Next Generation
WaveLinQ™ EndoAVF System

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Disclosure

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I have the following potential conflicts of interest to report: 
Consulting BD
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The opinions and clinical experiences presented herein are for informational purposes only. The results from this study report may not be predictive for all patients. Individual results may vary depending on a variety of patient specific attributes.

The clinicians have been compensated by Becton, Dickinson and Company to participate in this presentation.
What kind of AVF does the WavelinQ create?

Deep Vein AVF
Radial Artery - Radial Vein
Ulnar Artery - Ulnar Vein
CASE PLANNING
Confirm perforator
$\varnothing > 2.5 \text{ mm}$

Confirm outflow vessels
$\varnothing > 2.0 \text{ mm}$

Select creation site
$\varnothing > 2.0 \text{ mm}$

Select access/navigation
Surgical

WavelinQ

Superficial V.
Perforator V.
Deep V.
DIRECT CONNECTION

- Superficial V.
- Perforator V.
- Deep V.

WavelinQ
ULTRASOUND SCREENING
WRIST ACCESS CHECK
RADIAL VESSELS CHECK
ULNAR VESSELS CHECK
CEPHALIC VEIN CHECK
CONNECTION TO BASILIC VEIN
BRACHIAL VESSELS CHECK
THE PROCEDURE
PATIENT CHARACTERISTICS

• 63-year old male
• On dialysis with CVC
• Plan: Create a Left Radial AVF
• Venous Access: Basilic Vein (4mm)
• Arterial Access: Brachial Artery (4.2mm)
Rot  +6°
Ang  -8°
FD 37 cm

Cephalic Vein
Perforator Vein
Radial Vein
Anastomosis
Brachial Artery
Radial Artery
ULTRASOUND
2 DAYS LATER
Brachial artery

Volume Flow: 753 cc/min
Radial Artery

Volume Flow: 1356 cc/min
Perforator Vein

Volume Flow: 992 cc/min
Cephalic Vein

Volume Flow: 429 cc/min
CANNULATION
Next Generation
WavelinQ™ EndoAVF System

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WavelinQ™ 4F EndoAVF System for ELQ-002

Indications: The WavelinQ™ 4F 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 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™ 4F EndoAVF System is only to be used with the approved commercially available devices specified in the IFU. Do not attempt to substitute non-approved devices or use any component of this system with any other medical device system. The WavelinQ™ 4F EndoAVF 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. 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 should use the device. Adhere to universal precautions when utilizing the device. Do not kink, pinch, cut, bend, twist, or pull excessively or with excessive force on any portion of the device. Damage to the catheter body may cause the device to become inoperable. Avoid sharp bends. This may cause the device to become inoperative. Do not pinch or grasp the catheter with excessive force or with other instruments. This may cause the device to become inoperable. Do not bend the rigid portion of the catheter near the electrode or backstop. Do not touch or handle the active electrode. Electrode dislodgement may occur. Always use the hemostasis valve crossoer to assist insertion of the venous catheter through the introducer sheath. Insertion into introducer sheath without hemostasis valve crossoer may damage electrode. Do not attempt to remove the hemostasis valve crossoer located on the venous device. Device damage or fracture may occur.

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: The known potential risks related to the WavelinQ™ 4F 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 coldness; occlusion/stenosis; problem due to sedation or anesthesia; pseudoaneurysm; 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.
WavelinQ™ EndoAVF System for WQ4305

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/liquids 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 in the IFU. Do not attempt to substitute non-approved devices or use any component of this system with any other medical device system. The WavelinQ™ EndoAVF 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. Use caution when performing electrosurgery in the presence of pacemakers. Improper use could damage insulation that may result in injury to the patient. Do not use 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 for 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 should use the device. Adhere to universal precautions when utilizing the device. Do not kink, pinch, cut, bend, twist, or pull excessively or with excessive force on any portion of the device. Damage to the catheter body may cause the device to become inoperable. Avoid sharp bends. This may cause the device to become inoperable. Do not pinch or grasp the catheter with excessive force or with other instruments. This may cause the device to become inoperable. Do not bend the rigid portion of the catheter near the electrode or backstop. Do not touch or handle the active electrode. Electrode dislodgment may occur. Always use the hemostasis valve crosser to assist insertion of the venous catheter through the introducer sheath. Insertion into the introducer sheath without hemostasis valve crosser may damage electrode. Do not attempt to remove the hemostasis valve crosser located on the venous device. Device damage or fracture may occur.

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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.

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