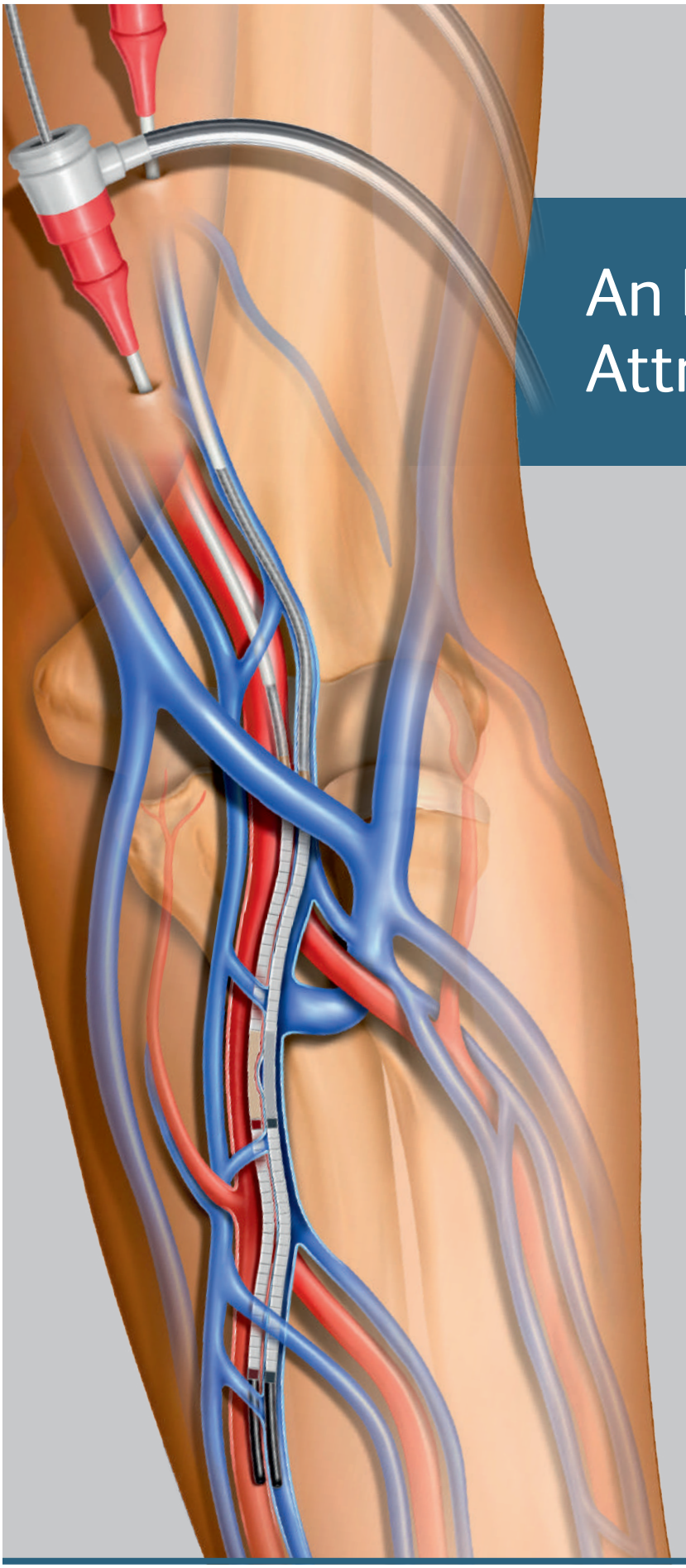
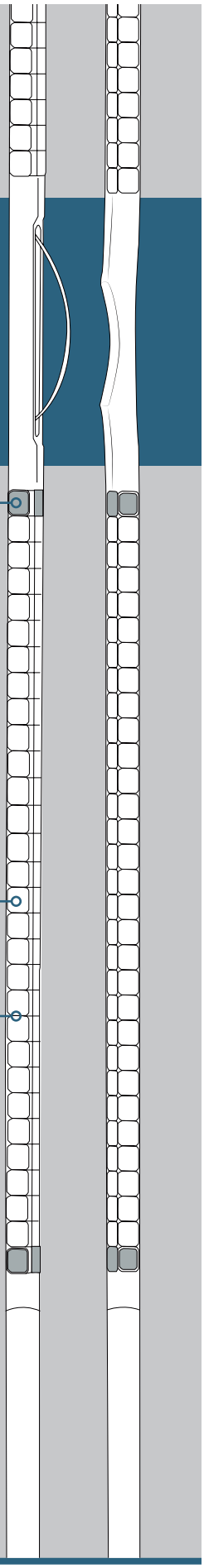


An Even More Attractive Option

The WavelinQ™ EndoAVF System now features more magnets and rotational indicators on our 4F catheters to help enhance alignment.

- **More clarity** with additional rotational indicators
- **More strength** with additional magnets
- **More flexibility** with longer magnet arrays



WavelinQ™

EndoAVF System

Bench test results compared to the WavelinQ™ 4F EndoAVF System. Data on file. Bard Peripheral Vascular Inc. Tempe, AZ. Bench tests may not be indicative of clinical performance

BD

WavelinQ™ EndoAVF System		
Disposable Components	**Description**	**Product Code**
WavelinQ™ EndoAVF Catheters	4F Venous Catheter & 4F Arterial Catheter	☐ WQ4305
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.

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 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 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.

Electrical Safety: The WavelinQ™ EndoAVF System complies with the electrical safety standards 60601-1, 60601-1-2 and 60601-2-2.

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 indications, contraindications, hazards, warnings and precautions.

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