

BD Advances Technology to Create Endovascular AV Fistulas for Chronic Kidney Disease Patients Who Require Hemodialysis

BD WavelinQ™ 4F EndoAVF System Receives 510(k) Clearance from U.S. Food and Drug Administration

FRANKLIN LAKES, N.J., February 13, 2019 - BD (Becton, Dickinson and Company), a leading global medical technology company, received 510(k) clearance from the U.S. Food and Drug Administration for the BD WavelinQ™ 4 French (4F) endoAVF system on February 7, 2019. The BD WavelinQ™ 4F endoAVF system is the company's most recent innovation in endovascular arteriovenous fistula (endoAVF) creation technology, which allows for the creation of an AVF in either the ulnar artery and ulnar vein or the radial artery and radial vein, expanding upon the current indication for the BD WavelinQ™ 6F endoAVF system.

In the U.S. alone, there are more than 440,000 patients with End-Stage Renal Disease (ESRD) who are surviving on hemodialysis.¹ The BD WavelinQ™ 4F endoAVF system provides clinicians with a minimally invasive AVF creation alternative to open surgery. The BD WavelinQ™ 4F endoAVF system, with its slim profile, increases the anatomical AVF location options and enables additional venous wrist access points (ulnar vein or radial vein), providing increased procedural flexibility for physicians while reducing risk of scarring or arm disfigurement for patients compared to open surgical AV fistula creation.

"With BD WavelinQ 4F endoAVF system, I can provide my ESRD patients with two additional fistula location options compared to a surgical fistula," said Paul Kreienberg, MD, Albany Medical Center. "These additional AV fistula sites and a minimally invasive procedure can increase the likelihood that patients will get a usable AV fistula."

When patients have ESRD, their kidneys can no longer keep up with the body's need to remove extra waste and water. Once kidney function goes below 10-15 percent of normal function, hemodialysis treatments, which are often achieved with an AV fistula, or a kidney transplant are necessary to sustain life.²

"People living with ESRD are an underserved patient population with very limited treatment options available to them," said Steve Williamson, worldwide president of Peripheral Intervention at BD. "We're excited to add BD WavelinQ 4F endoAVF system to our portfolio of technologies that create, restore and/or maintain AV access for patients on hemodialysis. Endovascular specialists now have an additional tool that enables the flexibility needed to support AV fistula creation for their patients."

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 healthcare by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for healthcare 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 healthcare. In 2017, BD welcomed C. R. Bard and its products into the BD family. For more information on BD, please visit bd.com

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<https://news.bd.com/2018-02-13-BD-Advances-Technology-to-Create-Endovascular-AV-Fistulas-for-Chronic-Kidney-Disease-Patients-Who-Require-Hemodialysis>