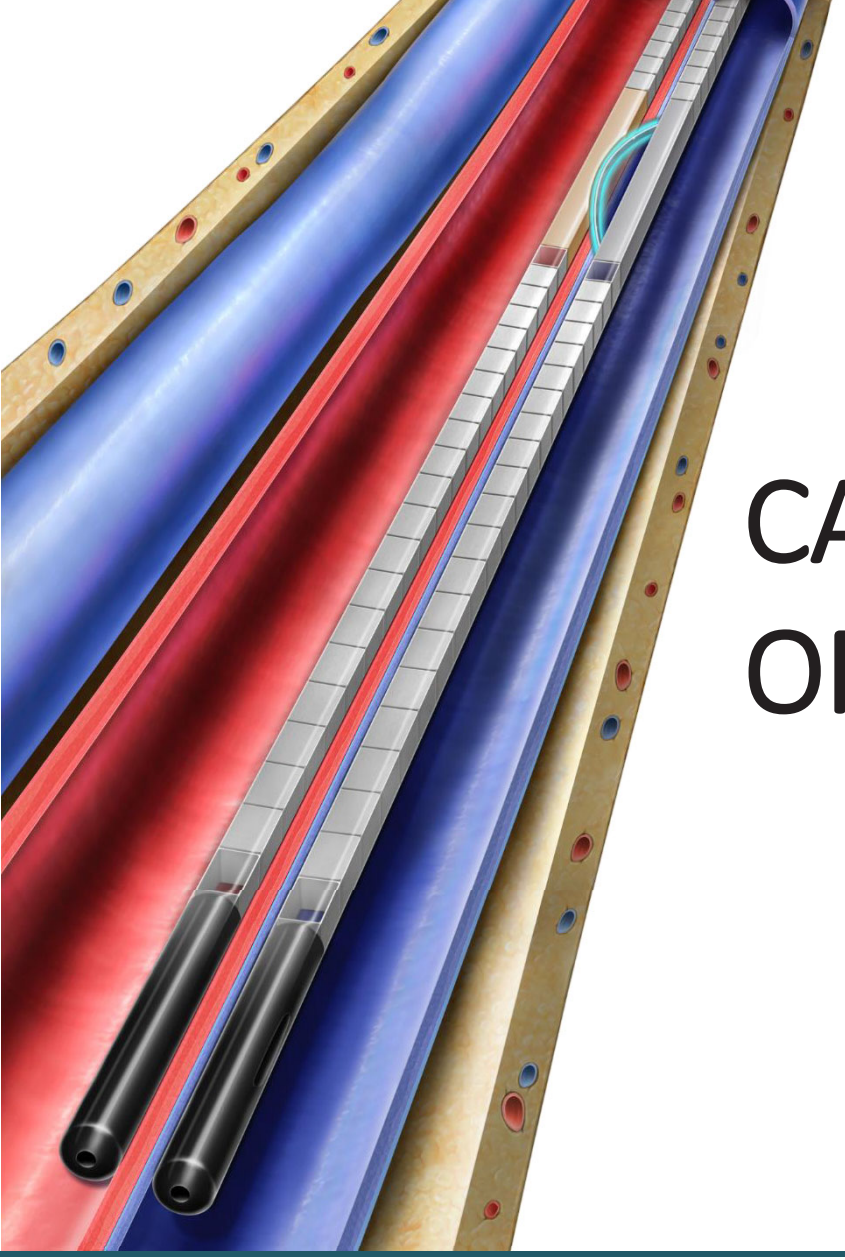


WavelinQ™
EndoAVF System

CANNULATION AND MANAGEMENT OF AN ENDOVASCULAR AVF

BD

Endovascular AVF Creation with WavelinQ™ EndoAVF System

WavelinQ™
EndoAVF System

Potential EndoAVF Benefits

- Avoids surgical scarring and minimizes arm disfigurement associated with open surgery
- Expands anatomic options for AVF creation
- Enables multiple cannulation options for patients

A major advancement in AV fistula creation

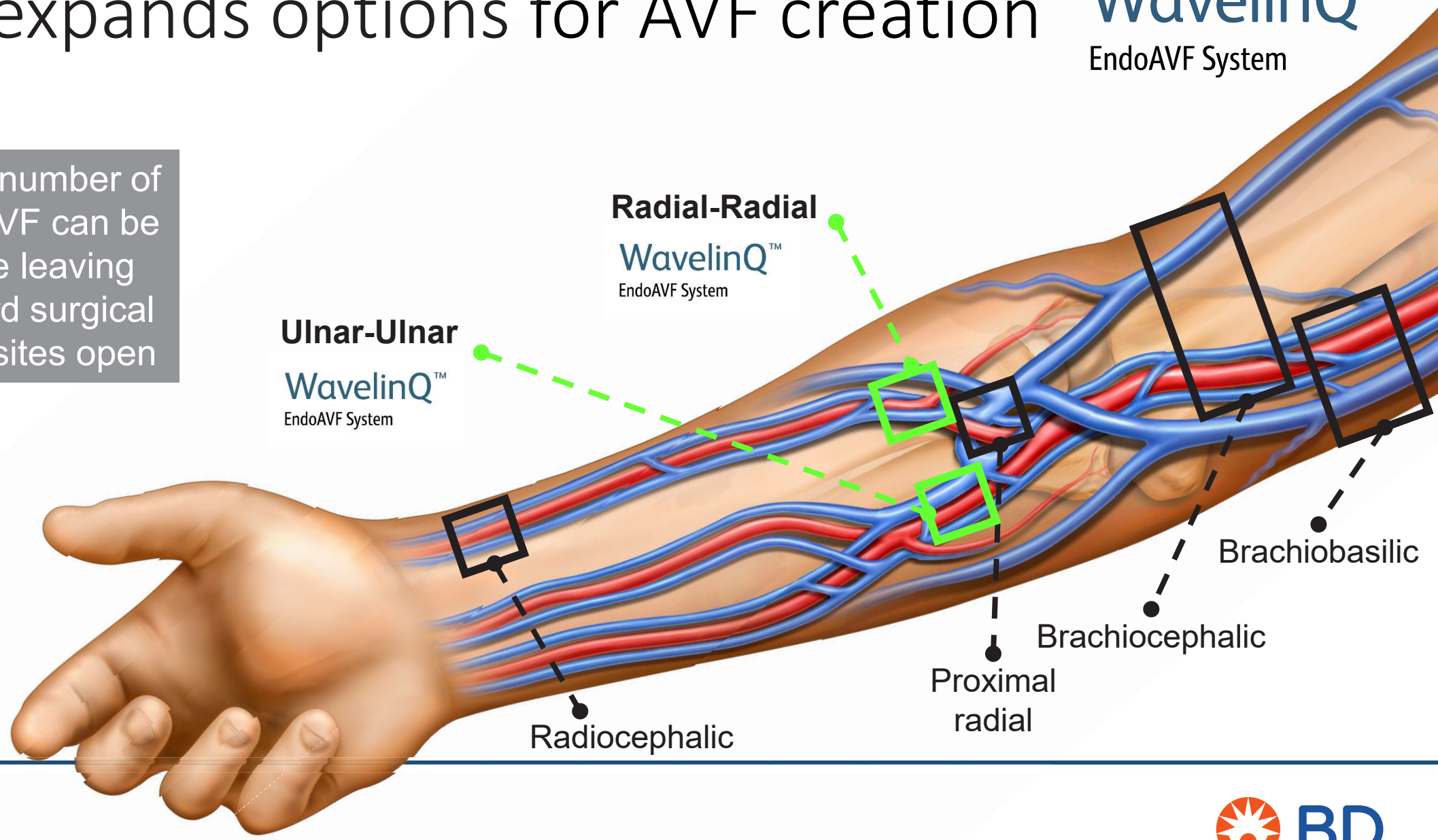
Increases the number of locations an AV fistula can be created while leaving future standard surgical AV fistula creation options open

