



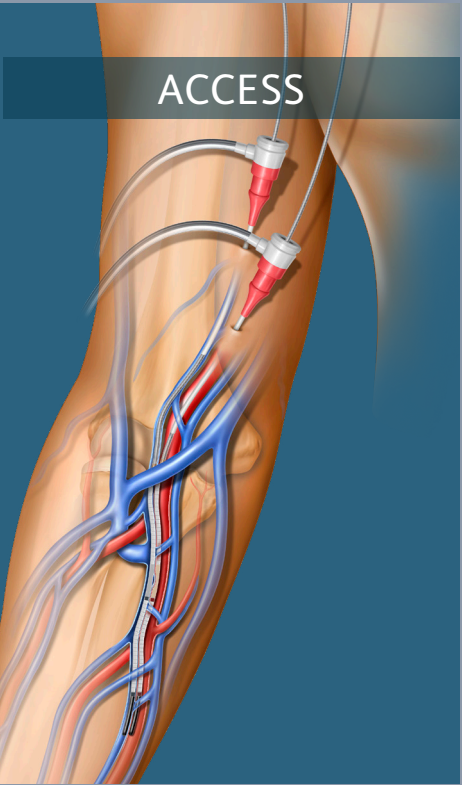
DON'T JUST CREATE
AN AV FISTULA,
**MAKE A
DIFFERENCE**

WavelinQ™
EndoAVF System

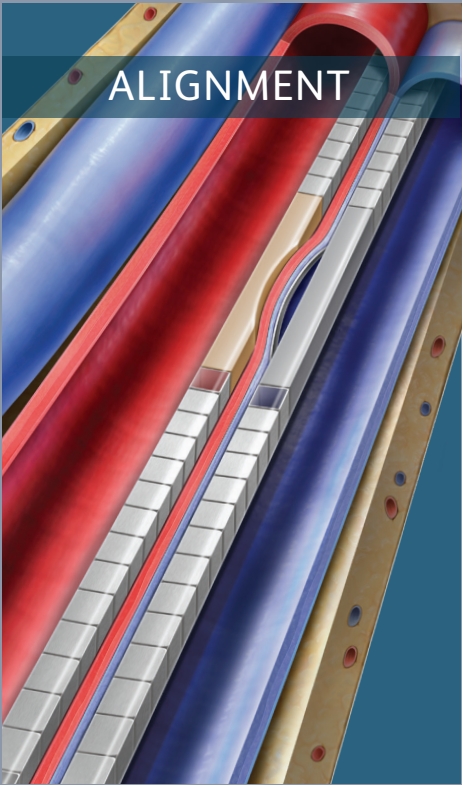


NON-SURGICAL AV FISTULA CREATION

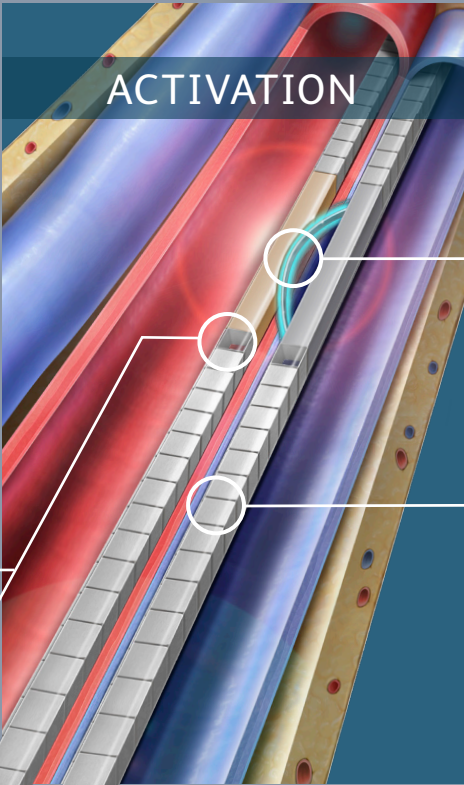
For far too long, hemodialysis access creation options for your patients have been limited. The WavelinQ™ EndoAVF System is designed to change that by providing a truly flexible, minimally-invasive procedural option for arteriovenous fistula creation.



