



Medical Device Product Safety Notice

NxStage Dialysate Sacks

**SAK-301, SAK-303, SAK-304, SAK-305
SAK-401, SAK-402, SAK-403**

January 29, 2018

Dear NxStage Customer:

Description of Problem

NxStage Medical, Inc. is issuing this Product Safety Notice to notify customers that certain lots of NxStage Dialysate Sacks may contain endotoxin levels which have been confirmed through internal testing to exceed the ISO quality standard for ULTRAPURE dialysis fluid of less than 0.03 EU/ml when used to prepare a dialysate batch with the PureFlow SL. NxStage Medical, Inc. was made aware of the issue through customer complaints indicating elevated endotoxin levels identified through routine dialysate testing. There have been no adverse health consequences or medical interventions reported.

The Dialysate Sack concentrate, a component of the NxStage PureFlow SL, 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 is an optional accessory to the NxStage System One™ cyclor 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 July 2017 and November 2017.

You are receiving this notice because our records indicate that NxStage either directly shipped one or more affected lots to your centre or to one or more of your current or former patients.

Potential Risk

There have been no adverse health consequences or medical interventions reported. The endotoxin levels of the affected lots range from 0.03 EU/ml to 0.28 EU/ml when the concentrate is fully diluted which is well within the ISO quality standard for Standard Dialysis Fluid of less than 0.5 EU/ml. Although Ultrapure Dialysis Fluid is more desired, dialysate meeting only Standard Dialysis Fluid requirements is routinely used safely worldwide. For this reason, NxStage believes that the likelihood of any serious adverse health consequences is extremely unlikely at the endotoxin levels currently tested.

Action to be taken by Customers

1. Please complete and return the attached reply form to acknowledge receipt of this notice.
2. Although dialysate meeting Standard Dialysate Fluid requirements for endotoxin levels less than 0.5 EU/ml is routinely used safely worldwide, NxStage is offering to exchange any product from the affected lots upon request.
3. If you need a list of patients who were shipped any of the affected lots, please contact NxStage UK Customer Care at 0800 0848 8352.
4. If you wish to exchange any affected product, please contact your NxStage Clinical Educator to discuss.

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 Matt Walker at 07 535 951 852 or mwalker@nxstage.com.

Regards,



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

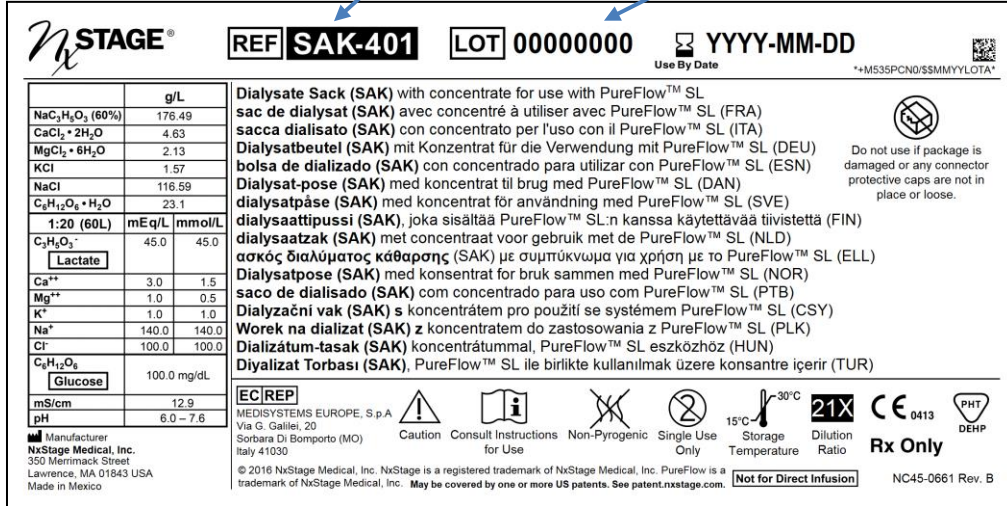
Attachment A- Affected SAK Lots

PRODUCT SAK Type	Manufacturing Date	Lot Number
SAK-301	Sept 2017	70979256
SAK-301	Oct 2017	71079294
SAK-303	Sept 2017	70979065
SAK-304	July 2017	70779178
SAK-304	Sept 2017	70979109
SAK-305	Aug 2017	70879247
SAK-401	Sept 2017	70979215
SAK-402	Aug 2017	70879256
SAK-403	Aug 2017	70879101
SAK-403	Nov 2017	71179046

