WAVELINQ™ | 4F
EndoAVF System

WAVELINQ™ 4F ENDOAVF SYSTEM VESSEL MAPPING

BD BARD has joined BD

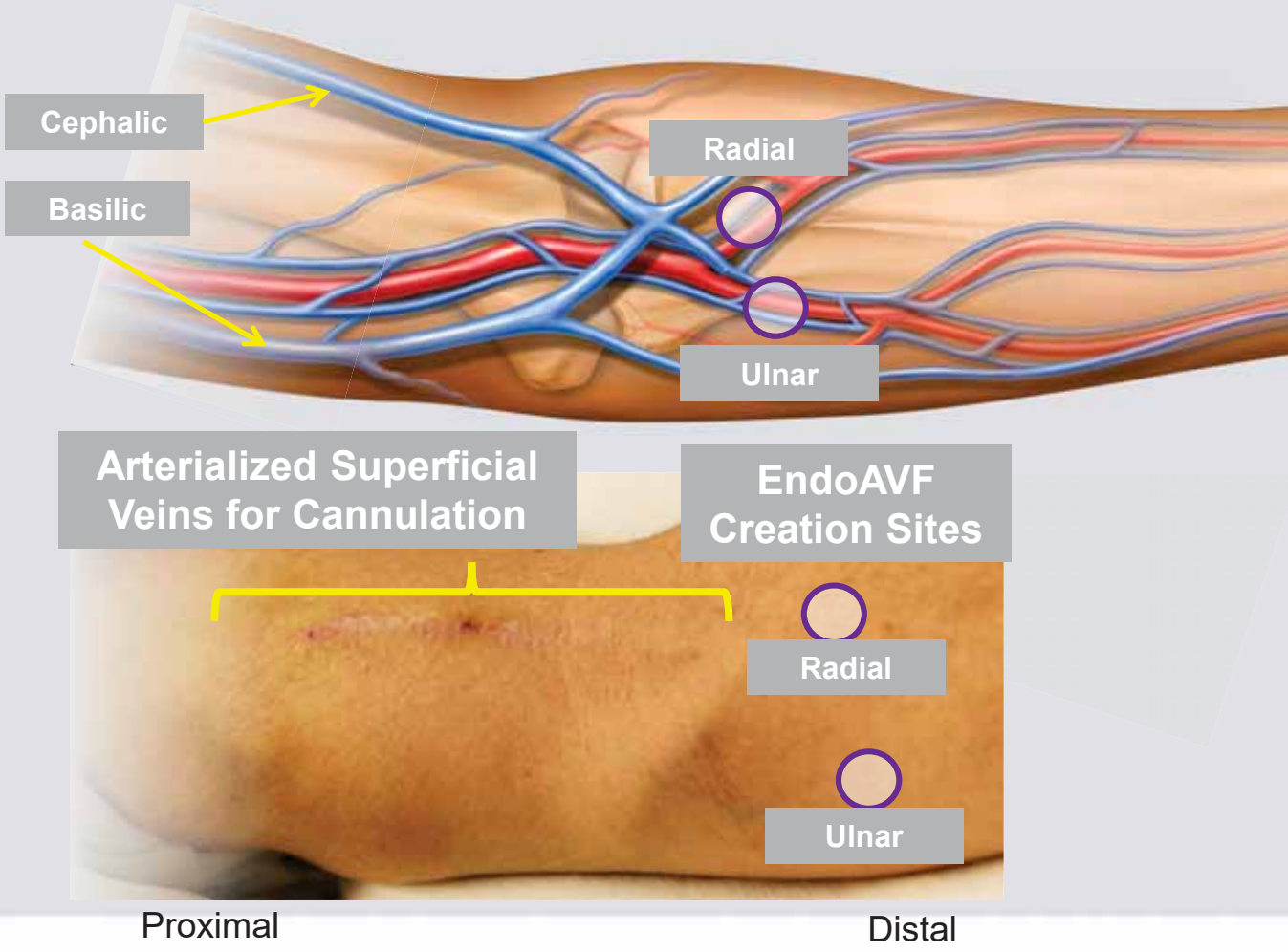
This procedure guide has been generated based upon the experience of multiple clinicians globally. This guide should not be considered the only applicable methodology or as a replacement for sound medical judgment on an individual patient basis. The following information presented is not intended to be treatment advice for any particular patient. Clinicians should use their clinical judgment and experience when deciding how to treat patients.

Please refer to the instructions for use for full prescribing information for the WavelinQ™ 4F EndoAVF System.

Endovascular AVF Creation with WAVELINQ™ 4F EndoAVF System

Potential EndoAVF Benefits

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



Who is a candidate?

Surgical AVF candidates with proximal forearm perforator

Standard AVF Screening

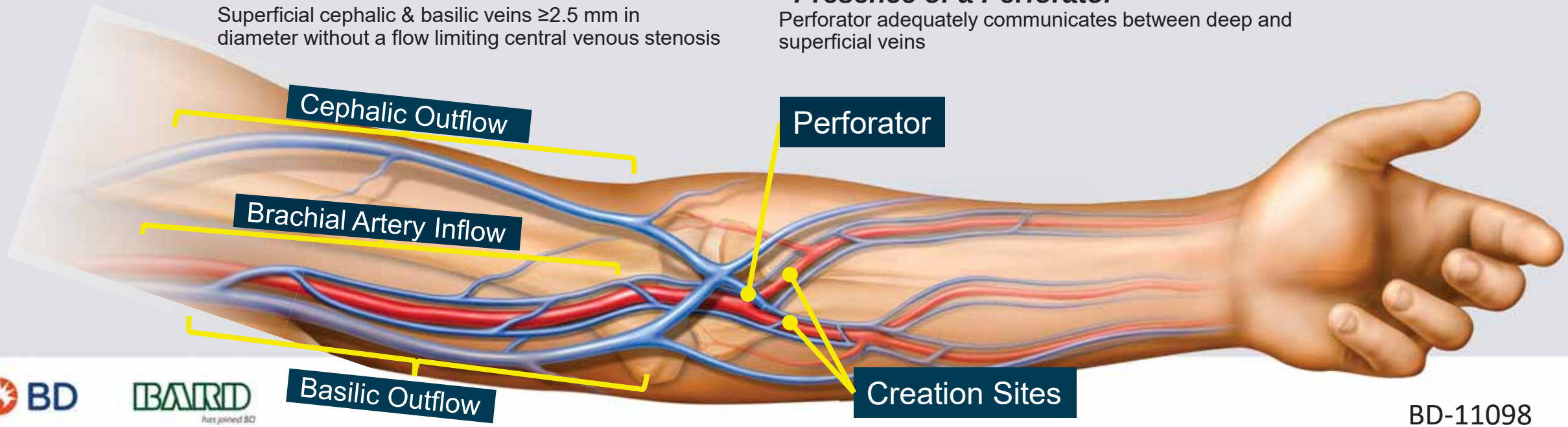
✓ ***Good Inflow***
Brachial artery ≥2 mm in diameter

✓ ***Good Outflow***
Superficial cephalic & basilic veins ≥2.5 mm in diameter without a flow limiting central venous stenosis

Additional WavelinQ EndoAVF Screening

✓ ***Vessels can accommodate device***
Target creation vessels ≥2 mm in diameter

✓ ***Presence of a Perforator***
Perforator adequately communicates between deep and superficial veins



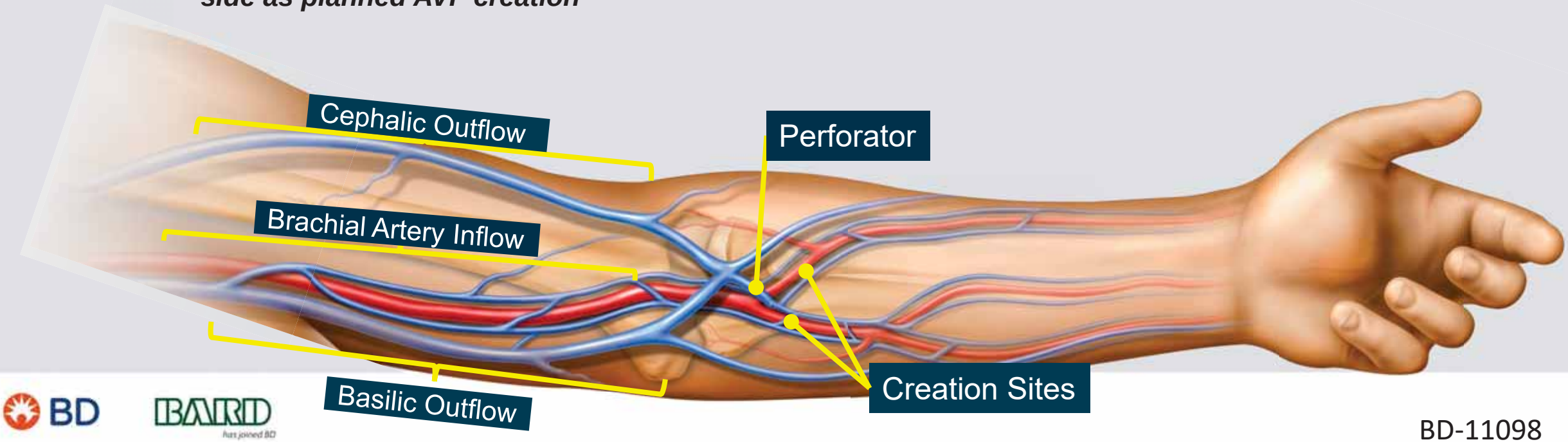
Who is NOT a candidate?

