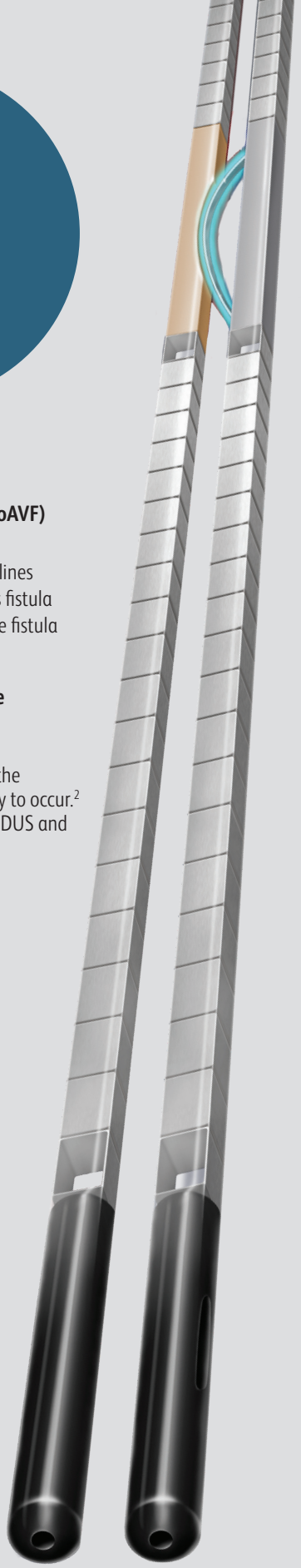
WavelinQ™ EndoAVF System
Reinterventions and Maturation Frequently Asked Questions



POST-PROCEDURE ENDOAVF CREATION MONITORING AND SURVEILLANCE

1. **What is the suggested frequency for patient follow-up after percutaneous endovascular arteriovenous fistula (endoAVF) creation with the WavelinQ™ EndoAVF System?**

   The follow-up protocol is specified by the individual physician. The Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines suggest evaluation for post-procedure complications by the physician who created the access within 2 weeks of arteriovenous fistula (AVF) creation and evaluation for maturation by a member of the vascular access team by 4-6 weeks after AVF creation. If the fistula has not matured as expected, additional investigation may be required.[1]

2. **What type of physical examination and diagnostic study should be performed following endoAVF creation with the WavelinQ™ EndoAVF system?**

   Physiologic maturation is defined as brachial artery blood flow volume >500 mL/min and cannulation vein diameter >5 mm.[2] Post-procedure evaluation may occur within 2 weeks to include physical examination and doppler ultrasonography (DUS) of the brachial artery blood flow volume.[2] Brachial artery blood flow volume of >500 mL/min suggest physiologic maturation is likely to occur.[2] Re-evaluate patient at 4-6 weeks to assess maturation and suitability for hemodialysis access.[2] Table 1 provides examples of DUS and physical examination findings suggestive of additional evaluation.

Table 1 - DUS and Physical Examination Findings Suggestive of Additional Evaluation[3]

Inflow	• Flat access • Excessive collapse of venous segment upon arm elevation (Arm Elevation Test) • Palpation of stenotic segments in the juxta-anastomotic or cannulation areas • Abnormal thrill (weak and/or discontinuous with only a systolic component) • Abnormal pulse (a weak or resistant pulse difficult to compress) • Failure of the pulse to increase when the outflow vein is temporarily occluded • DUS low brachial artery flow volume • DUS brachial artery flow rate <500 mL/min
Outflow	• Arm swelling • No partial vein collapse upon arm elevation • Palpation of stenotic segments in the venous region beyond the cannulation area • Abnormal thrill (weak and/or discontinuous with only a systolic component) in the venous region beyond the cannulation area • Abnormal bruit (high pitched with a systolic component) in the venous region beyond the cannulation area • Abnormal pulse (a weak or resistant pulse difficult to compress) in the venous region beyond the cannulation area • Fistula does not collapse with arm elevation (Arm Elevation Test) • DUS low flow in venous outflow (i.e., cephalic, basilic, and/or brachial) • DUS outflow vein diameter <4 mm

3. **What procedures should be conducted for an endoAVF that is not progressing toward maturation?**

   The goal for initial cannulation is 6-10 weeks following creation.[2] A DUS (if not already conducted) should be performed to investigate etiology that may minimize endoAVF maturation.[2] Based on DUS findings, next steps may include proceeding with a fistulogram and intervention.[2]

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4. What are the recommendations to enhance visualization of the endoAVF during angiography? How do I access?

Arterial access provides the most complete and reliable view to visualize the anastomosis, location of lesion, and document inflow and outflow (Figure 1)[5] Typically, venous access is avoided as the physician is unable to visualize arterial flow.

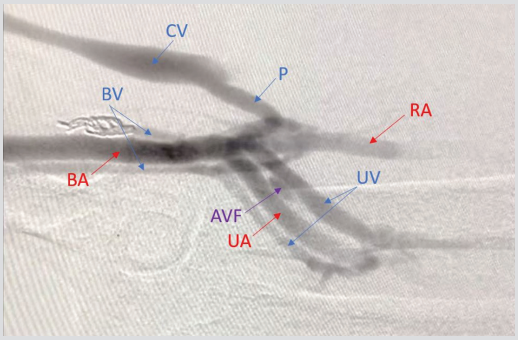

Figure 1 - Fistulagram, Left Arm

Image courtesy of Alejandro Alvarez, MD

CV = Cephalic Vein	P = Perforator
BV = Brachial Vein	BA = Brachial Artery
UV = Ulnar Vein	RA = Radial Artery
UA = Ulnar Artery	AVF = Arteriovenous Fistula

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

EndoAVF reintervention procedures may be required after creation. Reintervention procedures may include:

- Angioplasty[4]
- Arterial venous graft placement[4]
- Balloon angioplasty[2]
- Banding[4]
- Distal revascularization and internal ligation[4]
- Coil embolization[2,4]
- Ligation[2,4]
- New sAVF placement, including transposition/superficialization[4]
- Pseudoaneurysm treatment[4]
- Revision[4]
- Side branch ligation[2]
- Thrombectomy[4]
- Thrombolysis[4]

6. I have specific questions; where can I direct them?

Clinical and educational resources may be accessed at https://waveling.bd.com/clinical-and-educational-resources/ Please discuss specific questions with the local BD Representative, who will facilitate next steps that may include direct consultation with an Endovascular Fistula Specialist and/or a direct Peer-to-Peer consultation.

1. Lok CE, Huber TS, Lee T, et al. KDOQI clinical practice guideline for vascular access: 2019 update. an ASDN white paper. *Am J Kidney Dis*. 2020;75(4 Suppl 2):S1-S164. doi: 10.1053/j.ajkd.2019.12.001.
2. Wasse H, Alvarez AC, Brouwer-Maier D, et al. Patient selection, education, and cannulation of percutaneous arteriovenous fistulae: An ASDIN White Paper. *J Vasc Access*. 2020;21(6):810-817. doi: 10.1177/1129729819889793.
3. Tessitore N, Bedogna V, Melilli E, et al. In search of an optimal bedside screening program for arteriovenous fistula stenosis. *Clin J Am Soc Nephrol*. 2011;6(4):819-826. doi: 10.2215/CJN.06220710.
4. WavelinQ Clinical Study Guidelines. BD Data on file.
5. Dolmatch B. How not to evaluate and treat the immature AVF. *Endovascular Today*. 2014:48-54.

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 all indications, contraindications, hazards, warnings and precautions.