OVIK Health, LLC

April 1, 2024

URGENT: MEDICAL DEVICE RECALL

Sterile CoFlex NL (5400S), Batch 0031151359, Lot 10009897233

April 1, 2024

Customer Name:_____
Street Address: _____
City, State, Zip Code: _____

Dear Customer,

Patient safety is our first priority. Although no adverse events have been reported, OVIK Health, LLC is voluntarily recalling Sterile CoFlex NL Tan (5400S), Batch 0031151359, Lot 10009897233. These are sterilized cohesive bandages intended for use as a secondary wound dressing.

Some of the packaging in this lot may not have been sealed properly, and in an abundance of caution and to protect patient care, we are requesting all packages of Batch 0031151359, Lot 10009897233 to be returned to us. We will provide replacement products as soon as possible.

Reason for the Voluntary Recall:

One batch of Sterile CoFlex (5400S) products may be impacted by a packaging error in which an incomplete seal has formed on the packaging thereby creating a packaging seal gap. A packaging seal gap could impact the sterility of the product. This is limited only to Batch 0031151359, Lot 10009897233, which is Sterile CoFlex Non Latex Tan 4”x5YD (5400S). Each package is marked with a statement that the product should not be used if the seal is broken.

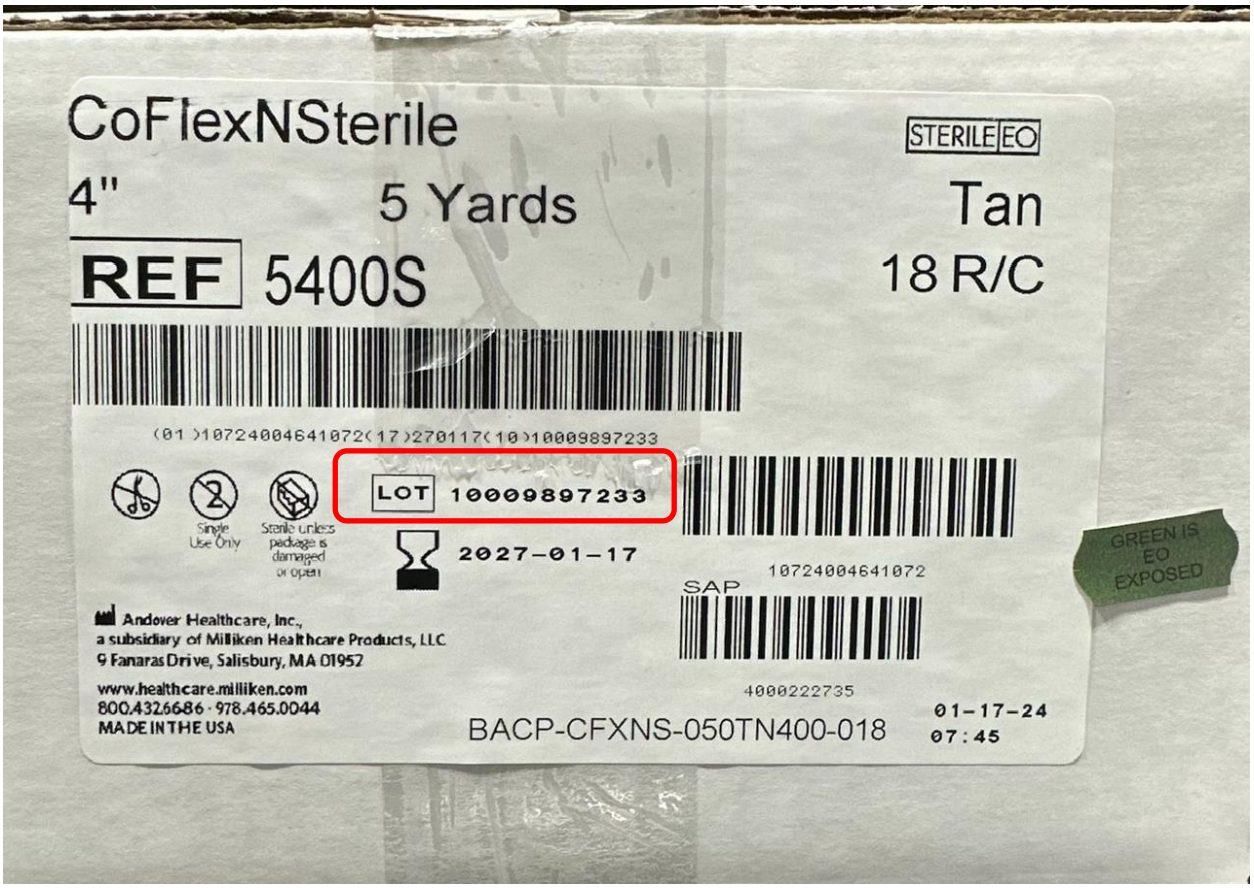
No adverse events have been reported.

