

Baxter

Urgent Product Recall

August 4, 2010

Subject:

**Certificate of Medical Necessity required for continued use of Colleague
Single Channel and Triple Channel Volumetric Infusion Pumps
Models: Mono, CX and CXE**

Product Codes: **2M8151, 2M8153, 2M8161, 2M8163, 2M9161**

Dear Hospital Administrator, Chief Executive Officer (CEO), Chief Operating Officer (COO), Chief Medical Officer (CMO) and Chief Nursing Officer (CNO):

On May 3, 2010, Baxter announced that it will recall all COLLEAGUE infusion pumps from the U.S. market pursuant to an order under its existing consent decree with the U.S. Food and Drug Administration (FDA). The final order was issued by FDA on July 13, 2010.

The purpose of this communication is to provide you with important information regarding the actions you must take prior to November 14, 2010, in order to continue using your Colleague pumps.

This recall encompasses all previously communicated safety issues with the COLLEAGUE infusion pumps. Customers may continue to use COLLEAGUE in accordance with the operator's manual and the additional instructions contained in previous COLLEAGUE Recall / Field Corrective Action communications. All open COLLEAGUE Recall / Field Corrective Action communications, as well as additional information related to the COLLEAGUE pump transition are available via Baxter's website at:
http://www.baxter.com/information/safety_information/colleague_information.html.

There will be a 24-month transition period which allows customers who complete and return the Certificate of Medical Necessity by **November 14, 2010**, to continue using COLLEAGUE pumps. Only facilities that complete and return the Certificate of Medical Necessity will receive ongoing support and service during this transition period. Therefore, your facility must complete the following actions:

1. **Complete a Certificate of Medical Necessity ("CN") form and return it to Baxter as soon as possible, but no later than November 14, 2010** (sample attached). Successful completion and submission of a CN form and accompanying list of pump serial numbers to Baxter by **November 14, 2010** will enable you to:
 - a. Receive ongoing support and service for your COLLEAGUE pumps throughout the transition period ending on July 14, 2012.
 - b. Be eligible for the replacement or refund options described in the forthcoming COLLEAGUE Volumetric Infusion Pump Transition Guide ("Transition Guide").
2. Identify alternative products for replacing your COLLEAGUE pumps.
3. Implement those alternative products by July 14, 2012. The forthcoming Transition Guide will help you identify and implement alternative products and facilitate an orderly transition.

In the coming weeks, your Baxter sales representative will contact you to answer any questions, assist in completing the CN form and discuss your replacement or refund options. You may also access www.Baxter.com for additional CN forms, Transition Guides and other information as they become available.



Please complete the attached CN form confirming your receipt of this letter, scan and email it to Baxter per the instructions provided. Returning the CN form promptly will prevent you from receiving a repeat notice.

It is important that this notification reach all users of COLLEAGUE pumps. If you provide COLLEAGUE pumps to other facilities, please forward this information to them as soon as possible.

We appreciate your consideration of this matter and your ongoing support. If you have additional questions, please contact your Baxter sales representative, or call Center for One Baxter at 1-800-422-9837 during the hours of 8:00 am—5:00 pm CST.

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by:

- Linking to the MedWatch website at www.fda.gov/medwatch,
- Calling 1-800-FDA-1088
- Faxing at 1-800-FDA-0178, or by
- Mailing to: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787

Sincerely,

/Richard Kirkendall/

Richard Kirkendall
Vice President, Quality
Medication Delivery Division
Baxter Healthcare Corporation

Encl:



CERTIFICATE OF MEDICAL NECESSITY (CN): COLLEAGUE VOLUMETRIC INFUSION PUMPS

Baxter Healthcare Corporation is committed to making your transition from COLLEAGUE Volumetric Infusion pumps as seamless as possible. In order for Baxter to continue to support COLLEAGUE pumps within your facilities and for you to be eligible for the refund and replacement options Baxter is providing to COLLEAGUE pump owners, you must:

- Provide Baxter with a completed Certificate of Medical Necessity ("CN") as soon as possible, but no later than **November 14, 2010**.
- The CN must be signed by one of the following individuals: Hospital Administrator, Chief Executive Officer, or Chief Medical Officer
- Return the completed CN along with a **complete list of COLLEAGUE pump serial numbers within your facility** by scanning and emailing to Baxter at:
 - **FCA@Baxter.com**

If the form is incomplete or not returned by **November 14, 2010**, we will be unable to accept your CN and will not be able to continue to provide service and support for your pumps through the transition period.

