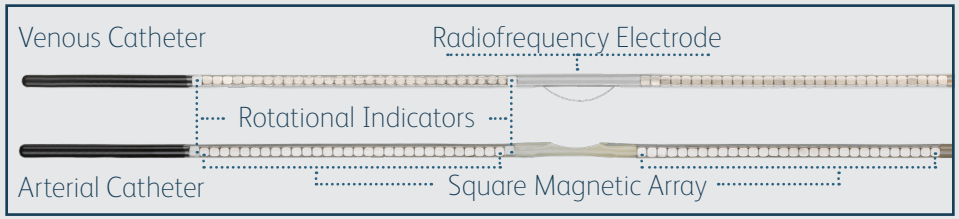
Technical Specifications

WavelinQ™
EndoAVF System

WavelinQ™ EndoAVF Catheters (WQ4300)		
Specifications	Venous Catheter	Arterial Catheter
Profile	4F	
Tip type	Rapid Exchange	
Maximum guidewire size	0.014 in (0.356 mm)	
Feature	Radiofrequency Electrode	Ceramic Backstop
Catheter working length	42 cm (16.9 in)	50 cm (19.7 in)
Location and length of hydrophilic coating	distal 26.4 cm (10.4 in)	
Maximum diagonal of square section	1.55 mm (0.061 in)	
Minimum sheath introducer inner diameter	1.78 mm (0.070 in)	



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Device and Accessory Ordering

WavelinQ™ EndoAVF System		
Disposable Components	**Description**	**Product Code**
WavelinQ™ EndoAVF Catheters	4F Venous Catheter & 4F Arterial Catheter	☐ WQ4300
Disposable Fixation Straps	Each pack contains three straps: two 2" x 24" and one 2" x 18". Sold as a case of 10 packs	☐ TVA-MC-2
Reusable Components	**Description**	**Product Code**
WavelinQ™ Generator	Electrosurgical radiofrequency generator	☐ ESU-1
WavelinQ™ Arm Board	Radiolucent carbon fiber arm board	☐ CZ-400-TVA

PHYSICIAN NAME

PHYSICIAN SIGNATURE

REPRESENTATIVE'S NAME

CONTACT PHONE NO.

WavelinQ™ EndoAVF System

Arterial and Venous Catheter Insertion Site Accessories*

- Ultrasound machine and ultrasound probe
- Microintroducer Kit
- Two (2) 5Fr Introducer Sheaths
- Two (2) 0.014in (0.356mm) guidewires
- 4 Fr Guide Catheter (as needed)
- Tourniquet or Blood Pressure Cuff

Electrode Activation

- Electrosurgical Unit: TVA or BD ESU-1
- Electrosurgical Pencil*: Must have a 3 prong universal connector that interfaces with an ESU-1. Must have a minimum Rated Accessory Voltage of 700V and a yellow button that activates the generator.
- Ground Pad*: Must have a universal connector that interfaces with a ESU-1 Generator. Must be rated to disperse a minimum of 60W for 2 seconds.
- Arm Board: WavelinQ™ Arm Board (CZ-400-TVA) and Fixation Straps (TVA-MC-2)

*Order through appropriate distributor

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 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 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 devices. 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 dislodgement may occur. 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. Do not attempt to remove the hemostasis valve crosser 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. The safety and performance of this device has not been established for pediatric patients. 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™ 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.

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

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