BD

EndoAVF expands options for AVF creation

WavelinQ™
EndoAVF System

Increases the number of locations an AVF can be created while leaving future standard surgical AVF creation sites open



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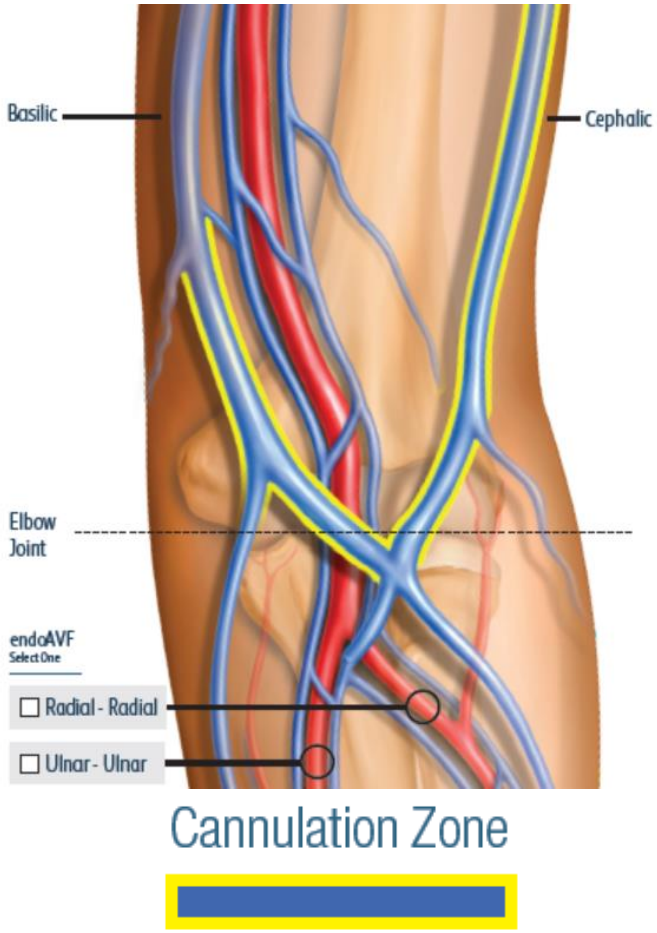
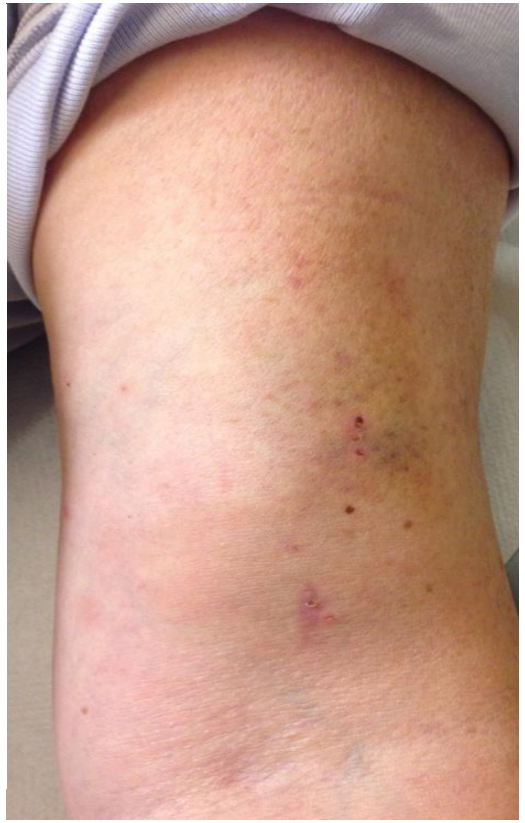
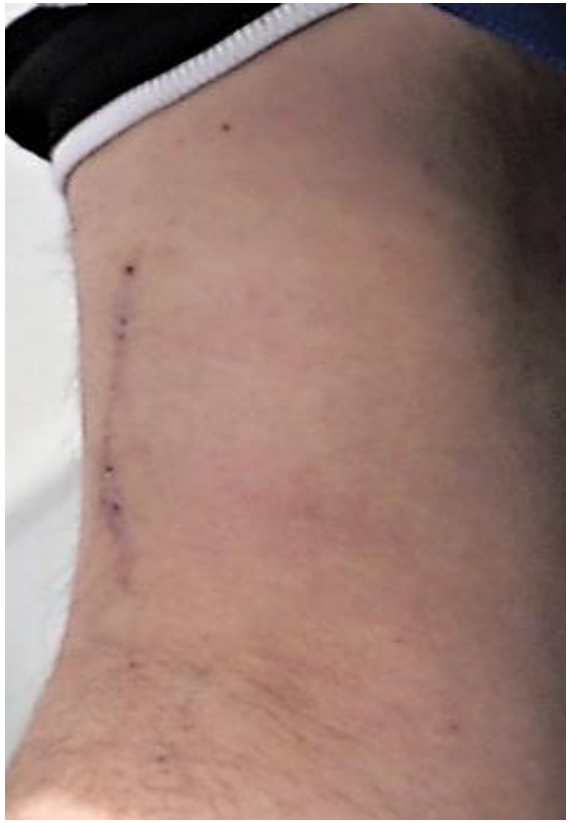
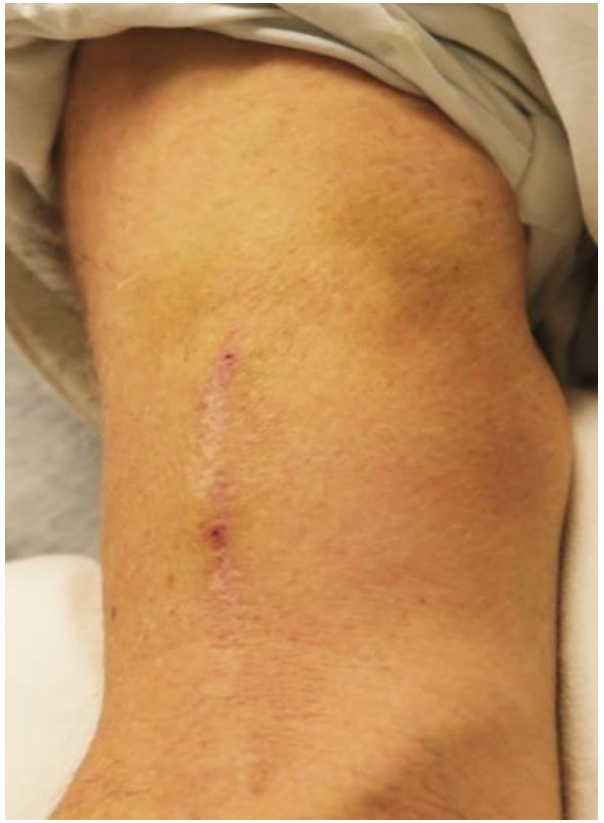
Maturation Process

