Don't just create an AV fistula, **make a difference**

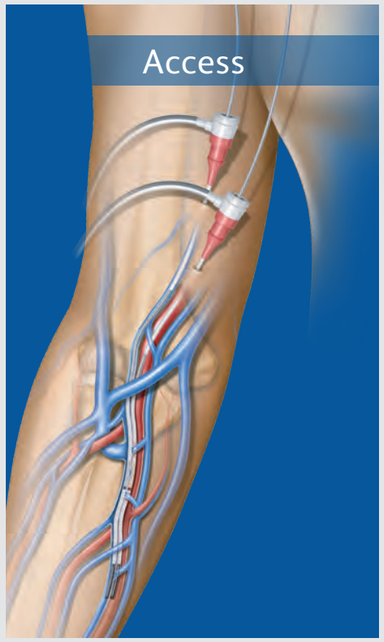
WavelinQ™

EndoAVF System

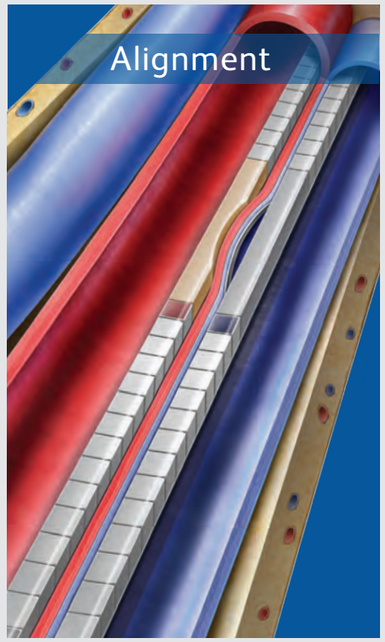
BD

Non-surgical
AV fistula creation

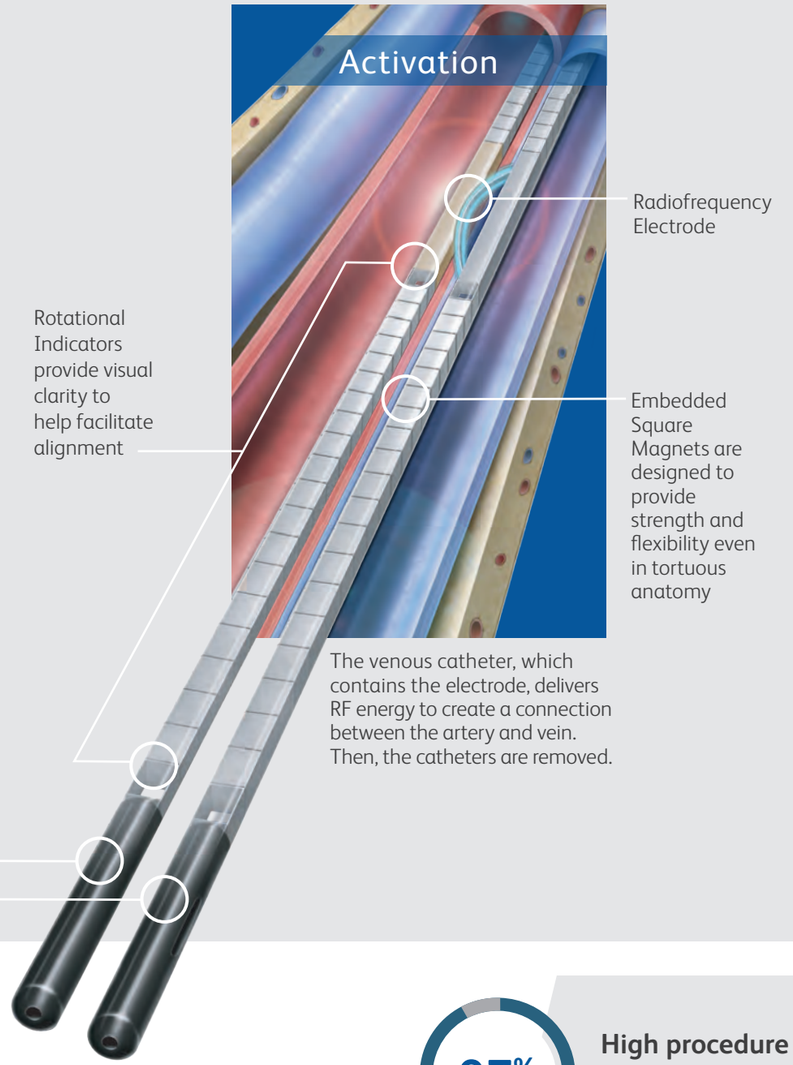
For far too long, hemodialysis access creation options for your patients have been limited. The WavelinQ™ EndoAVF System is designed to change that by providing a truly flexible, minimally-invasive procedural option for arteriovenous fistula creation.