Refer to Sample Labels below to locate the SAK Type and Lot Number

SAK Type

Lot Number



NxSTAGE REF **SAK-401** LOT 00000000 Use By Date YYYY-MM-DD

	g/L	
NaC ₂ H ₃ O ₂ (60%)	176.49	
CaCl ₂ • 2H ₂ O	4.63	
MgCl ₂ • 6H ₂ O	2.13	
KCl	1.57	
NaCl	116.59	
C ₆ H ₁₂ O ₆ • H ₂ O	23.1	
1:20 (60L)	mEq/L	mmol/L
C ₂ H ₃ O ₂ ⁻	45.0	45.0
[Lactate]		
Ca ⁺⁺	3.0	1.5
Mg ⁺⁺	1.0	0.5
K ⁺	1.0	1.0
Na ⁺	140.0	140.0
Cl ⁻	100.0	100.0
C ₆ H ₁₂ O ₆	100.0	mg/dL
[Glucose]		
mS/cm	12.9	
pH	6.0 – 7.6	

Dialysate Sack (SAK) with concentrate for use with PureFlow™ SL
sac de dialysat (SAK) avec concentré à utiliser avec PureFlow™ SL (FRA)
sacca dialisato (SAK) con concentrato per l'uso con il PureFlow™ SL (ITA)
Dialysatbeutel (SAK) mit Konzentrat für die Verwendung mit PureFlow™ SL (DEU)
bolsa de dializado (SAK) con concentrado para utilizar con PureFlow™ SL (ESN)
Dialysat-pose (SAK) med koncentrat til brug med PureFlow™ SL (DAN)
dialysatpåse (SAK) med koncentrat för användning med PureFlow™ SL (SVE)
dialysaattipussi (SAK), joka sisältää PureFlow™ SL:n kanssa käytettävää tiivistettä (FIN)
dialysaatzak (SAK) met concentraat voor gebruik met de PureFlow™ SL (NLD)
ασκός διαλύματος καθαρός (SAK) με συμπύκνωμα για χρήση με το PureFlow™ SL (ELL)
Dialysatpose (SAK) med konsentrat for bruk sammen med PureFlow™ SL (NOR)
saco de dialisado (SAK) com concentrado para uso com PureFlow™ SL (PTB)
Dialyzačni vak (SAK) s koncentrátem pro použití se systémem PureFlow™ SL (CSY)
Worek na dializat (SAK) z koncentratem do zastosowania z PureFlow™ SL (PLK)
Dializátum-tasak (SAK) koncentrátummal, PureFlow™ SL eszközhöz (HUN)
Diyalizat Torbası (SAK), PureFlow™ SL ile birlikte kullanılmak üzere konsantre içerir (TUR)

Do not use if package is damaged or any connector protective caps are not in place or loose.

EC/REP MEDISYSTEMS EUROPE, S.p.A
 Via G. Galilei, 20
 Sorbara Di Bormpoto (MO)
 Italy 41030

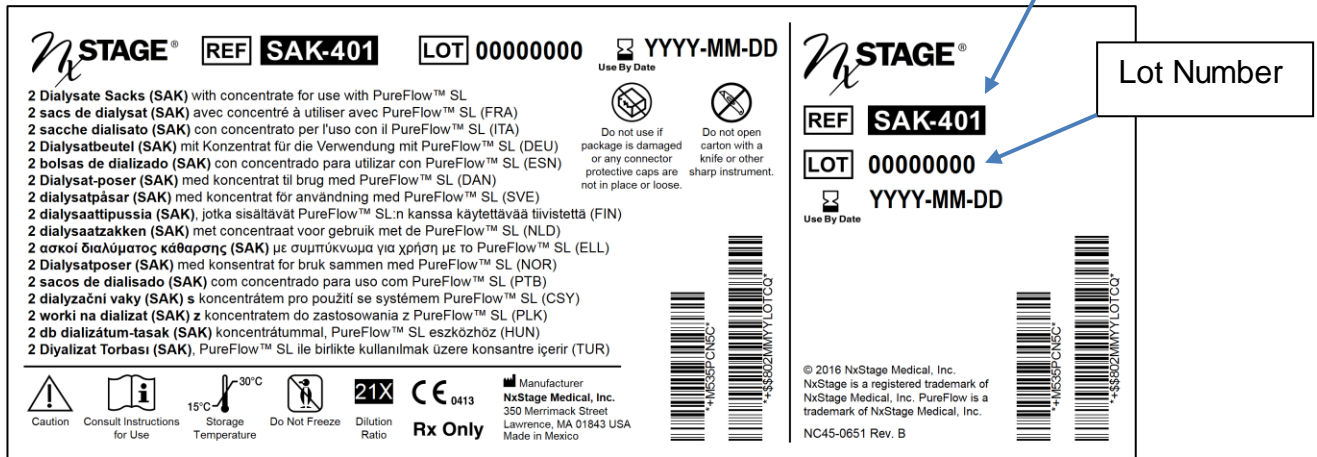
Caution Consult Instructions for Use Non-Pyrogenic Single Use Only Storage Temperature 15°C - 30°C Dilution Ratio 21X CE 0413 PHT DEHP Rx Only

