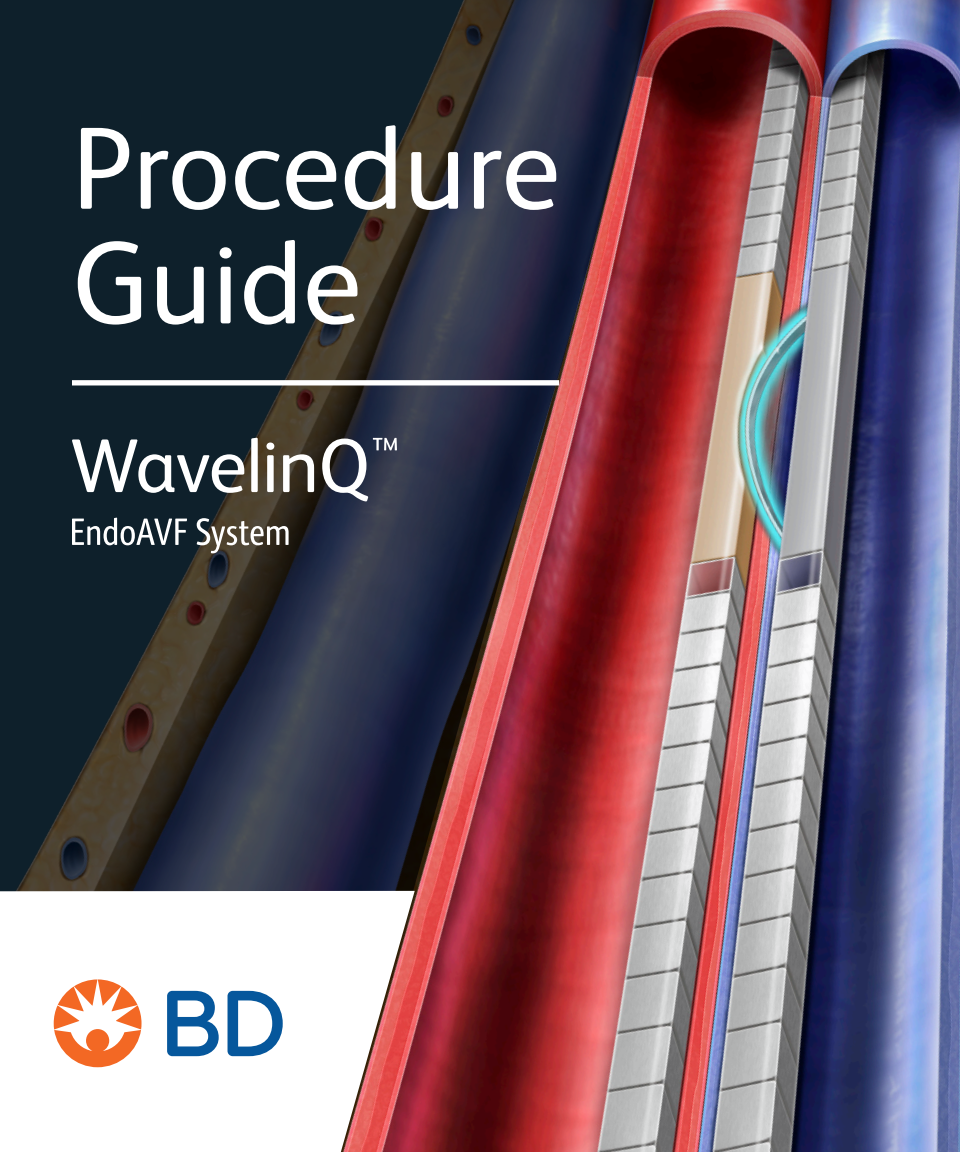
Procedure Guide

WavelinQ™

EndoAVF System



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Pre-Procedure Checklist

Equipment:

- Electrosurgical Generator (ESU-1) Cut-T, 60 W, 0.7 Sec
- Electrosurgical Pencil
- Arm Board (CZ-400-TVA)
- Disposable Fixation Straps (TVA-MC-2)
- Ground Pad
- Ultrasound Machine and Probe
- Micro Access Kit (4F)
- Two (2) 5F Introducer Sheaths
- Two (2) 0.014" Guidewires
- Tourniquet or Blood Pressure Cuff
- Embolic Device(s)

Additional Items to Consider:

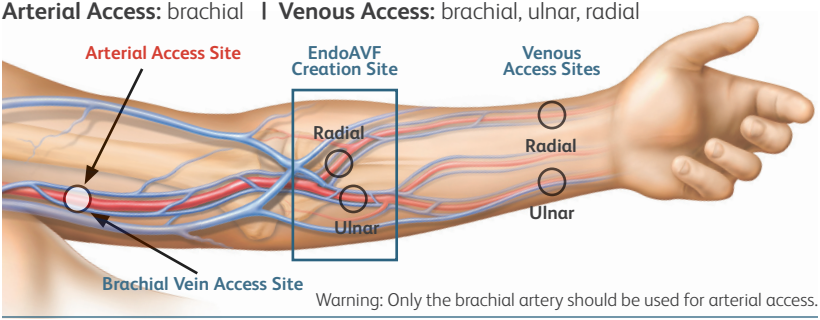
- Pressure Bag
- Guide Catheter (4F)
- Tuohy Borst

Medication Considerations:

- Anti-spasmodic
- Anesthesia
- Anticoagulant
- Vasodilator
- Saline Solution

Room & Patient Prep

Arterial Access: brachial | **Venous Access:** brachial, ulnar, radial



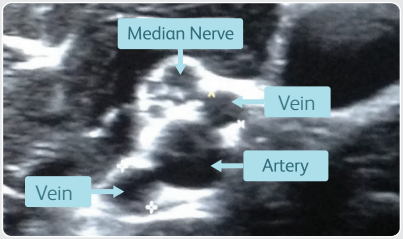
Warning: Only the brachial artery should be used for arterial access.

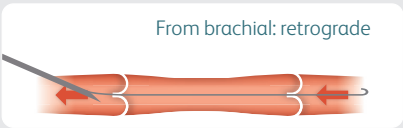
1. Arrange OR/Cath Lab per operator preference
2. Arm board placed under patient with the disposable fixation straps positioned according to images
3. Confirm procedure plan via ultrasound:
   - ✓ Access site location
   - ✓ Creation site location
   - ✓ Superficial communication
4. Ground pad on patient
5. Prep arm for procedure and drape to physician's preference (Include sterile tourniquet in draping)
6. Arm secured at ≥90° angle, hyperextended

Vessel Access

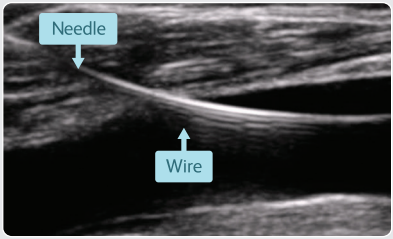
Gain Vessel Access Under Ultrasound Guidance

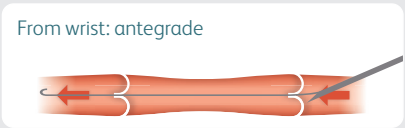
Short Access





Long Access



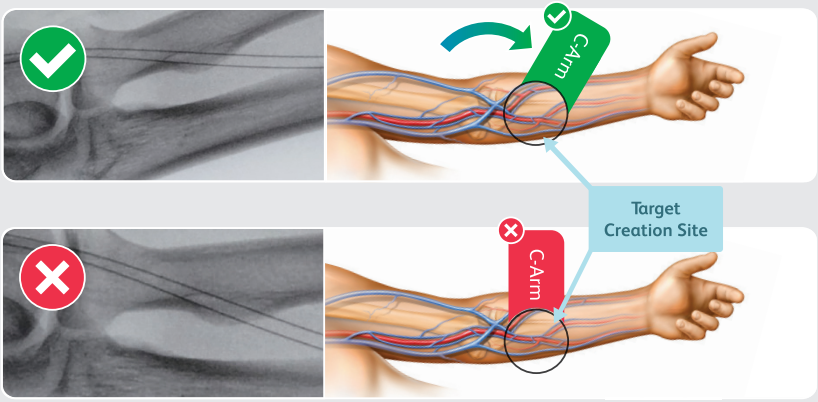


1. Gain ultrasound-guided percutaneous access to the target vein (brachial, ulnar or radial) with tourniquet up
2. a. If venous access from the wrist (ulnar or radial vein), perform venogram to assess vessel anatomy and confirm perforator communication
   b. If using upper arm (brachial vein), perform venogram once 4F guide catheter has been inserted to/past creation zone
3. Remove tourniquet or blood pressure cuff, if applied
4. Gain ultrasound-guided access to the brachial artery (consider anticoagulation)
5. Perform arteriogram (consider roadmapping)
6. Advance arterial wire ~10 cm beyond target creation site
7. Advance venous wire to target AVF creation site, parallel to arterial wire

Device Delivery

Advance Wires & Position C-Arm to Perpendicular View

Adjust the C-Arm to achieve a perpendicular view



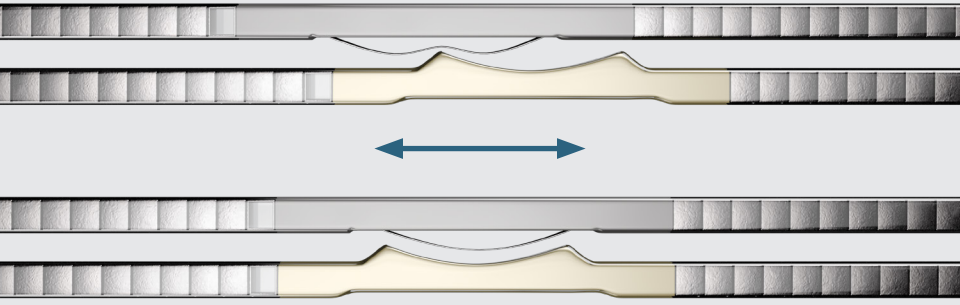
Achieving perpendicular fluoroscopic view between the target vein and artery is **CRITICAL** to achieving device alignment

1. Adjust fluoroscope, perpendicular to vessels using guidewires, ultrasound or contrast as guidance
2. Insert the arterial catheter over the wire and advance the catheter to the target AVF location

Device Alignment

Advance Catheters

Align and Slide



Electrode compressed by backstop peak when gently sliding catheters back and forth

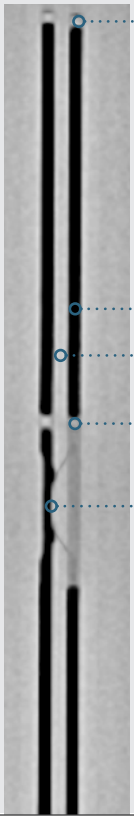
1. Rotate the arterial catheter until the illumination of the rotational indicators appear as open boxes and the peaks of the backstop are pointed towards the target vein
2. Advance venous catheter until the yellow valve crosser encounters the hemostatic valve of the introducer sheath grasp and insert the yellow hemostasis valve crosser through the hemostasis valve until it stops in the sheath hub
3. Align the venous device BEFORE allowing the magnets to engage with the arterial catheter by rotating the catheter until the illumination of rotational indicators are maximized and the arc of the electrode is pointed at the arterial catheter

   DO NOT MAKE CATHETER ADJUSTMENTS WHILE THE MAGNETS ARE ENGAGED
4. Advance venous catheter until arc of electrode is in line with concave surface of the arterial backstop. Electrode should appear compressed

Confirm Final Position

View Maximum Distance Between Catheters

Visual Alignment Confirmation



1. Retract or remove both guidewires from catheter activation zone (between proximal and distal magnet zones)

Activation & Creation Of EndoAVF

Pre-activation Checklist:

- ✓ Device aligned
- ✓ Generator set to Cut-T, 60 W and the maximum activation time of 0.7 sec
- ✓ Tourniquet down
- ✓ Patient arm restrained
  (hold procedure arm with firm pressure)
- ✓ Remove guidewires
- ✓ Patient verbally notified
- ✓ Physician reminded to press/hold **YELLOW** button until tone stops

1. Review pre-activation checklist
2. Record cine and deliver RF energy by pressing and holding the **YELLOW** button until the audible activation tone stops

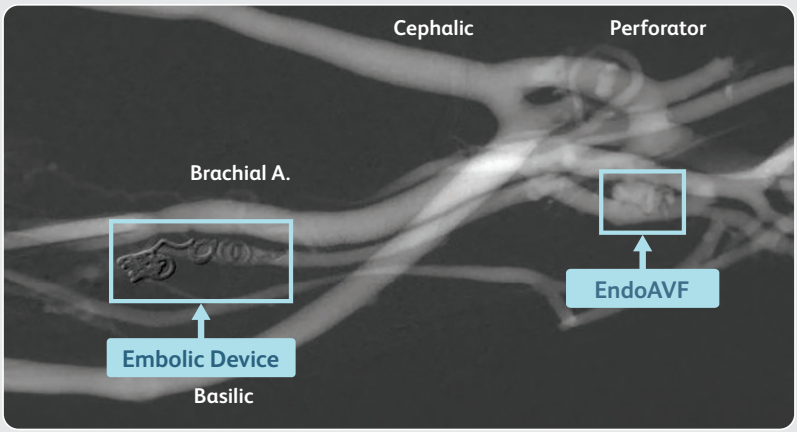
   The electrode should visibly advance and touch the arterial backstop