Two thin, flexible, magnetic catheters are inserted into an artery and vein in the arm through small punctures or incisions.



When placed in proximity, the magnets in each catheter attract to each other, pulling the vessels together and aligning the RF electrode.

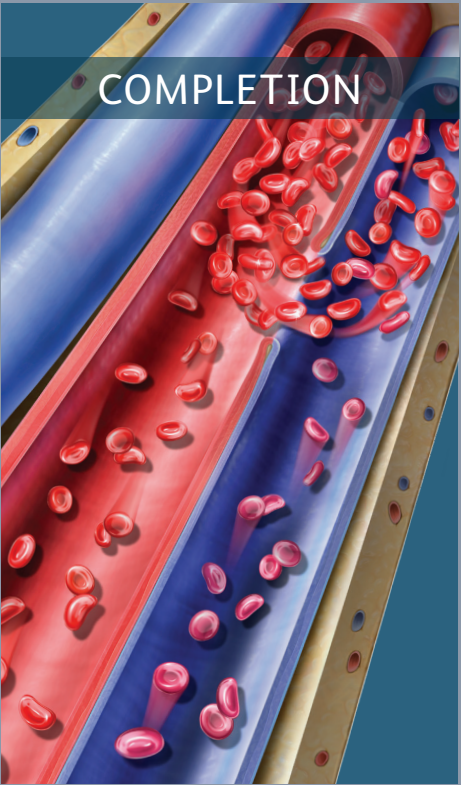


Rotational Indicators provide visual clarity to help facilitate alignment

Radiofrequency Electrode

Embedded Square Magnets are designed to provide strength and flexibility even in tortuous anatomy

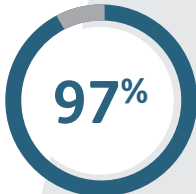
The venous catheter, which contains the electrode, delivers RF energy to create a connection between the artery and vein. Then, the catheters are removed.



A brachial vein embolization is then recommended to divert more flow through the perforator to the superficial veins (cephalic, median cubital and/or basilic veins) for hemodialysis.

