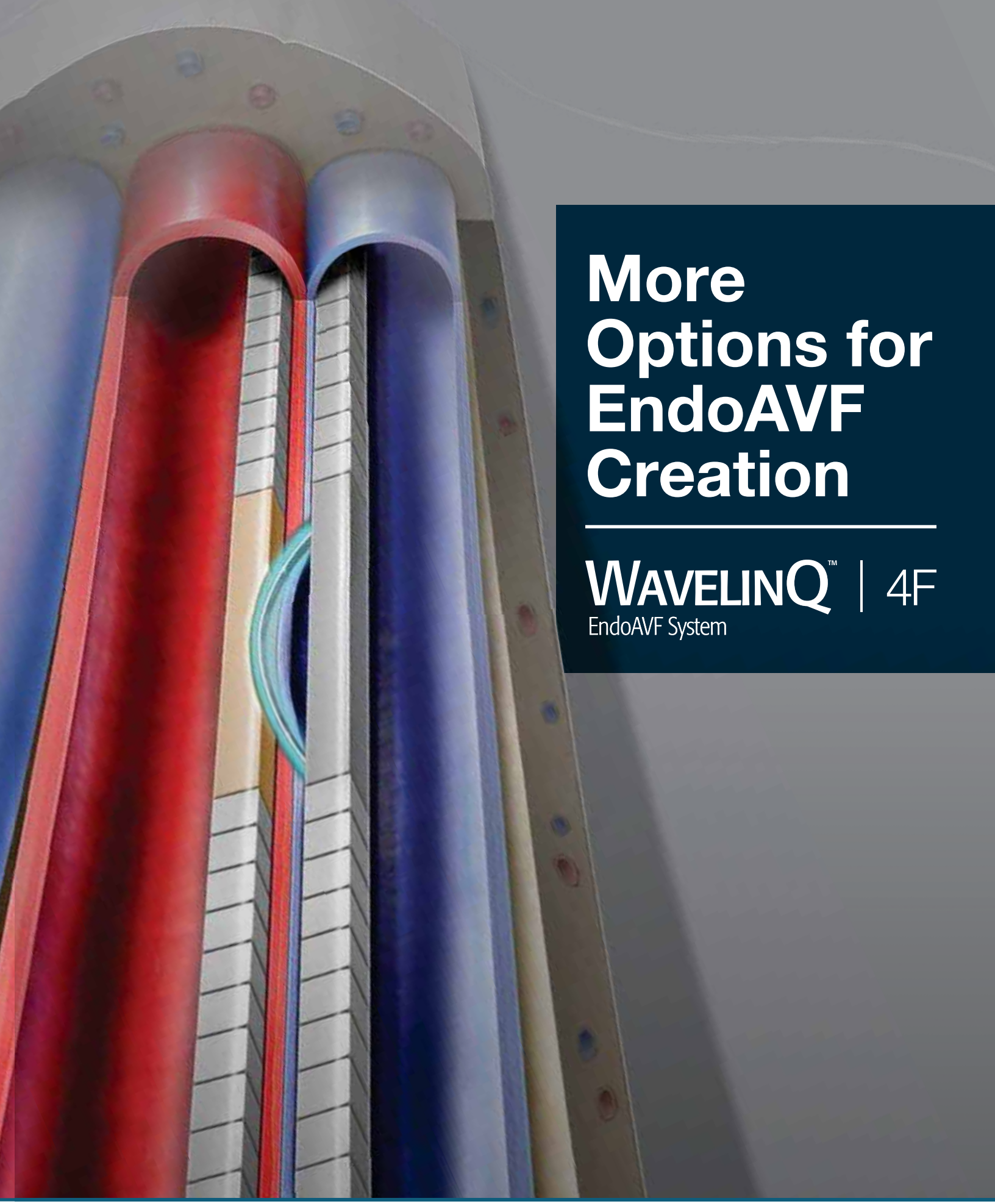

More Options for EndoAVF Creation

WAVELINQ™ | 4F
EndoAVF System

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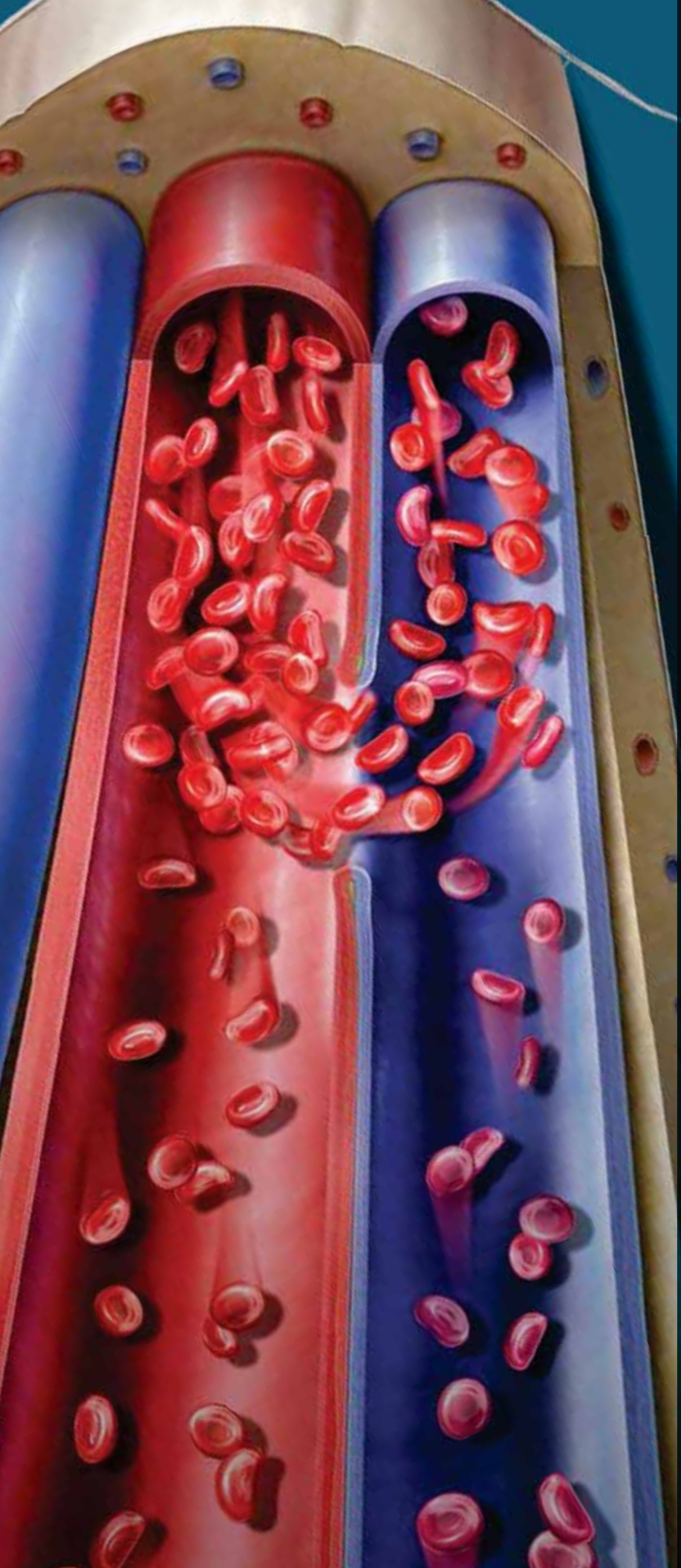


The First Major Advancement in Fistula Creation in Over 50 Years

When you reach for an innovation in AV access care, it is important that it is backed by a company that you have trusted for many years. It means that you will have the expert service and support, trusted data, and the leading medical devices that you count on to deliver care to your patients every day.

