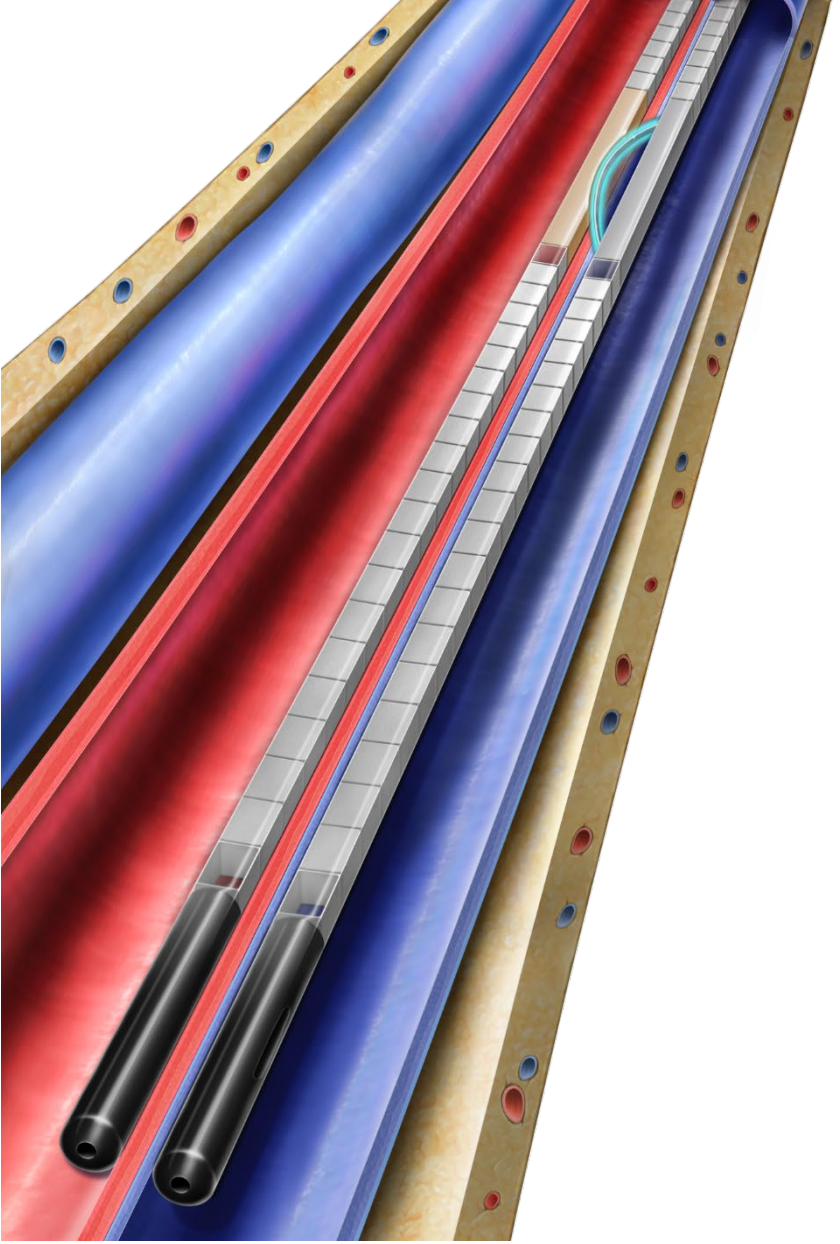

WavelinQ™
EndoAVF System

6-month update on European and Canadian clinical data on the **WAVELINQ™ ENDOAVF SYSTEM**

Nick Inston, MD, PhD
Clinical Lead for Renal Surgery and Transplantation
Queen Elizabeth Hospital Birmingham
Birmingham, United Kingdom

BD

WavelinQ™
EndoAVF System

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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.