4F Rapid Exchange Arterial Catheter

4F Rapid Exchange Venous Catheter

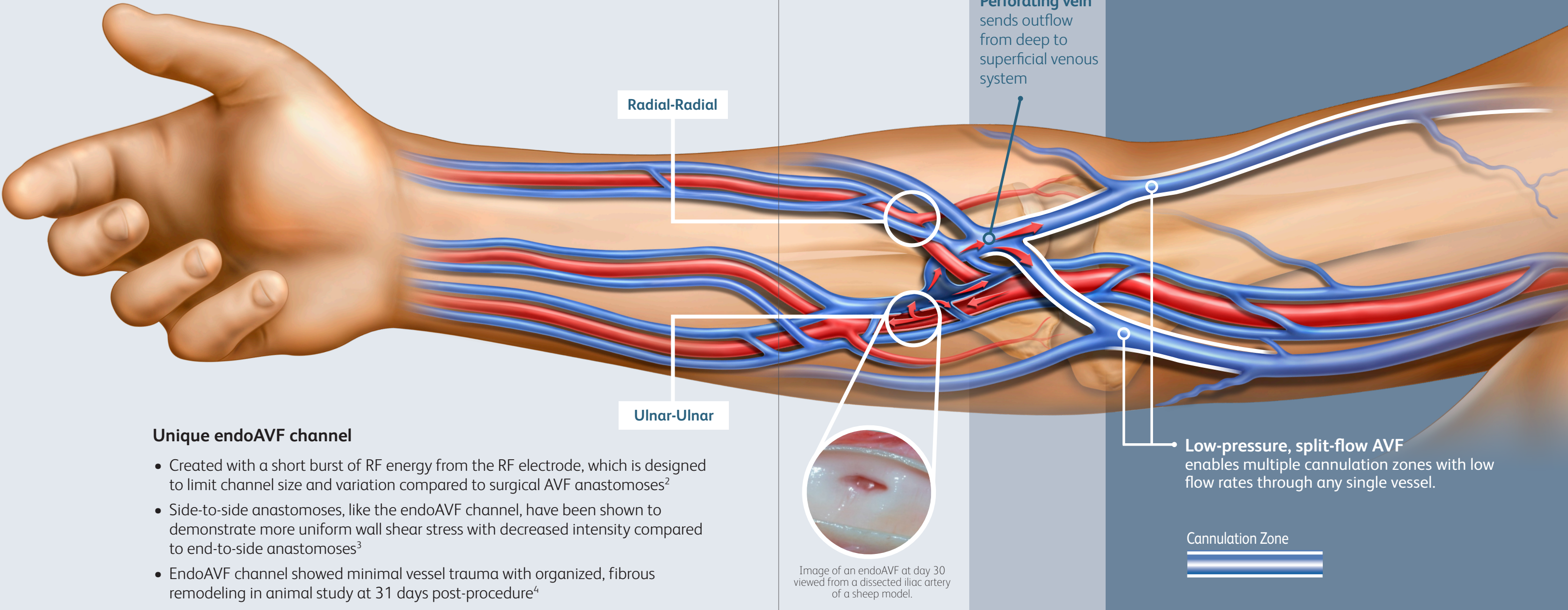


High procedure success

88 of 91 subjects in the 4F Global Analysis had a successful EndoAVF creation confirmed via intraprocedural fistulography or by duplex ultrasound performed post-procedure¹

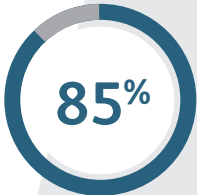
EXPANDING OPTIONS TO ADDRESS PATIENT NEEDS

Every patient is different, and every fistula is different. The WavelinQ™ EndoAVF System provides the flexibility to adapt your plan to help meet the unique anatomical needs of your patients by offering multiple options for access, creation, and cannulation, while also preserving future surgical AV fistula creation site options.



Unique endoAVF channel

- Created with a short burst of RF energy from the RF electrode, which is designed to limit channel size and variation compared to surgical AVF anastomoses²
- Side-to-side anastomoses, like the endoAVF channel, have been shown to demonstrate more uniform wall shear stress with decreased intensity compared to end-to-side anastomoses³
- EndoAVF channel showed minimal vessel trauma with organized, fibrous remodeling in animal study at 31 days post-procedure⁴