BD is the market leader in AV access with technologies to create, restore, and maintain access for patients on hemodialysis. The WAVELINQ™ 4F EndoAVF System is BD's next generation device, enabling the creation of an arteriovenous fistula for hemodialysis access without the need for open surgery.

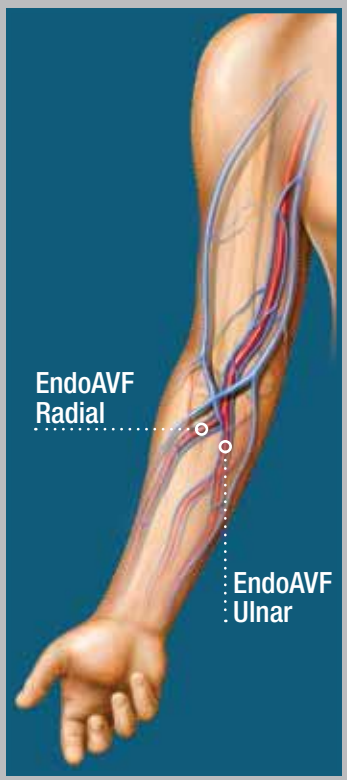
WAVELINQ™ | 4F
EndoAVF System

The **WAVELINQ™ 4F EndoAVF System** is designed to give you a versatile endovascular AV fistula creation alternative to open surgery. Using two thin, flexible, magnetic catheters and a burst of RF energy, you can create an endovascular AV fistula.

