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July 10, 2009

Important Clarification Communication

ARROW® Products Containing Non-Lipid Resistant Stopcocks

Dear Valued Customer,

Arrow International has recently received inquiries from customers regarding the letter to customers issued by Arrow in February 2009 and information recently published by the FDA and other organizations regarding Arrow products containing non-lipid resistant stopcock. The letter informed customers that the material in the stopcock was not lipid resistant and that use with lipid containing solutions or 70% isopropyl alcohol may cause leakage or air embolism. Listed below are clarifications to Arrow's notification.

- **Products do not need to be returned to Arrow.** The notification states if a lipid resistant stopcock is required to contact the firm for replacements.
- The notification to customers was a **correction** to the product labeling. The FDA uses the term "recall" to mean a removal **or correction** of a product.
- As part of their administrative process the FDA published the recall information, to include products affected and classification, on their website June 24, 2009. There are 15 product families listed on the website.
- In a notification letter to Arrow on June 25, 2009, FDA indicated that Arrow's actions for products containing non-lipid resistant stopcocks were appropriate.
- The FDA classified this as a Class II action meaning that while there is risk involved, there is either a possibility that the device will cause temporary or reversible health problems, or a remote chance that the device will cause serious health problems.

Please contact Arrow International, Customer Service Department at 800-523-8446 if additional information is needed.

Sincerely,

Stuart Williams
Stuart Williams
Director, Customer Service