WavelinQ™ EndoAVF System

Physician Hands-On Training Procedure Check List

Patient Selection

Fistula Location
- ☐ Radial-Radial
- ☐ Ulnar-Ulnar

Outflow Variations
- ☐ Basilic Dominant
- ☐ Cephalic Dominant
- ☐ Split Flow

Anatomical Considerations
- ☐ Perforator Anomalies
- ☐ Single Brachial
- ☐ High Bifurcation
- ☐ Calcification
- ☐ Arterial runoff

Supply List

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)

Medication Considerations:
- ☐ Anti-spasmodic
- ☐ Anesthesia
- ☐ Anticoagulant
- ☐ Vasodilator
- ☐ Saline Solution

Room & Patient Prep

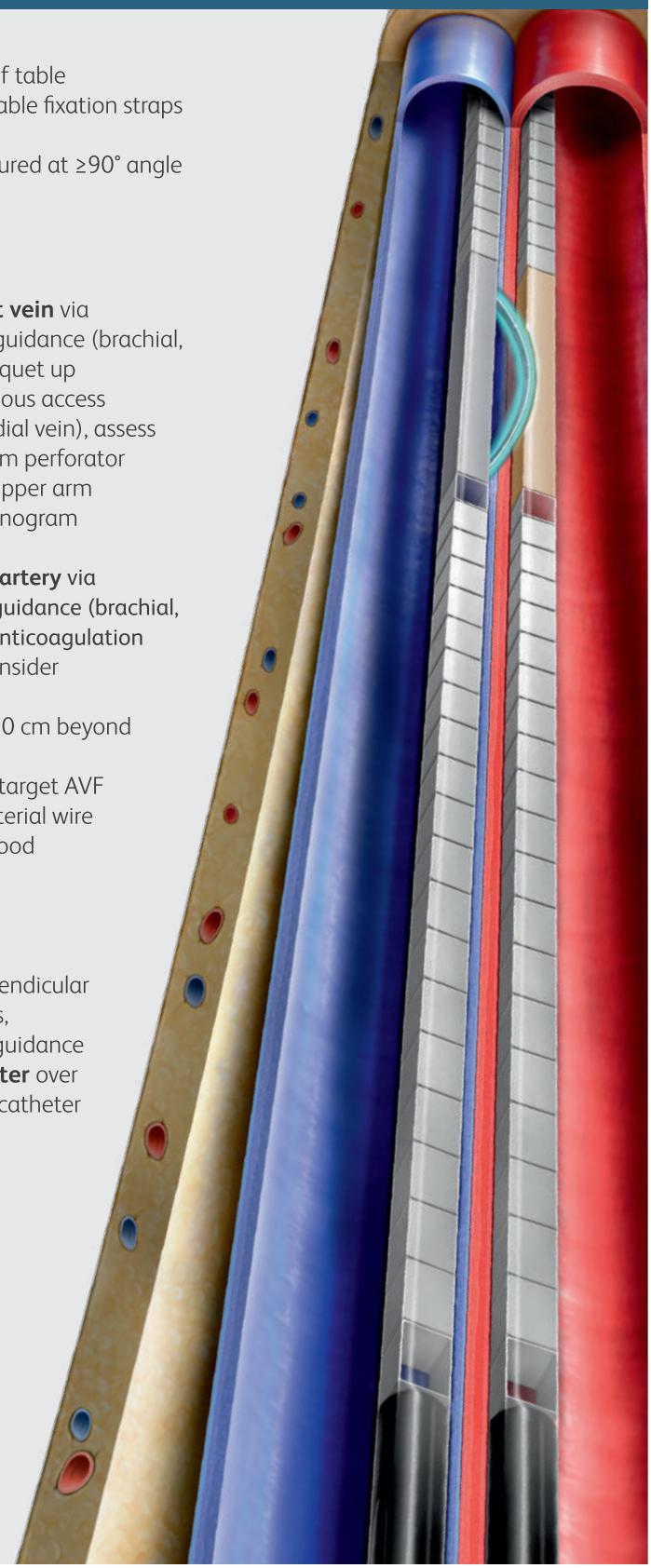
- ☐ **Arrange OR/Cath Lab** per operator preference and hand dominance
- ☐ **Arm board** placed under patient
- ☐ **Confirm procedure** plan via ultrasound
  - Access site location
  - Creation site location
  - Superficial communication
- ☐ **Ground pad** on patient
- ☐ **Patient placed** on edge of table
- ☐ **Strap** in arm using disposable fixation straps
- ☐ **Prep arm** for procedure
- ☐ **Arm hyperextended,** secured at ≥90° angle
- ☐ **Tourniquet up** (sterile)

