NxSTAGE®

# Voluntary Medical Device Recall

## SAK Dialysate Concentrate

## SAK-301, SAK-302, SAK-303, SAK-304, SAK-305, SAK-306, SAK-307

**May 16, 2014**

**Dear NxStage Customer:**

**Description of Problem**

NxStage Medical, Inc. has confirmed through internal testing that specific lots of SAK Dialysate Concentrate contain aluminum levels which exceed internal product specification. NxStage Medical, Inc. was made aware of the issue through customer complaints indicating an increase in the serum aluminum levels of patients over a one year period identified during routine, annual blood tests. There have been no adverse health consequences or medical interventions reported.

The NxStage SAK concentrate, a component of the NxStage Pureflow SL module, is intended to contain the essential electrolytes, buffer, and glucose in the appropriate concentrations that when proportioned with purified water produces dialysate. The NxStage Pureflow SL module is an optional accessory to the NxStage System One™ that prepares dialysate for use during hemodialysis, as prescribed by the physician.

The affected products and lots can be found in Attachment A.

The affected lots were manufactured between April 2013 and February 2014.

**Potential Risk**

NxStage Medical, Inc. initiated an extensive investigation and confirmed that specific lots of sodium lactate, a raw material used in the production of the SAK dialysate concentrate, contained levels of aluminum which would exceed specification when the concentrate was fully diluted.

There have been no adverse health consequences or medical interventions reported. Specifically increases in patient serum aluminum levels averaging 10µg/L have been reported within specific dialysis networks. The aluminum levels of the affected lots range from 11.5 µg/L to 13 µg/L when the concentrate is fully diluted. The product specification requires concentrate aluminum levels to be less than 10 µg/L. NxStage believes that the likelihood of any serious adverse health consequences is remote at the serum aluminum levels currently reported. NxStage has confirmed that other SAK lots in distribution meet the specification for aluminum levels.

**Action to be taken by Customers**

1. Check all boxes in your SAK inventory. If you find any boxes of the affected lots in Attachment A separate them from your other SAKs and do not use them.

2. Check all individual SAKs in all inventory locations. If you find any bags of the affected lots in Attachment A separate them from your other SAKs and do not use them.

3. Complete the attached Recall Reply Form and fax to NxStage UK Customer Care (0845 437 9544).

4. Contact NxStage UK Customer Care to arrange for return of all affected product and for replacement product to be sent.

Please know that we are committed to continuous improvement in order to provide you with the best products available and apologize for any inconvenience that this issue may have caused.

If you have any questions or comments, please feel free to contact NxStage UK Customer Care at 0800 048 8352.

Regards,

T M. Snell
Senior Vice President
Quality Assurance, Regulatory, Clinical Affairs

## Attachment A- Affected SAK Lots

### SAK-301

| Manufacturing Date | SAK-301 Lot Number |
|---|---|
| Jan-2014 | 40179162 |
| Dec-2013 | 31279127 |

### SAK-302

| Manufacturing Date | SAK-302 Lot Number |
|---|---|
| Dec-2013 | 31279118 |
| Apr-2013 | 3047923 |
| Jan-2014 | 40179127 |

### SAK-303

| Manufacturing Date | SAK-303 Lot Number |
|---|---|
| Jun-2013 | 3067902 |

### SAK-304

| Manufacturing Date | SAK-304 Lot Number |
|---|---|
| Jan-2014 | 40179029 |
| Dec-2013 | 31279094 |
| May-2013 | 3057908 |
| Jan-2014 | 40179019 |

### SAK-305

| Manufacturing Date | SAK-305 Lot Number |
|---|---|
| Jan-2014 | 40179026 |
| May-2013 | 3057901 |

### SAK-306

| Manufacturing Date | SAK-306 Lot Number |
|---|---|
| Apr-2013 | 3047917 |

### SAK-307

| Manufacturing Date | SAK-307 Lot Number |
|---|---|
| Jan-2014 | 40179036 |