Surgical AVF candidates with:

- *An absence of a Perforator*
- *Known Central Venous Stenosis, or*
- *Upper extremity venous occlusion on same side as planned AVF creation*

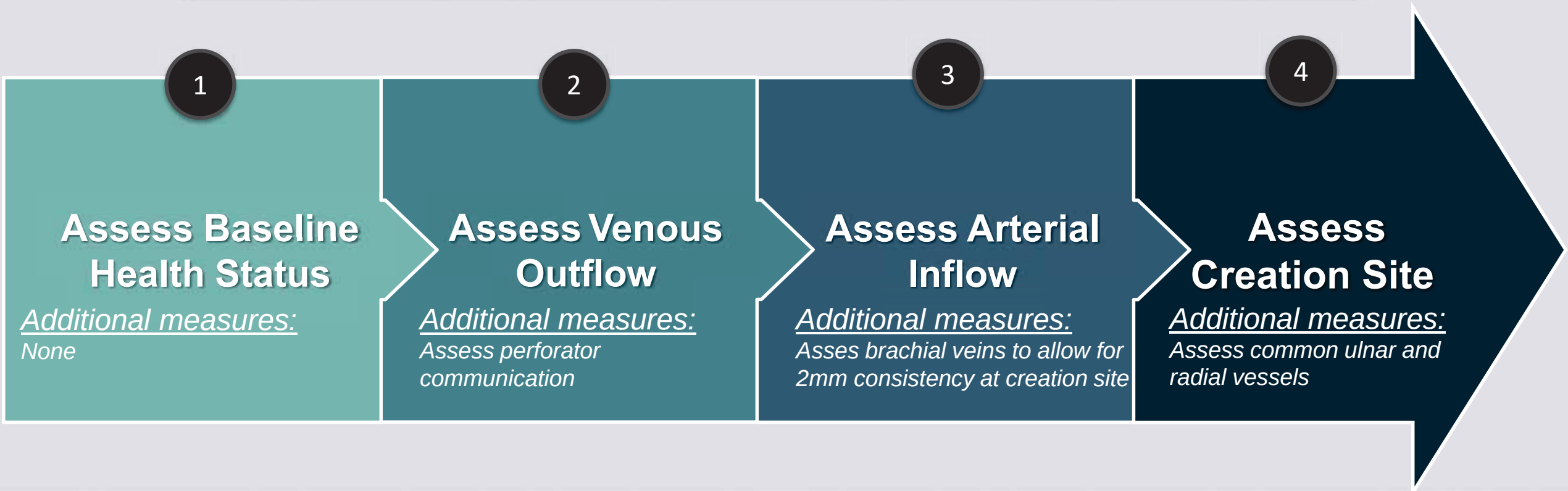
***Contraindicated* for patients with:**

- *Target creation vessels < 2mm in diameter*



Patient Selection Flowchart

Similar to standard surgical AVF vein mapping with minor modifications



Patient Selection Flowchart

1

Baseline Health Status

Patients considered healthy enough to have a standard endovascular procedure and an AV fistula qualify for further assessment.

Patient Selection Flowchart

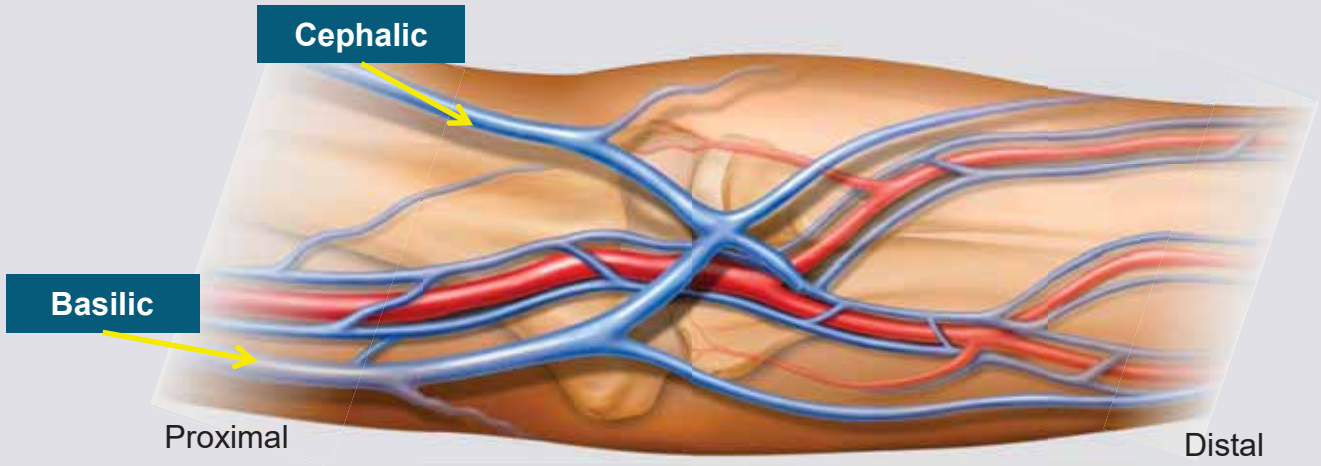
Standard AVF Screening

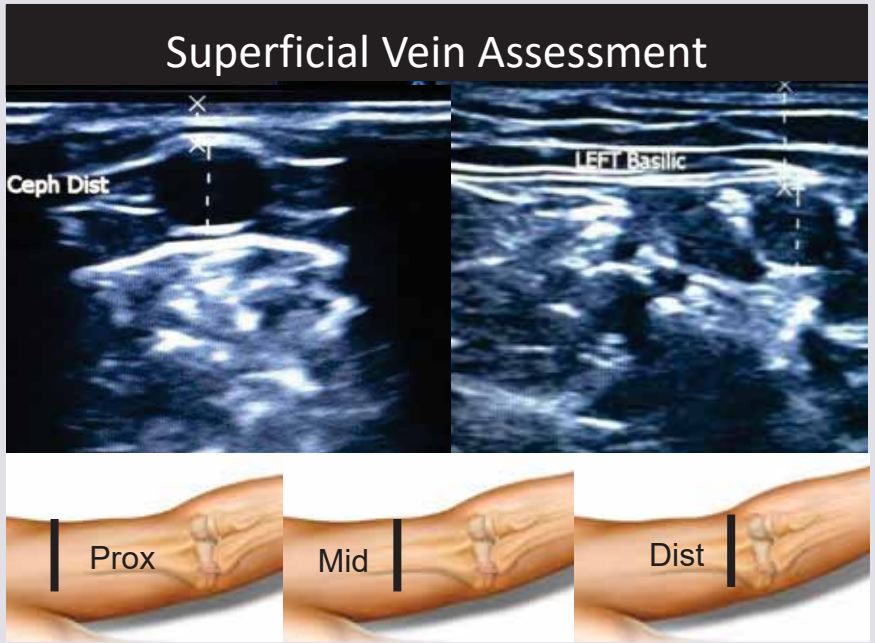
2

Assess Venous Outflow

Upper arm outflow vein

- Standard upper arm vein assessments apply
- Superficial cephalic & basilic veins ≥2.5 mm without a flow limiting central venous stenosis