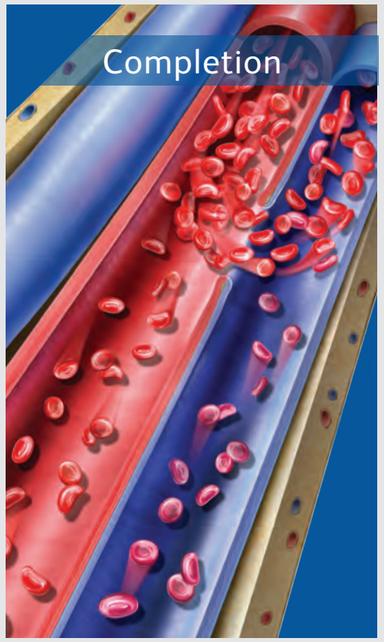
Two thin, flexible, magnetic catheters are inserted into an artery and vein in the arm through small punctures or incisions.



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



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



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

High procedure success

88 of 91 subjects in the 4F Global Analysis had a successful EndoAVF creation confirmed via intraprocedural fistulography or by duplex ultrasound performed post-procedure[1]

Expanding options
to address patient needs

Every patient is different, and every fistula is different. The WavelinQ™ EndoAVF System provides the flexibility to adapt your plan to help meet the unique anatomical needs of your patients by offering multiple options for access, creation, and cannulation, while also preserving future surgical AV fistula creation site options.

