

NEWS RELEASE



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BD Statement on FDA Recommendations to Health Care Providers Regarding Paclitaxel-Coated Devices

BD appreciates the Food and Drug Administration's (FDA) thoughtful, updated recommendations regarding the use of paclitaxel-coated devices following the Advisory Committee meeting of the Circulatory System Devices Panel in June. While the Panel concluded that a late mortality signal was present, the FDA and the Panel recognized the benefits of these devices and agreed that the magnitude of the signal should be interpreted with caution due to multiple limitations in the available data.

Specifically, the FDA communicated that paclitaxel-coated devices improve blood flow to the legs and decrease the likelihood of repeat procedures to reopen blocked blood vessels compared to uncoated devices, concluding the benefits of paclitaxel-coated devices (e.g., reduced reinterventions) should be considered in high risk patients for restenosis and repeat femoropopliteal interventions. We believe that LUTONIX® Drug Coated Balloons (DCB) should be a part of the optimal medical therapy for peripheral arterial disease (PAD) and, like the FDA, the benefits of DCB use should be considered for high risk patients along with potential risks (e.g., late mortality). We continue to collaborate with the FDA to update product labeling, which will include our investigation, as well as assess additional long-term DCB data.

BD stands behind the safety of its LUTONIX® DCB and is committed to improving the quality of life for patients with PAD. To ensure patients receive the best care possible, BD's broad range of treatment options for this serious disease will continue to be available for health care providers.

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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 65,000 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.