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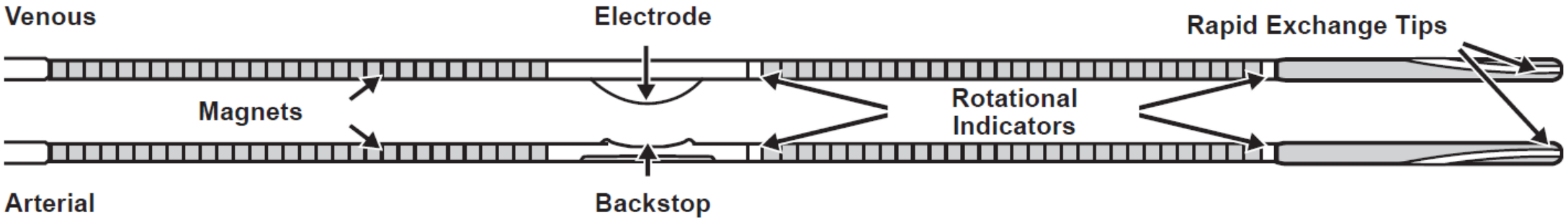
WavelinQ™ EndoAVF System

WavelinQ™
EndoAVF System



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Two devices & two fistula locations

WavelinQ™
EndoAVF System

Generation 1: **WavelinQ™ 6F**

- Two fluoroscopically-guided, **6F** magnetic catheters & a burst of radiofrequency energy create **ulnar-ulnar** EndoAVF via **brachial artery/vein** approach

Generation 2: **WavelinQ™ 4F**

- Two fluoroscopically-guided, **4F** magnetic catheters & a burst of radiofrequency energy create **ulnar-ulnar or radial-radial** EndoAVF via **brachial, ulnar and/or radial artery/vein** approaches

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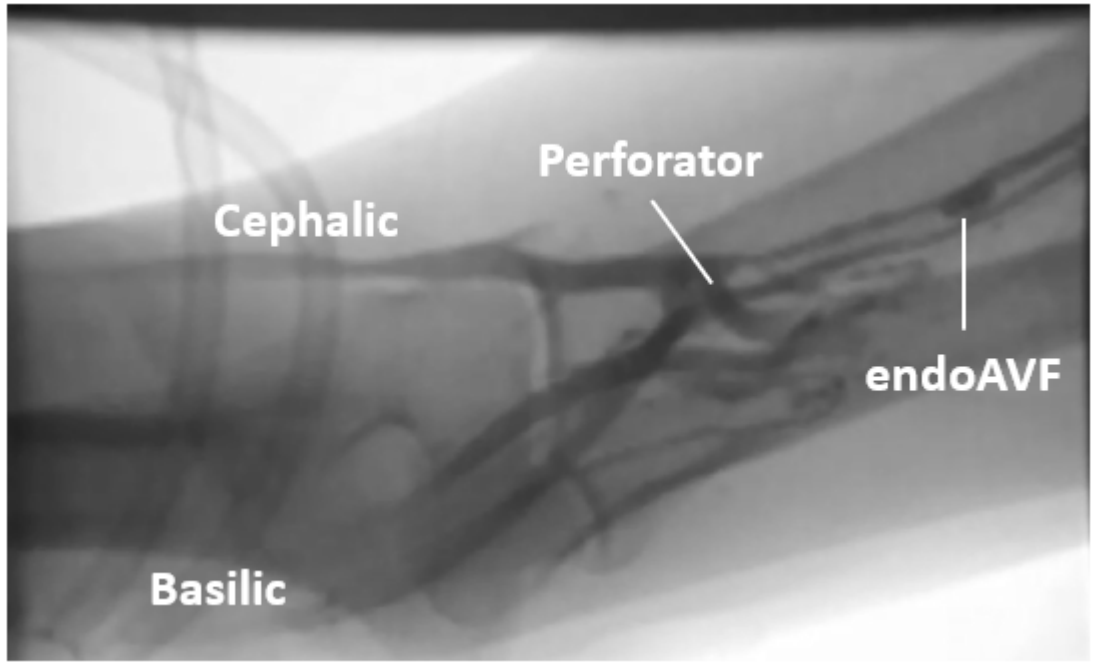
Procedural imaging

