



Voluntary Medical Device Recall RFP-401 Pureflow-B Solution Lot F023444

April 2, 2013

Dear NxStage Customer:

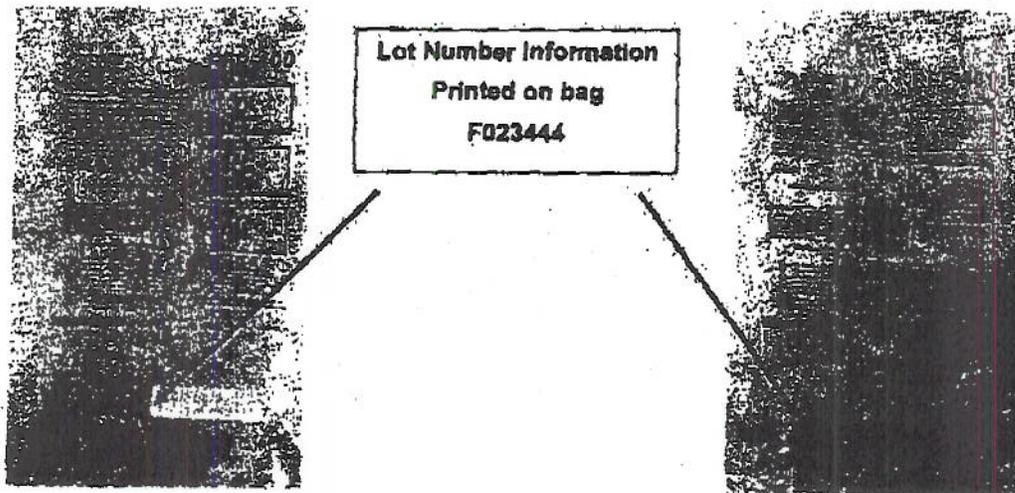
We recently sent a letter dated 3/18/2013 to your attention asking you to segregate and quarantine all product labeled as RFP-400 or RFP-401 from lot F023444. NxStage has determined that some cases of Premixed Sterile Dialysate Pureflow-B Solution RFP-401 lot F023444 may contain one or more bags mislabeled as RFP-400.

The main difference between RFP-400 and RFP-401 Premixed dialysate bags is that the RFP-401 formulation contains a potassium concentration of 4.0 mEq/L while the RFP-400 formulation contains a potassium concentration of 2.0 mEq/L.

All bags from Lot F023444 contain dialysate with a potassium concentration of 4.0 mEq/L. While NxStage believes that the overall risk to the patient is low, if product labeled RFP-400 from lot F023444 is used, the risk for some patients is that they may not achieve the expected decrease in serum potassium levels within the expected timeframe.

Recall Instructions:

1. Check all boxes in your inventory of RFP-401. Segregate and quarantine any boxes labeled RFP-401 lot F023444.
2. Check all individual bags RFP-401 and RFP-400 in all inventory locations. Segregate and quarantine all individual RFP-400 and RFP-401 bags labeled with lot F023444.



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DEVICE PRODUCT RECALL REPLY FORM

PureFlow-B Solution RFP-401 Lot Number: F023444

Please complete and fax this form to 878-687-4810 even if you do not have any of the affected product on hand.

PLEASE CHECK ALL BOXES THAT APPLY:

- We acknowledge receipt of the Recall Notification letter dated April 2, 2013.
- We have conducted a full inventory of all RFP-400 and RFP-401 at our location.
- We do not have any stock of product from the affected lot.
- We have the number of cases (in their original shipping container) and/or individual bags from RFP-401 Lot F023444 noted below.

Number of Full Cases of RFP-401 Lot F023444	Number of RFP-400 or F023444 Individual Bags/In a Case	Number of RFP-401 or F023444 Individual Bags/In a Case

Person Completing Form:

Signature: _____ Date: _____

Print Name: _____ Title: _____

Hospital Name _____

Hospital Address _____
