



10020 Pacific Mesa Blvd
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www.bd.com

February 14, 2020

Dear Valued BD Alaris™ System Customer:

BD is committed to our core values of continuous improvement and doing what is right to fulfill our purpose of *Advancing the world of health*. Above all, BD believes in transparency, and we are dedicated to providing updates on the Alaris™ System to help minimize any potential disruption to patient care. In line with this commitment, I personally wanted to make you aware of an important development that could affect your clinical operations.

In conjunction with the February 4, 2020 voluntary U.S. recall of the Alaris™ System, BD has been in discussions with the FDA about a number of modifications to the Alaris™ System since its last 510(k) clearance. Based on these discussions, FDA has requested that BD submit a new, comprehensive 510(k) for agency review.

BD takes our responsibility to our customers and patients very seriously. We stand behind the safety and clinical benefits of the Alaris™ System, which is used in the care of approximately 70% of patients undergoing infusion therapy in the U.S.

As noted in the recall notification, BD has assessed the potential risks associated with the Alaris™ System and determined that it can continue to be used in accordance with the Alaris™ System with Guardrails™ Suite MX User Manual, User Manual Addendum, and the recall notification until they are serviced and upgraded by BD.

BD intends to seek 510(k) clearance for the Alaris™ System that includes a new version of software that will include all prior modifications and address the current recall remediation. Until we have an agreement with FDA regarding our path forward with the clearance of the Alaris™ System, BD will suspend distribution of the Alaris™ System.

BD is working toward supporting limited shipment of the Alaris™ System to existing customers with software compatible devices upon certification of medical necessity. BD is in active discussions with FDA regarding this process and will notify customers as additional details about a possible medical necessity program become available.

We acknowledge the disruption this is causing while we work through next steps. We know that this has implications to your operations, and we are committed to providing you with updates, please visit: www.bd.com/alaris-system-software-recall.

Thank you for your understanding and for being a very valued customer.

Sincerely,

A handwritten signature in black ink, appearing to read "Ranjeet Banerjee", written over a white background.

Ranjeet Banerjee
Worldwide President
Medication Management Solutions
BD