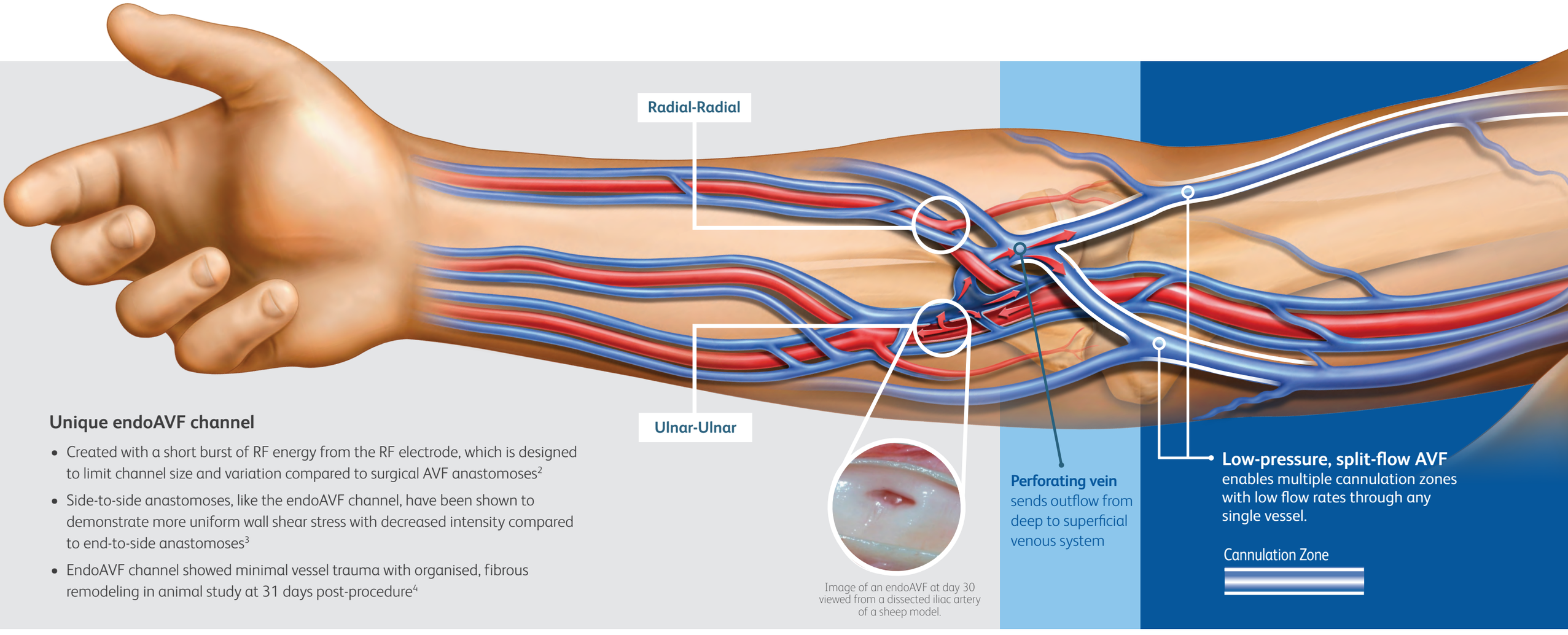


Image of an endoAVF at day 30 viewed from a dissected iliac artery of a sheep model.

Unique endoAVF channel

- Created with a short burst of RF energy from the RF electrode, which is designed to limit channel size and variation compared to surgical AVF anastomoses[2]
- Side-to-side anastomoses, like the endoAVF channel, have been shown to demonstrate more uniform wall shear stress with decreased intensity compared to end-to-side anastomoses[3]
- EndoAVF channel showed minimal vessel trauma with organised, fibrous remodeling in animal study at 31 days post-procedure[4]

High cannulation success

63 of 74 dialysis subjects in the 4F Global Analysis achieved successful 2-needle cannulation and hemodialysis through their endoAVF 6 months post-procedure[1]

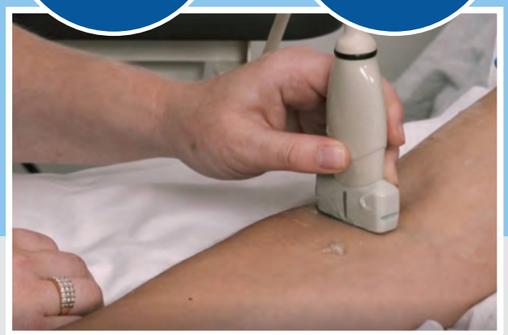
More than a product
A complete program

An effective endoAVF program requires a multidisciplinary commitment to the patient journey. To help support that effort, BD provides comprehensive training, ongoing support, and the resources and tools that you need to help you be successful.

Selection

1 Vascular Lab Readiness

2 EndoAVF Vein Mapping



Our specialised endovascular fistula teams help educate and train you and your ultrasound team on vein mapping for WavelinQ™ EndoAVF.

