Baxter

URGENT DEVICE CORRECTION

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

04-Nov-2019

Subject: Field Safety Notice – Recall – Artis Blood Tubing Set- Cartridge Set Occlusion

Product Name: Artiset HD DNL HC and Artset Prepost
Product Code: 955075
Lot numbers: 1000218859

Dear Sir/Madam

Baxter Healthcare Corporation is issuing a voluntary product recall for the ArtiSet Blood Tubing Sets due to the potential for an occlusion of the blood circuit pathway just after the pump segment. Occlusion of the blood tubing set may result in delay in therapy or minor blood loss; however, serious adverse health consequences are not expected. There have been no reports of serious injury associated with this issue.

A full investigation was performed at manufacturing plant confirming that the issue was the result of a wrong manufacturing mold intervention (corrective maintenance) resulting in total/partial occlusion of the cassette arterial chamber ports.

Baxter has identified corrective actions to mitigate the occurrence of cartridge set occlusion on the Artis Blood Tubing sets.

Since only certain lots are impacted by this Recall, customers can continue to order other unaffected lots of the ArtiSet Blood Tubing Sets.

Our records indicate that 2 customers have received this product in Denmark. For your information, please find attached the communication in Danish that is being sent to those customers.

Should you have any questions, please contact me on marion_line_rames@baxter.com

Kind regards
Baxter A/S

Marion Line Rames
Regulatory Affairs Senior Associate Nordic
T +45 4816 6430 / M +45 5192 7540
marion_line_rames@baxter.com

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