

**URGENT:**

**MEDICAL DEVICE RECALL**

**SECURE Compounder Bags**

June 22, 2016

Dear Sir/Madame:

The purpose of this letter is to advise you that The Metrix Company is voluntarily recalling the SECURE Compounder Bags as listed below. The recall of these bags has been initiated because when used with the AutoComp6, AutoComp6 XP and AutoComp6 XPS High Speed Compounders, the compounders may not be able to maintain the fill accuracy requirements for the compounded bag as outlined in the user's manual. Therefore, the patient receiving the compounded bag may not receive the correct quantity of individual parenteral nutrition solutions or the correct overall quantity of parenteral nutrition solutions.

No adverse events have been reported to The Metrix Company as a result of this issue.

Our records indicate that you received one or more of the affected products since January 1, 2006; see the details in the table below. The Metrix Company is asking all customers to follow the steps below:

1. Recalled products must not be used.
2. Locate and quarantine all affected products.
3. If this information is received by a dealer, wholesaler, or distributor/reseller that distributed any of these products to other facilities, then notify your customers as detailed below so that those customers can locate and remove all affected products.
  - a. Notify all customers which have been shipped or may have been shipped any of the products listed in the table below. A sample Customer Notification Letter and Response Form are enclosed.
  - b. Provide Metrix with a list of the customers notified.
4. Complete the Response form and return it to The Metrix Company according to the instructions on the form.

**RECALLED PRODUCT LIST**

Metrix Part #	Product Description	Lot Number	Quantity in Cases Since Jan.1, 2006
58733	Empty Dual Chamber Container with Attached Transfer Set 500ml/2500ml	All Lots	
58734	Empty Dual Chamber Container with Attached Transfer Set 250ml/1250ml	All Lots	
58740	Empty Container with Attached Transfer Set (Automated Fill Compatible) 1000ml	All Lots	

<b>Metrix Part #</b>	<b>Product Description</b>	<b>Lot Number</b>	<b>Quantity in Cases Since Jan.1, 2006</b>
58741	Empty Container with Attached Transfer Set (Automated Fill Compatible) 2000ml	All Lots	
58742	Empty Container with Attached Transfer Set (Automated Fill Compatible) 3000ml	All Lots	
58749	Empty Container with Attached Transfer Set (Automated Fill Compatible) 1500ml	All Lots	
58750	Empty Container with Attached Transfer Set (Automated Fill Compatible) 4000ml	All Lots	
58753	Empty Container with Attached Transfer Set (Automated Fill Compatible) 250ml	All Lots	
58754	Empty Container with Attached Transfer Set (Automated Fill Compatible) 500ml	All Lots	
58781	Compounder Fill Set (Automated Fill Compatible)	All Lots	
58785	Double Compounder Spike Fill Set	All Lots	
62005	Empty EVA Container with Attached Transfer Set (Automated Fill Compatible) 250ml	All Lots	
62010	Empty EVA Container with Attached Transfer Set (Automated Fill Compatible) 500ml	All Lots	
62015	Empty EVA Container with Attached Transfer Set (Automated Fill Compatible) 1000ml	All Lots	
62025	Empty EVA Container with Attached Transfer Set (Automated Fill Compatible) 2000ml	All Lots	
62030	Empty EVA Container with Attached Transfer Set (Automated Fill Compatible) 3000ml	All Lots	
62035	Empty EVA Container with Attached Transfer Set (Automated Fill Compatible) 4000ml	All Lots	
64005	Empty EVA Container with Attached Transfer Set (Automated Fill Compatible) 250ml	All Lots	
64010	Empty EVA Container with Attached Transfer Set (Automated Fill Compatible) 500ml	All Lots	
64015	Empty EVA Container with Attached Transfer Set (Automated Fill Compatible) 1000ml	All Lots	
64025	Empty EVA Container with Attached Transfer Set (Automated Fill Compatible) 2000ml	All Lots	
64030	Empty EVA Container with Attached Transfer Set (Automated Fill Compatible) 3000ml	All Lots	
64035	Empty EVA Container with Attached Transfer Set (Automated Fill Compatible) 4000ml	All Lots	
64781	Compounder Fill Set	All Lots	
65005	Empty EVA Container with Attached Transfer Set (Automated Fill Compatible) 250ml	All Lots	
65010	Empty EVA Container with Attached Transfer Set (Automated Fill Compatible) 500ml	All Lots	
65015	Empty EVA Container with Attached Transfer Set (Automated Fill Compatible) 1000ml	All Lots	
65025	Empty EVA Container with Attached Transfer Set (Automated Fill Compatible) 2000ml	All Lots	



