

## **RE: Urgent Medical Device Recall Notice**

Dear Valued Aveanna Customer,

This message is from Aveanna Healthcare Medical Solutions (AHMS). We are reaching out to inform you about an Urgent Medical Device Recall Notice issued by Coloplast, the manufacturer of various urological, ostomy and medical supplies. Our records indicate you or a member in your household may have received a recalled item manufactured by Coloplast.

AHMS was notified of this product recall on December 19, 2024, by McKesson Medical-Surgical Inc. (MMS), our third-party distributor. This recall is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA).

This recall is related to specific Coloplast product lots due to a potential sterility issue found during testing at their facility. The defect in the packaging is not easily visible to users, but the risk of clinical impact is considered low, per the manufacturer. The affected products were first shipped on April 20, 2020.

## Per manufacturer recommendations, please discontinue use of any products matching the affected item and lot number listed on

https://aveannamedicalsolutions.info/ColoplastRecall. Should you possess a recalled product in your home, and require disposal, please contact us to request a no-charge replacement. Please note, your upcoming supply orders will not include the specific lot numbers included in this recall. If your specific product is unavailable, an available and comparable alternative will be shipped to you.

If you have questions about the recalled products, please contact **Coloplast at (855) 745-8549**. Patients who have already used a product listed in this recall may contact Coloplast or speak with their medical care team for more information.

Should you have any additional questions or concerns, you may also contact AHMS toll-free at (866) 883-1188 during our normal business hours: Monday through Friday, 7:00 AM to 7:00 PM CST, or Saturday, 8:00 AM to 1:00 PM CST.

Thank you for trusting AHMS with your in-home care.

Sincerely,

## -Aveanna Healthcare Medical Solutions

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-888-255-8360 (TTY: 711).

注意:如果您使用繁體中文,您可以免費獲得語言援助服務。請致電 1-888-255-8360 (TTY: 711)。

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