WavelinQ™
EndoAVF System




At 1st cannulation


At ~1 year post-op


At ~2.5 years post-op

Disclaimer: These patient images are shared as an example of a potential outcomes for endoAVF patients. Individual patient outcomes can and do vary based on the condition of the patient, severity of disease, extent of surgery, and response to treatment.

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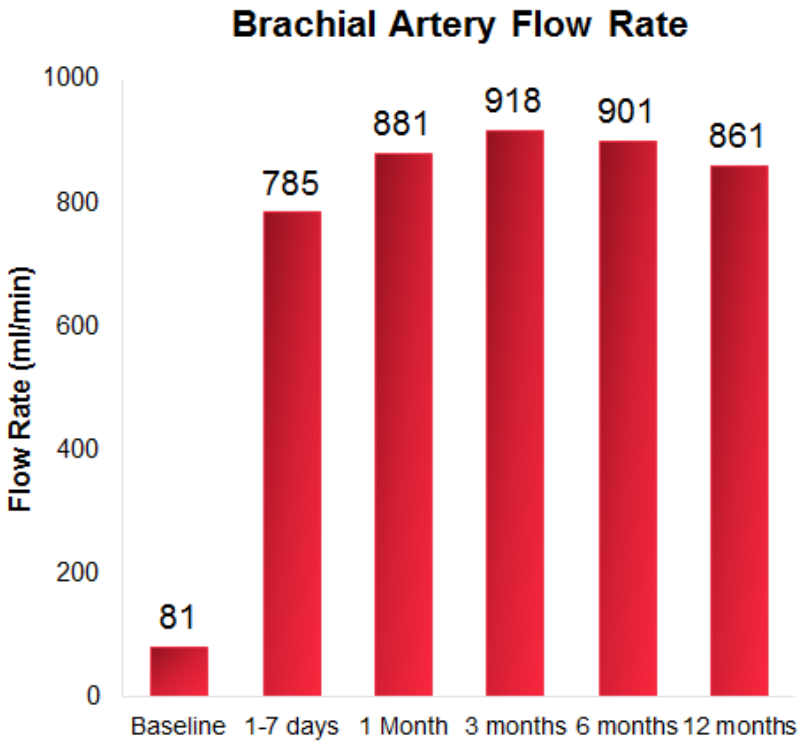
Fistula Maturation Results from NEAT Study

WavelinQ™
EndoAVF System

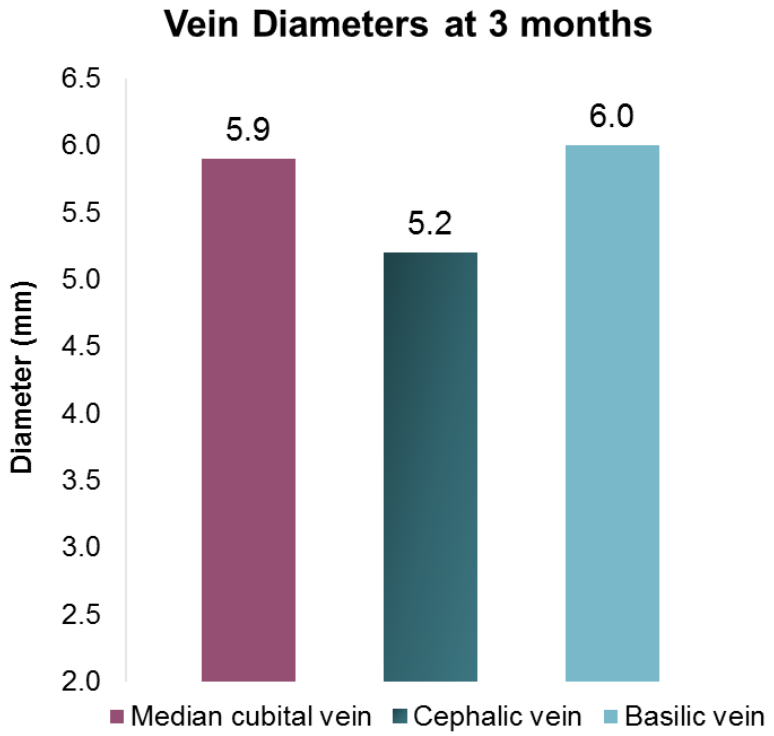


NEAT Study Criteria

The fistula should be free from thrombosis or stenosis and have:

- A brachial arterial flow rate of at least 500 ml/min
- A minimum vein diameter of 4 mm.

N=60



BD Data on file. NEAT study evaluated patients with an endoAVF created by the 6F WavelinQ™ System.

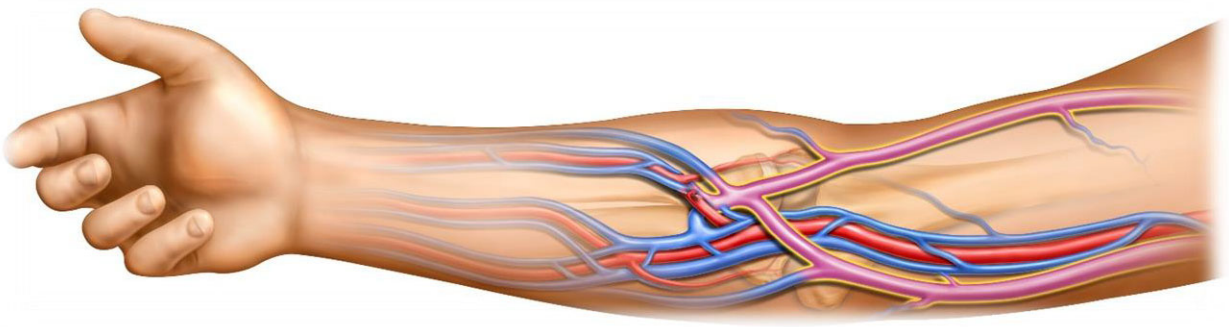
BD

Opportunities for Cannulation

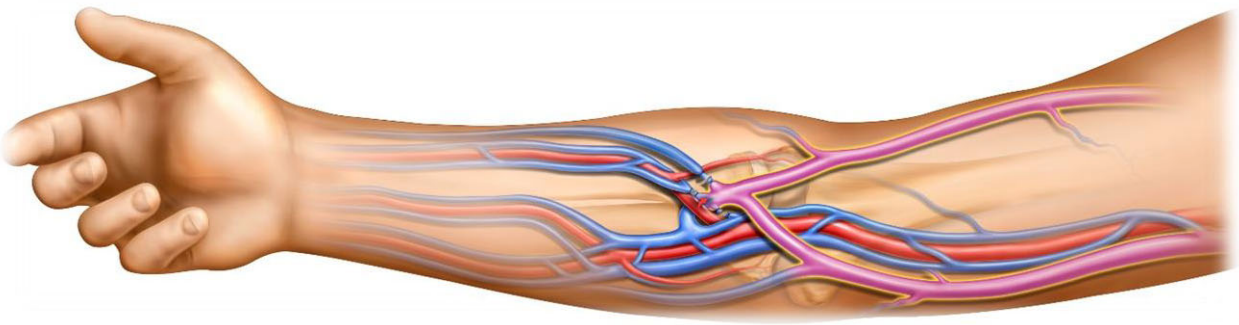
WavelinQ™
EndoAVF System

Split Flow AVFs

WavelinQ™ EndoAVF

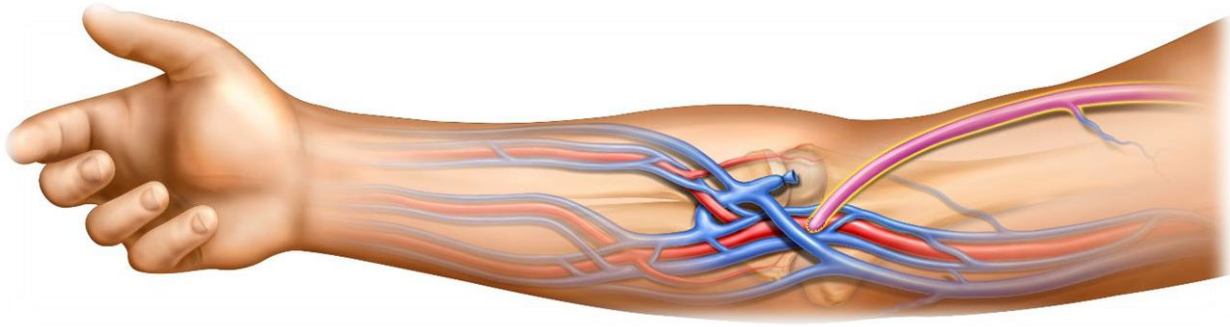


Surgical Gracz AVF

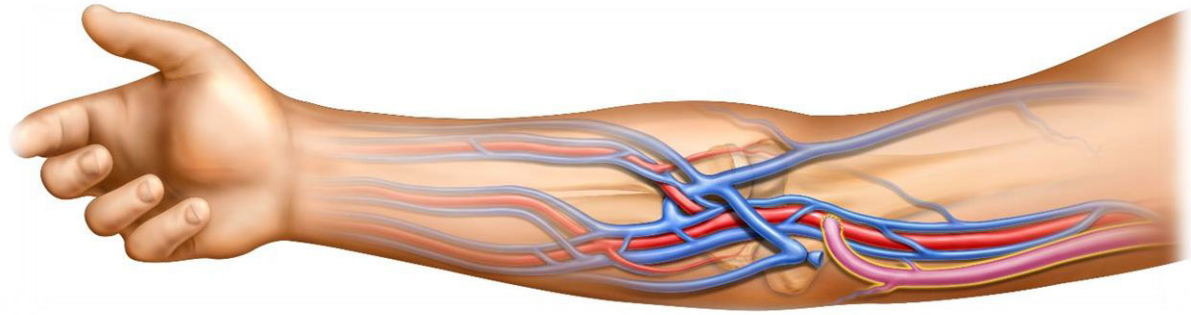


Single Vessel AVFs

Brachiocephalic AVF



Transposed Brachiobasilic AVF



Cannulation Zone