<b>Metrix Part #</b>	<b>Product Description</b>	<b>Lot Number</b>	<b>Quantity in Cases Since Jan.1, 2006</b>
65030	Empty EVA Container with Attached Transfer Set (Automated Fill Compatible) 3000ml	All Lots	
65035	Empty EVA Container with Attached Transfer Set (Automated Fill Compatible) 4000ml	All Lots	
66005	Empty EVA Container with Attached Transfer Set (Automated Fill Compatible) 250ml	All Lots	
66010	Empty EVA Container with Attached Transfer Set (Automated Fill Compatible) 500ml	All Lots	
66015	Empty EVA Container with Attached Transfer Set (Automated Fill Compatible) 1000ml	All Lots	
66020	Empty EVA Container with Attached Transfer Set (Automated Fill Compatible) 1500ml	All Lots	
66025	Empty EVA Container with Attached Transfer Set (Automated Fill Compatible) 2000ml	All Lots	
66030	Empty EVA Container with Attached Transfer Set (Automated Fill Compatible) 3000ml	All Lots	
66035	Empty EVA Container with Attached Transfer Set (Automated Fill Compatible) 4000ml	All Lots	
66305	Empty EVA Container with Detachable Transfer Set (Automated Fill Compatible) 250 ml	All Lots	
66310	Empty EVA Container with Detachable Transfer Set (Automated Fill Compatible) 500 ml	All Lots	
66315	Empty EVA Container with Detachable Transfer Set (Automated Fill Compatible) 1000 ml	All Lots	
66325	Empty EVA Container with Detachable Transfer Set (Automated Fill Compatible) 2000 ml	All Lots	
66330	Empty EVA Container with Detachable Transfer Set (Automated Fill Compatible) 3000 ml	All Lots	
66335	Empty EVA Container with Detachable Transfer Set (Automated Fill Compatible) 4000 ml	All Lots	
66505	EVA Bag, 250ml	All Lots	
66510	EVA Bag, 500ml	All Lots	
66515	EVA Bag, 1000ml	All Lots	
66525	EVA Bag, 2000ml	All Lots	
66530	EVA Bag, 3000ml	All Lots	
66535	EVA Bag, 4000ml	All Lots	
66617	Empty EVA Dual Chamber Container with Gravity/Attached Transfer Set 250 ml/1250 ml	All Lots	
66622	Empty EVA Dual Chamber Container with Gravity/Attached Transfer Set 300 ml/1700 ml	All Lots	
66632	Empty EVA Dual Chamber Container with Gravity/Attached Transfer Set 500 ml/2500 ml	All Lots	
66642	Empty EVA Dual Chamber Container with Gravity/Attached Transfer Set 500 ml/3500 ml	All Lots	
66705	Empty EVA Container with Detachable Transfer Set (Automated Fill Compatible) 250 ml	All Lots	

<b>Metrix Part #</b>	<b>Product Description</b>	<b>Lot Number</b>	<b>Quantity in Cases Since Jan.1, 2006</b>
66710	Empty EVA Container with Detachable Transfer Set (Automated Fill Compatible) 500 ml	All Lots	
66715	Empty EVA Container with Detachable Transfer Set (Automated Fill Compatible) 1000 ml	All Lots	
66725	Empty EVA Container with Detachable Transfer Set (Automated Fill Compatible) 2000 ml	All Lots	
66730	Empty EVA Container with Detachable Transfer Set (Automated Fill Compatible) 3000 ml	All Lots	
66735	Empty EVA Container with Detachable Transfer Set (Automated Fill Compatible) 4000 ml	All Lots	
66905	Empty EVA Container with Attached Transfer Set and Clamps (Automated Fill Compatible) 250ml	All Lots	
66910	Empty EVA Container with Attached Transfer Set and Clamps (Automated Fill Compatible) 500ml	All Lots	
66915	Empty EVA Container with Attached Transfer Set and Clamps (Automated Fill Compatible) 1000ml	All Lots	
66925	Empty EVA Container with Attached Transfer Set and Clamps (Automated Fill Compatible) 2000ml	All Lots	
66930	Empty EVA Container with Attached Transfer Set and Clamps (Automated Fill Compatible) 3000ml	All Lots	
66935	Empty EVA Container with Attached Transfer Set and Clamps (Automated Fill Compatible) 4000ml	All Lots	
67005	EVA Empty Flexible Container with Transfer Set 250ml	All Lots	
67010	EVA Empty Flexible Container with Transfer Set 500ml	All Lots	
67015	EVA Empty Flexible Container with Transfer Set 1000ml	All Lots	
67025	EVA Empty Flexible Container with Transfer Set 2000ml	All Lots	
67030	EVA Empty Flexible Container with Transfer Set 3000ml	All Lots	
67035	EVA Empty Flexible Container with Transfer Set 4000ml	All Lots	
69005	Empty EVA Container with Attached Transfer Set and Clamps (Automated Fill Compatible) 250ml	All Lots	
69010	Empty EVA Container with Attached Transfer Set and Clamps (Automated Fill Compatible) 500ml	All Lots	
69015	Empty EVA Container with Attached Transfer Set and Clamps (Automated Fill Compatible) 1000ml	All Lots	
69025	Empty EVA Container with Attached Transfer Set and Clamps (Automated Fill Compatible) 2000ml	All Lots	
69030	Empty EVA Container with Attached Transfer Set and Clamps (Automated Fill Compatible) 3000ml	All Lots	
69035	Empty EVA Container with Attached Transfer Set and Clamps (Automated Fill Compatible) 4000ml	All Lots	
69616	Empty EVA Dual Chamber Container, 1500ml	All Lots	



Metrix Part #	Product Description	Lot Number	Quantity in Cases Since Jan.1, 2006
69621	Empty EVA Dual Chamber Container, 2000ml	All Lots	
69631	Empty EVA Dual Chamber Container, 3000ml	All Lots	
69641	Empty EVA Dual Chamber Container, 4000ml	All Lots	

For any questions please contact:

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The Metrix Company  
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This Urgent Voluntary recall is being made with the knowledge of the Food and Drug Administration (FDA). Adverse reactions 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 at: [www.accessdata.fda.gov/scripts/medwatch](http://www.accessdata.fda.gov/scripts/medwatch). For Regular Mail: use postage-paid, pre-addressed FORM FDA 3500 available at [www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms](http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms).

Sincerely,



Jennifer Clasen  
Quality Assurance Manager  
The Metrix Company

Attachments: Recall Return Response Form  
Sample Customer Notification Letter  
Sample Customer Response Form