Safety Alert

October 28, 2010

RE: 3-Way Large Bore Stopcocks

Dear Director of Nursing and Director of Materials Management:

Baxter Healthcare Corporation is informing you of an issue regarding the following products that contain the 3-Way Large Bore Stopcock codes:

<table>
<thead>
<tr>
<th>1C8471</th>
<th>2N5600</th>
<th>3C0114</th>
<th>3C0180</th>
</tr>
</thead>
<tbody>
<tr>
<td>2C6201</td>
<td>3C0021</td>
<td>3C0174</td>
<td>3C0098</td>
</tr>
<tr>
<td>2C6202</td>
<td>3C0090</td>
<td>3C0175</td>
<td></td>
</tr>
</tbody>
</table>

Baxter has recently received complaints of leaking 3-Way Large Bore Stopcocks. Baxter has investigated these complaints and has determined that the cause of the leaking is due to the handle of the stopcock being forced beyond the stop (see Attachment 1). If increased resistance is encountered when rotating the handle, the stop has been reached and the handle should not be rotated past this point. Adverse events associated with this clinical practice, including patient injury, have been reported to Baxter.

Rotating the handle on the 3-Way Large Bore Stopcock past the stop can cause the stopcock to leak. A leak can lead to under-infusion or interruption of critical life-sustaining therapy.

The 3-Way Large Bore Stopcock products continue to be safe and effective when used in accordance with the written instructions for use along with the information contained in this notification.

If you distribute the product listed on this notification to other facilities, or if you are a dealer, wholesaler, or distributor/reseller of the product, please forward this communication as appropriate.

If you have clinical questions, please call Medical Information Services at Baxter at 1-800-933-0303, Monday through Friday during the hours of 8:00 am to 5:00 pm CT. If you have questions regarding this communication, please call Center for One Baxter at 1-800-422-9837 during the hours of 8:00 am to 5:00 pm CT Monday through Friday.

The United States Food and Drug Administration has been notified of this action.

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

Sincerely,

Mahshid Zahed
VP Quality, GIS
Medication Delivery
Baxter Healthcare
Please post this notification where 3-Way Large Bore Stopcocks are dispensed.

Baxter is providing the following information to address the issue of leaking 3-way stopcocks, product codes:

<table>
<thead>
<tr>
<th>1C8471</th>
<th>2N5600</th>
<th>3C0114</th>
<th>3C0180</th>
</tr>
</thead>
<tbody>
<tr>
<td>2C6201</td>
<td>3C0021</td>
<td>3C0174</td>
<td>3C0098</td>
</tr>
<tr>
<td>2C6202</td>
<td>3C0090</td>
<td>3C0175</td>
<td></td>
</tr>
</tbody>
</table>

Rotate the stopcock handle ONLY along the correct path/direction, as illustrated below.

![Diagram of incorrect and correct handle rotation]

Rotating the handle along the incorrect path/direction may cause the stopcock to leak.

Direction of Flow

![Diagram of flow direction]

Note: Stopcock handle marked "OFF" is always over closed port.
CUSTOMER REPLY FORM
SAFETY ALERT
October 28, 2010
3-Way Large Bore Stopcocks Product Codes:

<table>
<thead>
<tr>
<th>Code 1</th>
<th>Code 2</th>
<th>Code 3</th>
<th>Code 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1C8471</td>
<td>2N5600</td>
<td>3C0114</td>
<td>3C0180</td>
</tr>
<tr>
<td>2C6201</td>
<td>3C0021</td>
<td>3C0174</td>
<td>3C0098</td>
</tr>
<tr>
<td>2C6202</td>
<td>3C0090</td>
<td>3C0175</td>
<td></td>
</tr>
</tbody>
</table>

Please complete and return this form to (847) 270-5457 as confirmation that you have received this notification. A fax cover sheet is not required.

Facility Name and Address:

PLEASE ENSURE THE BELOW IS COMPLETED. BAXTER CANNOT PROCESS UNSIGNED FORMS. RESPONDING TO THIS REQUEST WILL PREVENT THE RECEIPT OF UNNECESSARY REPEAT NOTIFICATIONS CONCERNING THIS ISSUE.

Your signature below indicates understanding the contents of the attached letter; performing the actions as outlined in the letter, as needed; and dissemination of this information to staff and other services or facilities, as applicable.

Completed By: ____________________________________________
(Print Name)

Title: ________________________________________________

Phone Number: ______________________________________

Signature and Date: ____________________________________