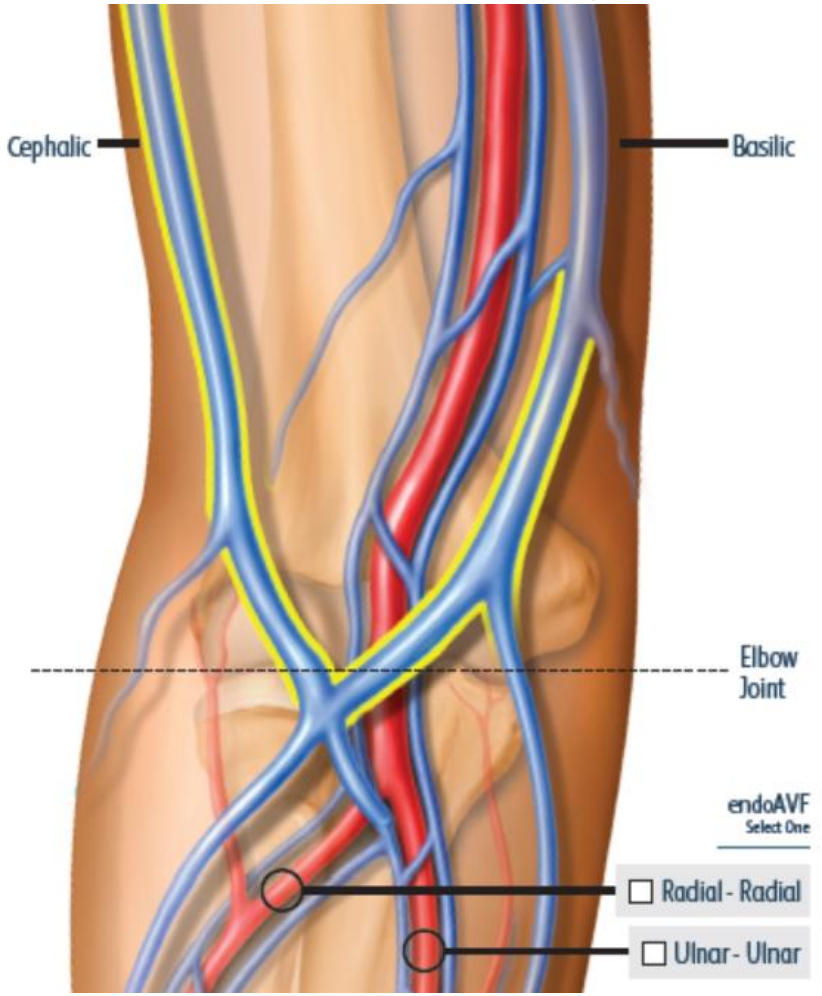
Note: Purple and yellow veins represent arterialized flow from the AVF

BD

Inflow / Arterial Needle Placement

WavelinQ™
EndoAVF System

- **Place inflow needle (arterial) in the highest flow vessel**; should be identified by ultrasound before patient visit
- **The arterial needle tip can point retrograde or antegrade**, depending on unit protocol



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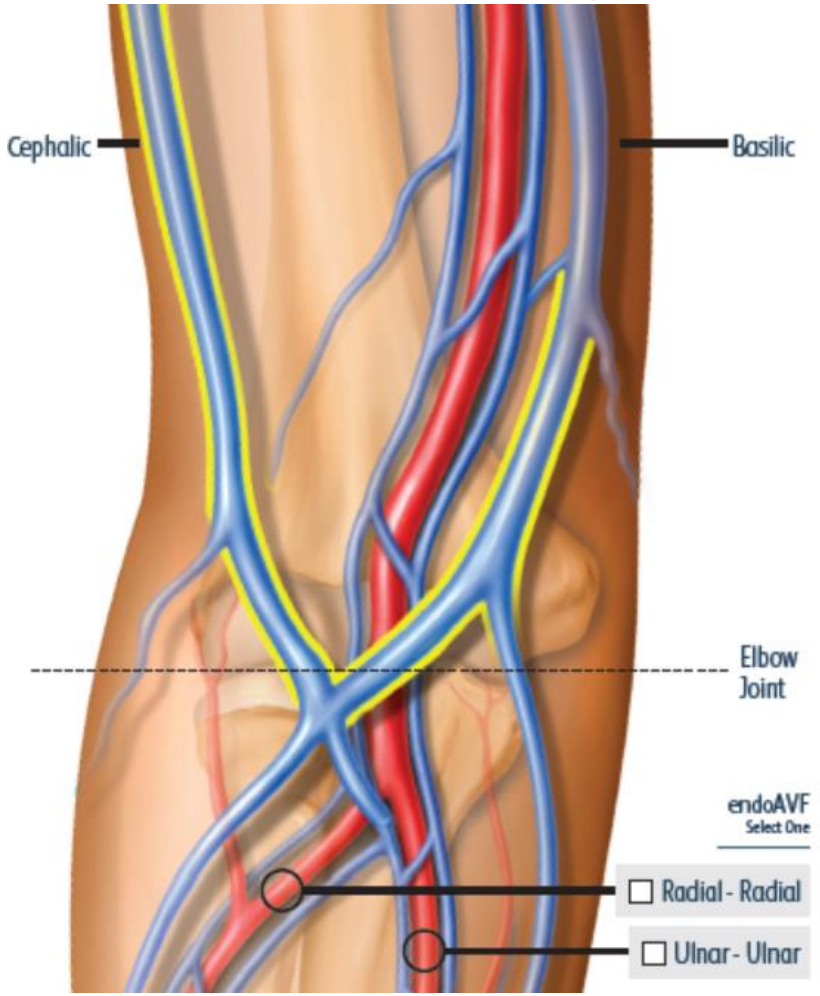
Outflow/Venous Needle Placement