Avoids surgical scarring and minimizes arm disfigurement associated with open surgery

Additional anatomic locations for AVF creation

How It Works



1. Two thin, flexible, magnetic catheters are inserted into an artery and vein in the arm through a small puncture or incision.

2. When placed in proximity, the magnets in each catheter attract to each other, pulling the vessels together and align the RF electrode.

3. The venous catheter, which contains the electrode, delivers a burst of RF energy to create a connection between the artery and vein. Then, the catheters are removed.

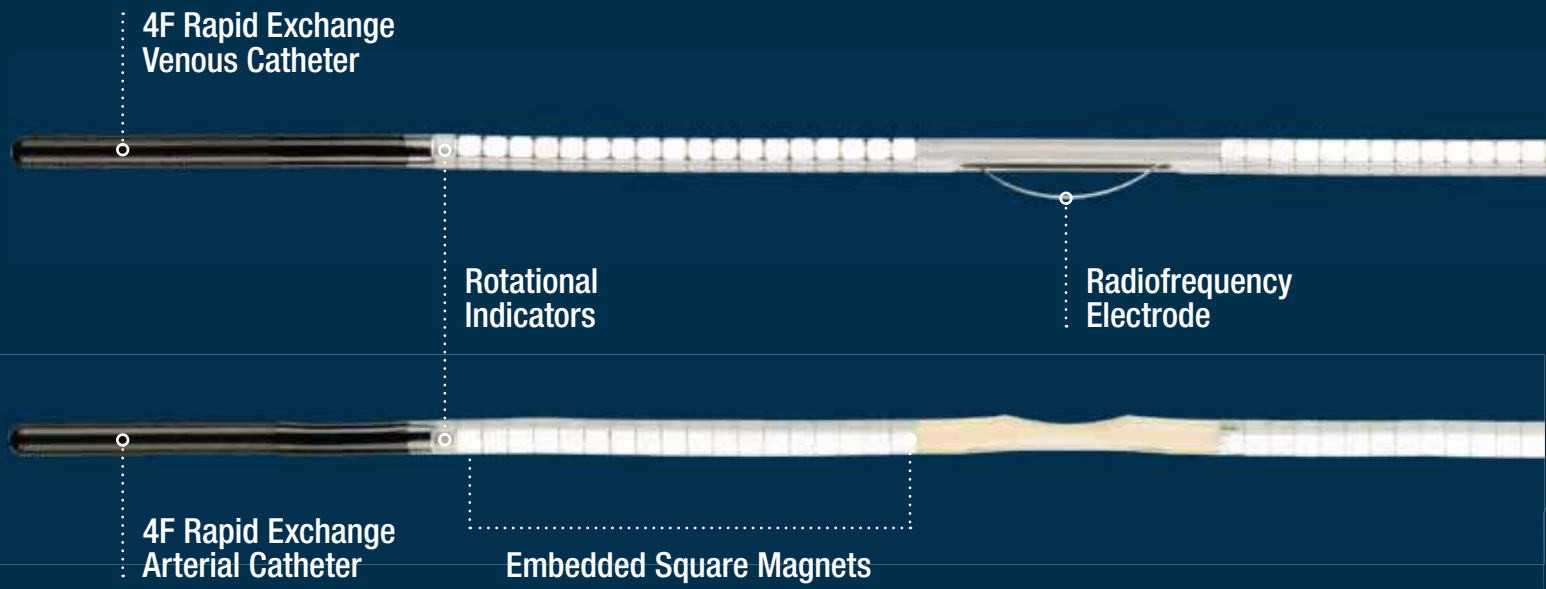
4. A brachial vein embolization is then recommended to divert more flow through the perforator to the superficial veins (cephalic, median cubital and/or basilic veins) for dialysis.

System Overview

The **WAVELINQ™ 4F EndoAVF System** consists of an RF generator, grounding pad, and two disposable catheters.