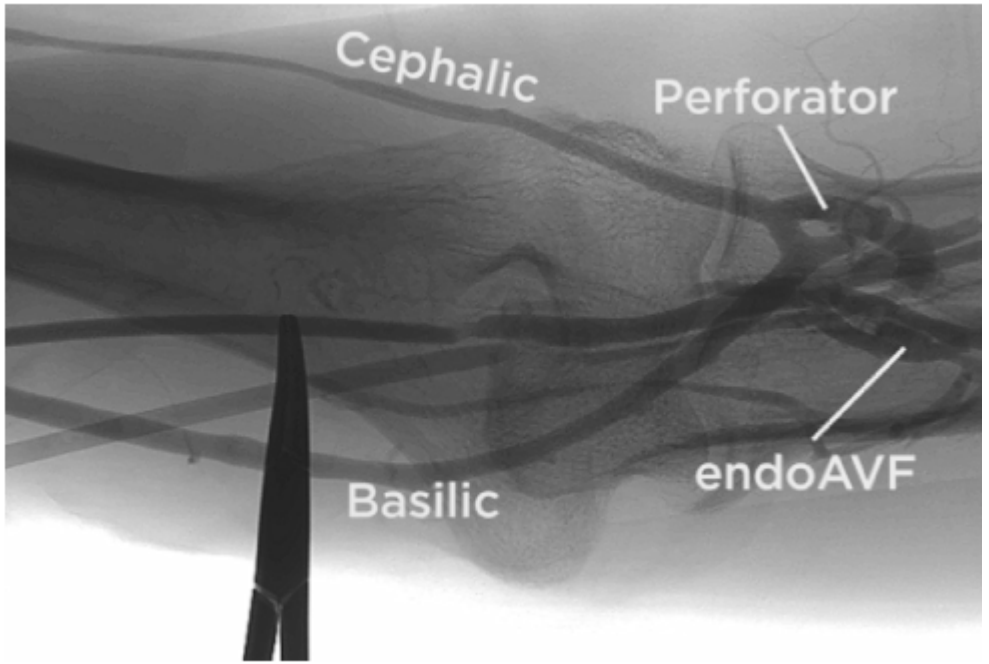
WavelinQ™
EndoAVF System

Familiar imaging technology is used with WavelinQ™ EndoAVF System for clear visualization and procedural roadmapping

Radial-Radial



Ulnar-Ulnar



Low-pressure, split-flow AVF

WavelinQ™
EndoAVF System

- Multiple outflow vessels can dilate and mature
- Low flow rates through any single vessel
- Minimal vessel trauma
- Preserves future surgical options