Patient Selection Flowchart

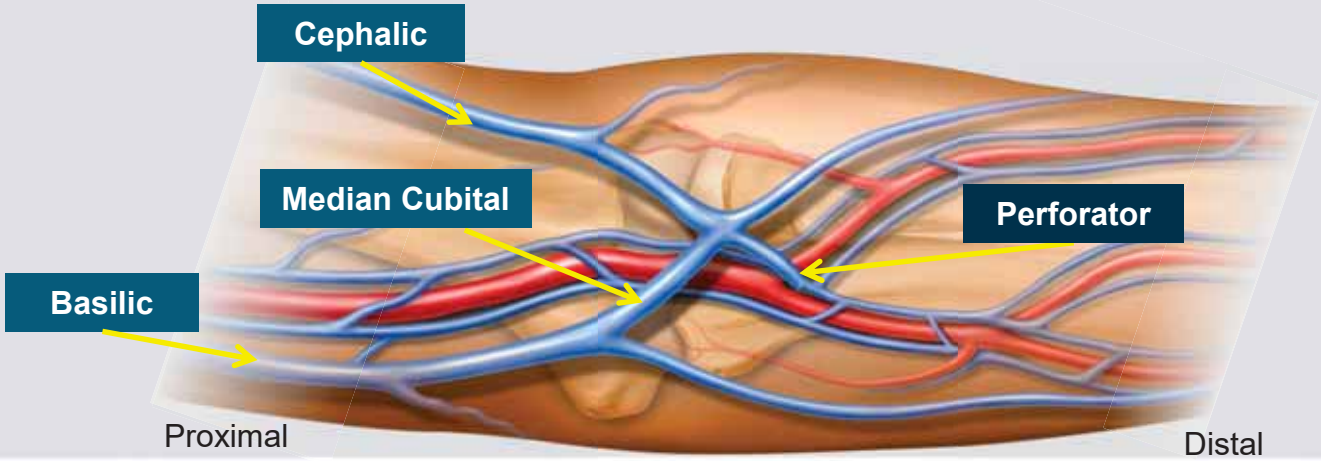
EndoAVF Addition

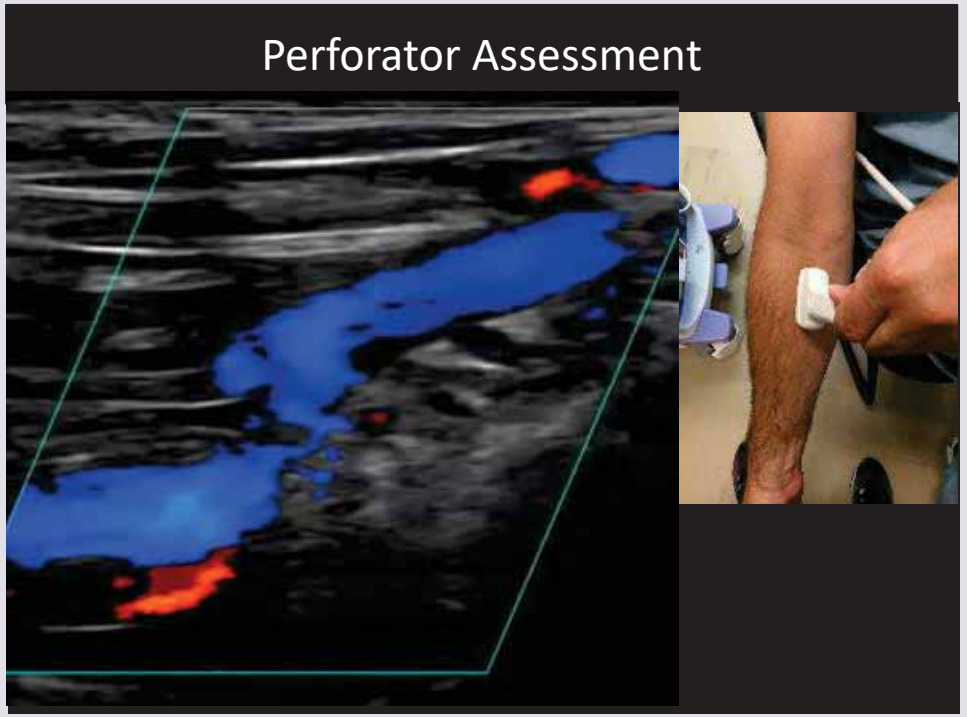
2

Assess Venous Outflow

Perforator communication

- Follow the cephalic or basilic vein to the proximal forearm to find the perforator
- Confirm direct communication between deep veins and superficial veins



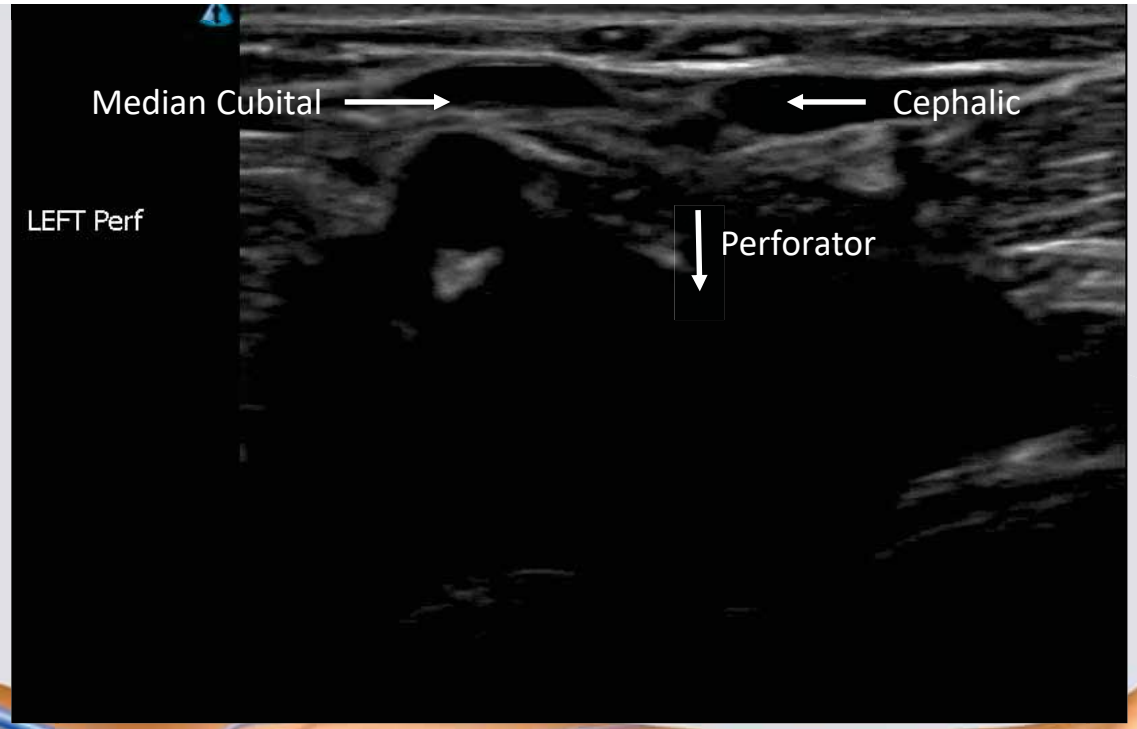


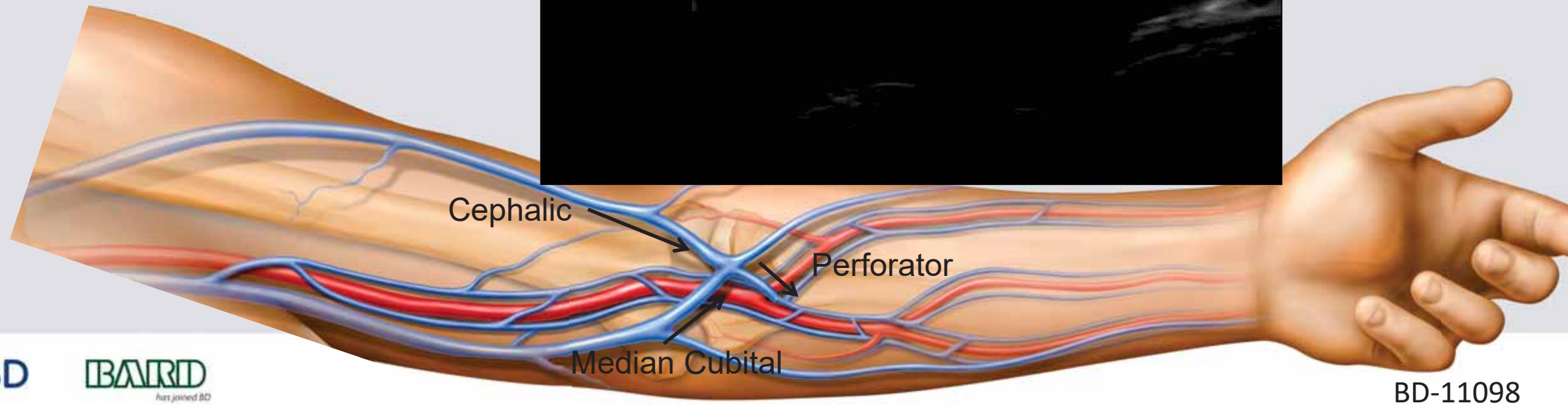
2

How to Find the Perforator

Perforator communication

- Confirm the perforator ≥ 2 mm in diameter
- Communication from the target creation to the superficial veins