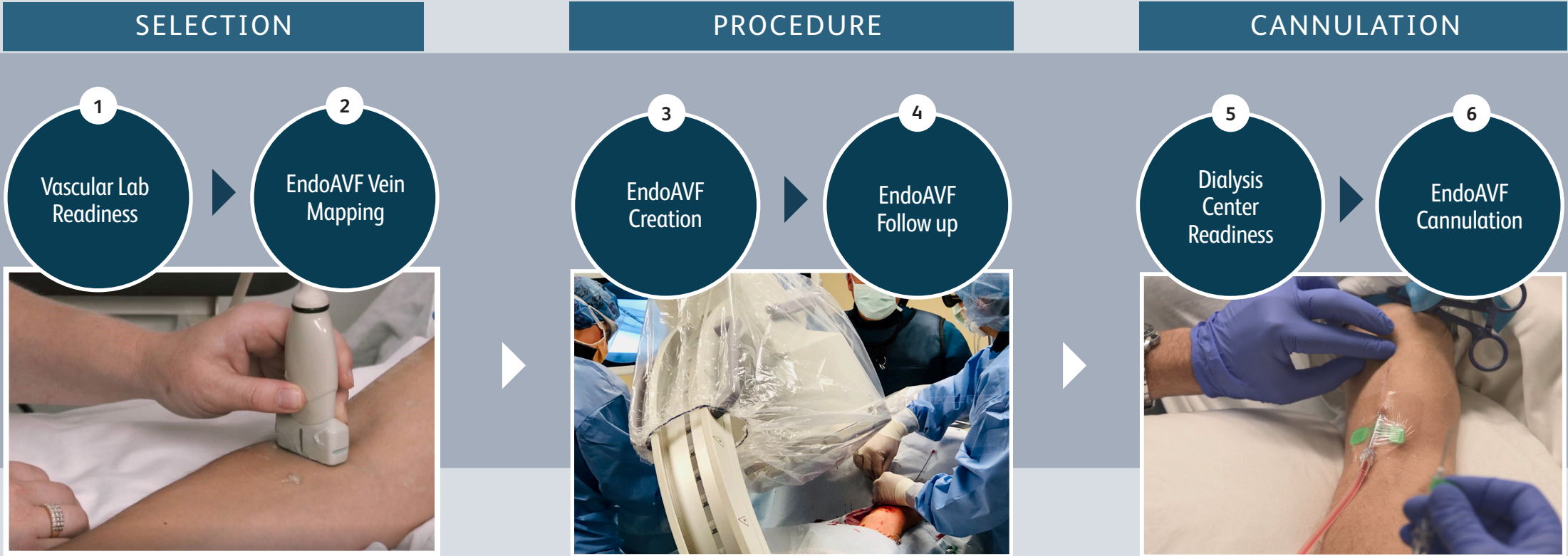
High cannulation success

63 of 74 dialysis subjects in the 4F Global Analysis achieved successful 2-needle cannulation and hemodialysis through their endoAVF 6 months post-procedure¹

MORE THAN A PRODUCT

A COMPLETE PROGRAM

An effective endoAVF program requires a multidisciplinary commitment to the patient journey. To help support that effort, BD provides comprehensive training, ongoing support, and the resources and tools that you need to help you be successful.



Our specialized endovascular fistula teams help educate and train you and your ultrasound team on vein mapping for WavelinQ™ EndoAVF.

Our expert physician trainers conduct procedural training using a mix of virtual technologies, simulators and hands-on demonstration and our local certified endovascular fistula specialists will in-service your full procedure team, proctor initial cases and follow up.

Our specialized dialysis team helps prepare your dialysis centers for endoAVF cannulation.

ADVANCE>

A CLINICAL TRAINING & EDUCATION PROGRAM

For videos, presentations, articles and more visit our WavelinQ™ EndoAVF Clinical Resources page at bd.com/wavelinq or scan the QR code below for access

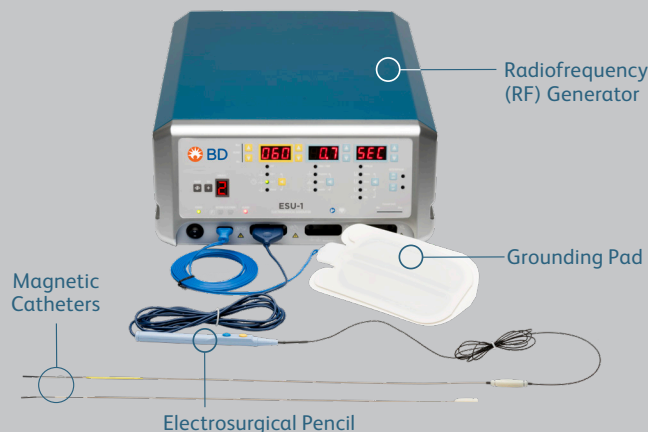




Low catheter use
Only 4 of 25 pre-dialysis subjects in the 4F Global Analysis initiated hemodialysis with a catheter¹

The WavelinQ™ EndoAVF System consists of an RF generator, two disposable magnetic catheters, and an arm board (not pictured).

