BD Announces 510(k) Clearance of Pristine™ Long-Term Hemodialysis Catheter

Clearance supported by clinical data from a feasibility study with favorable primary patency rates observed out to 180 days

FRANKLIN LAKES, N.J., April 14, 2021 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the Pristine™ Long-Term Hemodialysis Catheter, a new hemodialysis catheter with a unique side-hole free symmetric Y-Tip™ distal lumen design. The Pristine™ Catheter will be available in the U.S. in May 2021. The device was developed by Pristine Access Technologies, Ltd., a privately-owned company based in Israel, which was acquired by BD inJuly 2020 as part of the company's ongoing growth strategy focused on tuck-in acquisitions and R&D investments in improved treatments for chronic diseases.

Hemodialysis catheters are often challenged by complications. Certain catheter tip designs can lead to complications such as positional occlusion, high recirculation rates, and thrombus formation. These complications can potentially lead to reduced catheter patency and decreased catheter performance. The Pristine™ Catheter is designed to help address these challenges.

The Pristine™ Catheter's side-hole free tip is designed to help minimize thrombus adhesion that can be associated with side-hole catheters and to help facilitate blood clot aspiration prior to hemodialysis treatment. The symmetric tip is designed to help minimize recirculation rates in both forward and reverse.

In a prospective, single-center non-randomized, open-label feasibility study performed outside ofthe United States, 45 patients who received the 15.5F Pristine™ Catheter were followed for 6 months post-catheter implantation. All catheters were patent at 30 days post implantation. Primary patency at 60- and 180-days post procedure was 100.0% and 90.9%, respectively.

"The clearance of the BD Pristine™ Catheter adds to our diversified portfolio of products in support of clinicians who care for patients with end stage kidney disease (ESKD) who require hemodialysis," said Padraic O'Brien, Worldwide President of Peripheral Intervention for BD. "This exciting technology is highly complementary to our current ESKD portfolio and will enable us to offer a differentiated product that can help to improve the patient experience."

"A majority of hemodialysis patients inthe United States start their treatment with a catheter and many of those catheter-dependent patients will suffer a catheter-related complication at some point during treatment, which can adversely impact the patient and create additional healthcare system costs." said Michael Tal, M.D., founder of Pristine Access Technologies, Ltd. and inventor of the Pristine™ Catheter. "The Pristine™ Catheter was designed with hemodialysis patients in mind and to help address some of these concerns."

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 70,000 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 or connect with us on LinkedIn at www.linkedin.com/company/bd1/ and Twitter @BDandCo.

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