



NxStage Medical, Inc.  
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Fax 978-687-4800  
[www.nxstage.com](http://www.nxstage.com)

## IMPORTANT MEDICAL DEVICE RECALL

August 24, 2007

Re: **CAR-170 CARTRIDGE LOTS:**

**7037802, 7037803, 7037804, 7047702, 7047703, 7047704, 7047705,  
7057702, 7057703, 7057704, 7057705, 7057706, 7057707, 7057708,  
7057709, 7067701, 7067702, 7067703, 7067705, 7067709, 7067710,  
7067711, 7067712, 7067713, 7067714, 7067715, 7077703**

Dear NxStage User:

This letter follows up a notification sent to you several weeks ago, and is to inform you that NxStage Medical is undertaking a voluntary recall to request your assistance in removing certain NxStage cartridges from use and to provide you replacements for those cartridges. Specifically, cartridges in the lots listed above are associated with an increased rate of dialysate leaks. Based on our investigation of reports of leaks, we believe that the leaks are associated with a small break in the seam of the Fluid Management Pathway (FMP) bags, located on the back side of the cartridge. Although many of our patients have not reported experiencing any cartridge leaks, our overall reported incidence of leaks is higher than we have seen in the past.

**If you have cartridges from any of the following lots, please set them aside from cartridges from other lots and discard them:**

**7037802, 7037803, 7037804, 7047702, 7047703, 7047704, 7047705,  
7057702, 7057703, 7057704, 7057705, 7057706, 7057707, 7057708,  
7057709, 7067701, 7067702, 7067703, 7067705, 7067709, 7067710,  
7067711, 7067712, 7067713, 7067714, 7067715, 7077703**

**Importantly, this voluntary recall relates only to the lots of cartridges listed above, and does not relate to other cartridges, the NxStage Cyclor, the NxStage warmer, or PureFlow SL.**

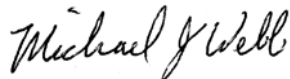
## SPECIFIC RECALL INSTRUCTIONS:

1. You have received, either prior to or with this letter, replacement inventory of cartridges from unaffected lots.
2. Please immediately discontinue use of, and set aside, cartridges from the lots listed above.
3. Once the inventory has been set aside, please complete the enclosed "Reply Form".
  - a. On this form, we will ask you to record your inventory of cartridges from the affected lots; i.e., please provide lot numbers, number of cases, and number of individual cartridges, if a case is open.
  - b. We appreciate your help in completing this form. This information is essential in order to maintain recall effectiveness information required by the FDA.
4. After completing your cartridge inventory as required in the Reply Form, please dispose of the cartridges following your normal waste management practices, and check the box on the Reply Form certifying that you have disposed of the affected cartridges. **PLEASE BE CAREFUL TO ONLY DISCARD CARTRIDGES THAT CORRESPOND TO THE LISTED LOT NUMBERS ON THE FIRST PAGE OF THIS LETTER.** You may continue to use your System One with cartridges from other lots.
5. Please return your completed Reply Form to NxStage Customer Service in the pre-addressed, postage-prepaid return envelope provided.
6. Note that all of your future inventory needs will be sent from unaffected lots. NxStage customer service will work with you to ensure you have sufficient inventory of replacement cartridges to meet your treatment needs.

The United States Food and Drug Administration has been made aware of NxStage Medical's voluntary recall.

We thank you for your attention and support of this effort. If you have any questions concerning this notice, please call Karen St. Onge, our Director of Corporate Quality Assurance and Regulatory Affairs at 978-687-4710. We regret any inconvenience that this action may cause, and we appreciate your cooperation.

Sincerely,



Michael J. Webb  
Senior Vice President, Quality, Regulatory and Clinical Affairs  
NxStage Medical, Inc.

**REPLY FORM**  
**DEVICE PRODUCT RECALL REPLY**

**NxStage® Cartridge CAR 170 Lots:**

**7037802, 7037803, 7037804, 7047702, 7047703, 7047704, 7047705,  
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7057709, 7067701, 7067702, 7067703, 7067705, 7067709, 7067710,  
7067711, 7067712, 7067713, 7067714, 7067715, 7077703**

**PLEASE COMPLETE AND RETURN THIS FORM IN THE ENCLOSED POSTAGE PREPAID REPLY ENVELOPE, EVEN IF YOU DO NOT HAVE ANY OF THE AFFECTED PRODUCT ON HAND.**

**PLEASE CHECK ALL BOXES THAT APPLY**

- I acknowledge receipt of the Recall Notification dated August 24, 2007.
- I have conducted a full inventory of all CAR 170's at my location.
- I do not have any stock of product from the affected lots.
- I have the number of cases and/or cartridges from the affected lots noted below. (List the information requested below for any cases and/or cartridges you have from affected lots).

Lot #	Number of Full Cases You Have	Number of Cartridges You Have From Partial Cases

- I have thrown out all of the affected cartridges listed in the table above.

Signature: \_\_\_\_\_

Please Print: \_\_\_\_\_  
(Name)

Date: \_\_\_\_\_