OVIK Health, LLC

April 1, 2024

URGENT: MEDICAL DEVICE RECALL

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

Concordance Healthcare Solutions LLC
85 Shaffer Park Dr
Tiffin OH 44883

Dear Concordance,

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.

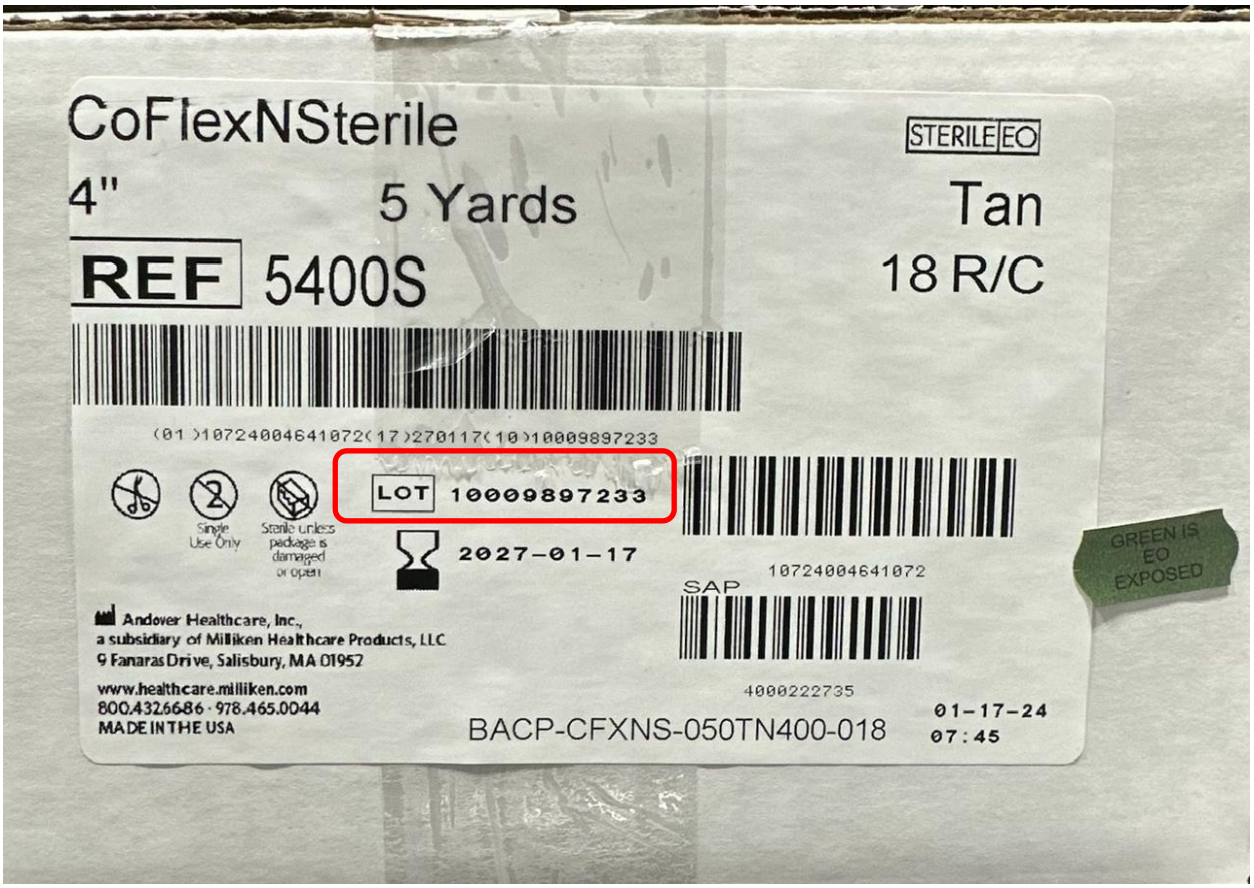
No adverse events have been reported.

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).



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 identify all customers that purchased inventory of Batch 0031151359, Lot 10009897233, Sterile CoFlex NL Tan 4”x5YD (5400S). Email the attached Customer Notice to each of those customers so that they can participate in the recall. If you have a physical address, please also mail them the attached Customer Notice. Retain written proof that the Customer Notice has been sent and received. We will reimburse you for your postage and shipping costs upon receipt of reasonable proof of those costs. If you would prefer for us to handle the communications to your customers, we will do so at no charge if you provide all available contact information. Refer to our contact information below for all questions and requests for reimbursement.

- 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

- Attachments: Acknowledgement and Receipt Form; Notice to Customers Form (separate sheets)

Authorized by:
Name: (Print)

_____

Signature:

_____

Title:

_____

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.

MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form

Response is Required

Sterile CoFlex NL, Batch 0031151359, Lot 10009897233

I have read and understand the recall instructions provided in the April 1, 2024 letter. Yes _ No_

Any adverse events associated with recalled product? Yes _ No _

If yes, please explain: _____
_____

Were any cases shipped to a customer? (If yes, please s**pecify the ship dates, the ship quantities, and provide available tracking information**).

Affected Product Information Table				
Product/Brand Names	Batch Number	Lot Number	Quantity in inventory	Quantity returned
Sterile CoFlex NL	0031151359	10009897233		

Return Response Box:

Please provide any additional information, if applicable.

I have checked my stock and have identified and returned inventory consisting of _____ <units, cases, etc.>.

I have identified and notified my customers that were shipped or may have been shipped this product by _____ (**specify date and method of notification**) [Attached is a model customer notification letter]; <or>
Attached is a list of customers who received/may have received this product. Please notify my customers. _____

Questions: (when applicable)

☐ Please have Customer Service contact me.

Signature of Receipt _____

Name/Title	
Telephone	
Email address	

PLEASE EMAIL TO: customerservice@ovikhealth.com