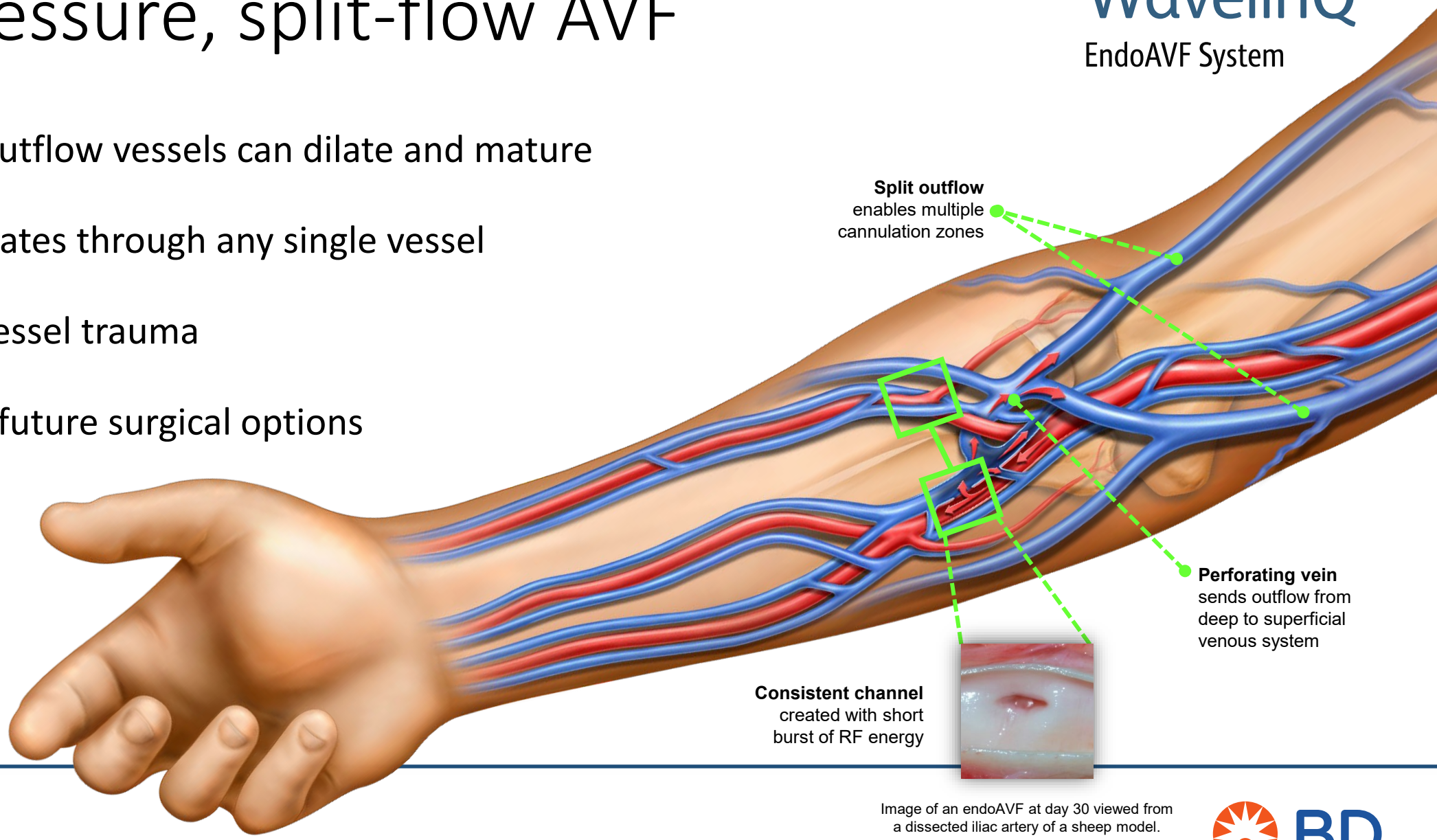


Image of an endoAVF at day 30 viewed from a dissected iliac artery of a sheep model.

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Clinical program overview

WavelinQ™
EndoAVF System

		FLEX	NEAT	EASE	EUR/CA Post-Market	EASE-2
Device(s)	**6F (Gen 1)**	✓	✓		✓	
	4F (Gen 2)			✓	✓	✓
Fistula Location(s)	**Ulnar-Ulnar**	✓	✓	✓	✓	✓
	Radial-Radial			✓	✓	✓
Study Type	**Prospective, single arm**	✓	✓	✓	✓	✓
	Multiple operators	✓	✓	✓	✓	✓
	Multiple centers		✓		✓	
	Single center	✓		✓		✓
Study Details	**Number of patients**	33	60 (+20 roll-in)	32	**100**	24
	Location(s)	Paraguay	Canada, Australia, New Zealand	Paraguay	**Germany, UK, Canada**	Paraguay
	Status	*Rajan et al. Percutaneous Creation of an Arteriovenous Fistula for Hemodialysis Access (FLEX) JVIR 2015;26:484-490*	*Lok et al. Endovascular Proximal Forearm Arteriovenous Fistula for Hemodialysis Access: Results of the Prospective, Multicenter Novel Endovascular Access Trial Am J Kidney Disease 2017;70(4):486-497*	*Berland et al. Endovascular Creation of Arteriovenous Fistulae for Hemodialysis Access with a 4Fr Device: Clinical Experience from the EASE Study Annals of Vascular Surgery 2019;60:182-192*	**Completed**	Completed

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Post-Market Study

WavelinQ™
EndoAVF System

- Study Objective
  - Collect post-market data on outcomes of endovascular AV fistula creation using the WavelinQ™ (previously EverlinQ) EndoAVF System in Europe and Canada at 12 study sites

- Study Design
  - Prospective, multi-center study of 100 subjects
  - Duplex ultrasound core lab
  - Clinical Events Committee
  - Independent CRO & statistical analysis

NCT 02682420

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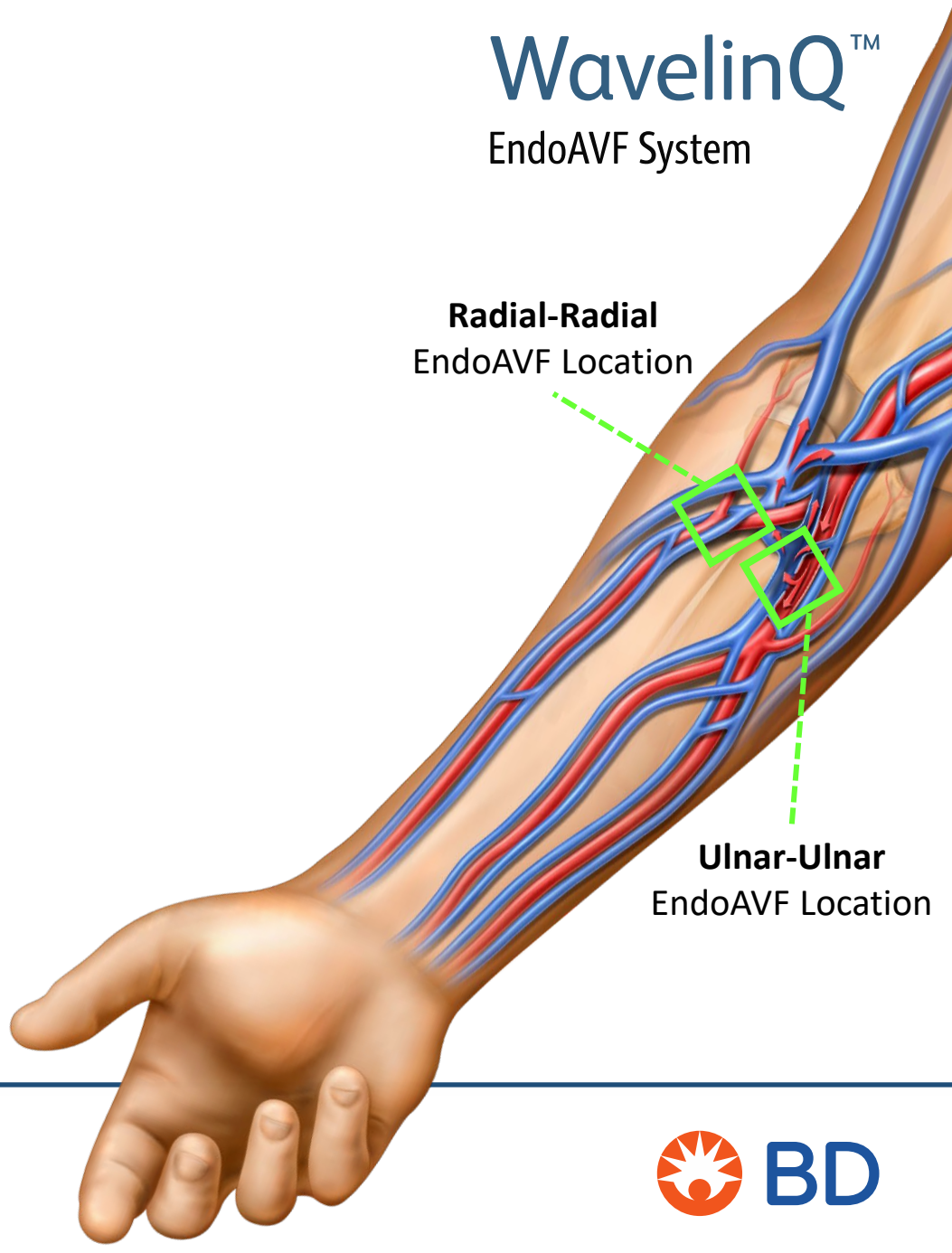
Study devices & procedures

