First time announcement of clinical study protocols:

The WavelinQ™ arterio-venous endovascular fistula: a global, post-market investigation (WAVE-Global)

Post-market surveillance study of the WavelinQ™ EndoAVF System (CONNECT-AV)

Mr Nick Inston

Queen Elizabeth Hospital

University Hospitals Birmingham, UK

Disclosure

Speaker name:

Mr Nick Inston

I have the following potential conflicts of interest to report:

- ☒ Consulting BD Bard
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ☐ I do not have any potential conflict of interest

Disclaimer

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The opinions and clinical experiences presented herein are for informational purposes only. The results from this case report may not be predictive for all patients. Individual results may vary depending on a variety of patient specific attributes.

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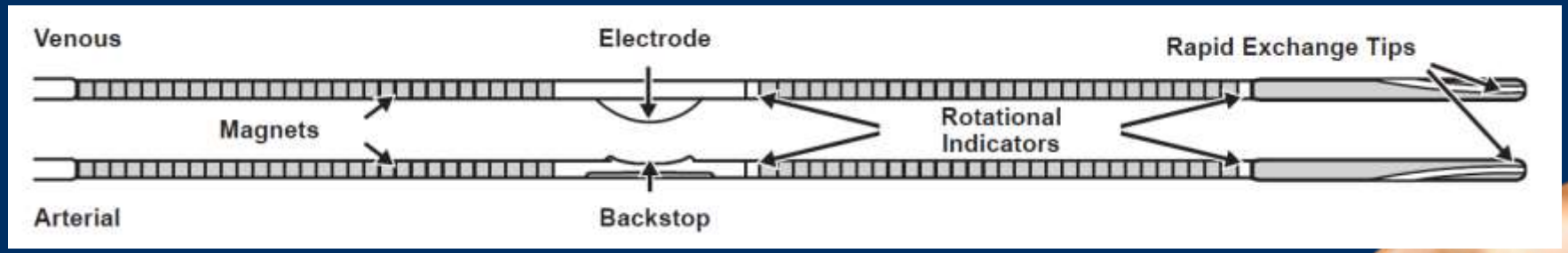
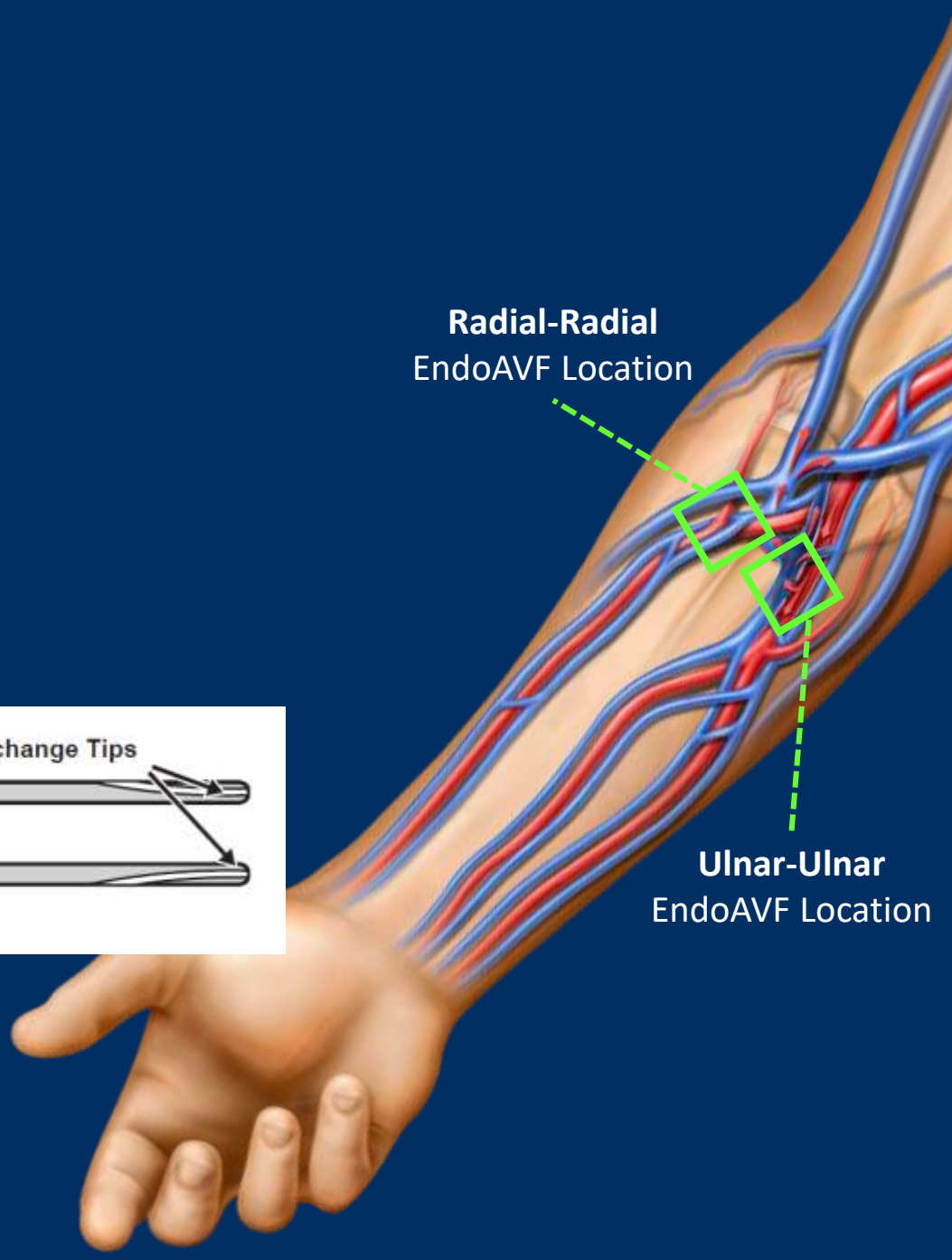
Study device & procedure