Procedure

3 EndoAVF Creation

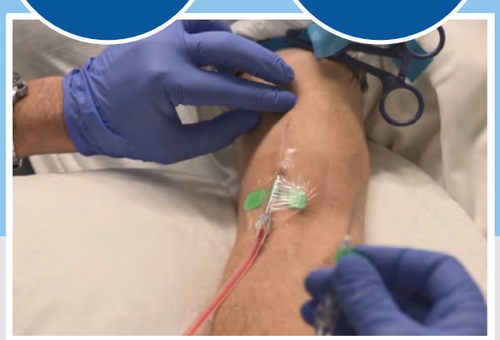
4 EndoAVF Follow up

Our expert physician trainers conduct procedural training using a mix of virtual technologies, simulators and hands-on demonstration and our local certified endovascular fistula specialists will in-service your full procedure team, proctor initial cases and follow up.

Cannulation

5 Dialysis Center Readiness

6 EndoAVF Cannulation



Our specialised dialysis team helps prepare your dialysis centers for endoAVF cannulation.

ADVANCE
A CLINICAL TRAINING & EDUCATION PROGRAM

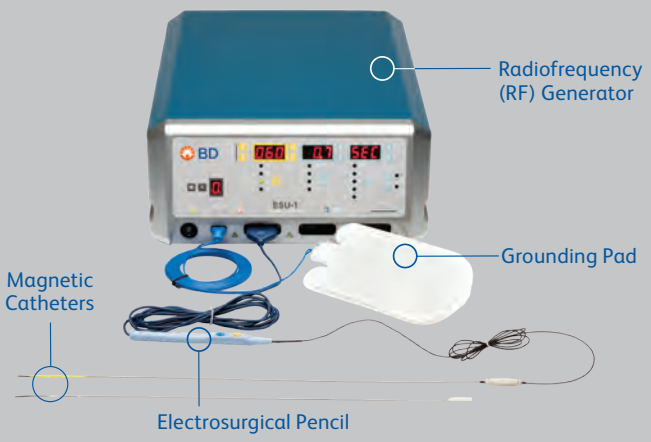
For videos, presentations, articles and more please contact your BD sales representative or send email to:
WavelinQsupportEMEA@BD.com

Low catheter use

Only 4 of 25 pre-dialysis subjects in the 4F Global Analysis initiated hemodialysis with a catheter[1]

The WavelinQ™ EndoAVF System consists of an RF generator, two disposable magnetic catheters, and an arm board (not pictured).

Other procedural components (sold separately) include: arm board fixation straps (not pictured), electrosurgical pencil, and a grounding pad.



WavelinQ™ EndoAVF System

Disposable Components	Description	Product Code
WavelinQ™ EndoAVF Catheters	4F Venous Catheter & 4F Arterial Catheter	☐ WQ4300
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

[1]Data from the EASE (n=32), EASE-2 (n=24) and the EUR Post-Market (n=35) Studies of the WavelinQ™ 4F EndoAVF System was aggregated and analysed in the 4F Global Analysis (n=91). Procedural Successful was defined as successful endoAVF creation confirmed via intraprocedural fistulography or by duplex ultrasound performed post-procedure. Cannulation Success (Dialysis subset) was defined as 2-needle access and dialysis through the endoAVF. CVC Initiation: pre-dialysis patients who initiated hemodialysis with a CVC through 6 months. See the WavelinQ™ EndoAVF System Instructions for Use for the full analysis, including more details on each of the studies.

[2]Rajan. Seminars in Interventional Radiology 2016;33(1):6-9

[3]Hull et. Al. JVA 2013;58(1):187-193,

[4]Results from preclinical study where 4 sheep received percutaneously created fistulae utilising WavelinQ™ EndoAVF and the tissue healing response was evaluated at 30 ± 2 days. Data on file. GLP Animal Study, using WavelinQ™ 6F EndoAVF System. Preclinical data may not be predictive of actual clinical outcomes. Different tests methods may yield different results.

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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 above. Do not attempt to substitute nonapproved devices or use any component of this system with any other medical device system. The WAVELINQ™ catheters are single use devices. DO NOT re-sterilise 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, who have received appropriate training with the device, should use the device.

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: 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 all indications, contraindications, hazards, warnings and precautions.

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