

URGENT: FIELD SAFETY NOTICE

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



CardinalHealth

December 11, 2023

Various Kits/Trays Containing Nurse Assist Products

File #: Event-2023-05907

Manufacturer SRN: US-MF-000017721

Dear Valued Customer:

Cardinal Health was recently informed that Nurse Assist, LLC initiated an Urgent Field Safety Notice regarding several products that cannot be verified as having the required sterility assurance level of (SAL) of 10^{-6} . In populations most at risk, such as patients who are immunocompromised, there is a possibility that the use of the affected product could potentially result in severe or life-threatening adverse events. Please see enclosed Nurse Assist, LLC Urgent Field Safety Notice.

Cardinal Health has completed its investigation regarding this recall and determined that you may have received trays/kits containing the affected Nurse Assist component(s). Please refer to the table below for list of Impacted Products along with the corresponding lot numbers that are affected by this action.

Product Code	Lot #	Product Description
8887705146	22D178FHX	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 14 Fr/Ch (4.7 mm)
8887705146	22D179FHX	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 14 Fr/Ch (4.7 mm)
8887105123	22D031FHX	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 12 Fr/Ch (4.0 mm)
8887105180	22D172FHX	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 18 Fr/Ch (6.0 mm)
8887705161	22E136FHX	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 16 Fr/Ch (5.3 mm)
8887105149	22D177FHX	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 14 Fr/Ch (4.7 mm)
8887105149	22E203FHX	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 14 Fr/Ch (4.7 mm)
8887105164	22E135FHX	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 16 Fr/Ch (5.3 mm)
8887705203	22F041FHX	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 20 Fr/Ch (6.7 mm)

If you locate affected product within your facility, please do the following:

1. **QUARANTINE** affected kits/trays.
2. **ALERT** your clinicians of this action.
3. **AFFIX** the enclosed WARNING LABEL to the front of each kit/tray so that it is clearly visible to clinicians, instructing them to remove and **discard** the recalled component(s).
4. **NOTE** if you have transferred the affected kits/trays to other departments or facilities within your system, please provide a copy of this notice and recall acknowledgement form to them.
5. **DISTRIBUTOR** if you have further distributed affected kits/trays, please notify your customers of this recall.
6. **RETURN** a copy of the enclosed Acknowledgment Form confirming your receipt of this action and the completion of over labeled product by following the directions on the Form.

Additional labels will be sent to your facility upon request.

Available Assistance:	If you have any questions regarding this field safety notice, please contact your local sales representative, or local sales office.
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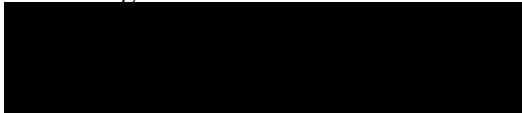


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Additional Information:	<u>Regulatory Notification</u> The applicable regulatory agencies are being notified that Cardinal Health is taking this action.
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We sincerely apologize for any inconvenience this notice may have caused you and your staff. Should you have any questions, require additional labels or desire special assistance relating to this Field Safety Notice, please feel free to contact your local sales representative, or local sales office.

Sincerely,



Director, Quality Management

WARNING

THE NURSE ASSIST COMPONENTS
(#6496722, #6492775, #6492776,
#6496723,
#1022, #1024, #PT00103419,
#PT00103427)

HAVE BEEN RECALLED

REMOVE AND DISCARD RECALLED
COMPONENT(S)

UPON OPENING KIT

ALL OTHER COMPONENTS ARE SAFE FOR
USE

REFER TO RECALL LETTER



FIELD SAFETY NOTICE
CUSTOMER ACKNOWLEDGEMENT FORM
Products containing Nurse Assist Products – Event-2023-05907

Cardinal Health is issuing a field safety corrective action for specific product codes and lot numbers listed in the table below due to a potential sterility issue with Nurse Assist components which are sold along with the listed Cardinal Health products.

Product Code	Lot #	Product Description
8887705146	22D178FHX	Dover™ 100% Silicone Foley Catheter, 5-10 mL, 2-Way, 14 Fr/Ch (4.7 mm)
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Nurse Assist part number 6496722 (Syringe Prefilled 10ml) and lot number 2203000465 is included with the above products.

Note: This is NOT a product removal.

Customer Account No. and Name:	
Customer Contact Name:	
Customer Address:	

Our records indicate that your facility received product subject to the above field safety notice.

Please select the appropriate answers below:

- We have affected inventory within our possession **AND** have over labeled product
- We have affected inventory within our possession **AND** have contacted the appropriate customer service group for credit if requested **Quantity on hand:** _____
- We have further distributed affected product and have notified our customers
- We have no affected inventory within our possession

Part 1: Letter Acknowledgement (Customer)

Name/Signature: (Customer)

Position: (Customer)

Date: (Customer)



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Please return this completed acknowledgement form to your sales representative

OR

Part 2: Letter Acknowledgement (Cardinal Health Representative)

I confirm that this Field Safety Notice has been communicated to the following person/department as the representative(s) of this customer. The above questions were answered based on information supplied by the customer.

Customer Representative Name/Position or Customer Department

Name/Signature: (Cardinal Health Representative)

Position:

Date: