WavelinQ™ 4F EndoAVF System Vascular Access Creation

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Disclosure

Speaker name: Rob Jones, MD

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)
- I do not have any potential conflict of interest

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WAVELINQ™ 4F EndoAVF System

Dual catheter system utilizing RF energy to create an autologous fistula

4 Fr Rapid Exchange Catheters
*for vessel access and navigation*

Square Magnets
*for automatic alignment*

Rotational Indicators
*for easy alignment confirmation*

Radiofrequency electrode
*for endoAVF creation*

DISCLAIMER: The WAVELINQ™ 4F EndoAVF System is not available for sale or distribution in the United States of America.

WAVELINQ™ 4F EndoAVF System has been previously referred to as the everlinQ™ endoAVF System
Endovascular AVF (EndoAVF) Creation

Potential EndoAVF Benefits

- Avoids surgical scarring and minimizes arm disfigurement associated with open surgery
- Required fewer interventions to maintain patency than surgical AVF at 12 months\(^1-3\)
- Expands anatomic options for AVF creation

EndoAVF Creation Sites

Arterialized Superficial Veins for Cannulation

Cephalic
Basilic
Radial
Ulnar

Who is a candidate?

Surgical AVF candidates with proximal forearm perforator

**Standard AVF Screening**

- **Good Inflow**
  - Brachial artery ≥2 mm

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

**Additional WavelinQ™ 4F EndoAVF Screening**

- **Vessels can accommodate device**
  - Target ulnar vessels ≥2 mm

- **Presence of a Perforator**
  - Perforator adequately communicates between deep and superficial veins
Approach to choosing access site using the 4F system:

- Diameter of arteries and vein at the wrist (Ulnar or Radial).
- Wrist approach preferential.
- Antiparallel approach used most common (retrograde arterial and venous).

Multiple Procedural Approaches

Parallel:
Access From Wrist

Target Creation Site

Parallel:
Access From Wrist

Anti-Parallel:
Access From Wrist and Upper Arm
EndoAVF Procedure Steps

1. Gain access *parallel or anti-parallel direction*

2. Navigate devices to target creation site *ulnar-ulnar or radial-radial*

3. Align devices then activate to create endoAVF

4. Embolize deep brachial vein to divert flow superficially

Please consult product instructions for use for full procedural steps.

The opinions and clinical experiences presented herein are for informational purposes only. Individual results may vary depending on a variety of patient specific attributes.
EndoAVF Procedure Steps

1. **Gain Access**
   - Plan approach: parallel or anti-parallel
   - Venous access first (use tourniquet), then arterial access
   - U/S guided
   - Can access via basilic and use bridging vein to navigate wire to the brachial vein

Please consult product instructions for use for full procedural steps.

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2. Navigate devices to target creation site

- 0.018"
- Antispasmodics
- Gentle wire manipulation to avoid extravasation
- Use arterial wire as a guide for parallel vein catheterization
EndoAVF Procedure Steps

2. Navigate devices to target creation site
   Retrograde access requires navigating through the valves

Please consult product instructions for use for full procedural steps.

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EndoAVF Procedure Steps

3. Device alignment and activation to create endoAVF

4. Embolize deep brachial vein to divert flow superficially

Please consult product instructions for use for full procedural steps.

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2 Weeks Post EndoAVF Creation

- Dual dominance shared flow
- Follow up with doppler U/S

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Summary

• WavelinQ™ 4F EndoAVF System = rapid learning curve

• WavelinQ™ 4F EndoAVF System provides a non-surgical AVF creation option that allows for multiple access and creation sites
**WAVELINQ™ 4F EndoAVF System**

**INDICATIONS**
The everlinQ 4 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**
1. Known central venous stenosis or upper extremity venous occlusion on the same side as the planned AVF creation.
2. Known allergy or reaction to any drugs/fluids used in this procedure.
3. Known adverse effects to moderate sedation and/or anesthesia.
4. Distance between target artery and vein > 1.5 mm.
5. Target vessels < 2 mm in diameter.

**WARNINGS, CAUTIONS, PRECAUTIONS**

**Warnings**
1. The everlinQ 4 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.
2. The everlinQ 4 System 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.
3. Use caution when performing electrosurgery in the presence of pacemakers.
4. Improper use could damage insulation that may result in injury to the patient or operating room personnel.
5. Do not plug device into the electrosurgical pencil with ESU on.
6. Keep active accessories away from patient when not in use.
7. Do not permit cable to be parallel to and/or in close proximity to leads of other devices.
8. Do not wrap cable around handles of metallic objects such as hemostats.
9. Consult the ESU User’s Guide on its proper operation prior to use.
10. Do not use closure devices not indicated to close the artery used for access.

**Cautions**
1. Only physicians trained and experienced in endovascular techniques should use the device.
2. Adhere to universal precautions when utilizing the device.
3. Do not kink, pinch, cut, bend, twist, or pull excessively or with excessive force on any portion of the devices. Damage to the catheter body may cause the device to become inoperable.
4. Avoid sharp bends. This may cause the device to become inoperable.
5. Do not pinch or grasp the catheter with excessive force or with other instruments. This may cause the device to become inoperable.
6. Do not bend the rigid portion of the catheter near the electrode or backstop.
7. Do not touch or handle the active electrode. Electrode dislodgement may occur.
8. Always use the hemostasis valve crosser to assist insertion of the venous catheter through the introducer sheath. Insertion into introducer sheath without hemostasis valve crosser may damage electrode.
9. Do not attempt to remove the hemostasis valve crosser located on the venous device. Device damage or fracture may occur.

**Precautions**
1. Care should be taken to avoid the presence of fluid on the ESU.
2. 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.
3. Care should be taken to avoid attempting fistula creation in a heavily calcified location of a vessel as fistula may not be adequately formed.
4. 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.
5. Keep magnetic ends of catheters away from other metallic objects which may become attracted and collide with devices.

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