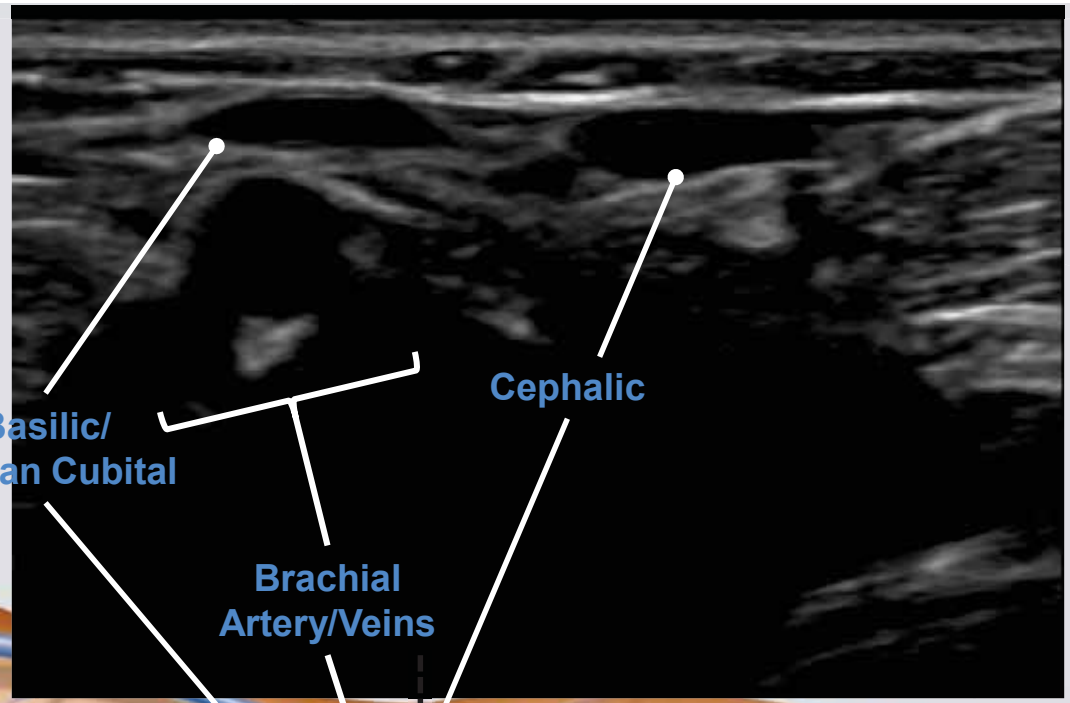


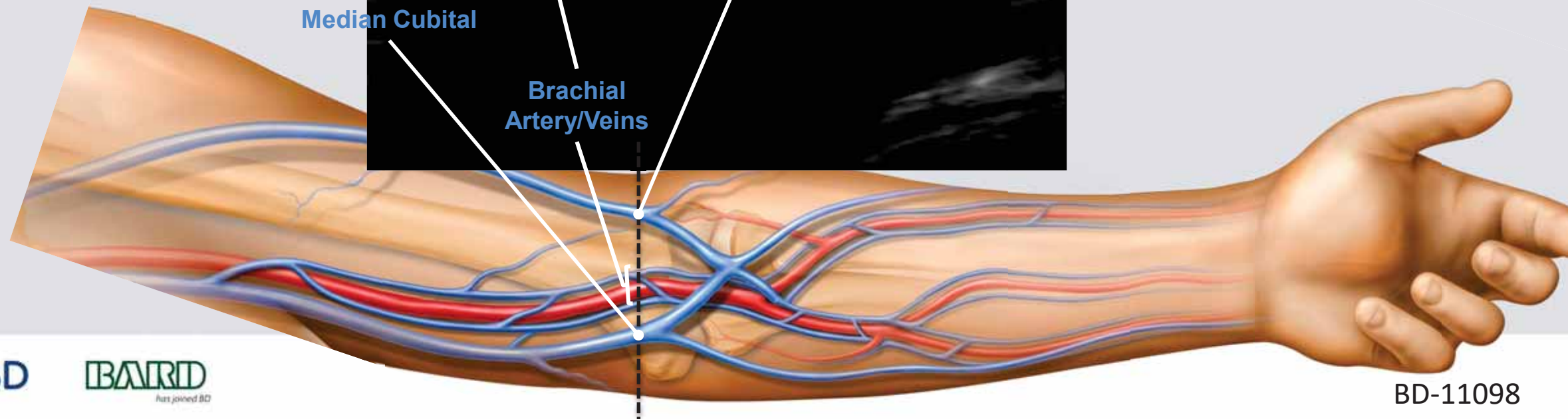
2

How to Find the Perforator

Finding the Perforator

- Follow the cephalic vein to the proximal forearm
- Observe the perforator dive down from the cephalic as it meets the median cubital in the proximal forearm





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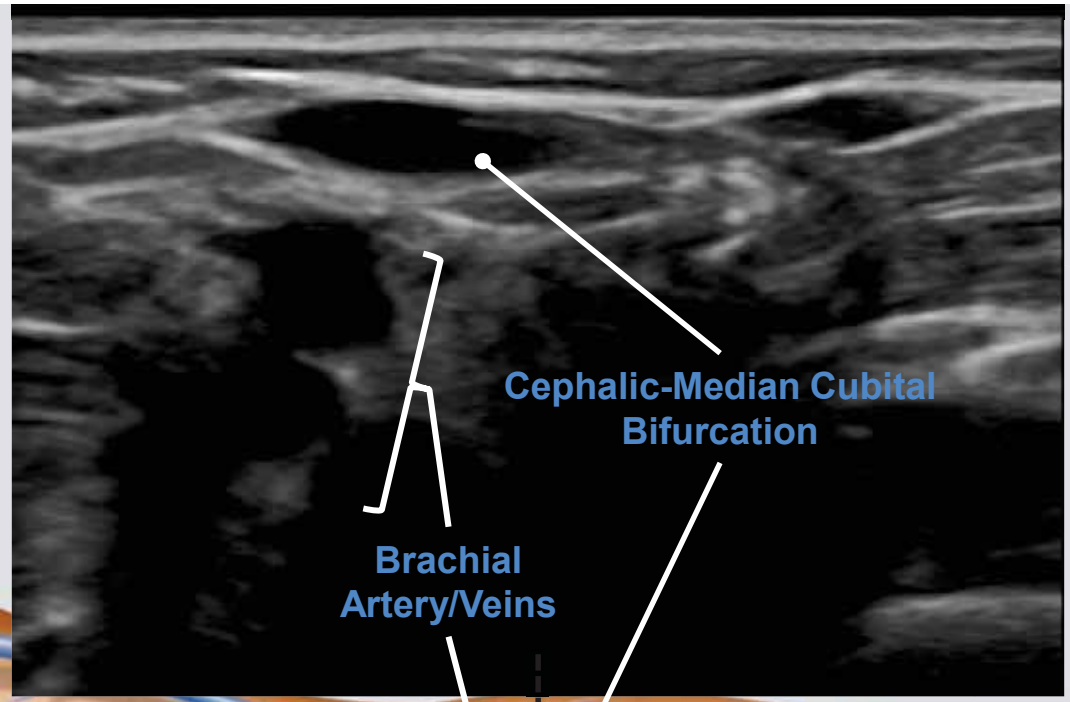

