Cardinal Health
15 Hampshire Street
Mansfield, MA 02048
cardinalhealth.com

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PRODUCT ADVISORY

Product Code	Product Description	First Produced Lot Number
2283	Webril BDG 2 inch STERILE	**23E062262**
2394	Webril BDG 3 inch STERILE	**23G063362**
2502	Webril BDG 4 inch STERILE	**23E071262**
2554	Webril BDG 6 inch STERILE	**23E068862**
1418	Webril Cast Padding 2inx4yd Non-Sterile	**23E057362**
2059	Webril Cast Padding 3inx4yd, Non-Sterile	**23E077162**
3175	Webril Cast Padding 4inx4yd, Non-Sterile	**23E019362**
3489	Webril Cast Padding 6inx4yd, Non-Sterile	**23E091262**

November 20, 2023

Dear Valued Customer:

Product Overview	Cardinal Health is issuing this advisory notice to ensure awareness of changes to Webril™ Undercast Padding. By way of background, the product is made of cotton and is intended to provide cushioning between skin and an immobilization device, such as a cast, while absorbing moisture.

Description of the issue:	What is the issue? In June 2023, due to market disruptions outside of our control, Cardinal Health changed the supplier for the cotton used to manufacture Webril™ Undercast Padding. Although the Webril™ Cotton Undercast Padding continues to meet product specifications, customers have expressed dissatisfaction with the product change, reporting difficulty tearing, bunching, and lack of adherence (sticking to itself during wrapping). No reports of serious adverse events have been received to date. Why are we sending this letter? Cardinal Health is sending this letter to raise awareness of the change so that users can ensure that clinical guidelines continue to be used for proper cast and splint application. What other actions is Cardinal Health taking? We take customer feedback seriously and are working to address the feedback received regarding customer preferences.

Actions Required:	1. **REVIEW** your inventory for the affected product code above. 2. **COMMUNICATE** the product update with personnel that will utilize the Webril™ products. 3. **POST** a copy of this notification in the storeroom or where product will be stored. 4. **NOTIFY** any customers to whom you may have distributed/forwarded affected product to or will send the product on to about this product notice and share a copy of this notice. 5. **RETURN** the enclosed acknowledgment form via fax to 614-652-9648 or email to GMB-FieldCorrectiveAction@cardinalhealth.com, whether you have affected product or not. 6. No product return is required

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Available Assistance:	**CONTACT** the appropriate Customer Service group for any additional questions. This is a product advisory, and product does not need to be returned. **Monday – Friday between 8:00am - 5pm EST**: Hospital—800-964-5227 Federal Government—800-444-1166 Distributor—800-635-6021 All other customers—888-444-5440 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.**

Additional Information:	In the event you have experienced quality problems or adverse events related to the products listed above, please utilize the contacts below: Hospital—800-964-5227 Federal Government—800-444-1166 Distributor—800-635-6021 All other customers—888-444-5440 **Adverse Events Reporting Process** 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.

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,

JoAnne Zwiers

Joanne Zwiers
Director, QRA Management

3/14/2024

Cardinal Health - Webril Cast Padding Correction

Please fill out and fax/email this distributor form within 10 business days, even if you do not have the recalled product.

Please complete and email to: Compliance@ndc-inc.com

Acknowledgment of Receipt

Customer Information

Account No. _____

Account Name _____

Address _____

City/State/Zip _____

Contact Name _____

Phone No. _____

Fax No. _____

Email _____

Inventory Information

Item#	LOT #	Exp Date	Quantity

☐ I have read and understood the information within the accompanying notification. All relevant customers/ personnel have been informed of its contents, any necessary actions taken and records retained as part of our documentation.

☐ We have inspected our inventory and have no product related to this correction

_____

Completed by: (Print Name /Signature/Date)

Returned Completed form to:

compliance@ndc-inc.com

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