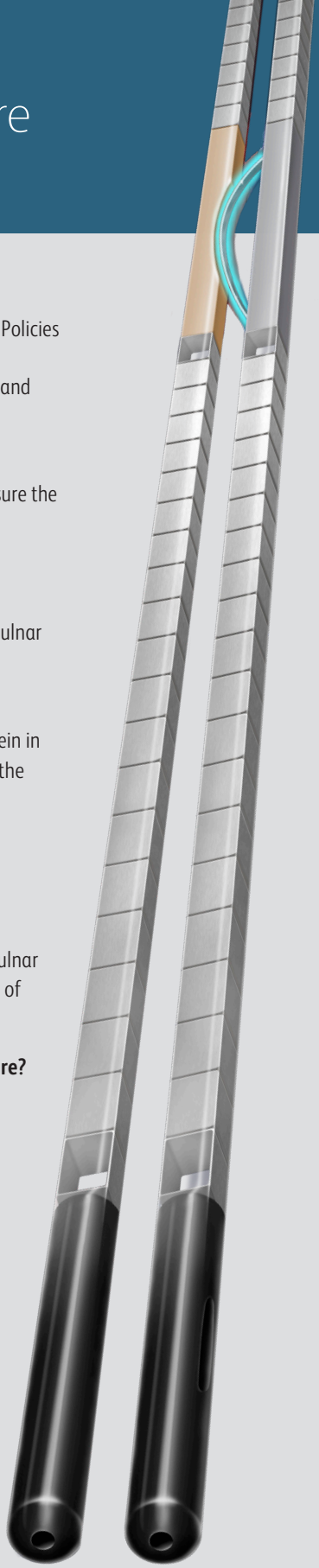
WavelinQ™ EndoAVF Screening and Procedure Frequently Asked Questions



1. **What approach should be taken to implement vein mapping requirements for patient selection?**
   Selection of the appropriate candidate for an endoAVF is a multidisciplinary process that begins with vessel mapping. Policies and procedures along with education and training on required vessel mapping protocols assist in appropriate patient selection. Initial steps include the physician meeting with the ultrasound department to discuss the screening process and collaboratively developing standardized protocols intended to avoid repeat studies and additional economic burden.

2. **What is the recommendation for precise measure of vessel diameter?**
   For a precise measurement of vessel diameter, measure the vessel from inner-to-inner vessel wall. Additionally, make sure the vessel is not being distorted in size by an inappropriate amount of pressure.

3. **What are the recommendations for forearm measurements?**
   Forearm measurements should include: concomitant radial veins and artery immediately distal to the perforator: concomitant ulnar veins and artery distal to the perforator and prior to the interosseous veins, as well as concomitant ulnar veins and radial veins at the wrist within a 3 inch window.

4. **How do I determine if the perforating vein communicates with the radials and ulnars?**
   Use ultrasound screening to observe the perforating vein. Once the perforating vein is in view, follow the perforating vein in the transverse view distally towards the wrist. First, view how the perforator communicates with the radials, then with the ulnars.

5. **What is the size of the anastomosis at the time of endoAVF creation?**
   1 mm x 5 mm

6. **What is the smallest vessel diameter that can be used to create a AV fistula?**
   The WavelinQ™ EndoAVF System is indicated for the creation of an arteriovenous AV 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 mm at the fistula creation site.

7. **What resources are available to review anatomy for the WavelinQ™ EndoAVF patient selection and procedure?**
   A variety of clinical and educational resources, including an Anatomy Flipbook, are available at bd.com/wavelinq.

8. **Can an endoAVF be created if calcium is present?**
   Calcification may inhibit electrode cutting; care should be taken to avoid attempting fistula creation in a heavily calcified location of a vessel as the fistula may not be adequately formed.

9. **It is possible to create an endoAVF provided the perforating vein communicates with the vein being used.**
   Yes, provided the perforating vein communicates with the vein being used to create the endoAVF.

10. **Is there a preference for which brachial vein to select for access?**
    Ideally, select the brachial vein that ties directly to the target vein for endoAVF creation. For example, if targeting a lateral ulnar vein, attempt to access the lateral brachial vein. If this isn't an option, considering choosing the larger, more anterior brachial vein.