		N=100
Device(s)	6F (Gen 1)	36
	4F (Gen 2)	**64**
Fistula Location(s)	**Ulnar-Ulnar**	**96**
	Radial-Radial	4
Main Procedural Access Site	**Brachial vein**	**80**
	Ulnar vein	12
	Brachial artery	**50**
	Ulnar artery	48
Index Procedure	**Coil Embolization** *(to divert flow to superficial system)*	**73**

WavelinQ™
EndoAVF System



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Results @ 6 months

WavelinQ™
EndoAVF System

Endpoint	Result	Definition
Procedural Success	94%	94/100 (N=6 endoAVF not created)
Device-Related Serious Adverse Events	3%	3/100 (N=1 pseudoaneurysm w/ 6F brachial access, N=1 compartment syndrome w/ 6F brachial access, N=1 occlusion/stenosis)
Primary Patency	71% ± 5%	Interval of time from access placement until any intervention designed to maintain or re-establish patency, access thrombosis, access abandonment, or the time of measurement of patency
Assisted Primary Patency	81% ± 5%	Interval of time from access placement to thrombosis or abandonment; not triggered by access circuit interventions performed in the absence of occlusion
Secondary Patency	91% ± 3%	Interval of time from access placement until access abandonment, loss to thrombosis, or the time of patency measurement including intervening manipulations (surgical or endovascular interventions) designed to re-establish functionality in thrombosed access
Functional Patency	95% ± 3%	Interval of time from first 2-needle dialysis utilizing access until access abandonment

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Reintervention rates

WavelinQ™
EndoAVF System

Reinterventions Per Patient Year	All Subjects N=100	Coiling at Index N=73	No Coiling at Index N=27
All Reinterventions	**0.73**	**0.61**	**1.18**
Maturation Reinterventions	**0.36**	**0.31**	**0.55**
Superficialization	0.18	0.14	0.31
Coiling	0.16	0.14	0.24
Ligation of Tributaries	0.02	0.02	0.00
Maintenance Reinterventions	**0.37**	**0.31**	**0.65**
PTA	0.29	0.23	0.47
Stent Placement	0.04	0.02	0.08
Thrombolysis	0.04	0.05	0.00
Thrombectomy	0.02	0.00	0.08

52% fewer reinterventions when coiled at index procedure

Calculated as the total number of reinterventions divided by exposure (where exposure = subjects x mean duration of follow-up)
Each subject may have more than one type of reintervention; the individual rows do not necessarily sum to the summary rows.

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Catheter exposure

WavelinQ™
EndoAVF System

47 pre-dialysis subjects enrolled

24 initiated dialysis during study follow up

22 were catheter free within 30 days

21 were catheter free at 6-month follow-up

92%
initiated dialysis with WavelinQ™ EndoAVF (22/24)

Based upon dialysis log CRF (DA Data)

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Post-Market Study Summary

WavelinQ™
EndoAVF System

- Prospective post-market study of 100 subjects at 13 unique sites
- Data analyses pre-specified
- Key findings
  - ***Seven out of ten subjects were intervention free at 6 months***
    - 71% Primary Patency
  - ***Nearly half as many reinterventions (52%) required when coil embolization performed at index procedure***
    - 0.61 vs. 1.18 reinterventions PPY for coil vs. not coiled subjects
  - ***Most pre-dialysis subjects initiated hemodialysis without a catheter***
    - 92% (22/24) catheter free 0-30 days

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Consistent with previous findings

WavelinQ™
EndoAVF System

	EUR/CA Post-Market	NEAT[1]	EASE[2]
Device(s)	**6F & 4F**	6F	4F
Follow-up	**6 months**	12 months	6 months
Number of Subjects	**100**	60	32
Procedural Success	**94%**	98%	94%
Device-Related Serious Adverse Events	**3%**	2%	0%
Primary Patency	**71%**	69%	83%
Reinterventions per Patient Year	**0.73**	0.46	0.21
Catheter Free (pre-dialysis patients) at 30 days	**92%**	75%	n/a

