

**URGENT MEDICAL DEVICE RECALL  
NOTIFICATION LETTER  
MEDIHONEY® Wound & Burn Dressing Paste**

October 15, 2024

Dear Valued Customer,

We have been notified of a recall for the MediHoney® Wound & Burn Dressing Paste with Sterile Applicator (see Table 1) that you purchased from Performance Health.

*Table 1: Impacted Product Information*

Performance Health Part Number	Manufacturer's Product Number	Product Name (Description)	UDI Number	Lot Number	Expiration Date (MM/YY/YYYY)
081593482	31515	MEDIHONEY® TUBE – 1.5 FL OZ (44 ML) – W/APPLICATOR- STERILE	10381780486824	All lots distributed from 12/17/2020 to 07/22/2024.	08/01/2024 to 06/01/2028
081593466	31535	MEDIHONEY® TUBE – 3.5 FL OZ W/APPLICATOR- STERILE	10381780486831		

**Reason for Recall:**

This voluntary recall has been initiated due to the potential for pinholes in the applicator pouch film (see Figures 1a and 1b) which creates a sterility concern. The paste is not impacted by this potential sterility concern. There is no risk to the end user if the applicator is not used to apply the paste directly on the wound.

Upon additional review, these units were identified as the US SKU of the product, not the Canadian SKU licensed for sale into Canada.



**Figure 1a:** SKU# 31515 Carton and Contents



**Figure 1b:** SKU# 31535 Carton and Contents



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**Risk to Health**

Based on the health hazard evaluation conducted for this issue, the potential harm is infection if a non-sterile product is used on a patient. There are no long-range health consequences expected due to this issue. If product was used and standard post-operative care is followed, no further patient follow-up is required.

No additional risk has been identified with sale of the US SKUs into Canada, as there is no difference in functionality from the licensed Canadian SKU.

**Actions to be Taken by Customers:**

1. Contact [SMB-PH-US03-Regulatory@performancehealth.com](mailto:SMB-PH-US03-Regulatory@performancehealth.com) with the number of units on hand. A return label will be provided.
2. Use the provided return label to return the impacted units to Performance Health.

Should you have any questions regarding these instructions, please contact Regulatory at [SMB-PH-US03-Regulatory@performancehealth.com](mailto:SMB-PH-US03-Regulatory@performancehealth.com).

We apologize for the inconvenience and thank you for your cooperation in this effort.

Best Regards,

A handwritten signature in black ink, appearing to read 'Paul Hanneman'.

Paul Hanneman,  
Vice President, Quality and Regulatory  
Performance Health