



URGENT MEDICAL DEVICE RECALL

February 23, 2010

Re: Recall of Arrow Walrus OR Products

Dear Risk Manager:

Arrow International Inc. ("Arrow") has issued a voluntary recall for all lots of the products listed on the attachment.

Some of the pouches in which these sterile products are packaged have been found to have pin holes. Therefore, the sterility of the product cannot be guaranteed. If a non-sterile IV product is used, there is potential for infection to occur.

Our records indicate you have received product included in the scope of this recall. We are notifying our customers to take the following actions:

- 1. If you have no affected stock, please indicate so on the Recall Acknowledgement form and fax to Arrow International's fax number: 800-343-2935.**
- 2. If you do have stock, please contact Arrow's Customer Service IV Tubing hotline at 866-396-2111 for a Return Authorization Number. Once you have received the Return Authorization Number, please enter it in the space provided on the enclosed Recall Acknowledgement & Stock Status Form.**
- 3. Complete the enclosed Recall Acknowledgement & Stock Status Form and immediately fax the completed form to Arrow International, Fax number: 800-343-2935, Attn: Customer Service. This will allow us to document your receipt of this letter and the amount of product you have on hand for return.**
- 4. Return any affected product freight collect, along with the original completed Recall Acknowledgement & Stock Status Form to the following:**

**Arrow International, Inc.
312 Commerce Place
Asheboro, NC 27203
Attn: Asheboro Quality Assurance Manager**

- 5. Arrow International can credit your account when the product is returned.**

We sincerely apologize for any disruptions this action may cause to your operation. Arrow International remains committed to providing high quality, safe and effective products. If you require additional information or clarification regarding this matter, please contact Arrow International, Customer Service Department at 800-523-8446.

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

Sincerely,

Stuart Williams
Director of Customer Service

Enclosures

FAX TO: Customer Service
FAX # 800-343-2935

RECALL ACKNOWLEDGEMENT AND STOCK STATUS FORM
Medical Device Recall Concerning Arrow Products
Immediate Attention Requested

Please check the appropriate box and return this form by Fax to the number above.

- We have no inventory within the scope of this recall.
- We have the following affected product at our facility and have discontinued use and distribution. We have quarantined the affected product, and will return the following quantities. When the product is received by Arrow International, please credit our account.

Return Authorization Number: _____

Please print product numbers clearly.

Product #	Qty (ea)

Product #	Qty (ea)

Print Name/Title

Date

Signature

Institution Name

Address

City, State, Zip Code

Telephone Number

Complete this Acknowledgement Form and immediately fax to Arrow International at the number given above.