

***BD WavelinQ™ 4F EndoAVF System Receives U.S. Food and Drug Administration Clearance: Baylor Scott & White Heart and Vascular Hospital's Vascular Surgeon First in United States To Deploy For Patients Suffering from End-Stage Renal Disease***

**DALLAS (March 8, 2019)** - The Baylor Scott & White Heart and Vascular Hospital vascular surgery program's leadership received word that a new and innovative treatment option for patients suffering End-Stage Renal Disease (ESRD) was recently approved by the U.S. Food and Drug Administration. Vascular surgeon on the medical staff, Stephen Hohmann, MD, FACS, became the first surgeon and the hospital is the first site in the U.S. to deploy this latest technology to benefit patients.

The company, BD (Becton, Dickinson and Company) received 510(k) clearance from the U.S. Food and Drug Administration for the BD WavelinQ™ 4 French (4F) endoAVF system in February. The BD WavelinQ™ 4F endoAVF system is the company's most recent development for vascular surgeons to use for the procedure known as endovascular arteriovenous fistula (AVF). This new technology 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 that has already been in use at Baylor Scott & White Heart and Vascular Hospital – Dallas.

In the U.S. alone, there are more than 440,000 patients with End-Stage Renal Disease (ESRD) who are surviving on hemodialysis. This new technology provides clinicians with a less 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.

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.

"With BD WavelinQ 4F endoAVF system, I can now provide ESRD patients with unique fistula location options that are less invasive compared to a surgical fistula," said Stephen Hohmann, MD, FACS. "These additional AV fistula sites and a minimally invasive procedure may increase the likelihood that patients will get a usable AV fistula." Dr. Hohmann is also the vascular surgery fellowship program director for Baylor University Medical Center, a part of Baylor Scott & White Health.

Vice Chair for Vascular Surgery at Baylor Scott & White Heart and Vascular Hospital - Dallas, John Eidt, MD, RVT, RPVI, FACS, commented that the entire team is proud to have been the first the U.S. to bring this technology to patients. "People living with ESRD are often underserved with limited treatment options. Having this system available can help create and maintain AV access for patients on hemodialysis which is important to our well-known program. We are proud that Dr. Hohmann was the first surgeon in the nation to use this technology and we add this 'first' to a long list of 'firsts' we are proud to claim for our vascular surgery program in Dallas."

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