



B. Braun Medical Inc.
2525 McGaw Ave
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Telephone: (949) 660-2000

November 27, 2013

B. BRAUN ISSUES VOLUNTARY PRODUCT REMOVAL

Dear Valued Customer:

B. Braun Medical Inc. (B. Braun) is conducting a Voluntary Removal of product lots listed in the table below.

Some of these product lots were found to have visible particulate matter in reserve samples and are being removed from the market as a precautionary measure. B. Braun has not received any reports of adverse events related to these lots to date.

Catalog Number	Product Description	Size (mL)	NDC Number	Lot No(s).	Expiration Date
3153-11	Ceftriaxone for Inj. (1g) Dextrose for Inj	50	0264-3153-11	H3B702	02/28/2015
3193-11	Cefepime 1g for Injection USP	50	0264-3193-11	H2L712	03/31/2014
3103-11	Cefazolin 1 gm in DUPLEX	50	0264-3103-11	H3H507	01/31/2015
				H2S725	07/31/2014
				H2S726	07/31/2014
				H3D724	11/30/2014
				H3E724	12/31/2014
3105-11	Cefazolin 2 gm in DUPLEX	50	0264-3105-11	H2S723	07/31/2014
				H3H711	01/31/2015
S9350-58SS	6.9% FreAmine HBC Glass	750/1000	0264-9350-55	J2H002	06/30/2014
				J2S018	12/31/2014
S3200-SS	15% Amino Acids Injection PBP Glass	1000	0264-3200-55	J2J012	01/31/2014
				J3B002	08/31/2014
S4000-SS	0.9% Sodium Chloride USP Glass	1000	0264-4000-55	J0B003	02/28/2014
S9341-SS	TrophAmine 10% Glass	500	0264-9341-55	J3A028	07/31/2014
S9050	ProcalAmine Inj SS Glass	1000	0264-1915-07	J2K023	02/28/2014
S9432	Hyperlyte CR Conc Glass	250	0264-1943-20	J3B007	08/31/2014

In the event the particles are small enough to pass through a syringe, there is the potential for patient injury. Intravenous injection of visible particulate matter may result in acute local inflammation, phlebitis, and/or low level allergic response through mechanical disruption of tissue or immune response to the particulate. Particulates may embolize to other organs in the body or obstruct small capillaries. Patients with preexisting condition of trauma or other medical condition that adversely affects the microvascular blood supply are at an increased risk. Chronic granuloma formation in the lungs is also possible if product is sequestered in lung tissue.

Please discontinue use of the above referenced product immediately and follow the below instructions for returning product to B. Braun. If you are an authorized B. Braun distributor, please discontinue further distribution of these lots and contact your customers that have received these lots to inform them of this Product Removal.

Utilizing the attached "Product Removal Acknowledgement Form" record the number of individual units in your current inventory. If you have no inventory, please enter zero on this form. Please return the completed form in the self-addressed envelope provided within two weeks of receipt.

To ensure proper credit for affected product, please return the product to B. Braun. Do not destroy any product.



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If you have any full or partial cases of these affected products and associated lot numbers in your possession, please call our Customer Support Department at **800-227-2862** Monday through Friday, 8 a.m. to 6 p.m. ET, to arrange for return of this material. A Customer Support Representative will provide you with instructions for handling the product and we will arrange for all products to be returned to B. Braun Medical Inc. Should you have any questions or concerns regarding the attached information, please contact our Customer Support Department 800-227-2862.

This product removal is being conducted with the knowledge of the United States Food and Drug Administration.