URGENT MEDICAL DEVICE PRODUCT SAFETY NOTICE

AFFECTED PRODUCT: NxStage System One

October 10, 2019

Dear NxStage User,

NxStage Medical is issuing this Safety Notice to alert chronic dialysis facilities and home haemodialysis users of a potential patient health risk while performing chronic haemodialysis treatments in the home setting with the NxStage System One (inclusive of NxStage System One S).

What is the risk to the patient?

During a typical home haemodialysis treatment, the NxStage System is used to remove a user-defined volume of fluid from the patient using a process called ultrafiltration (UF). In some instances, UF removed during dialysis may be greater or less than the target UF volume, which in the worst case could result in hypovolaemia/hypotension or hypervolaemia/hypertension and potential serious injury requiring medical intervention or hospitalization.

Based on the overall rate of reported events, review of each event reported, and our health risk assessment, we consider the risk to the general patient to be low. Variability of patient weight is a commonly experienced issue for patients requiring dialysis. Home haemodialysis patients have the experience and training to respond if they experience the signs or symptoms of hypotension or hypertension due to removing too much or too little fluid during treatment. Patients with cardiovascular co-morbidities or who are tightly fluid managed may be at a greater risk for development of serious injury associated with hypertension and or fluid overload.

NxStage has received seven complaints (0.00009% of total patient treatments) of patients who experienced symptoms of fluid overload requiring hospitalization. In each report a direct causal relationship was not confirmed by the treating health care professional and testing of the returned device could not identify a product problem.

Other than these seven, NxStage has received additional reports at a rate of 0.03% of treatments where the actual UF removed during treatment differed from the target UF, none of which resulted in a serious injury or required medical intervention. NxStage has been unable to determine if the discrepancy between actual vs target UF removal was due to system error or other variables which are outside the control of the NxStage System One.

Adverse reactions or quality problems experienced with the use of this product may be reported to MHRA online via the MHRA Yellow Card Scheme https://yellowcard.mhra.gov.uk

What causes this risk?

Fluid management in the haemodialysis patient is a complex process, and there are multiple contributing factors that may contribute to a patient ending treatment without reaching their target weight:

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- The NxStage Cycler and Cartridge ("System") are intended to remove a user-programmed amount of fluid during treatment within a specified range of accuracy. In other words, when the system is performing as intended, the actual UF from a patient will not necessarily exactly match the target UF defined by the user for a given treatment.

- Patients should carefully weigh themselves and adjust their target UF to the appropriate amount each treatment to achieve their dry weight target at the conclusion of each treatment without allowing fluid to build up.

- Variables, which are often immeasurable, can affect the ability to accurately assess net fluid removal. These include inaccuracy in patient weighing, fluid/food consumption during treatment, saline boluses delivered during treatment, and rinseback variation at the end of treatment (stopping early or rinsing an extra amount).

- NxStage has received a higher number of reports of patients not reaching their target weight in treatments utilizing higher volume therapy.

What should I do?

1. Ensure all home haemodialysis users of the NxStage System One are aware of this notice.

2. When performing haemodialysis treatments, always ensure that patients with cardiac conditions or those who are tightly fluid managed are monitored more closely.

3. Remain aware and account for all fluid/food consumption, saline bolus volume, and rinseback volume during treatment. Weigh and calculate amount to remove for each treatment.

4. When treating with higher fluid volumes, users should closely monitor patient blood pressure throughout treatment and immediately address signs and symptoms of hypertension and hypotension.

5. Complete the enclosed customer reply form and return it to NxStage. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

What is NxStage doing?

We are providing this Urgent Product Safety Notice to increase user awareness and attention to use of the NxStage System One for chronic home haemodialysis treatment. We are continuing to investigate ways to optimize fluid management with the NxStage System One for home patients.

If you have any questions or comments, please contact recallcoordinator@fmc-na.com.

Regards,

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