K273 6A303 6A313 6B133 6B143 6D123 6D133
82121 Ch12-17 Onli	5E093 5E113 5E123 5E133 5E143 5E153 5E163 5F233 5F243 5H273 5H283 5H293

	5J103 5J113 5K163 5K173 5K183 5K193 5K213 6A253 6A263 6B013 6B033 6B043 6B053 6B073 6C303 6C313 6D113 6D123
82141 Ch14-17 Onli	5E063 5E073 5E083 5F193 5F203 5F213 5F223 5F233 6B133
88081 Ch08-17 Infyna	5G023 5H293 5J173 5J203 5K273 5K283
88101 Ch10-17 Infyna	5F273 5G023 5G033 5G043 5G073 5J123 5J133 5K293 6A293 6D153

88121 Ch12-17 Infyna	5E193 5E203 5E213 5F263 5H303 5H313 5I013 5I023 5I043 5I053 5J113 5J123 5K213 5K233 5K243 5K303 5L013 5L023 5L033 6A273 6A283 6A293 6B073 6B083 6B093 6B103
88141 Ch14-17 Infyna	5E163 5E173 5E183 5E193 5F243 5F253 5I053 5K243 5K253 5L033 6B113 6D083
82084 Ch08 40cm Onli	5E033 5E043 5E293 5G213 5G223

	5G233 6A213 6A223
82104 Ch10 40cm Onli	5E033 5E293 5E303 5G243 5G253 5G263 5G273 5J063 5J073 5J083 5J093 5L153 5L173 6A193 6A203 6D193 6D203 6D213 6E273 6E283 6E293 6E303
82124 Ch12 40cm Onli	5E303 5F013 5F033 5F043 5F053 5F063 5F073 5F093 5G173 5H213 5H223 5H233 5H243 5I153 5I163 5I173 5I193 5I203

	5J223 5J233 5J243 5J283 5J293 5K143 5K153 5K163 5L083 5L093 5L103 5L113 6A133 6A143 6A153 6A163 6B153 6B163 6B173 6B183 6C073 6C083 6C093 6C103 6C113 6C123 6C143 6E103 6E113 6E123 6E133 6E203 6E213 6E223 6E233 6E253 6E263
82144 Ch14-40cm Onli	5E043 5E233 5E243 5E253 5E263 5E273

	5E283 5F093 5F103 5F113 5F123 5F133 5F143 5F153 5G083 5G093 5G173 5G183 5I063 5I073 5I103 5I113 5I123 5I133 5I143 5I153 6A163 6A173 6A193 6B213 6B223 6B233 6B243 6B253 6B263 6B273 6B283 6C013 6C023 6C033 6C043 6C053 6C193 6D243 6D263 6E063
82164 Ch16 40cm Onli	5F153 5F163 5F173

	5F183 5G103 5G113 5G143 5G153 6A223 6A233 6B183 6C223 6C233 6C243 6C253 6D283 6D293 6D303
88084 Ch08 40cm Infyna	5G243
88104 Ch10 40cm Infyna	5G313 6A203
88124 Ch12 40cm Infyna	5G163 5I223 5J203 5J213 6C163
88144 Ch14 40cm Infyna	5G093 5I233 5I263
88164 Ch16 40cm Infyna	5G283 5G293 5G303 5I293 5I303 5J023
85124 CH12 40cm Onli Coude	5K133 5K143 6B193
85144 CH14 40cm Onli Coude	5J013 5K043 5K053 5K063 5K073 5K103 5K113

	5K123 5K133 6A093 6A103 6A113 6A123 6A133 6B263 6B273 6C253 6C263 6C273 6C283 6E013
85164 CH16 40cm Onli Coude	5K133 5L043 5L053 5L193 5L223 6A023 6A053 6A083 6A093 6B193 6C283 6C293 6D303