- Slim 4F profile catheters for vessel access and navigation
- Square magnets for automatic alignment
- Rotational indicators for alignment confirmation

4F Catheter Details:



Expanding Options to Address Patient Needs

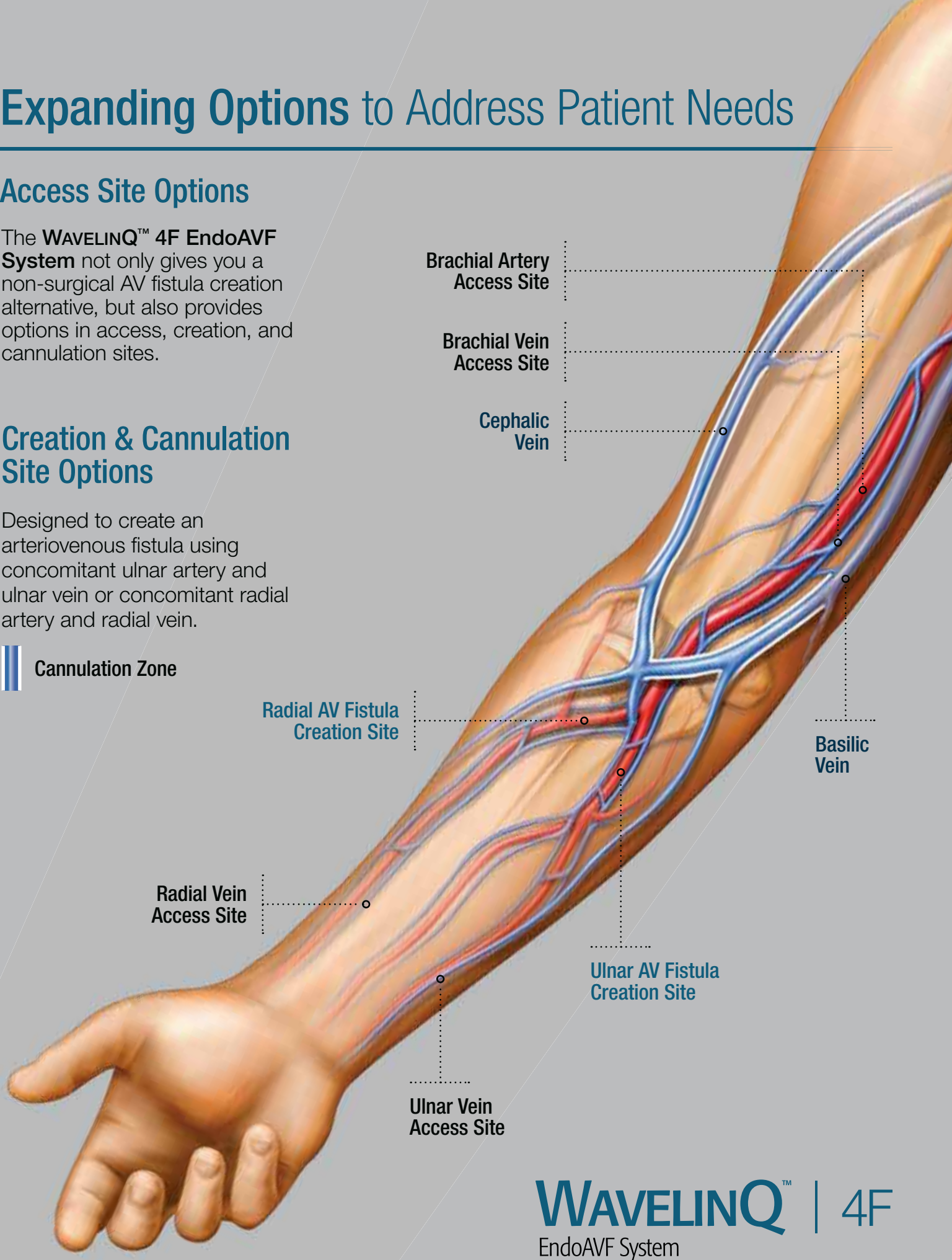
Access Site Options

The **WAVELINQ™ 4F EndoAVF System** not only gives you a non-surgical AV fistula creation alternative, but also provides options in access, creation, and cannulation sites.

Creation & Cannulation Site Options

Designed to create an arteriovenous fistula using concomitant ulnar artery and ulnar vein or concomitant radial artery and radial vein.

Cannulation Zone



WAVELINQ™ | 4F
EndoAVF System

Warning: Only the brachial artery should be used for arterial access.

