

## **Field Safety Corrective Action**

Product Name: **alfapump®** System

Type of Action: Reminder for safe use – Updated Instructions for Use

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**Date:** 25-September-2014

**Sender:**

Sequana Medical AG

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**Attention: User, Clinical Personnel**

**Identification of affected device:**

Product category: AIMD

Device name: **alfapump®** System

Model number: 00777, 01116

Lot- or serial number: NA

**Description of the problem**

Sequana Medical has received information about cases of disconnection of the peritoneal catheter from the **alfapump®** after the initial implantation. This can occur if the peritoneal catheter is not fully attached to the inlet nipple on the pump, if the peritoneal catheter is cut too short – leading to stretch of the catheter - or if the locking cap is not fully engaged with the pump. Following the Current Instructions for Use provided with the devices shall ensure safe use.

The risk associated with this use error is the fact that the patient will need to have a surgical re-intervention (in local or general anaesthesia) in order to resolve the problem.

**Products potentially affected**

All **alfapump®** systems are potentially impacted by this use error. Our traceability analysis has determined that you have received one or more of these products over the last 3 years.

Please note that the risk of this problem occurring is very low. To date, this use error has occurred in only 2 out of 220 cases (< 1%). However, it is important that all users are aware of this use error, so that such potential errors can be eliminated entirely.

### **Action required**

There is no immediate action required. All patients already implanted showing normal operation of the alfapump are not affected. The updated instructions are applicable for patients for whom an implant is planned in the future.

To avoid disconnection of the catheter Sequana Medical has updated the alfapump system Instructions for Use.

Please ensure that the enclosed addendum of the Instructions for Use are carefully read and understood, in particular regarding the following points:

- Using the **alfapump®** as a guide, trim the length of the bladder and peritoneal catheters to fit. Make sure to allow sufficient slack to slide the alfapump® into the pocket and for normal movement of the upper body, but not too much as it can lead to “kinking”.
- Push the catheters fully onto the alfapump® nipples using the catheter locking cap to determine correct orientation. Before securing the catheter locking cap into place on the **alfapump®**, test the **alfapump®** (**Note: Please push the catheters carefully on the nipples avoiding pinching the catheters with a sharp tool. Damaging the catheters may lead to leakage inside the pump pocket.**)
- Lock the catheters in place with the catheter locking cap. For this push the locking cap firmly unto the pump until you feel the little hook settling into place.
- **Caution: Failing to follow the above mentioned steps can potentially lead to a disconnection of the catheter from the pump requiring a re-intervention to re-attach the catheter.**

### **Transmission of this Field Safety Notice:**

This notice should be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred (if appropriate).

Please transfer this notice to other organizations upon which this action has an impact (if appropriate).

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action (if appropriate).

**Contact reference person:**

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