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# BD Announces Publication of an Independent Analysis of Drug-Coated Balloon Safety Data for Femoropopliteal Peripheral Arterial Disease

## Independent analysis of LUTONIX® 035 Drug Coated Balloon patient-level data showed no statistically significant mortality increase

FRANKLIN LAKES, N.J., Sept. 28, 2019 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced the publication of a company-initiated, independent analysis of the LUTONIX® 035 Drug Coated Balloon (DCB) femoropopliteal clinical program in the *Journal of the American College of Cardiology (JACC): Cardiovascular Interventions.* These data were simultaneously presented in a late-breaking session at Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation.


This independent analysis evaluated LUTONIX® 035 DCB (N=1093) and standard percutaneous transluminal angioplasty (PTA) (N=250) safety outcomes using patient-level data and propensity-matching from three LUTONIX® DCB randomized, controlled trials: LEVANT 1, LEVANT 2 and LEVANT Japan, as well as the Continued Access cohort of the LEVANT 2 trial, and confirmed that there was no statistically significant increase in mortality with the use of LUTONIX® 035 DCB.

"While the FDA and Advisory Committee of Circulatory System Devices Panel in June identified a late mortality signal after treatment with paclitaxel-coated devices using a meta-analysis of randomized, controlled trials at five years from multiple companies, they recognized the benefits of these devices, including fewer reinterventions. They agreed that the magnitude of the signal should be interpreted with caution due to multiple limitations in the available data," said Kenneth Ouriel, MD, president and CEO, Syntactx, the clinical

research firm that conducted the independent analysis, and former chairman of Surgery at the Cleveland Clinic. "This large patient-level analysis found no statistically significant increase in mortality associated with LUTONIX DCB treatment. LUTONIX DCB remains a viable medical therapy for patients with peripheral arterial disease who demonstrate a high risk for restenosis and repeat femoropopliteal interventions."

Further, a medical advisory committee comprised of an interventionalist and oncologist re-evaluated the cause of death in the LEVANT 1 and LEVANT 2 trials, including the LEVANT 2 Continued Access cohort. This independent review confirmed through adjudication that zero deaths were determined to be related to paclitaxel. Moreover, no clustering or pattern of death in any cardiovascular or non-cardiovascular categories was observed, which would have indicated a causal relationship between paclitaxel and death.

"The published patient-level analysis from Syntactx provides important information that health care providers can use to make an informed decision on the use of paclitaxel devices until additional long-term data are available," said J.D. Meler, MD, vice president of Medical and Clinical Affairs for BD's Peripheral Intervention business. "Patient safety is our top priority, and BD remains committed to improving the quality of life of patients with PAD."

**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 improve patient outcomes, improve the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to better diagnose 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.

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