WavelinQ™
EndoAVF System

Venous needle tip should point towards the venous return. Select one of the below options for the outflow (venous) needle:

1. Same vessel, but more proximal than inflow needle
2. Parallel vessel, if diameter is large enough (≥ 4 mm)

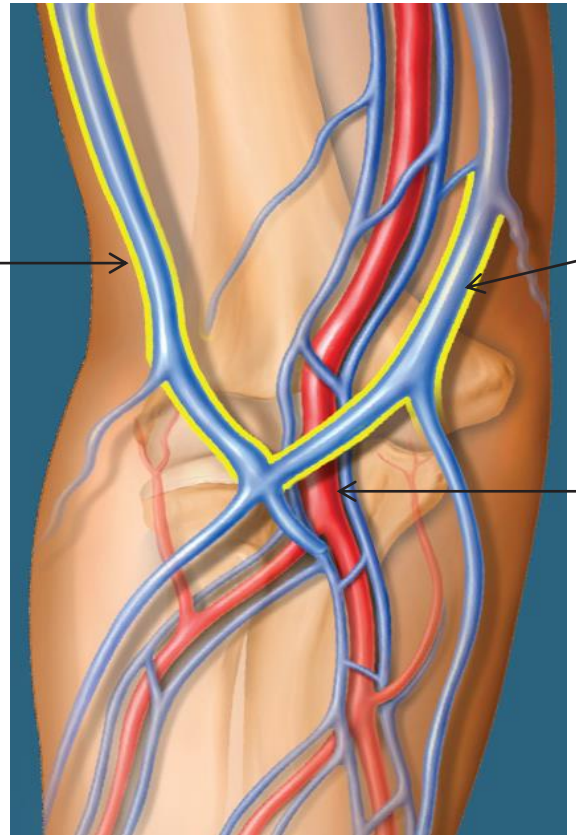


Note: The outflow needle can be more distal than the inflow needle if placed in a different vein than the inflow needle

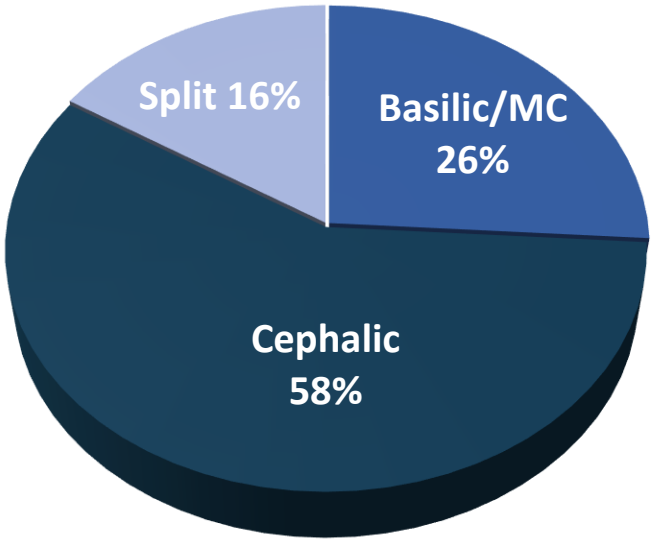
BD

EndoAVF Cannulation Zones

WavelinQ™
EndoAVF System



Needle Locations from the NEAT Study (WavelinQ™ 6F EndoAVF System)



- **Mean available cannulation length was >10 cm[1]**
- **Cephalic most common vein utilized[1]**

[1] Lok et al. Am J Kidney Dis. 2017 Jun 9. pii: S0272-6386(17)30692-3

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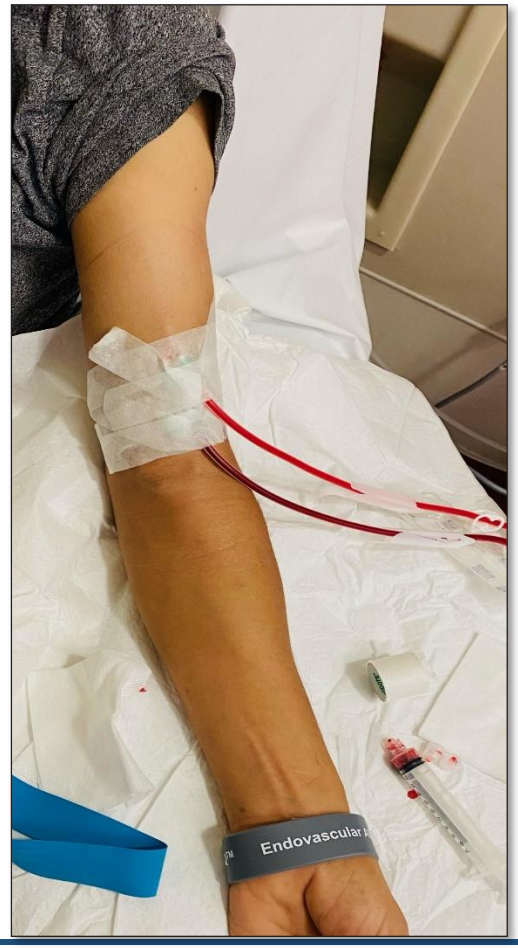
Multiple Cannulation Options

