Urgent Product Recall

Baxter

July 28, 2014

Dear Director of Materials Management:

Affected Product

2C7564 – BURETROL Solution Set with 150ml INTERLINK Burette
2C8864 – BURETROL Solution Set with 150ml CLEARLINK Burette
2H8864 – Non-DEHP BURETROL Solution Set with 150ml CLEARLINK Burette
Lot Numbers - see enclosed Table of Affected Lot Numbers
Distributed to Baxter customers between September 27, 2013 and July 2, 2014.

Problem Description

Baxter Healthcare Corporation is voluntarily issuing a recall for specific lots of the above BURETROL Solution Set product codes due to complaints for separation between the burette chamber and the drip chamber (see enclosed Table of Affected Lot Numbers). The root cause for this issue has been identified and resolved.

Hazard Involved

Although the confirmed and reported instances of separation were obvious to the user, there may be instances where the separation is not readily visible. If not detected before connection with the administration set, there is a risk of contamination of the sterile fluid path which could lead to blood stream infection (BSI) or sepsis and may be life-threatening. Additionally, air may be aspirated into the vascular system, causing venous air embolism, which while is improbable may be life-threatening. There have been no adverse events reported for this issue.

Action to be taken if product was purchased directly from Baxter

Baxter is requesting that you take the following actions:

1. Locate and remove all affected product from your facility (the product code and lot number can be found on the individual product package or shipping carton.)
2. Contact Baxter's Center for Service to arrange for return and credit. The Center for Service can be reached at 888-229-0001 between the hours of 7:00 am and 6:00 pm Central Time. Please have your Baxter eight digit ship-to account number ready when calling.
3. Complete the attached enclosed customer reply form, and return it to Baxter by either fax or scanned e-mail.

Baxter Healthcare Corporation
25212 W IL Rte 120 / Round Lake, IL 60073

Action to be taken if product was purchased directly from Baxter (cont.)

4. If you are a dealer, wholesaler, or distributor / reseller that distributed any product to other facilities, please conduct a recall with your end user customers in accordance with your customary procedures. Baxter distributed this product to customers between September 27, 2013 and July 2, 2014.

Action to be taken if product was purchased from a distributor or reseller

1. Locate and remove all affected product from your facility (the product code and lot number can be found on the individual product package or shipping carton.)
2. Contact Baxter's Center for Service to arrange for return and credit. The Center for Service can be reached at 888-229-0001 between the hours of 7:00 am and 6:00 pm Central Time. Please have your Baxter eight digit ship-to account number ready when calling.
3. Follow your suppliers' reply and recall process. Please do not return the customer reply form to Baxter.

Further information and support

If you have questions regarding the content of this communication, please call The Center for One Baxter at 800-422-9837 during the hours of 8:00 am to 5:00 pm Central Time.

The United States Food and Drug Administration has been notified of this action. Any adverse reactions or quality problems experienced with the use of these products may be reported using one of the following options:

- Calling Baxter Product Surveillance at 800-437-5176, Monday through Friday, between the hours of 8:00 am and 5:30 pm, Central Time
- Emailing to Baxter at: corporate_product_complaints_round_lake@baxter.com
- Reporting to the FDA by completing and submitting the report Online: www.fda.gov/medwatch/report.htm
- Reporting to the FDA by Regular Mail or Fax: Download form from: www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-332-0178

Baxter

We apologize for any inconvenience this may cause you and your staff.

Sincerely,

Loretta M. Inamoto

Loretta Inamoto
Sr. Director, Quality
Medical Products
Baxter Healthcare

Cc: Director of Nursing
Enclosures

Baxter

Table of Affected Lot Numbers for FCA-2014-076

BURETROL Separation between Burette and Drip Chamber

2C7564 – BURETROL Solution Set with 150ml INTERLINK Burette			
DR13E06019	DR13E07017	DR13E07025	DR13I14023
DR13I16010	DR13I16028	DR13I23016	DR13I23024
DR13J03033	DR13J04015	DR13J04023	DR13J08024
DR13J09014	DR13J09022	DR13J24021	DR13J24039
DR13K07024	DR13K08022	DR13K12024	DR13K13022
DR13K18021	DR13K19029	DR13K25026	DR13K26024
DR13L02023	DR13L03039	DR13L10018	DR13L11016
DR13L18011	DR13L18029	DR13L19035	DR14A09052
DR14A10035	DR14A23012	DR14A23020	DR14A29027
DR14A30017	DR14B06049	DR14B07013	DR14B07047
DR14B11023	DR14B13037	DR14B13045	DR14B14019
DR14B20016	DR14B20032	DR14B21014	DR14B26013
DR14B26039	DR14C05015	DR14C05031	
2C8864 – BURETROL Solution Set with 150ml CLEARLINK Burette			
DR13E08015	DR13E08023	DR13E09013	DR13I26027
DR13I27017	DR13I27025	DR13I28015	DR13I28023
DR13J16027	DR13J17025	DR13J28022	DR13J29020
DR13K01019	DR13K20027	DR13K21025	DR13L19019
DR13L19027	DR14A11017	DR14A14011	DR14A24010
DR14A24036	DR14A31049	DR14B07054	DR14B22012
DR14B28050	DR14C01030	DR14C06013	DR14C06039
2H8864 - NonDEHP BURETROL Solution Set with 150ml CLEARLINK Burette			
DR13E10011	DR13E10029	DR13E11019	DR14A13013
DR14C08043			