Other procedural components (sold separately) include: arm board fixation straps (not pictured), electrosurgical pencil, and a grounding pad.



WavelinQ™ EndoAVF System		
Disposable Components	Description	Product Code
WavelinQ™ EndoAVF Catheters	4F Venous Catheter & 4F Arterial Catheter	<input type="checkbox"/> WQ4300
Fixation Straps	Each pack contains three straps: two 2" x 24" and one 2" x 18". Sold as a case of 10 packs	<input type="checkbox"/> TVA-MC-2
Reusable Components	Description	Product Code
WavelinQ™ Generator	Electrosurgical radiofrequency generator	<input type="checkbox"/> ESU-1
WavelinQ™ Arm Board	Radiolucent carbon fiber arm board	<input type="checkbox"/> CZ-400-TVA

<hr/> <p>PHYSICIAN NAME</p> <hr/>
<hr/> <p>PHYSICIAN SIGNATURE</p> <hr/>

<hr/> <p>REPRESENTATIVE'S NAME</p> <hr/>
<hr/> <p>CONTACT PHONE NO.</p> <hr/>

¹Data from the EASE (n=32), EASE-2 (n=24) and the EUR Post-Market (n=35) Studies of the WavelinQ™ 4F EndoAVF System was aggregated and analyzed in the 4F Global Analysis (n=91). Procedural Success (Dialysis subset) was defined as successful endoAVF creation confirmed via intraprocedural fistulography or by duplex ultrasound performed post-procedure. Cannulation Success (Dialysis subset) was defined as 2-needle access and dialysis through the endoAVF CVC. Initiation: pre-dialysis patients who initiated hemodialysis with a CVC through 6 months. See the WavelinQ™ EndoAVF System Instructions for Use for the full analysis, including more details on each of the studies.

²Rajan. Seminars in Interventional Radiology 2016;33(1):6-9

³Hull et. Al. JVA 2013;58(1):187-193.

⁴Results from preclinical study where 4 sheep received percutaneously created fistulae utilizing WavelinQ™ EndoAVF and the tissue healing response was evaluated at 30 + 2 days. Data on file. GLP Animal Study, using WavelinQ™ 6F EndoAVF System. Preclinical data may not be predictive of actual clinical outcomes. Different tests methods may yield different results.

WavelinQ™ EndoAVF System

Indications: The WavelinQ™ EndoAVF System is indicated for the creation of an arteriovenous fistula (AVF) using concomitant ulnar artery and ulnar vein or concomitant radial artery and radial vein in patients with minimum artery and vein diameters of 2.0 mm at the fistula creation site who have chronic kidney disease and need hemodialysis.

Contraindications: Target vessels < 2 mm in diameter.

Warnings: The WavelinQ™ EndoAVF System is only to be used with the approved components specified in the instructions for use (IFU). Do not attempt to substitute non-approved devices or use any component of this system with any other medical device system. Use of the system with other components may interfere with proper functioning of the device. The WavelinQ™ catheters are single use devices. DO NOT re-sterilize or re-use either catheter. Potential hazards of reuse include infection, device mechanical failure, or electrical failure potentially resulting in serious injury or death. The WavelinQ™ EndoAVF System should not be used in patients who have known central venous stenosis or upper extremity venous occlusion on the same side as the planned AVF creation. The WavelinQ™ EndoAVF System should not be used in patients who have a known allergy or reaction to any drugs/fluids used in this procedure. The WavelinQ™ EndoAVF System should not be used in patients who have known adverse reactions to moderate sedation and/or anesthesia. The safety and performance of the device via arterial wrist access has not been fully established. The incidence of vessel stenosis or occlusion that occurs in the radial and ulnar arteries after