WAVE GLOBAL

The WavelinQ™ Arterio-Venous Endovascular Fistula: A Global, Post-Market Investigation

Charmaine Lok, MD, MSc

Nicholas Inston, MD, PhD

Panagiotis Kitrou, MD, MSc, PhD

1. PI investigators listed. Currently enrolling.

WAVE GLOBAL

Objective	A post-market study to observe the performance of the of the WavelinQ EndoAVF System when used for endovascular arteriovenous fistula (endoAVF) creation
Study Design	Prospective, single arm, multi-center, multi-operator NCT 04626427
Study Details	N=150 (estimated)
	Location(s): Global (excluding the US)
	Follow-up to 24 months
	Enrolling

Complete description available at www.clinicaltrials.gov NCT04626427

WAVE GLOBAL

Safety Primary Endpoint	Device and procedure related serious adverse events (SAE's) at 30 days
Efficacy Primary Endpoint	Number of post-creation interventions at 6 months
Secondary Endpoints	Device and procedure related SAE's at 6 and 24 months
	Physiological maturation at 6 weeks
	Cannulation success at 6 months
	Cumulative functional patency at 12 months

Complete description available at www.clinicaltrials.gov NCT04626427

WAVE GLOBAL

Key Inclusion Criteria	**Patient Criteria**
	Male or non-pregnant female ≥ 18 years and expected lifespan ≥ 24 months
	On hemodialysis at screening *or* in need of a vascular access for hemodialysis
	Adequate collateral circulation to the hand
	Anatomical Criteria
	Target vein ≥ 2.0mm
	Target artery ≥ 2.0mm
	Superficial outflow ≥ 2.5 in communication with target creation site via proximal forearm perforating vein (min. 1)