1. Lok et al. Endovascular Proximal Forearm Arteriovenous Fistula for Hemodialysis Access: Results of the Prospective, Multicenter Novel Endovascular Access Trial Am J Kidney Disease 2017;70(4):486-497
2. Berland et al. Endovascular Creation of Arteriovenous Fistulae for Hemodialysis Access with a 4Fr Device: Clinical Experience from the EASE Study Annals of Vascular Surgery 2019;60:182-192

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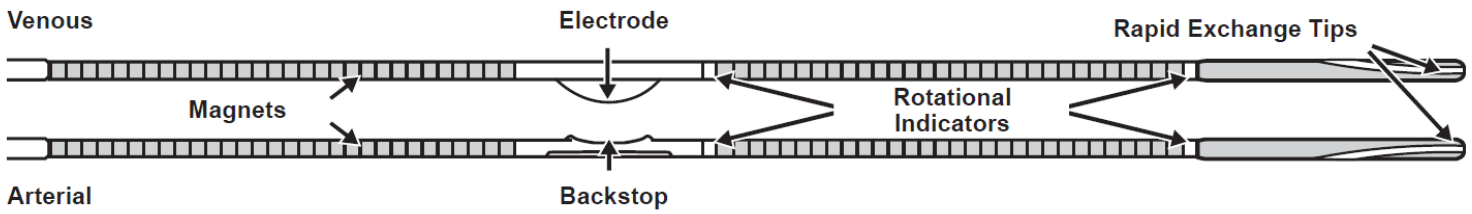
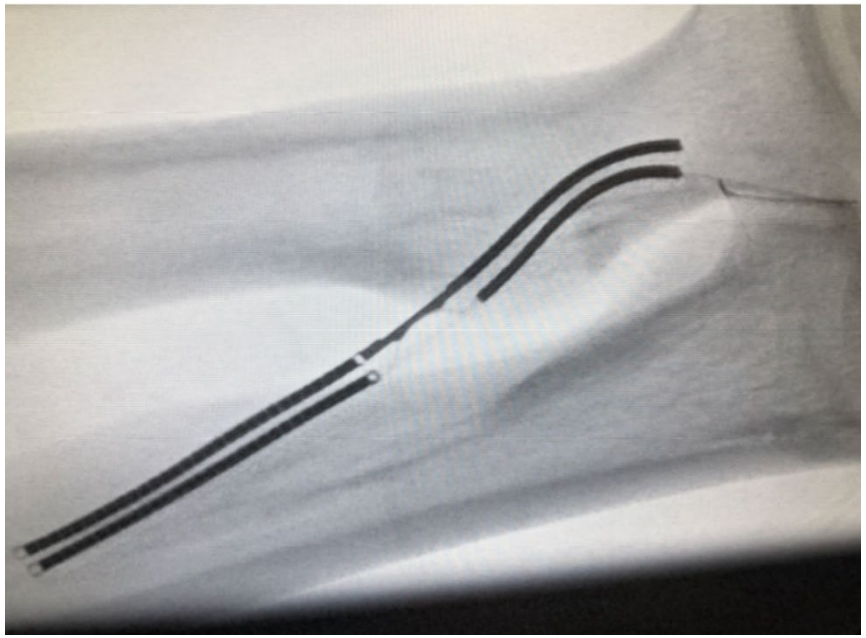
Third generation device

WavelinQ™
EndoAVF System

- WavelinQ™ EndoAVF System launched in Europe June 2020
- 4F catheters with new features to help enhance alignment
  - Additional rotational indicators
  - Additional magnets
  - Longer magnet arrays





Conclusions

WavelinQ™
EndoAVF System

- WavelinQ™ EndoAVF EUR/CA Post-Market Study demonstrates device performance consistent with previous studies

- BD is committed to continued clinical study of the next generation system in prospective, multi-center, multi-operator studies

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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 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. 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 WavelinQTM 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; eletrocution; 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 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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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/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.

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