Vessel Access

- ☐ **Gain access** to the **target vein** via percutaneous ultrasound guidance (brachial, ulnar or radial) with tourniquet up
- ☐ **Perform venogram** if venous access from the wrist (ulnar or radial vein), assess vessel anatomy and confirm perforator communication. If using upper arm (brachial) vein, perform venogram after wire insertion
- ☐ **Gain access** to the **target artery** via percutaneous ultrasound guidance (brachial, ulnar or radial). Consider anticoagulation
- ☐ **Perform arteriogram** (consider roadmapping)
- ☐ **Advance arterial wire** ~10 cm beyond target creation site
- ☐ **Advance venous wire** to target AVF creation site, parallel to arterial wire
- ☐ **Remove tourniquet** or blood pressure cuff if applied

Device Delivery

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



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Device Alignment

- ☐ **Rotate the arterial catheter** until the illumination of the rotational indicators are maximized and the concave surface of the backstop is pointed at the venous wire.
- ☐ **Advance venous catheter** until the yellow hemostasis valve crosser encounters the hemostasis valve of the introducer sheath.
- ☐ **Insert the yellow hemostasis valve crosser** through the hemostasis valve until it stops in the sheath hub.
- ☐ **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.
- ☐ **Advance venous catheter** until arc of electrode is in line with concave surface of the arterial backstop. Electrode should appear compressed.

Activation & Creation of EndoAVF

- ☐ **Rotate the fluoroscope** to visualize the maximum tissue thickness between the arterial and venous catheters (as needed)
- ☐ **Retract or remove both guidewires** from catheter activation zone (between proximal and distal magnet zones)
- ☐ **Observe electrode compression** to the backstop

Confirm Final Position

- ☐ **Review pre-activation checklist**
- ☐ **Deliver RF energy** (and record cine) 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.
- ☐ **Remove venous catheter**
- ☐ **Remove arterial catheter**
- ☐ **Perform arteriogram/fistulogram** through arterial sheath

Divert Flow & Achieve Hemostasis

- ☐ **Embolization** of a brachial vein is recommended
- ☐ **Remove arterial sheath** and perform manual compression (>20 min.)
- ☐ **Remove venous sheath** and perform manual compression until hemostasis has been achieved
- ☐ **Dress puncture sites** per facility protocol

Date: **Location:**

WavelinQ™ EndoAVF Trainer(s): **Physician Trainee:**

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_____ _____

WavelinQ™ EndoAVF System

Indications: The WAVELINQ™ EndoAVF System is intended for the cutting and coagulation of blood vessel tissue in the peripheral vasculature for the creation of an arteriovenous fistula used for hemodialysis.

Contraindications: Known central venous stenosis or upper extremity venous occlusion on the same side as the planned AVF creation. Known allergy or reaction to any drugs/fluids used in this procedure. Known adverse effects to moderate sedation and/or anesthesia. Distance between target artery and vein > 1.5 mm.
Target vessels < 2 mm in diameter.

Warnings: · The WAVELINQ™ EndoAVF System is only to be used with the approved commercially available devices specified above. Do not attempt to substitute non-approved devices or use any component of this system with any other medical device system.
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. Use caution when performing electrosurgery in the presence of pacemakers. 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 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's Guide on its proper operation prior to use. Do not use closure devices not indicated to close the artery used for access.

Cautions: Only physicians trained and experienced in endovascular techniques, who have received appropriate training with the device, should use the device.

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.

Potential adverse events: 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 .

Please consult product labels and instructions for use for all indications, contraindications, hazards, warnings and precautions.

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