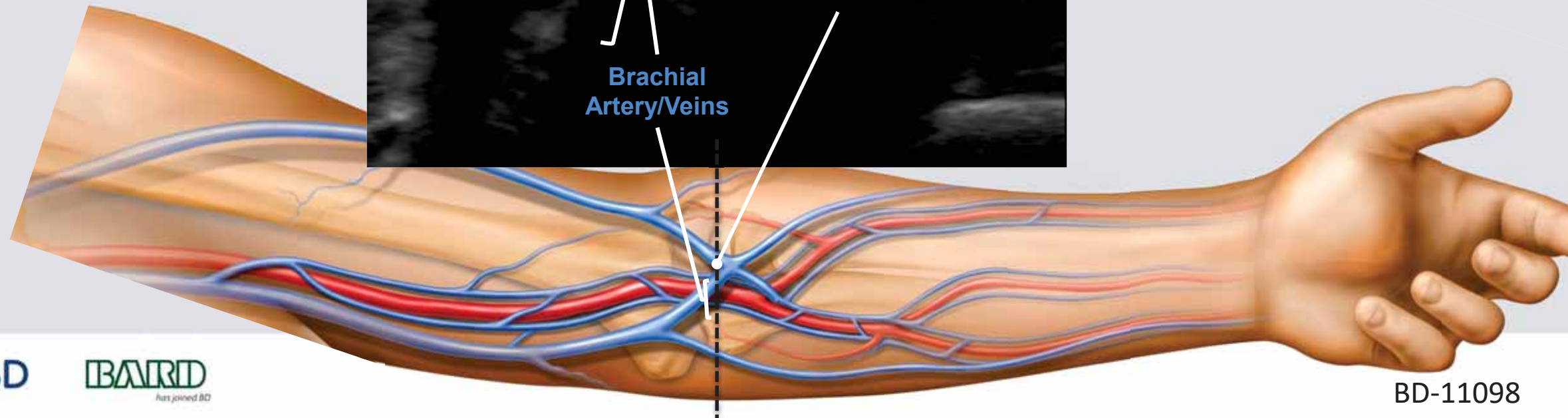

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How to Find the Perforator

Finding the Perforator

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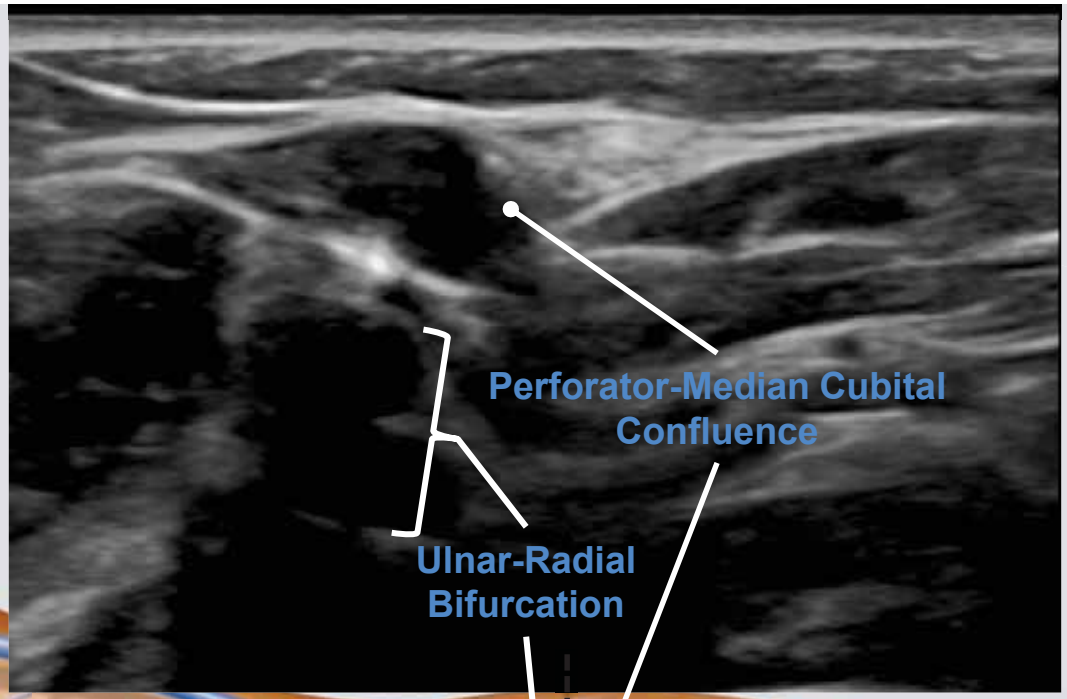
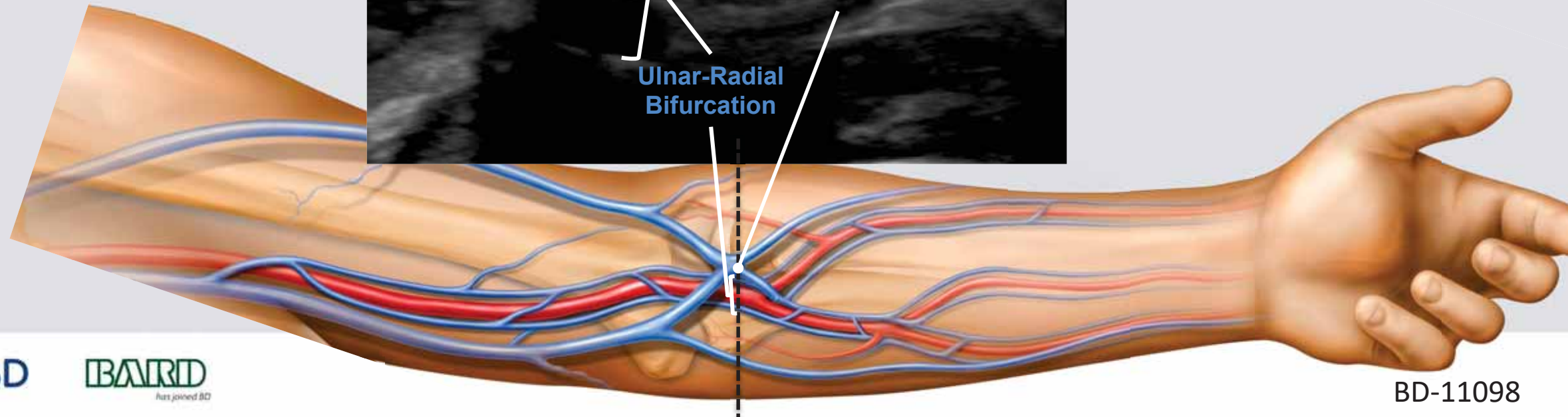
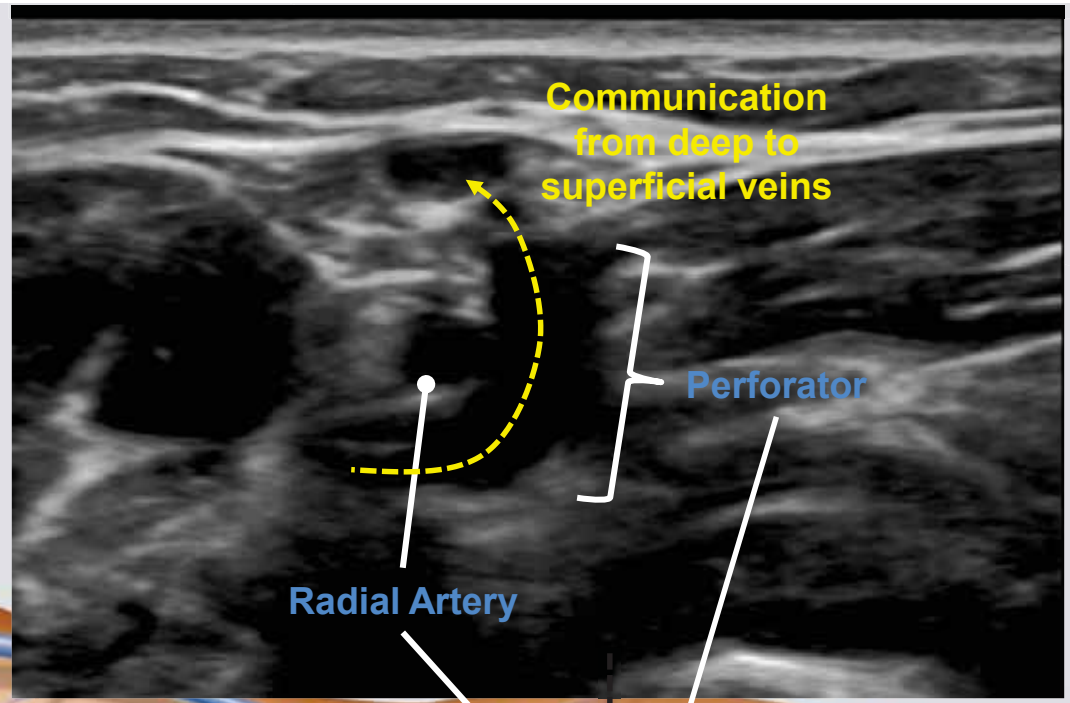


