

Danish Medicines Agency  
Axel Heides Gade 1  
2300 København S  
Att.: Medicinsk Udstyr

05-May-2020

**Subject: Field Safety Notice – Safety Alert – Artiset Blood Tubing Sets (for Artis machines),  
Cartridge Sets (for Phoenix/Innova machines)– Tube Disconnections**

**Product Name:** Artiset Tubig Set, Cartridge – See Attachment A – Affected Product Table for a complete list

**Product Code:** Refer to Attachment A – Affected Product Table for a complete list

**Lot numbers:** Refer to Attachment A – Affected Product Table for a complete list

Dear Sir/Madam

Baxter Healthcare Corporation is issuing a Safety Alert regarding Cartridge Sets (for Phoenix/Innova Machines) and ArtiSet Blood Tubing Sets (for Artis machines) due to reports of disconnection events. The issue has been isolated to a subset of lots, based on production dates. A disconnection event may result in external blood loss, air embolism, or delay in therapy. Baxter has received three reports of serious injury associated to this issue.

Currently the demand for this product has greatly exceeded supply and there are no alternative suppliers of this product. The product quality issue can be detected during set-up or priming of the device. Baxter is asking that customers perform product inspections to check the sets for disconnections prior to use to minimize the disruption of required hemodialysis treatments.

Following root cause investigation, Baxter has identified corrective actions to mitigate the occurrence of tube disconnection events on the Artis Blood Tubing sets.

Our records indicate that 15 customers have received this product in Denmark. For your information, please find attached the communication that is being sent to those customers.

Should you have any questions, please contact my colleague Anni Keinänen (anni\_keinanen@baxter.com).

Kind regards  
Baxter A/S



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