arterial wrist access has not been evaluated. Do not use the device to create an EndoAVF using arterial access via the radial or ulnar artery. The EndoAVF should only be created using brachial artery access. Use caution when performing electrosurgery in the presence of pacemakers or implantable cardioverter defibrillators. Improper use could damage insulation that may result in injury to the patient or operating room personnel. Do not plug device into the electrosurgical pencil with ESU powered on. Consult the ESU User Guide on its proper operation prior to use. Do not use closure devices not indicated to close the artery used for access. Ensure the patient's arm is restrained to minimize movement during device activation; potential hazards of patient arm movement during activation are hematoma or pseudoaneurysm near the fistula site. The puncture site should be closed and hemostasis should be achieved by manual compression per the instructions in the IFU. Use of closure devices with the WavelinQ™ EndoAVF System may be associated with an increased risk of access site complications. The WavelinQ™ EndoAVF System has only been evaluated for the creation of an AVF between the ulnar artery and concomitant ulnar vein and between the radial artery and concomitant radial vein in the clinical studies described in the IFU. Refer to the latest National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI) guidelines for recommendations and considerations for AV access creation in patients on or requiring hemodialysis. For patients expected to have prolonged durations on hemodialysis, a distal to proximal approach to AVF creation provides the best opportunity to preserve vessels for future vascular access sites following the individual patient ESKD Life-Plan. This device is coated with a hydrophilic coating at the distal end of the device for a length of 26.4 (10.4 in). Please refer to the AVF Creation section in the instructions for use for further information on how to prepare and use this device to ensure it performs as intended. Failure to abide by the warnings in this labeling might result in damage to the device coating.

Cautions: Only physicians trained and experienced in endovascular techniques, who have received appropriate training with the device, should use the device. Endovascular technique training and experience should include ultrasound vessel access in the arm, guidewire navigation, radiographic imaging, placement of the vascular embolization devices (including embolization coils), and access hemostasis. Adhere to universal precautions when utilizing the device.

Precautions: Care should be taken during handling of the arterial and venous catheters in patients with implantable cardiac defibrillators or cardiac pacemakers to keep the distal 3 inches of the catheters at least 2 inches from the implanted defibrillator or pacemaker. Care should be taken to avoid attempting fistula creation in a heavily calcified location of a vessel as fistula may not be adequately formed. If the device does not perform properly during the creation of the endovascular fistula it is possible that a fistula will not be created or there may be some vessel injury. Some patients who have veins deeper than 6mm may

require superficialization per KDOQI guidelines. Ensure the patient has adequate collateral blood flow to the hand before use of the device. Prior to the procedure, ensure that the access location, access vessels, and target AVF location are of appropriate size to account for the devices during use. Oversizing the device to the access vessel may increase risk of vessel injury, which may result in stenosis and/or occlusion. Vessel injury may impact future dialysis access options and/or the ability to perform future endovascular procedures from the target access vessels. Users should consider the potential risk of distal arterial stenosis and/or occlusion on end stage renal disease patients when selecting vascular access sites for the procedure. Adjunctive procedures are expected to be required at the time of the index procedure to increase and direct blood flow into the AVF target outflow vein to assist maturation. Care should be taken to proactively plan for any adjunctive procedures, such as embolization coil placement, when using the device.

Potential Adverse Events: The known potential risks related to the WavelinQ™ device and procedure, a standard AVF and endovascular procedures may include but are not limited to: aborted or longer procedure; additional procedures; bleeding, hematoma or hemorrhage; bruising; burns; death; electrocution; embolism; failure to mature; fever; increased risk of congestive heart failure; infection; numbness, tingling and/or coolness; occlusion/stenosis; problem due to sedation or anesthesia; pseudoaneurysm; aneurysm; sepsis; steal or ischemia; swelling, irritation, or pain; thrombosis; toxic or allergic reaction; venous hypertension (arm swelling); vessel, nerve, or AVF damage or rupture; wound problem.

Please consult package insert for more detailed safety information and instructions for use.



bd.com/wavelinq BD, Tempe, AZ, USA, 1 800 321 4254

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WavelinQ™
EndoAVF System

