

BD CEO Tom Polen Addresses FDA 510(k) Clearance of BD Alaris™ Infusion System

FRANKLIN LAKES, N.J., July 24, 2023 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX) Chairman, CEO and President Tom Polen issued the following message regarding the [U.S. Food and Drug Administration \(FDA\) 510\(k\) clearance for the updated BD Alaris™ Infusion System](#):

"Hello, I'm Tom Polen, chairman, CEO and president of BD. I wanted to share some exciting news and explain what it means for our company and our stakeholders. I'm very pleased to announce that we have reached the important milestone of obtaining FDA 510(k) clearance of the updated BD Alaris™ Infusion System.

"For more than 20 years, frontline clinicians have relied on the Alaris System to safely deliver medications, fluids and blood products to support patient care. Securing this clearance has been the top priority for our teams who have worked diligently to achieve this outcome, so that clinicians and their patients can benefit from the Alaris System's unique capabilities. Everyone at BD is grateful for the support and patience that our customers afforded us through the 510(k) submission and review process.

"Now that we have FDA clearance, we are eager to return to full commercial operations with an enhanced and updated Alaris System that we believe is the most comprehensive and innovative infusion solution on the market. The updated Alaris System addresses all open recalls, with the latest hardware, a new version of software, and important cybersecurity updates. With this release, we've improved the fundamental capabilities and features of the Alaris System. This further embodies and demonstrates BD's commitment to quality and developing smart, connected devices to support the safe and efficient care of patients.

"At no time has it been more critical for these types of systems to connect, coordinate and simplify care. Our healthcare system is over-stressed, with staffing shortages, nursing burnout and resource constraints that put caregivers in dire need of simplification and automation. The BD Alaris System addresses this very requirement. Operating as a single, comprehensive system with one user interface across multiple types of pumps and monitors, with analytics and apps that provide clinicians with real-time infusion status and automated medication documentation in the most widely used electronic medical records.

"The Alaris System is a vital tool in patient care, and we will continue to strive to bring further innovation and utility to this system in the coming years.

"We now turn our attention to bringing the updated system to our customers, with an initial focus on remediating or replacing those systems currently operating in the U.S. market. The BD team is poised, eager and ready to execute this roll out with excellence. We intentionally retained our infusion sales representatives and enhanced our implementation and service teams during the 510(k) submission process to ensure we could execute seamlessly upon clearance. We've also worked hard to ensure we have the necessary plans in place to meet customer demand by increasing our manufacturing capacity, strengthening our supply chains and increasing supplier redundancy. As you can see, we are more prepared than ever to execute for our customers.

"In closing, let me again thank our customers for their loyalty and patience as we worked through this challenging period. We're incredibly excited to support you and your infusion requirements and are confident the updated Alaris System will meet your expectations for quality, security and innovation.

"And finally, let me acknowledge our BD team for their perseverance and professionalism through the 510(k) process and thank them in advance for the hard work and commitment to our customers and patients that they will no doubt be leaning into in the coming weeks and months. We appreciate the trust that our customers and stakeholders have placed in us, and we look forward to our continued work together in ***advancing the world of health™***. Thank you."

About BD

BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its 77,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable

laboratory scientists to accurately detect disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care. For more information on BD, please visit [bd.com](https://www.bd.com) or connect with us on LinkedIn at www.linkedin.com/company/bd1/ and Twitter [@BDandCo](https://twitter.com/BDandCo).

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Additional assets available online:  [Video \(1\)](#)

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