BD | WavelinQ™ EndoAVF System

ENGLISH

Instructions For Use

WavelinQ™ EndoAVF System (REF WQ4300) Components

- WavelinQ™ Arterial Catheter
- WavelinQ™ Venous Catheter

WavelinQ™ EndoAVF System Rated Accessory Voltage

- WavelinQ™ Venous Catheter is rated for 700Vpeak

Commercially Available Devices

- Electrosurgical Unit: TVA or BD ESU-1
- Electrosurgical Pencil
  - Must have a 3 prong universal connector that interfaces with an ESU-1
  - Must have a minimum Rated Accessory Voltage of 700V and a yellow button that activates the generator.
- Ground Pad
  - Must have a universal connector that interfaces with an ESU-1
  - Must be rated to disperse a minimum of 60W for 2 seconds
- Arm Restraint
  - TZ Medical Arm Board (CZ-400-TVA) and Fixation Straps (TVA-MC-2)

Device Description

The WavelinQ™ EndoAVF System consists of two 4 French (4F) single-use, disposable, magnetic, hydrophilic coated catheters: a venous catheter and an arterial catheter (Figure 1). It is used with a commercially available ESU-1 Electrosurgical Unit (ESU) and Electrosurgical Pencil.

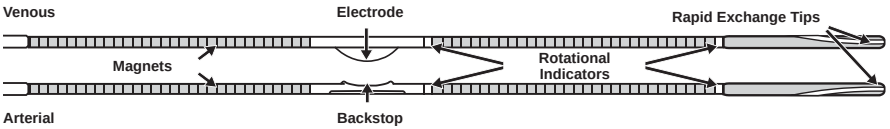

Figure 1. WavelinQ™ Venous and Arterial Catheter Cross-Section

The WavelinQ™ venous catheter is a flexible magnetic catheter that contains a radiofrequency (RF) electrode for the delivery of radiofrequency energy, a yellow hemostasis valve crosser (valve crosser) for interfacing with the introducer sheath on the distal end (Figure 2), and a cable and plug. The WavelinQ™ venous catheter connects via an Electrosurgical Pencil to an ESU for delivery of radiofrequency energy with standard grounding pads as described above.

Figure 2. WavelinQ™ Venous Catheter with Hemostasis Valve Crosser in place

The WavelinQ™ arterial catheter contains a backstop for receiving the electrode. When placed in proximity, the magnets contained in each catheter attract to each other, while aligning the electrode with the backstop. Rotational indicators, seen fluoroscopically, are present in each catheter and are used to accurately position the catheters. The catheters may be advanced and engaged in either a parallel (same direction) (Figure 3) or antiparallel (opposite direction) (Figure 4) configuration. Radiofrequency (RF) energy can then be delivered through the electrode for cutting and/or coagulating tissue. Figure 5 below shows the packaging layout and catheter identification.

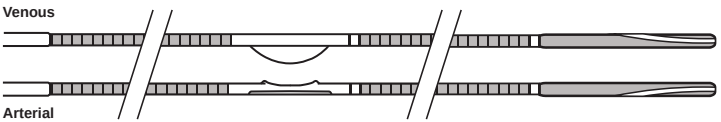

Figure 3. WavelinQ™ Venous and Arterial Catheter Parallel Configuration (same direction)

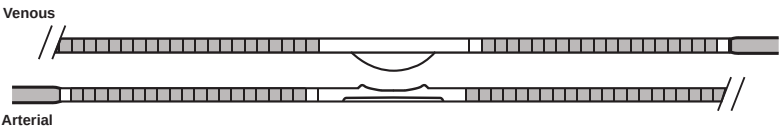

Figure 4. WavelinQ™ Venous and Arterial Catheter Antiparallel Configuration (opposite direction)

