

Liberty Medical Pty Ltd
Ground Floor
990 Whitehorse Road
Box Hill, VIC 3128
Phone: 1800 880 851

July 21, 2022

MEDICAL DEVICE RECALL
Urinary Drainage Bags – Actuator leakage
ARTG Numbers: 107134 & 148032
TGA Ref. RC-2022-RN-00971-1

Dear Valued Business Partner/Customer,

In order to best serve the needs of our customers, Liberty Medical Pty Ltd (Australian Sponsor) and Hollister Incorporated (US Manufacturer), following consultation with the Therapeutic Goods Administration (TGA), are undertaking this communication to advise their Urinary Drainage Bags customers of a voluntary recall of the following product:

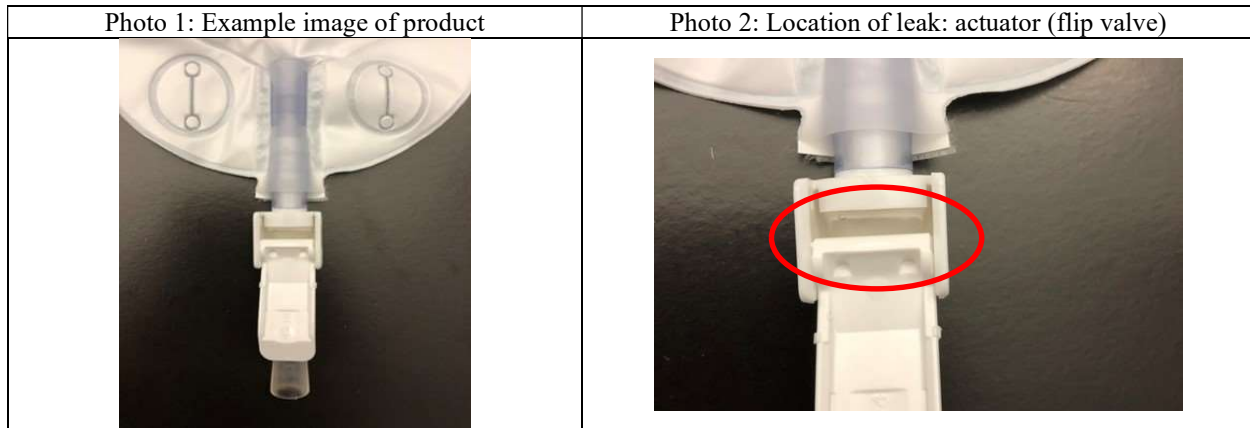
SKU Number	Lot Number
9650 Drainage Collection Bag 2000mL Sterile	1J03
	1J05
	1J12
9621K Leg Bag 500mL 10cm Tubing w/ Straps Sterile	1K05
9624K Leg Bag 500mL 50cm Tubing w/ Straps Sterile	1K19
9631K Leg Bag 800mL 10cm Tubing w/Leg Straps Sterile	1J14
9653K Leg Bag 800mL 50cm Tubing w/Straps Non-Sterile	1K168

Device Use

Urinary leg bags and night drainage bags collect and contain urine.

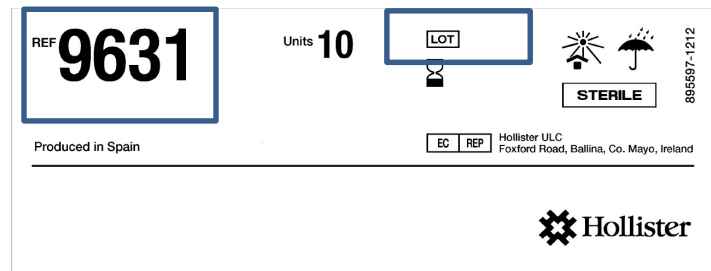
Reason for Recall

Hollister is recalling these Urinary Drainage Bags due to a potential of leakage of urine at the location of the actuator (flip valve) during use, see photo images below (Photo 1: example image of product, Photo 2: Location of leak). 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.



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.
 - a. Please refer to Image below and note the blue box around the SKU and lot location



2. If you have further distributed this product, forward a copy of this letter to any consignees who may have received affected products from your inventory. Date(s) distributed: Between November 2021, to June 2022.
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 **ComplaintCommunication@Hollister.com**.

Product Replacement or Credit requests

5. If you are a direct customer of Hollister's, contact our Australian Representative, Liberty Medical Pty Ltd at 1-800-880-851 for product replacement or credit as applicable. 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. If you have any questions regarding the content of this notification, please contact Mr. Igor Mikolajewski, Compliance Manager, at 1-800-880-851 from our Australian Representative, Liberty Medical Pty Ltd. 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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 Ground Floor
 990 Whitehorse Road
 Box Hill, VIC 3128
 Phone: 1800 880 851

MEDICAL DEVICE RECALL RESPONSE FORM

Urinary Drainage Bags

ARTG Numbers: 107134 & 148032

TGA Ref. RC-2022-RN-00971-1

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

For **Credit or Replacement Requests** please contact Liberty Medical Customer Service at 1800 880 851.

SKU Number	Lot Number	Quantity of boxes in your possession
9650 Drainage Collection Bag 2000mL Sterile	1J03	
	1J05	
	1J12	
9621K Leg Bag 500mL 10cm Tubing w/ Straps Sterile	1K05	
9624K Leg Bag 500mL 50cm Tubing w/ Straps Sterile	1K19	
9631K Leg Bag 800mL 10cm Tubing w/Leg Straps Sterile	1J14	
9653K Leg Bag 800mL 50cm Tubing w/Straps Non-Sterile	1K168	

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"/>	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 Form:

Name and title:		Date:
Telephone Number and/or email:		
Facility/Business name <i>(please use full facility name. Do not use abbreviations):</i>		
Address including city, state, zip		

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Urinary Drainage Bags – Actuator leakage
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Customer Frequently Asked Questions (FAQ)

1. What lot number and product are impacted for this Recall?

SKU Number	Lot Number
9650 Drainage Collection Bag 2000mL Sterile	1J03
	1J05
	1J12
9621K Leg Bag 500mL 10cm Tubing w/ Straps Sterile	1K05
9624K Leg Bag 500mL 50cm Tubing w/ Straps Sterile	1K19
9631K Leg Bag 800mL 10cm Tubing w/Leg Straps Sterile	1J14
9653K Leg Bag 800mL 50cm Tubing w/Straps Non-Sterile	1K168

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.

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 Liberty Medical 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

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 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 affected by this recall.

9. Who do I contact for more assistance?

Please contact one of the following Hollister Incorporated departments:
Liberty Medical Customer Service: 1800 880 851
Hollister Quality: ComplaintCommunication@Hollister.com