Complete description available at www.clinicaltrials.gov NCT04626427

WAVE GLOBAL

Key Exclusion Criteria	**Anatomical Criteria**
	Central venous stenosis/narrowing ≥ 50%, or any degree of central venous stenosis with accompanying signs or symptoms, on the same side as the planned AVF
	Absence of a proximal forearm perforating vein feeding the target cannulation vein(s) from the target creation
	Occlusion or stenosis ≥ 50% and/or accompanying signs or symptoms of target cannulation vein(s)
	Significantly compromised venous/arterial architecture (e.g. severe vessel calcification) or flow in the treatment arm
	Presence of significant calcification at the target endoAVF location that could potentially impact the effectiveness

Complete description available at www.clinicaltrials.gov NCT04626427

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CONNECTAV
CLINICAL STUDY

Post-Market Surveillance Study of the BD® WavelinQ™ EndoAVF System

Eric Peden, MD
Paul Kreienberg, MD

CONNECTAV CLINICAL STUDY

Objective	Post-market surveillance of the WavelinQ™ EndoAVF System in patients requiring hemodialysis
Study Design	Prospective, single arm, multi-center, multi-operator NCT 04634916

Study Details	N= 280 (estimated)
	Location: United States
	Follow-up to 24 months
	Upcoming

Complete description available at www.clinicaltrials.gov NCT04634916

CONNECTAV CLINICAL STUDY

Safety Primary Endpoint	Device and procedure related serious adverse events (SAE's) at 30 days

Efficacy Primary Endpoints	1. Functional cannulation success at 6 months 2. Primary patency at 6 months

Complete description available at www.clinicaltrials.gov NCT04634916

CONNECTAV
CLINICAL STUDY

Secondary Endpoints	1. Procedure success 2. Procedural adjunctive procedures 3. Physiological maturation- 2 wks, 6 wks, 6 and 24 months 4. Functional maturation- 6 wks; 3, 6, 12, 18, and 24 months 5. Cannulation success- 6 wks; 3, 6, 12, 18, and 24 months 6. Primary patency- 6 wks; 3, 12, 18, and 24 months 7. Assisted primary patency- 6 wks; 3, 6, 12, 18, and 24 months 8. Secondary patency- 6 wks; 3, 6, 12, 18, and 24 months 9. Functional patency- through 24 months 10. Functional cannulation success- 3, 12, 18, and 24 months 11. CVC exposure/use- 6 wks; 3, 6, 12, 18, and 24 months 12. Post procedural secondary procedures- 2, 6 wks; 3, 6, 12, 18, and 24 months

CONNECTAV
CLINICAL STUDY

Key Inclusion Criteria	**Patient Criteria**
	Male or non-pregnant female ≥ 18 years and expected lifespan ≥ 24 months
	On dialysis at screening or are in immediate need (within 6 months of endoAVF creation) of dialysis
	Adequate collateral circulation to the hand
	Anatomical Criteria
	Target vein ≥ 2.0mm
	Target artery ≥ 2.0mm
	Superficial outflow ≥ 2.5 in communication with target creation site via proximal forearm perforating vein (min. 1)

Complete description available at www.clinicaltrials.gov NCT04634916

CONNECTAV
CLINICAL STUDY

Key Exclusion Criteria	**Anatomical Criteria**
	Central venous stenosis/narrowing ≥ 50%
	Absence of a proximal forearm perforating vein feeding the target cannulation vein(s) from the target creation
	Occlusion or stenosis ≥ 50% and/or accompanying signs or symptoms of target cannulation vein(s)
	Significantly compromised venous/arterial architecture (e.g. severe vessel calcification) or flow in the treatment arm
	Presence of significant calcification at the target endoAVF location that could potentially impact the effectiveness

Summary

Announcing Two Prospective Multi-Center Studies

- Global patient population
- 430 subjects (est.)
- Key endpoints

  # of interventions, functional cannulation, primary patency

WAVE GLOBAL

CONNECTAV
CLINICAL STUDY

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.

CE
0344

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.

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

CE 0344

Thank you