Your Baxter sales representative will be contacting you to assist in completing the CN form, confirm the number of pumps within your facility and discuss your replacement or refund options.

1. Customer Information:

Customer name: _____ 34232451 2010-024-MD 1
 Address: _____ USPHS INDIAN HEALTH SVC
 _____ ATTN: CHIEF NURSING OFFICER
 _____ 501 NE 122ND ST STE F
 _____ OKLAHOMA CITY, OK 73114
 City: _____

2. Pump Information:

According to our records there are _____ (#) of pumps within this facility. # Owned _____ # Leased _____
(Please ensure your completed serial number list is attached to this form)

Anticipated completion date for the removal of the Colleague pumps from use: _____

Other large volume infusion pumps currently in use at your facility:

Manufacturer: _____ : Make: _____ Model: _____

3. I certify that the facility has an immediate medical need for continued use of, and product support for, COLLEAGUE pump(s), because this facility requires the:

- Ability to administer IV fluids, blood products and medications in a precise manner across all care areas
- Time to identify and implement a replacement infusion pump in a manner that does not adversely impact patient care
- Other _____

OR:

- I have received the Baxter Urgent Product Recall communication and determined I do not have a medical necessity for these devices and will work with my Baxter representative to identify a schedule for removal

OR:

- We no longer have Colleague infusion pumps at this facility (please provide details as to the disposition of the facility's Colleague infusion pumps, e.g., destroyed, lost or stolen, sold or transferred, etc.)

4. Authorized Signature: _____

Name (Print): _____
 Title: (Circle One) Hospital Administrator CEO CMO

Date: _____ Telephone #: _____ E-mail Address: _____

**PLEASE READ THESE IMPORTANT INSTRUCTIONS PRIOR TO COMPLETING THE
CERTIFICATE OF MEDICAL NECESSITY FORM**

Dear Valued Customer:

We greatly appreciate your continued loyalty to the Baxter family of products and we want to make your transition from COLLEAGUE Volumetric Infusion pumps to an alternative pump as seamless as possible.

As stated in the Urgent Product Recall letter of August 4, 2010, in order to continue receiving support for your COLLEAGUE pumps and be eligible for Baxter's replacement and refund program, customers must complete a Certificate of Medical Necessity ("CN") form. The CN form must be returned to Baxter as soon as possible but no later than **November 14, 2010**.

PLEASE COMPLETE YOUR CN FORM AND INCLUDE THE FOLLOWING INFORMATION:

Section 1 – Customer Information

- Customer name, account #, and complete address

Section 2 – Pump Information

- Number of COLLEAGUE pumps in the facility
- List of serial numbers and owned/lease status for all COLLEAGUE pumps used at your facility. Baxter has provided the following form(s) to assist you in collecting this information:
 - A "Blank Colleague Serial Number List" on which you can fill out the serial number and owned/lease status of each pump at your facility; If a pump is leased from a company other than Baxter, you must provide the name and contact information for that company
 - For Baxter's direct customers only, a "Colleague Serial Number List" that includes the COLLEAGUE pump serial numbers that Baxter has on file for your facility. For each such pump, you can check the appropriate box to let us know whether the pump is still in your possession. If any pumps that you possess are not listed on the "Colleague Serial Number List," you should include those additional pumps on the "Blank Colleague Serial Number List" described above
- Anticipated completion date for removal of COLLEAGUE pumps from use
- The names of the manufacturer, make and model of other large volume infusion pumps in use at your facility

Section 3 – Complete the certification:

- Certify that COLLEAGUE pumps are an immediate and continued medical necessity and state the reason by checking the appropriate box (or boxes), OR
- Certify that you do not have a medical necessity for these devices, OR
- Certify that you no longer have COLLEAGUE infusion pumps at the facility; if you no longer have COLLEAGUE pumps at your facility, we ask that you provide us with details as to the disposition of those pumps (direct customers can do so on the "Colleague Serial Number List" provided by Baxter)

Section 4 – Authorized Signature – CN MUST BE SIGNED BY ONE OF THE FOLLOWING:

- Hospital Administrator
- Chief Executive Officer
- Chief Medical Officer

We apologize for any inconvenience this may cause you and your staff. However, you must adhere exactly to these requirements to ensure that you receive uninterrupted service and support from Baxter. Your Baxter sales representative is available to help you complete the CN form and assist with any other transition matter. Please contact the Center for One Baxter at **1-800-422-9837** if you need any assistance.

Thank you.

Colleague Transition Team