October 22, 2013

IMPORTANT SAFETY INFORMATION

Product: **Various Intravenous or Irrigation Flexible Containers**

Subject: **Lot Numbers and Expiration Dates – Embossed on container With No Ink**

ACTION REQUIRED

Dear Healthcare Professional,

Hospira is issuing this Important Safety Information letter to alert Healthcare Professionals to a situation that could occur involving intravenous or irrigation solutions in flexible containers. There have been customer reports where the lot number and expiration date information was not clearly printed on flexible containers for intravenous use. With the complaints Hospira has received to date each returned flexible container has been confirmed to be embossed with correct lot and expiration date information however, the ink may not be clearly visible. In some cases the flexible container needs to be rotated to visually identify the lot and expiration date.

Hospira has identified the root cause as a manufacturing issue involved in the labeling process of the flexible containers. Corrective actions have been taken to prevent a reoccurrence. To date, there have been no adverse events associated with this issue.

Healthcare professionals follow facility specific guidelines for checking lot/expiration date. If the lot number and/or expiration date is missing from a flexible container, the trained healthcare professional will note that the information is not present and the solution will not be used. However, if expired product is used, it may not have the labeled strength or purity at the time of use, which could potentially impact patient safety.

Healthcare Professionals should visually inspect the flexible containers as described under the Directions for Healthcare Professionals section of this letter.

Directions for Healthcare Professionals:
Follow your specific facility's protocol in confirming the lot number and expiration date for the flexible container. If the lot number and expiration date are not readily visible, do not use the product and report the issue to Hospira by calling product complaints at 1-800-441-4100, between the hours of 8am to 5pm CST, Monday through Friday, or e-mail productComplaintsPP@hospira.com. Please return the flexible container to Hospira for evaluation.

For medical inquiries, please contact Hospira Medical Communications at 1-800-615-0187, (Available 24 hours a day / 7 days per week) or e-mail Medcom@hospira.com.

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To report any product complaints, such as flexible containers not having visible printed lot numbers or expiration dates, or adverse events, call 1-800-441-4100, between the hours of 8am to 5pm CST, Monday through Friday, or e-mail productComplaintsPP@hospira.com.

Adverse events or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail or by fax:

- Online: www.fda.gov/medwatch/report.htm
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

We thank you for your attention to this important matter.

Sincerely,

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