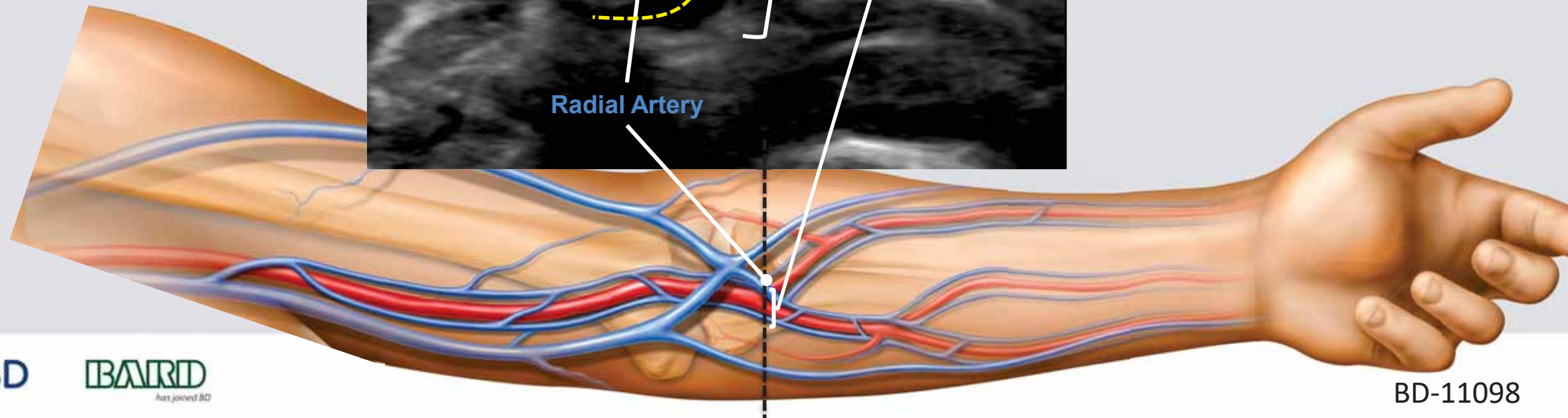


Assess Venous Outflow

Finding the Perforator

- Follow the cephalic vein to the proximal forearm
- Observe the perforator dive down from the cephalic as it meets the median cubital in the proximal forearm





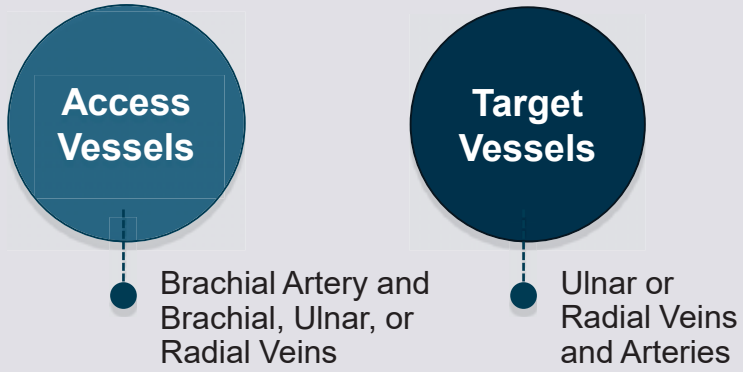
Patient Selection Flowchart

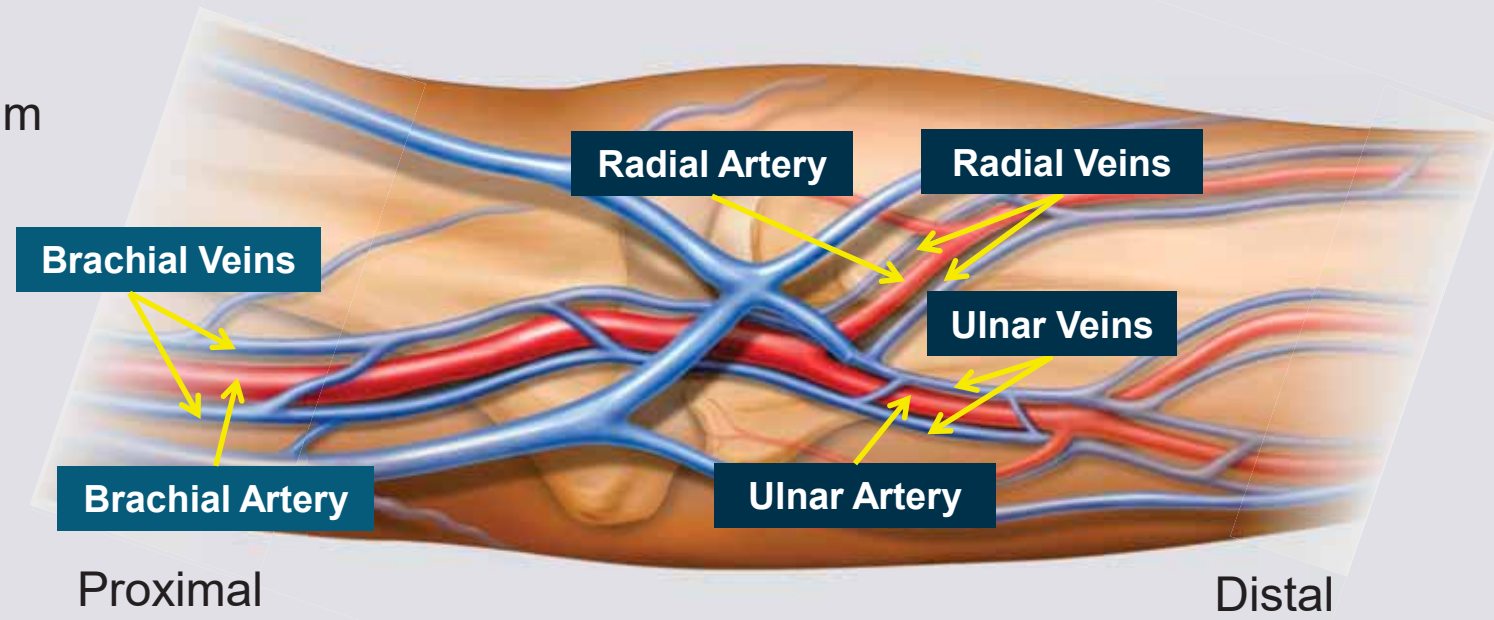
3

Assess Arterial Inflow At Access and Target Sites

At ultrasound screening:

Ensure artery and at least one vein is ≥ 2mm in diameter:





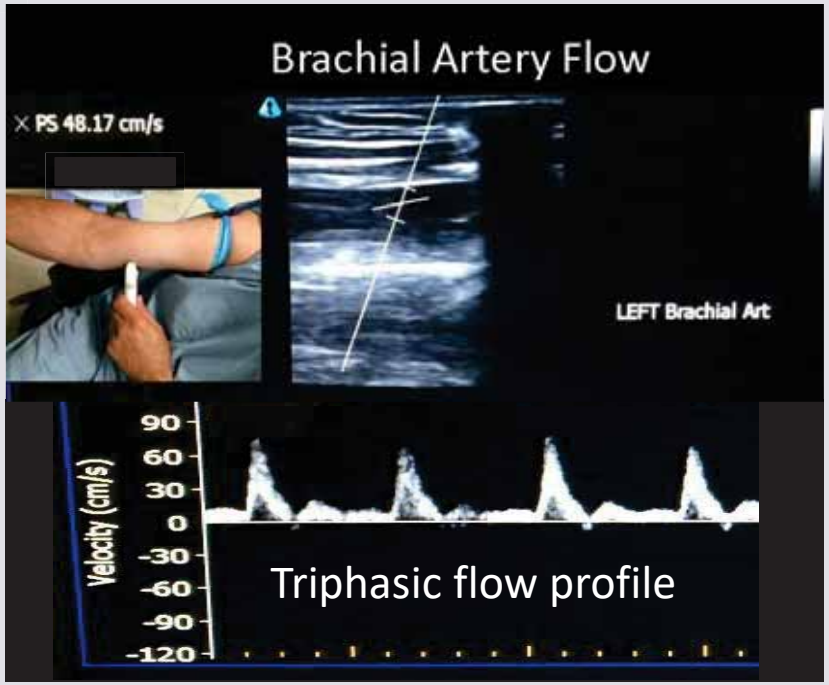
Warning: Only brachial artery should be used for arterial access.

