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COVER SHEET

From: *NDC Homecare dba Preferred Medical* *Compliance* ***URGENT*** ****This is being emailed to the "bill to" account for your company. Please distribute to any/all branches.******	
To: *Purchasing or Regulations Department*	**Date:** *9/15/2020*
Pages: *5* *(Including cover page)*	
Regarding: *Urgent Medical Device Recall* *Items CHC 47-4000 & CHC 48-4000*	

Comments:

Dear Distributor,

Attached is a letter we received from Cardinal Health regarding the recall on items CHC 47-4000 and CHC 48-4000. Our records indicate that you purchased one of these products from us. Please read attached letter and check your inventory for any affected product with listed lot number. If you have any of this product in stock please fill out attached "Customer Response" form, and send it to the email address provided (compliance@ndc-inc.com). ***If you have any questions please feel free to contact me. It is very important that we receive a response, a record of receipt is very important in documentation of these types of notices.*** *Additionally, if you have distributed these products to your customers, please advise them of the recall, and have return any affected product to you.*

Thanks,

Michael Patton

402 BNA Dr STE 500, Nashville, TN 37217
Michael Patton- Compliance Specialist / compliance@ndc-inc.com / Phone: 615-366-3230
Tammy Beasley- Compliance Manager / Phone: 615-366-3225

CARDINAL HEALTH
1500 S Waukegan Rd
Waukegan, IL 60085
cardinalhealth.com

3rd Notification
URGENT MEDICAL DEVICE RECALL

EVENT #: 2020-02844

September 11, 2020

Dear Valued Customer:

Cardinal Health had previously notified you about an issue related to specific lots of NPWT 300cc canisters back on June 4, 2020 and again on August 7, 2020. This is a third notice requesting a response to this market action. The products were distributed between August 2019 and March 2020.

Issue Description
This recall is being conducted due to Canisters produced in August 2019 that potentially contain an oversized O-ring. The canisters with the oversized O-ring cannot be installed into the mating connector on the device causing the device to be unusable until a properly fitting canister is available. Canisters that cannot be properly installed could result in a delay of treatment. Cardinal Health is not aware of any reports of patient harm.

Cardinal Health is initiating this voluntary recall on the following item codes and lot numbers:

Item Code	Item Description	Lot No.
47-4000	Cardinal Health NPWT 300cc Canister With Gel	201921913, 201921915, 201921919, 201922009, 201922017, 201922019, 201922021, 201922118, 201922419, 201922120, 201922121, 201922421
48-4000	Cardinal Health NPWT 300cc Canister With Gel Occlusion Detection	201829015, 201923314, 201923316, 201923319, 20192347, 201923414, 201923410

Action Required:

1. **CHECK** all storage and usage locations to confirm whether you have any units of the affected product codes and lot numbers containing the labeling outlined in Exhibit A in your possession. Exhibit A outlines examples of product labeling and how to identify the affected product.

2. **SEGREGATE and QUARANTINE** all on-hand product that is confirmed to be labeled per Exhibit A.

3. **PLEASE RETURN** the enclosed acknowledgment form via facsimile (847-689-9101 or 614-652-9648) or email (GMB-FieldCorrectiveAction@cardinalhealth.com) and indicate the product code, lot and quantity of product you've quarantined or discarded. Please respond regardless of whether or not you have affected product.

4. **NOTIFY** any customers to whom you may have distributed, or forwarded product affected by this recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

5. **CONTACT** the appropriate Customer Service group to arrange for return and credit/replacement of any affected product Monday – Friday between 8:00am - 5:00pm EST:

   - Hospital—800-964-5227
   - Federal Government—800-444-1166

CARDINAL HEALTH
1500 S Waukegan Rd
Waukegan, IL 60085
cardinalhealth.com

- Distributor—800-635-6021
- All other Customers—888-444-5440

6. **Customers** that did not receive product directly from Cardinal Health should return product through the location where they purchased it.