   Do not activate the device more than 3 times
3. Remove venous catheter
4. Remove arterial catheter
5. Perform arteriogram/fistulogram through arterial sheath

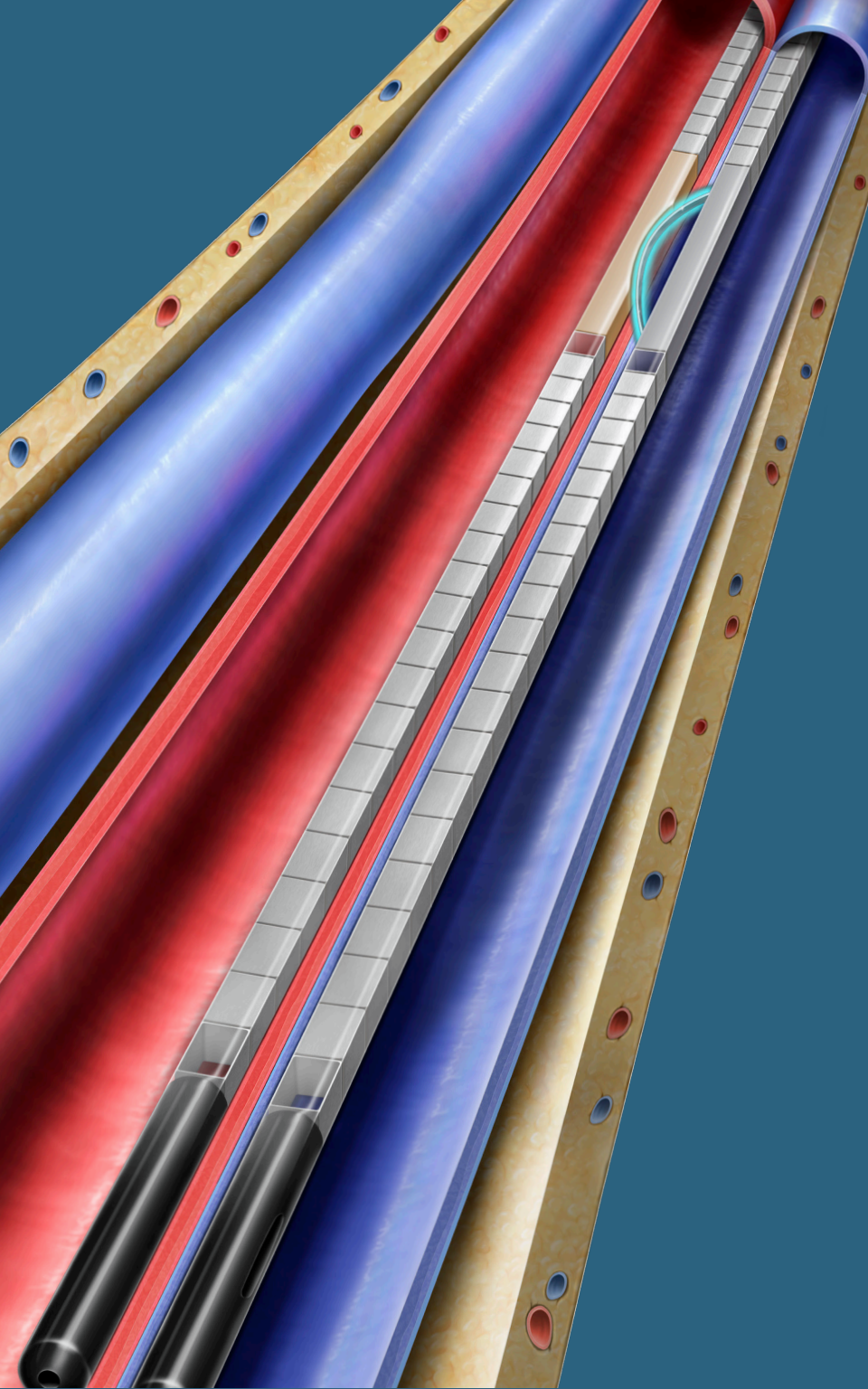
Divert Flow & Achieve Hemostasis

Create EndoAVF, Divert Flow & Achieve Hemostasis

Final Fistulogram



1. Embolization of a brachial vein is recommended
2. Remove arterial sheath and perform manual compression (≥20 min)
3. Dress arterial and venous puncture sites per facility protocol



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 < 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.

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