Patient Selection Flowchart

Standard AVF Screening

3

Assess Arterial Inflow At Creation Site



- Assess with tourniquet up
- ≥ 2 mm dia. is required

***Clinical Consideration**: If patient has severe arterial disease or calcification in the brachial or ulnar arteries, physician may choose to do further assessment, such as the Allen's test, to confirm adequate distal perfusion.*

Patient Selection Flowchart

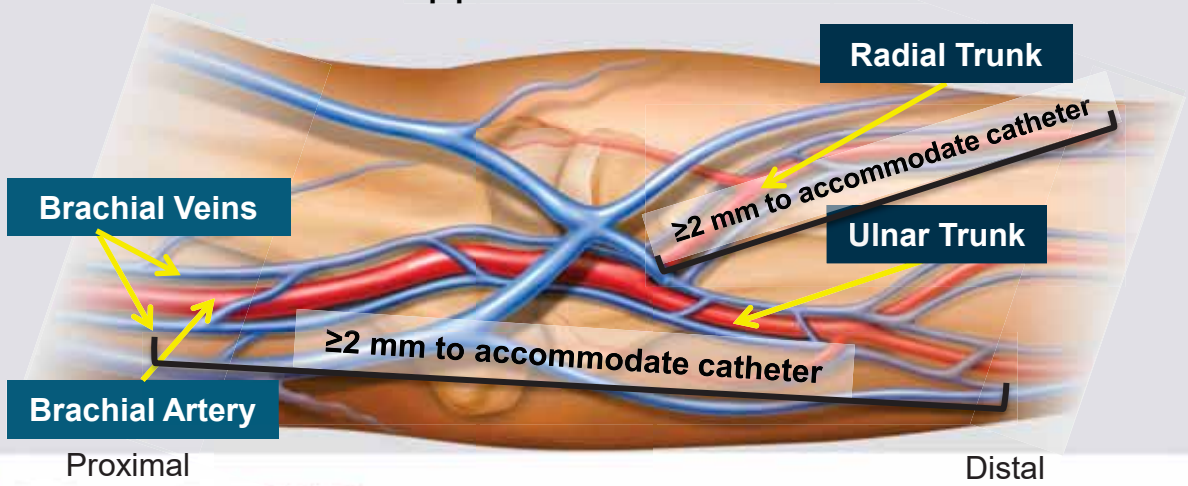
EndoAVF Addition

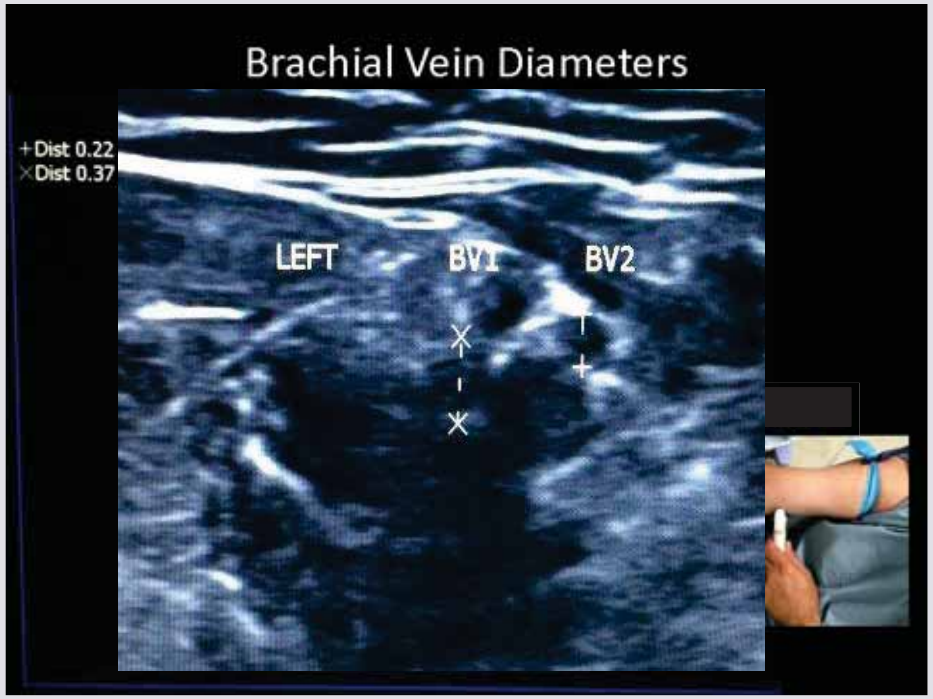
3

Assess Brachial Veins

Assess Paired Brachial Veins

- Perform this measurement while assessing the brachial artery with tourniquet up
- Ensure at least one brachial vein is ≥ 2 mm in dia. from the upper arm to the creation site





Patient Selection Flowchart

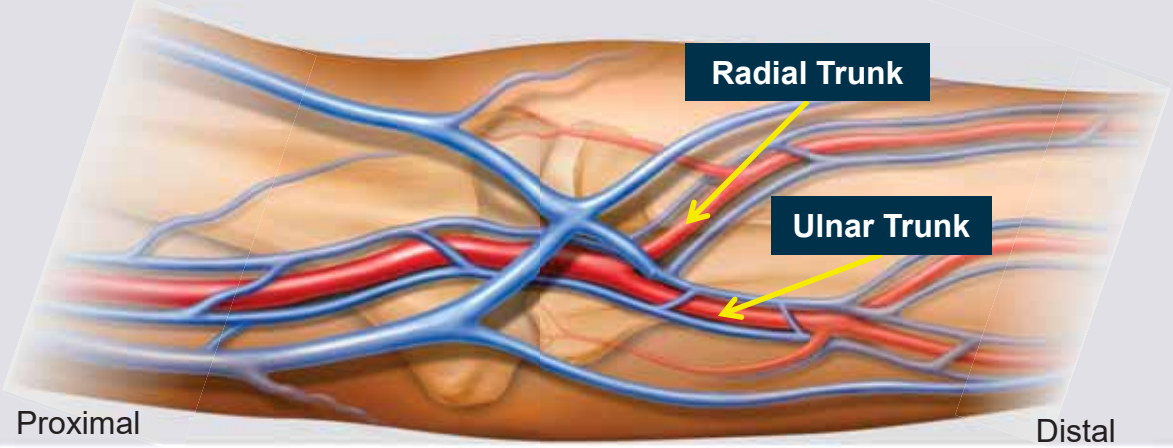
EndoAVF Addition

4

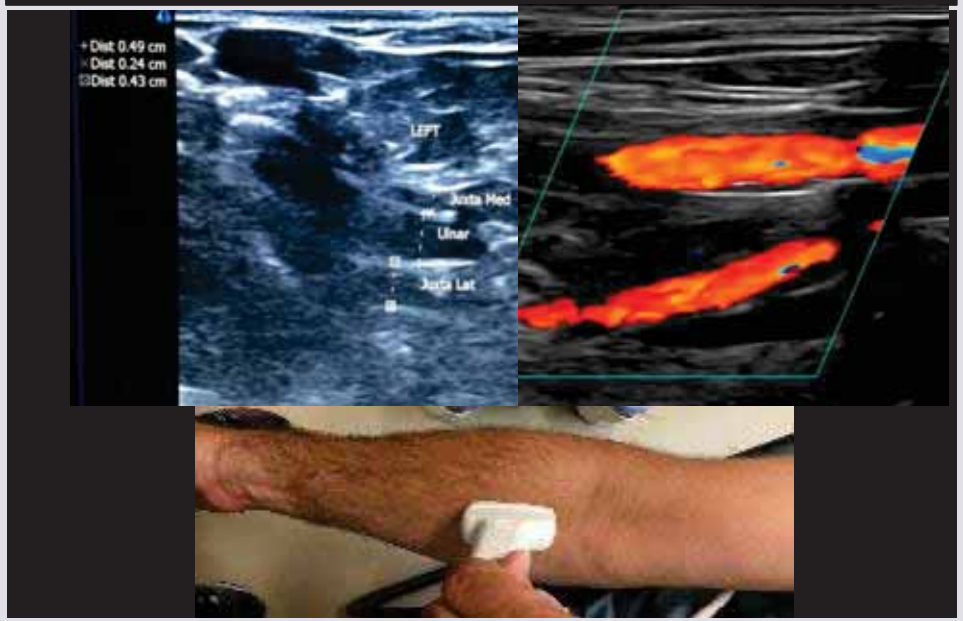
Assess Creation Site

Creation site in the ulnar or radial vessels

- Found in the proximal forearm
- Ensure ulnar or radial artery and at least one ulnar or radial vein is ≥ 2 mm in dia.
- Assess for calcification at either creation sites