Risk to Health:

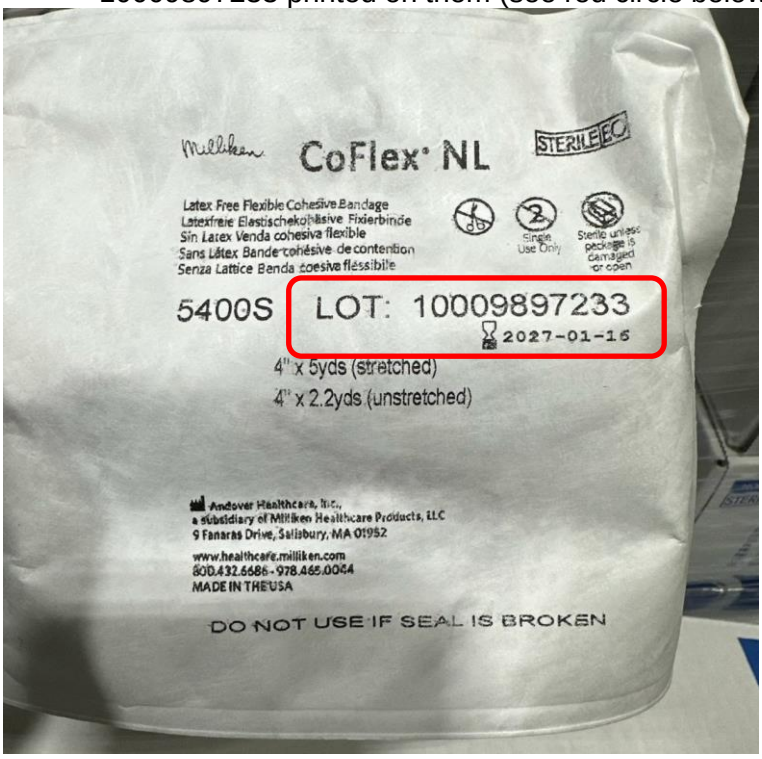
Although intended for use as a secondary wound dressing, it is possible that the use of nonsterile cohesive bandages could increase risk of infection.

How to recognize a product with compromised packaging:

- Below is a picture of the case. We are recalling only Lot 10009897233, which is printed on each case (see red circle below).



- If case has been opened, then individual packages inside also have the Lot 10009897233 printed on them (see red circle below).



Actions to be taken by the Customer/User:

Please identify and return all cases of Batch 0031151359, Lot 10009897233 Sterile CoFlex NL, Tan, 4”x5YD (5400S) made January 2024, shipped February 2024 – March 2024. Please make sure everyone in your organization is fully aware of this corrective action and follows these instructions.

- Please discontinue the distribution and use of Batch 0031151359, Lot 10009897233, Sterile CoFlex NL Tan 4”x5YD (5400S).

- Please return all cases of Batch 0031151359, Lot 10009897233, Sterile CoFlex NL, Tan, 4”x5YD (5400S) to OVIK Health, LLC, c/o Customer Care, 9 Fanaras Drive, Salisbury, MA 01952.

- Please phone or email your acknowledgement of this recall notice (using the attached Acknowledgement and Receipt Form or otherwise) to:
    - Phone: 1 (800) 432-6686 (toll free)
    - E-mail: customerservice@ovikhealth.com

Upon receipt of returned products, OVIK Health, LLC will issue a credit. We will continue to provide these products with minimal interruption in the supply chain.

Type of Action by the Company:

Our investigation findings indicate a variation in sealing settings which could prevent a full seal on the primary packing of Batch 0031151359, Lot 10009897233. The sealing settings have been corrected and controlled to prevent future variations and ensure the long-term success of the sterile packout process.

OTHER INFORMATION:

- For further information, questions, or concerns please do not hesitate to reach out to OVIK Health, LLC at:
    - Phone: 1(800) 432-6686
    - Address: OVIK Health, LLC
c/o Customer Care
9 Fanaras Drive
Salisbury, MA 01952

Contact Information: Monday through Friday, 8:00 AM to 4:30 PM, Eastern Time. Toll free number: 1(800) 432-6686, customerservice@ovikhealth.com

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA’s MedWatch Adverse Event Reporting program either online, by regular mail or by fax.