

# BD Registry Underscores Value of the Lutonix™ Drug Coated Balloon (DCB) Technology in Treating Femoropopliteal Disease

*Results of the SAFE-DCB Registry support long-term safety and effectiveness for the Lutonix™ DCB in a real-world patient population with femoropopliteal disease.*

**FRANKLIN LAKES, N.J., Nov. 1, 2023** - BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, presented the results of the SAFE-DCB Registry assessing the clinical use of the Lutonix™ 035 DCB in a heterogeneous patient population in a real-world, on-label clinical application.

The SAFE-DCB Registry is a prospective, single-arm study of 1,005 patients across 74 sites in the U.S. Patients with stenotic or obstructive lesions in the femoropopliteal arteries underwent on-label treatment with the Lutonix™ DCB at the physician's discretion. Primary effectiveness results showed a freedom from target lesion revascularization rate of 89.1 percent at 12 months, 79.8 percent at 24 months, and 74.4 percent at 36 months.<sup>1</sup> Freedom from a composite of device- or procedure-related perioperative death, target limb major amputation and target vessel revascularization, was 98.2 percent at 30-days.<sup>1</sup> At the end of the registry, 629 (65.1 percent) patients completed the 36-month follow up visit.

The real-world registry evaluated patients with complex femoropopliteal disease, including 340 patients (35.2 percent) with critical limb ischemia, defined as Rutherford Class 4-6, 523 patients (54.1 percent) with diabetes, 688 (71.2 percent) with cardiovascular disease, and 136 (14.1 percent) with lesions 140 mm or longer. In addition, 60 percent of target lesions had moderate to severe calcification.

"These results support the Lutonix™ DCB as an effective, durable technology providing positive, long-term outcomes for patients suffering from femoropopliteal disease," said Dr. Nicolas W. Shammas, a lead principal investigator for the SAFE-DCB Registry. "The all-comers design of this registry reflects the challenging patient population that often presents with comorbid conditions, advanced levels of disease, and complex lesion morphologies that operators must combat every day in the real world."

BD pioneered balloon catheter drug coated technology with the launch of the Lutonix™ DCB in 2014, a paclitaxel-coated balloon that was the first of its kind in the United States. With a paclitaxel concentration of 2 $\mu$ g/mm<sup>2</sup>, the Lutonix™ DCB is designed to deliver an optimal therapeutic dose to the vessel wall. The SAFE-DCB registry brings the total number of global patients evaluated in BD-sponsored studies to over 3,000<sup>2</sup>. Positive safety and effectiveness results have been confirmed in this large, real-world study that followed patients out to 36 months.

"The Lutonix™ DCB has been used to treat over 400,000 patients worldwide,<sup>2</sup>" said Tim Hug, Global vice president and general manager of vascular for BD. "The results from the SAFE-DCB Registry provide additional clinical evidence to help assure our physician partners that our DCB technology offers safe, effective, and durable treatment for patients with femoropopliteal disease."

BD remains steadfast in its commitment to providing physicians with proven technologies intended to deliver positive, patient-centric outcomes.

## 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](http://bd.com) or connect with us on LinkedIn at [www.linkedin.com/company/bd1/](http://www.linkedin.com/company/bd1/) and Twitter @BDandCo.

<sup>1</sup> Kaplan-Meier estimates.

<sup>2</sup> Data on file. BD, Tempe, AZ.

BD-109001

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