WavelinQ™
EndoAVF System

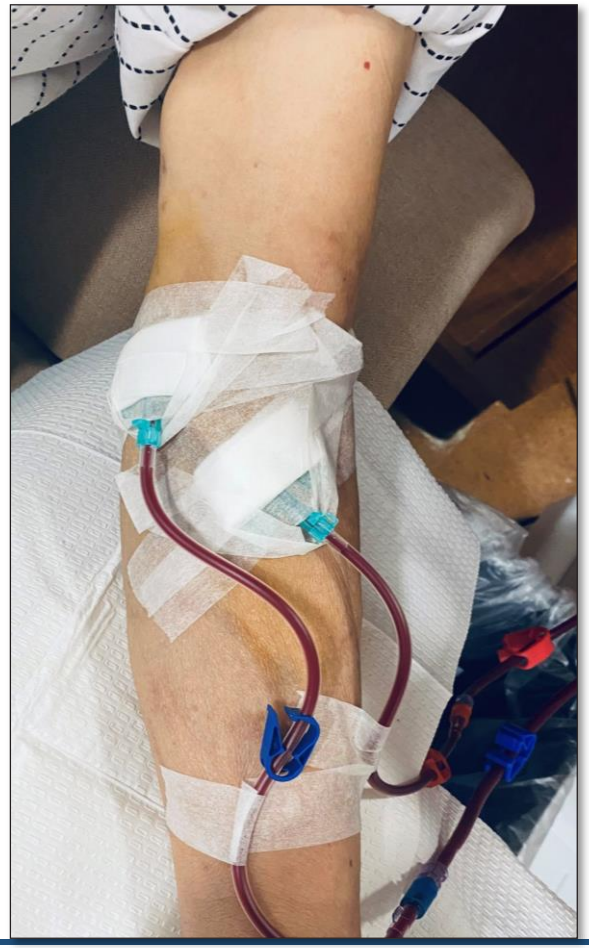
Upper Cephalic

Upper & Lower Cephalic



Basilic & Upper Cephalic

Basilic & MC



Individual patient outcomes can and do vary based on the condition of the patient, severity of disease, extent of surgery, and response to treatment.

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Cannulation Considerations: Basics

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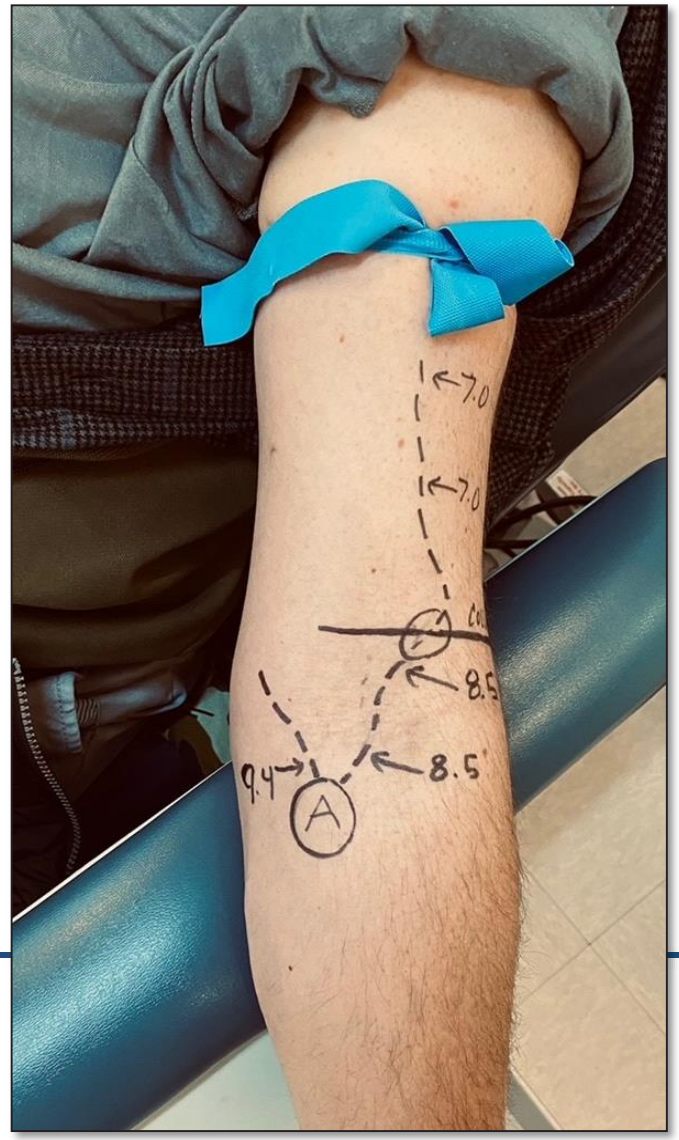
EndoAVF System



It is recommended that a **cannulation guide** be made prior to cannulation, detailing cannulation zones, blood flow direction, and vessel depth from the skin for successful needle placement.

- Refer to provider recommendations for cannulation sites
- Use tourniquet to facilitate vessel access as required per standard protocol

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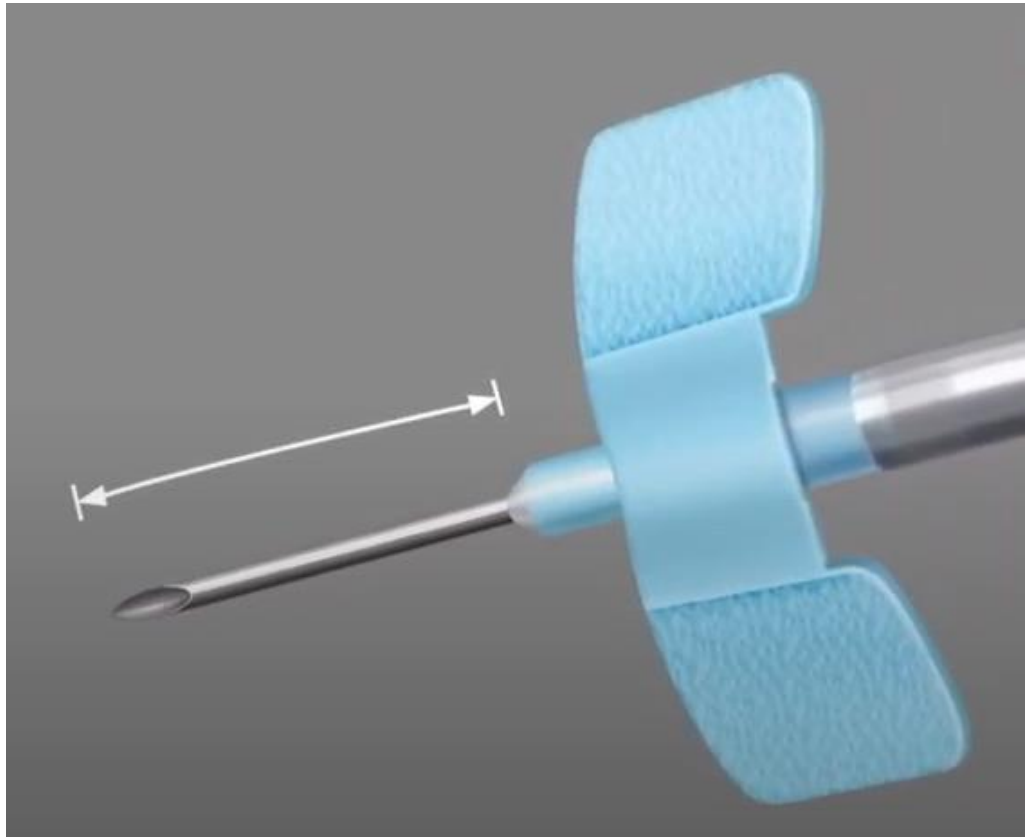
Cannulation Considerations: Needle Selection