We have notified the U.S. Food and Drug Administration (FDA) that we are taking this action.

In the event you have experienced quality problems or adverse events related to the products listed above, send an email to: GMB-CAH-Dist-Domestic@cardinalhealth.com

Report any adverse events associated with the use of these products to the FDA:

- Online @ http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (return completed form via email or facsimile)
- Call (800) 332-1088.

We sincerely apologize for any inconvenience this notice may have caused you and your staff. Should you have any questions, or desire special assistance relating to this product, please contact Cardinal Health at 800-292-9332.

Sincerely,

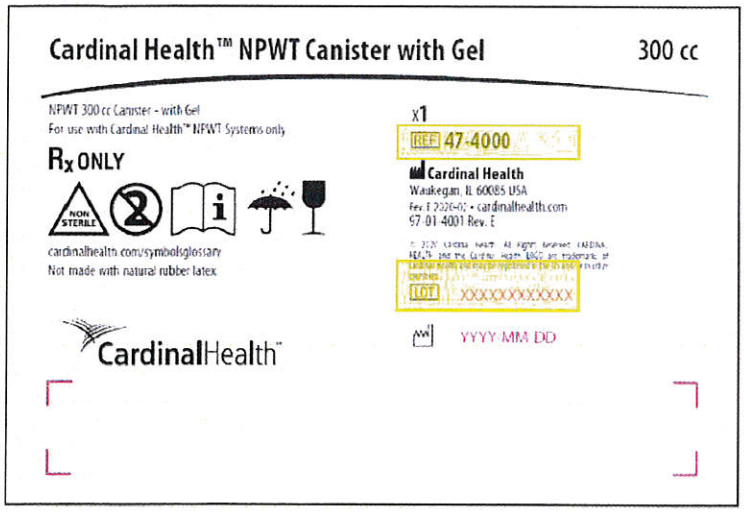
Matt Hedrick

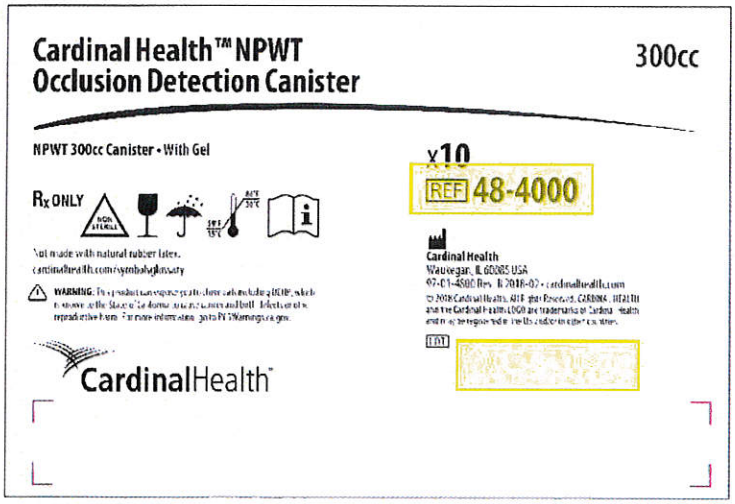
Matt Hedrick
Director, Quality Assurance

Attachment (1)

CARDINAL HEALTH
1500 S Waukegan Rd
Waukegan, IL 60085
cardinalhealth.com

EXHIBIT A – Packaging of Affected Product





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9/15/2020

Cardinal Health - CHC 47-4000 & CHC 48-4000

Please fill out and 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

RECALL RESPONSE FORM

Customer Information

Account No. _____

Account Name _____

Address _____

City/State/Zip _____

Contact Name _____

Phone No. _____

Email _____

Inventory Information

Item number	Lot number	Expiration date	Quantity to return
CHC 47-4000			
CHC 48-4000			

☐ 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 recall

_____

Completed by: (Print Name /Signature/Date)

Returned Completed form to:
Email:

Michael Patton
compliance@ndc-inc.com