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Sample SAK bag label

SAK Type

Lot Number



NxSTAGE REF **SAK-401** LOT 00000000 Use By Date YYYY-MM-DD

2 Dialysate Sacks (SAK) with concentrate for use with PureFlow™ SL
 2 sacs de dialysat (SAK) avec concentré à utiliser avec PureFlow™ SL (FRA)
 2 sacche dialisato (SAK) con concentrato per l'uso con il PureFlow™ SL (ITA)
 2 Dialysatbeutel (SAK) mit Konzentrat für die Verwendung mit PureFlow™ SL (DEU)
 2 bolsas de dializado (SAK) con concentrado para utilizar con PureFlow™ SL (ESN)
 2 Dialysat-poser (SAK) med koncentrat til brug med PureFlow™ SL (DAN)
 2 dialysatpåsar (SAK) med koncentrat för användning med PureFlow™ SL (SVE)
 2 dialysaattipussia (SAK), jotka sisältävät PureFlow™ SL:n kanssa käytettävää tiivistettä (FIN)
 2 dialysaatzakken (SAK) met concentraat voor gebruik met de PureFlow™ SL (NLD)
 2 ασκοί διαλύματος καθαρός (SAK) με συμπύκνωμα για χρήση με το PureFlow™ SL (ELL)
 2 Dialysatposer (SAK) med konsentrat for bruk sammen med PureFlow™ SL (NOR)
 2 sacos de dialisado (SAK) com concentrado para uso com PureFlow™ SL (PTB)
 2 dialyzační vaky (SAK) s koncentrátem pro použití se systémem PureFlow™ SL (CSY)
 2 worki na dializat (SAK) z koncentratem do zastosowania z PureFlow™ SL (PLK)
 2 db dializátum-tasak (SAK) koncentrátummal, PureFlow™ SL eszközhöz (HUN)
 2 Diyalizat Torbası (SAK), PureFlow™ SL ile birlikte kullanılmak üzere konsantre içerir (TUR)

Do not use if package is damaged or any connector protective caps are not in place or loose.
 Do not open carton with a knife or other sharp instrument.

Caution Consult Instructions for Use Storage Temperature 15°C - 30°C Do Not Freeze Dilution Ratio 21X CE 0413 Rx Only

Manufacturer NxStage Medical, Inc.
 350 Merrimack Street
 Lawrence, MA 01843 USA
 Made in Mexico

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Sample SAK box or case label



FIELD SAFETY NOTICE REPLY FORM for Dialysis Centres

NxStage Dialysate Sacks SAK-301, SAK-303, SAK-304, SAK-305 SAK-401, SAK-402, SAK-403

Please complete this form even if you do not have any of the affected product on hand. Returning the reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

Please return the completed form to NxStage in the prepaid enclosed envelope. You may also fax the completed form via 0845 437 9544 or email to nxstagecustomercare@nxstage.com

PLEASE CHECK THE BOX BELOW:

- I have read and understand the Field Safety Notice dated Jan 29, 2018.
- I have conducted a full inventory of all product at my location.

PLEASE INDICATE RESULTS OF YOUR INVENTORY CHECK:

- We do not have any stock of product from the affected lots.
- We have the number of cases and/or individual SAKs from affected lots listed below.

Product SKU	Lot Number	Number of Full Cases	Number of individual SAKs from Open Cases

Centre Name: _____

Centre City: _____

Form completed by: (Print Name) _____

Date: _____

Signature: _____

Title: _____

May we contact you if we have any questions? Yes No

Contact Phone _____

Email _____