



January 16, 2014

IMPORTANT SAFETY INFORMATION

Product: Ampuls

Subject: Safety Precautions when Opening Ampuls

ACTION REQUIRED

Dear Health Care Provider,

Hospira is issuing this Important Safety Information letter to remind Healthcare Providers to follow facility protocol and exercise caution when opening an ampul. Hospira has received reports of ampuls not properly breaking along the score lines. If an ampul is open without proper precaution and if the score line varies in depth, the break may not be clean and leave a sharp edge or shatter. A sharp edge may potentially pose a physical risk to the Health Care Provider as well as a delay in therapy. Always refer to specific facility policies and procedures for opening an ampul.

The breaking off/shattering of the head and neck on an ampul which is difficult to open, may result in spillage of drug. Drug spillage may lead to exposure to equipment, flooring, and personnel. Physical injury may result in a localized wound, which may result in infection and/or scarring, as well as exposure to the drug substance by the Health Care Provider opening the ampul. A delay in therapy may occur while another ampul is procured.

The root cause of hard to break glass potentially relates to adjustments made on the scoring system by the glass manufacturer. Hospira continues to work with the supplier to institute process controls that minimize the potential for these events.

For medical inquiries, please contact Hospira Medical Communications at 1-800-615-0187 (24 hours a day / 7 days a week) or e-mail Medcom@hospira.com. To report product complaints or adverse events call 1-800-441-4100 (M-F, 8am to 5pm CT) or e-mail productcomplaintspp@hospira.com.

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Important Safety Information
Ampuls



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

This letter is being conducted with the knowledge of the U.S. Food and Drug Administration.

Sincerely,

A handwritten signature in cursive script, appearing to read "C. Rodriguez".

Claudio E. Rodriguez, MD
Global Medical Director
Global Pharmacovigilance and Product Safety

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