WavelinQ™ | 4F
EndoAVF System

WavelinQ™ 4F EndoAVF System			
Product	**Cat. Number**	**Company**	**Qty**
WavelinQ™ 4F EndoAVF System	W04200	BD	1

Additional Components			
Product	**Cat. Number**	**Company**	**Qty**
Electrosurgical Generator	ESU-1	BD	1
Arm Restraint	CZ-400-TVA	Distributed by BD	1

WavelinQ™ | 4F EndoAVF System

Indications: The WavelinQ™ 4F EndoAVF System is indicated for the creation of an arteriovenous fistula (AVF) using concomitant ulnar artery and ulnar vein or concomitant radial artery and radial vein in patients with minimum artery and vein diameters of 2.0 mm at the fistula creation site who have chronic kidney disease and need hemodialysis.

Contraindications: Target vessles <2 mm in diameter.

Warnings: The WavelinQ™ 4F EndoAVF System is only to be used with the approved components specified in the instructions for use (IFU). Do not attempt to substitute non-approved devices or use any component of this system with any other medical device system. Use of the system with other components may interfere with proper functioning of the device. The WavelinQ™ 4F 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. The WavelinQ™ EndoAVF System should not be used in patients who have known central venous stenosis or upper extremity venous occlusion on the same side as the planned AVF creation. The WavelinQ™ EndoAVF System should not be used in patients who have a known allergy or reaction to any drugs/fluids used in this procedure. The WavelinQ™ EndoAVF System should not be used in patients who have known adverse reactions to moderate sedation and/or anesthesia. The safety and performance of the device via arterial wrist access has not been fully established. The incidence of vessel stenosis or occlusion that occurs in the radial and ulnar arteries after arterial wrist access has not been evaluated. Do not use the device to create an EndoAVF using arterial access via the radial or ulnar artery. The EndoAVF should only be created using brachial artery access. Use caution when performing electrosurgery in the presence of pacemakers or implantable cardioverter defibrillators. 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 powered on. Consult the ESU User Guide on its proper operation prior to use. Do not use closure devices not indicated to close the artery used for access. Ensure the patient's arm is restrained to minimize movement during device activation; potential hazards of patient arm movement during activation are hematoma or pseudoaneurysm near the fistula site. The puncture site should be closed and hemostasis should be achieved by manual compression per the instructions in the IFU. Use of closure devices with the WavelinQ™ 4F EndoAVF System may be associated with an increased risk of access site complications. The WavelinQ™ 4F EndoAVF System has only been evaluated for the creation of an AVF between the ulnar artery and concomitant ulnar vein and between the radial artery and concomitant radial vein in the clinical studies described in the IFU. According to the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI clinical guidelines), the device should not be used in place of a more distal AVF. This device is coated with a hydrophilic coating at the distal end of the device for a length of 23.9 cm (9.4 in). Please refer to the AVF Creation section in the instructions for use for further information on how to prepare and use this device to ensure it performs as intended. Failure to abide by the warnings in this labeling might result in damage to the device coating.

Cautions: Only physicians trained and experienced in endovascular techniques, who have received appropriate training with the device, should use the device. Endovascular technique training and experience should include ultrasound vessel access in the arm, guidewire navigation, radiographic imaging, placement of vascular embolization devices (including embolization coils), and access hemostasis. Adhere to the universal precautions when utilizing the device.

Precautions: 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. Some patients who have veins deeper than 6 mm may require superficialization per KDOQI guidelines. Ensure the patient has adequate collateral blood flow to the hand before use of the device. Prior to the procedure, ensure that the access location, access vessels, and target AVF location are of appropriate size to account for the devices during use. Oversizing the device to the access vessel may increase risk of vessel injury, which may result in stenosis and/or occlusion. Vessel injury may impact future dialysis access options and/or the ability to perform future endovascular procedures from the target access vessels. Users should consider the potential risk of distal arterial stenosis and/or occlusion on end stage renal disease patients when selecting vascular access sites for the procedure. Adjunctive procedures are expected to be required at the time of the index procedure to increase and direct blood flow into the AVF target outflow vein to assist maturation. Care should be taken to proactively plan for any adjunctive procedures, such as embolization coil placement, when using the device.

Potential Adverse Events: The known potential risks related to the WavelinQ™ 4F device 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; sepsis; steal 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.

BPV/ENDO/0918/0030a

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