Cardinal Health 200, LLC
3651 Birchwood Drive
Waukegan, IL 60085
cardinalhealth.com

CardinalHealth

URGENT:MEDICAL DEVICE PRODUCT CORRECTION

MacGill Item Numbers	Product Code	Product Description	Lot Number
18045/15691	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
18030/15693	80104	24/CASE 6x8.75" GEL REUSE INSUL H/C	ALL LOTS
18025/15692	80204A	24/CASE 4.5x6" GEL REUSE INSUL H/C	ALL LOTS
18040/15694	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.

Description of the issue:	What is the issue? 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. Why are we sending this letter? 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**". What actions are needed from the Customer? Please review this enhanced caution statement with your staff to ensure product is not used on infants and/or neonates.

Actions Required:	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.

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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	In the event you have experienced quality problems or adverse events related to the products listed above, please utilize the contacts below: Please contact the Customer Service group for any questions related to this action or to return defective product: • Hospital—800-964-5227 • Federal Government—800-444-1166 • Distributor—800-635-6021 • All other customers—888-444-5440 **Adverse Events Reporting Process** Cardinal Health has notified the U.S. Food & Drug Administration that we are taking this action. In the event you have experienced quality problems or adverse events related to the products listed above, send an email to: GMB-PRComplaints@cardinalhealth.com. The FDA can be contacted to report any adverse events experienced with these products: • Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or email) or call FDA 1-800-332-1088. **Regulatory Notification** The FDA and other applicable regulatory bodies have been notified and are aware Cardinal Health is voluntarily taking this action.

We apologize for any inconvenience this communication may cause. We know that you place high value in our products, and we appreciate your cooperation in this matter. Cardinal Health is committed to maintaining your confidence in the safety and quality of the products that we supply.

Respectfully yours,

Govindaraj Coimbatore Sriram
Director, QRA Management