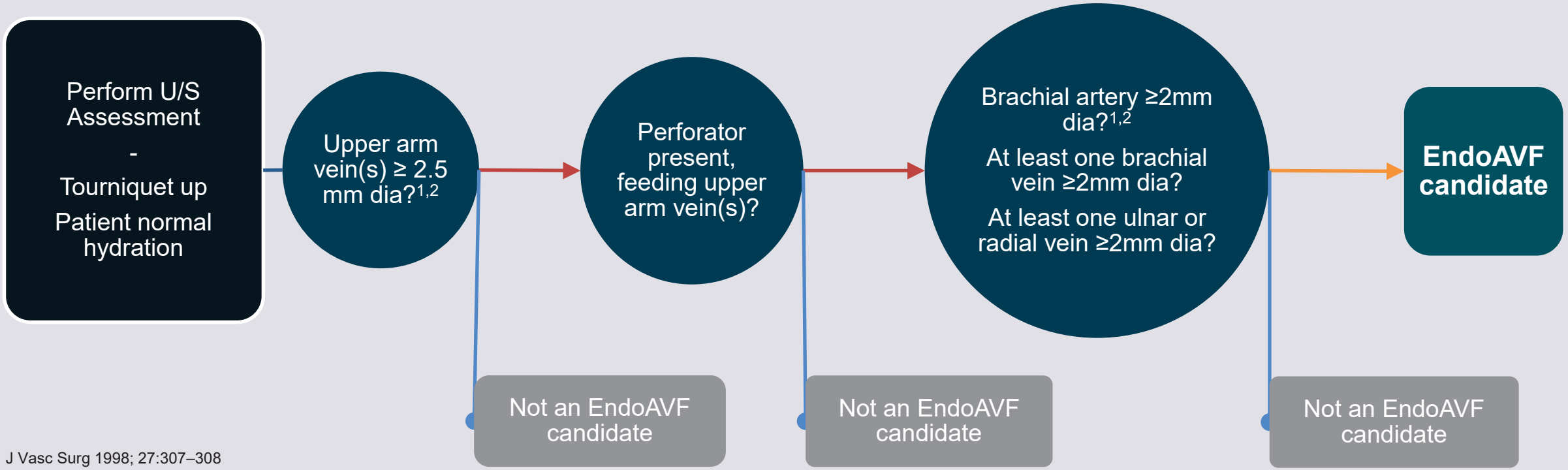


Ulnar Trunk Measures



Patient Selection Flowchart

Patients considered healthy enough to have a standard endovascular procedure and an AV fistula qualify for further assessment.



1. J Vasc Surg 1998; 27:307–308
2. Dialysis & Transplantation (2011);40(10):434-9

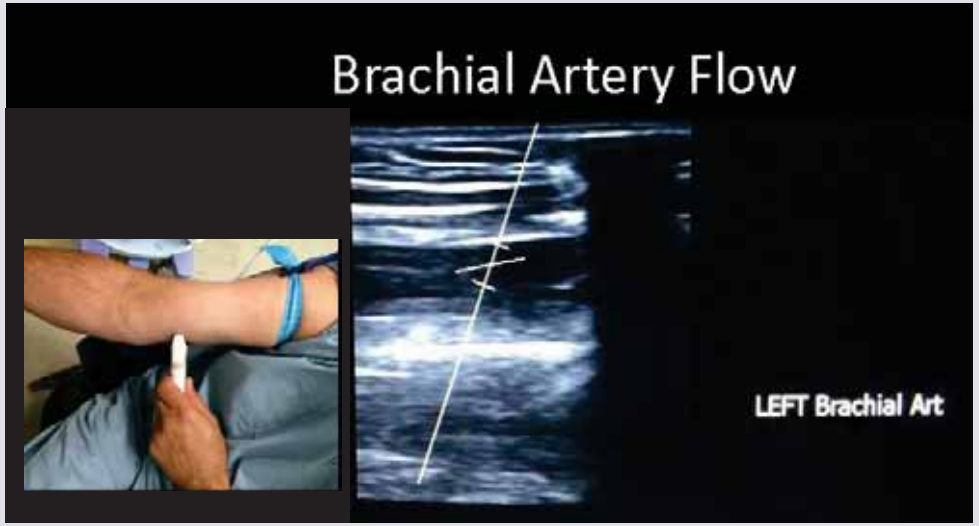
Post-Procedure Assessment

Standard AVF Screening

Assess Maturity by Duplex Ultrasound

Assess Access Circuit

- DUS assessment of maturity provides an index of usability
- Fistula flow: Arterial inflow ≥ 500 ml/min[1]
- Target vein to cannulate: ≥ 4mm in diameter[1]



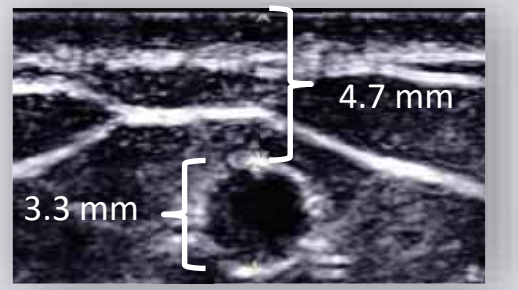
1. Robbin; Radiology 2002 Oct, 225 (1) 59-64

WavelinQ™ 4F EndoAVF Quick Check

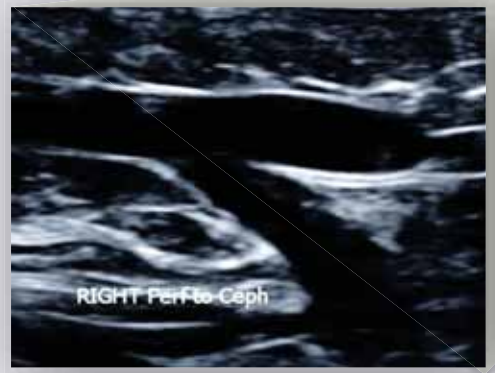
Consider checking for a patent perforator before proceeding with additional EndoAVF measurements

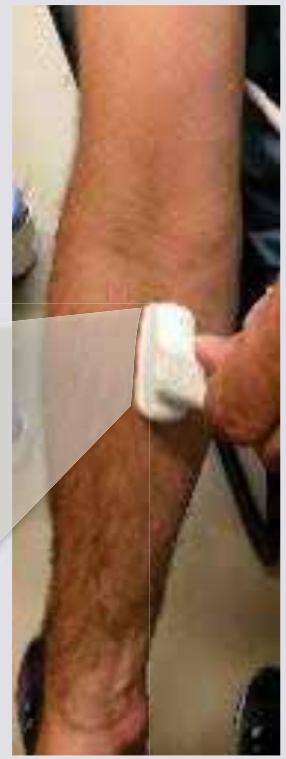
- ✓ Usable cephalic and/or basilic vein for fistula outflow
- ✓ Has a patent perforator
- ✓ Ulnar or radial artery and ulnar or radial vein ≥ 2mm in diameter
- ✓ Brachial vein ≥ 2 mm in diameter

Cephalic Vein



Perforator to Cephalic





WAVELINQ™ 4F EndoAVF System

Indications
The WavelinQ™ 4F 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™ 4F EndoAVF System is only to be used with the approved components specified above. 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™ 4F 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. Keep active accessories away from patient when not in use. Do not permit cable to be parallel to and/or in close proximity to leads of other devices. Do not wrap cable around handles of metallic objects such as hemostats. 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 below. Use of closure devices with the WavelinQ™ 4F EndoAVF System may be associated with an increased risk of access site complications. The WavelinQ™ 4F 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 below. According to the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI clinical guidelines), the device should not be used in place of a more distal AVF. This device is coated with a hydrophilic coating at the distal end of the device for a length of 23.9 cm (9.4 in). Please refer to the AVF Creation section (Step 28) 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.

Precautions: Care should be taken to avoid the presence of fluid on the ESU. 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. Keep magnetic ends of catheters away from other metallic objects which may become attracted and collide with devices. 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 WavelinQTM 4F 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; 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.