



URGENT: MEDICAL DEVICE PRODUCT CORRECTION

Product Code	Product Description	Lot Number
61115	JF Blue Gel Extra Small (sample)	ALL LOTS
70304	4.5x10.5" GEL REUSE MICRO H/C	ALL LOTS
70204	24/CASE 4.5x7 GEL REUSE MICRO H/C	ALL LOTS
70304A	24/CASE 4.5x7 GEL REUSE MICRO H/C	ALL LOTS
80104	24/CASE 6x8.75" GEL REUSE INSUL H/C	ALL LOTS
80204A	24/CASE 4.5x6" GEL REUSE INSUL H/C	ALL LOTS
80304A	24/CASE 4.5x10.5" GEL REUSE INSUL H/C	ALL LOTS
80600	6/CASE 7.7"x16.5" GEL REUSE INSUL H/C	ALL LOTS
170916-24	REUSEABLE TRANSPORT GEL 12oz	ALL LOTS
170948	REUSABLE TRANSPORT GEL 8oz	ALL LOTS

October 03, 2022

Dear Valued Customer:

Product Overview	Cardinal Health is issuing this correction to make you aware of a labeling update on its Reusable Hot and Cold Gel Pack products. Specifically, a caution statement is being added to ensure the products are not used on infants or neonates.
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Description of the issue:	<p><u>What is the issue?</u> Cardinal Health recently received one (1) complaint in which the pack was used on an infant and resulted in a second-degree burn. Over the course of a five-year timeframe in which approximately 5.95 million devices were distributed, this is the only complaint we have received regarding a burn injury to a user.</p> <p><u>Why are we sending this letter?</u> We are sending this letter to inform users that the product should not be used on infants/neonates. A caution statement will be added to the labeling stating: "Not for use on infants/Neonates".</p> <p><u>What actions are needed from the Customer?</u> Please review this enhanced caution statement with your staff to ensure product is not used on infants and/or neonates.</p>
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Actions Required:	<ol style="list-style-type: none"> 1. COMMUNICATE with all personnel that utilize these gel packs regarding appropriate use. 2. NOTIFY any customers to whom you may have distributed/forwarded affected product to or will send the product on to about this product correction notice and share a copy of this notice. 3. POST a copy of this notification in your storeroom where the product is stored 4. RETURN the enclosed acknowledgment form via fax to 614-652-9648 or email to gmbfieldcorrectiveaction@cardinalhealth.com, whether or not you have affected product.
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Additional Information:	For questions related to this notification and/or acknowledgement form that are not adequately addressed in this letter, please contact the market action team at: GMB-FieldCorrectiveAction@cardinalhealth.com or call 800-292-9332.
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