WavelinQ™
EndoAVF System

Needle length may be altered; shorter needle length may be more beneficial for superficial cannulation zones and certain body habitus



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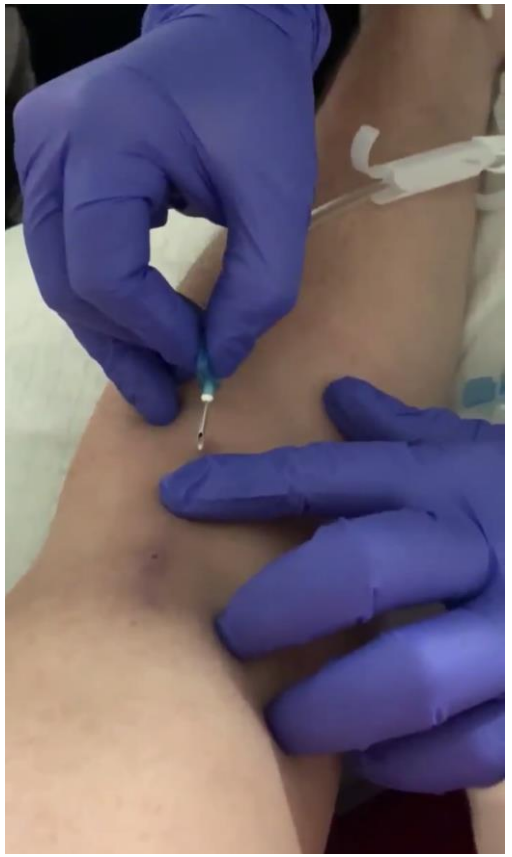
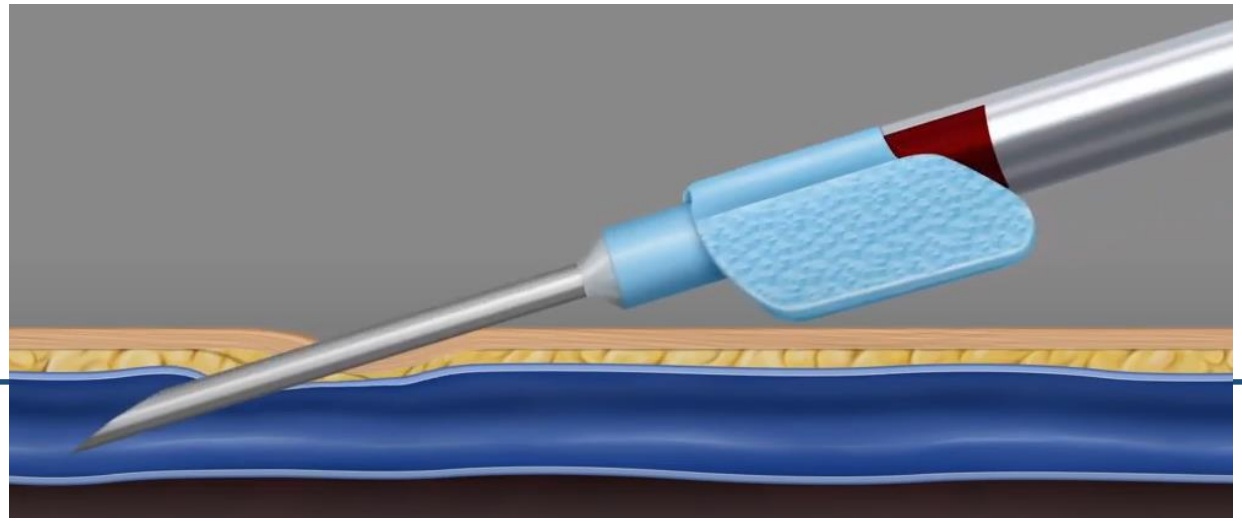
Cannulation Considerations: Cannulation Technique

WavelinQ™
EndoAVF System

- Angle of needle insertion is dependent on the depth of the AVF; consider a shallow angle for more superficial veins
- Be gentle in order to not sidewall or backwall the needle tip. The endoAVF feels softer than an upper arm SAVF when the needle tip enters the vessel. The blood flashback will occur but may be less vigorous than a SAVF.





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Tips for Success

WavelinQ™
EndoAVF System

- **Consider referring to ultrasound images** to plan target needle sites
- Consider **managing conditions like hypotensive and dehydrated patients prior to needling**, as these conditions may complicate needling
- Designate an **expert cannulator** to do initial cannulations on patients to get experience
- **Be gentle in order to not sidewall or backwall the needle tip.** The endoAVF feels softer than an upper arm surgical AVF when the needle tip enters the vessel. The blood flashback will occur but may be less vigorous than a surgical AVF.
- Remember to **evaluate possible cannulation sites** below the elbow as the fistula site is very deep in the forearm (median cephalic and median basilic are commonly used)

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Summary

WavelinQ™
EndoAVF System

- EndoAVF offers **multiple vein segment options** for cannulation
- WavelinQ™ EndoAVF System provides **two additional anatomical options for fistula creation** located in the proximal forearm
- EndoAVF avoids **surgical scarring and minimizes arm disfigurement** associated with open surgery

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Additional Questions

WavelinQ™
EndoAVF System

Visit: www.bd.com/wavelinq

Call: Medical Services & Support **800-555-7422**

Email: WavelinQCannulation@bd.com

Scan QR Code for Cannulation Resources:

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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.