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Table 1

Item	Description	Quantity Needed
Introducer Sheath	Halo One™ Thin-Walled Guiding Sheath 10cm, 5 French, 0.018" guidewire	2
Guidewire (Device Delivery)	V-14 ControlWire - .014 x 182cm Short Taper/Straight Tip/Shapeable	2
Guidewire (Venous Wire Navigation)	V-18 ControlWire - .018 x 110cm Short Taper/Straight/ Tip/Shapeable	1
Micro Accessed Kit	MAK - 4Fr x 10cm x .018" Micro Introducer Kit	2
Diagnostic Catheter	Impress Angiographic Catheter - 4Fr x 30cm x .035" Braided	1
Touhy Borst Connector	Single Y w/6" 500 PSI Extension Procedure Kit	1
Ground Pad	Thermoguard Dual Dispersive Electrode	1
Electrosurgical Pencil	Bovie Disposable Electrosurgical Pencil w/Blade	1
Fixation Straps	Hand Straps	1

11. What basic supplies are required for endoAVF creation?

Recommended supplies are listed in Table 1.

12. Why is a 5F sheath recommended for a 4F device?

The WavelinQ™ EndoAVF catheters utilize a rapid-exchange style tip/delivery to accommodate for the internal components of the device. Because the guidewire resides outside of the catheter in the rapid-exchange design, a slightly larger sheath is required to accommodate the catheter and the wire.

13. Why is the arterial catheter placed first?

Placing the arterial catheter first allows operators to perform a final venogram with one catheter in place to confirm the target endoAVF location.

14. Why is an arm board recommended when it is not typically used in a surgical arteriovenous creation?

The intent of utilizing an arm board is to restrain the arm to minimize movement during the device activation. Potential hazards of patient arm movement during activation are hematoma or pseudoaneurysm near the fistula site.

15. Do dialysis facility personnel require supplemental training on endoAVF cannulation techniques?

This is highly recommended. BD has multiple training offerings for dialysis personnel including: in-person didactic and training by a WavelinQ™ EndoAVF cannulation expert; WavelinQ™ EndoAVF cannulation wall chart; FAQs on cannulation; cannulation diagrams; and educational training videos. These may be accessed at bd.com/wavelinq.

16. Following a WavelinQ™ EndoAVF creation, what types of procedures may be required if indicated?

The Novel Endovascular Access Trial (NEAT study), a prospective clinical study enrolled 60 subjects and followed for 12 months.[1] Twenty-eight percent (17/60) subjects experienced 1 or more reintervention during the NEAT Study. A total of 20 reinterventions were reported. Seven reinterventions were conducted to support maturation of the arterialized vein segments (5 secondary coil embolizations and 2 angioplasties), 5 reinterventions were conducted to facilitate cannulation (transpositions), and 2 reinterventions to provide a new access where the endoAVF was abandoned. There were 6 additional reinterventions to treat adverse events. Overall, the reported patient-event rate for WavelinQ™ EndoAVF creation when compared to surgically created hemodialysis arteriovenous fistula at 12 months in a propensity scored matched cohort were 0.59 and 3.43 respectfully.[2]

1. Lok, C E, Rajan, DK, Clement J, et al. Endovascular proximal forearm arteriovenous fistula for hemodialysis access: Results of the prospective, multicenter novel endovascular access trial (NEAT). Am J Kidney Dis. 2017;70(4):486-497. doi: 10.1053/j.ajkd.2017.03.026
NEAT study evaluated patients with an endoAVF created by the WavelinQ™ 6F System.
2. Yang, S., C. Lok, R. Arnold, et al. Comparison of post-creation procedures and costs between surgical and an endovascular approach to arteriovenous fistula creation. J Vasc Access. 2017;18(no. Suppl. 2):8-14. doi: 10.5301/jva.5000723
NEAT study evaluated patients with an endoAVF created by the WavelinQ™ 6F 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 < 2mm 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 cm (10.4 in). Please refer to the AVF Creation section in the IFU 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 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. Pre-planned vessel superficialization is acceptable and not considered an additional intervention for fistula maturation, per KDOQI Clinical Practice Guideline for Vascular Access: 2018. 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™ EndoAVF System 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 syndrome 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 product labels and instructions for use for indications, contraindications, hazards, warnings and precautions.