

BD Launches First-in-Human Trial of Sirolimus Drug-Coated Balloon to Expand Treatment Options for Peripheral Arterial Disease

First patient enrollment in PREVISION trial marks opportunity to further advance the safety and performance of drug-coated balloon technology and aligns with the company's commitment to developing innovations that enhance Chronic Disease Outcomes

FRANKLIN LAKES, N.J., Aug. 18, 2022 - BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, has announced the start of enrollment in a first-in-human trial of a peripheral sirolimus drug-coated balloon (DCB).

BD is a pioneer in DCB technology as the first to gain U.S. FDA approval for a paclitaxel DCB. BD's Lutonix™, which received FDA approval in 2014, is celebrating its 10-year anniversary globally this year. Over this time, BD has continued to innovate and lead in DCB technology with advancements such as additional indications, lower sheath profile, longer treatment lengths, and additional guidewire configurations. Today, DCBs remain a broadly accepted endovascular interventional treatment option for patients with peripheral arterial disease (PAD) of the femoropopliteal artery.

"PAD impacts more than 200 million people across the globe and is often associated with morbidity, functional declines and higher health care costs.¹ BD is committed to delivering much-needed solutions to address these challenges," said Paddy O'Brien, Worldwide President of BD Peripheral Intervention. "The launch of our PREVISION first-in-human study demonstrates our ongoing commitment to advancing the drug coated balloon category. It marks an important milestone on the path towards bringing this technology to clinicians and patients around the globe."

The PREVISION trial is a prospective, multicenter, single arm, non-randomized study designed to evaluate the safety of the BD sirolimus DCB in the treatment of peripheral arterial disease in the femoropopliteal arteries.

BD initiated this trial to determine the viability of sirolimus as a future treatment option for patients with PAD. The first patient was successfully treated by Dr. Andrew Holden, principal investigator at Auckland City Hospital, New Zealand.

"It is an honor to enroll the first patient in the PREVISION study," said Dr. Holden. "The burden of PAD continues to impact patients and challenge physicians around the globe. A continued focus on developing next-generation technology is important for the patients suffering from PAD."

PREVISION is being conducted across multiple sites in Australia, New Zealand, and Singapore. The trial will enroll and follow-up on approximately 50 patients over the coming months.

¹ Fanaroff A, Rao S, Swaminathan R. Radial Access for Peripheral Interventions. *Interventional Cardiology Clinics*. 2020;9:53-61. doi: <https://doi.org/10.1016/j.iccl.2019.08.005>

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 75,000 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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