Recorded WavelinQ™ 4F EndoAVF System Case

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Disclosure

Speaker name: Robert Shahverdyan, M.D.

I have the following potential conflicts of interest to report:

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

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The physician has been compensated by Becton, Dickinson and Company to participate in this presentation.
Recorded Case

Patient Information
• Age: 63
• Sex: male
• Access History:
  • CKD Stage V
  • Not yet started dialysis
  • Not a radiocephalic candidate
• Planned radial-radial endoAVF on 30.10.18
• Secondary options
  • Ellipsys™ EndoAVF
  • Surgical Gracz AVF
Case Example – Alternative to Surgery

Outcomes

- Procedure outcome
  - 4 ml contrast agent
  - 250 ml/min flow

- 6 week follow-up
  - 820 ml/min flow
  - Mid cephalic diameter increased from 2.5 mm to 6.3 mm
  - Ready for dialysis
**WAVELINQ™ 4F EndoAVF System IFU**

**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.

**Disclaimer:** The WAVELINQ™ 4F EndoAVF System has been previously referred to as the everlinQ™ endoAVF System.

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