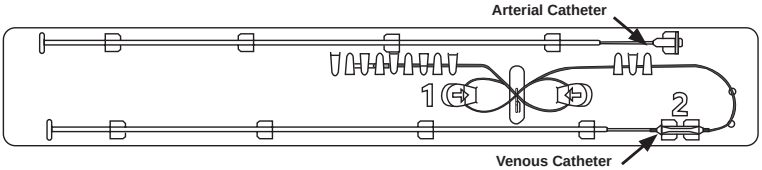

Figure 5. WavelinQ™ EndoAVF System Packaging and Catheter Identification

Specifications		
	WavelinQ™ Venous Catheter	**WavelinQ™ Arterial Catheter**
Maximum guidewire size	0.014 in (0.356 mm)	0.014 in (0.356 mm)
Catheter working length, cm/in	42 cm (16.4 in)	50 cm (19.7 in)
Length and location of hydrophilic coating	distal 26.4 cm (10.4 in)	distal 26.4 cm (10.4 in)
Maximum diagonal of square section	1.55 mm (0.061 in)	1.55 mm (0.061 in)
Minimum sheath introducer inner diameter	1.78 mm (0.070 in)	1.78 mm (0.070 in)
Recommended sheath introducer size	5 Fr	5 Fr
Rated Accessory Voltage	700 Vp	-
Electrosurgical Generator Settings	Cut T, 60 W, 0.7 Sec	-

Indications

The WavelinQ™ 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 vessels < 2mm in diameter.

Warnings

1. **The WavelinQ™ EndoAVF System is only to be used with the approved components specified above. 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.**
2. **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.**
3. **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.**
4. **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.**
5. **The WavelinQ™ EndoAVF System should not be used in patients who have known adverse reactions to moderate sedation and/or anesthesia.**
6. **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.**
7. **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.**
8. **Use caution when performing electrosurgery in the presence of pacemakers or implantable cardioverter defibrillators.**
9. **Improper use could damage insulation that may result in injury to the patient or operating room personnel.**
10. **Do not plug device into the electrosurgical pencil with ESU powered on.**
11. **Keep active accessories away from patient when not in use.**
12. **Do not permit cable to be parallel to and/or in close proximity to leads of other devices.**
13. **Do not wrap cable around handles of metallic objects such as hemostats.**
14. **Consult the ESU User Guide on its proper operation prior to use.**
15. **Do not use closure devices not indicated to close the artery used for access.**
16. **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.**
17. **The puncture site should be closed and hemostasis should be achieved by manual compression per the instructions below. Use of closure devices with the WavelinQ™ EndoAVF System may be associated with an increased risk of access site complications.**
18. **The WavelinQ™ 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 below.**
19. **Refer to the latest National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI) guidelines for recommendations and considerations for AV access creation in patients on or requiring hemodialysis. For patients expected to have prolonged durations on hemodialysis, a distal to proximal approach to AVF creation provides the best opportunity to preserve vessels for future vascular access sites following the individual patient ESKD Life-Plan.**
20. **This device is coated with a hydrophilic coating at the distal end of the device for a length of 26.4 cm (10.4 in). Please refer to the AVF Creation section 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

1. 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.
2. Adhere to universal precautions when utilizing the device.
3. 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.
4. Avoid sharp bends. This may cause the device to become inoperable.
5. Do not pinch or grasp the catheter with excessive force or with other instruments. This may cause the device to become inoperable.
6. Do not bend the rigid portion of the catheter near the electrode or backstop.
7. Do not touch or handle the active electrode. Electrode dislodgement may occur.
8. 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.
9. Do not attempt to remove the hemostasis valve crosser located on the venous device. Device damage or fracture may occur.

Precautions

1. Care should be taken to avoid the presence of fluid on the ESU.
2. 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.
3. Care should be taken to avoid attempting fistula creation in a heavily calcified location of a vessel as fistula may not be adequately formed.
4. 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.
5. Keep magnetic ends of catheters away from other metallic objects which may become attracted and collide with devices.
6. Some patients who have veins deeper than 6mm may require superficialization. Pre-planned vessel superficialization is acceptable and not considered an additional intervention for fistula maturation, per KDOQI Clinical Practice Guideline for Vascular Access: 2018.
7. Ensure the patient has adequate collateral blood flow to the hand before use of the device.
8. 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.
9. 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.
10. Avoid wiping the device with dry gauze as this may damage or contaminate the device coating.
11. Avoid excessive wiping of the coated device.
12. Avoid using alcohol, antiseptic solutions, or other solvents to pre-treat the device because this may cause unpredictable changes in the coating which could affect the device safety and performance.
13. Avoid pre-soaking devices for longer than instructed, as this may impact the coating performance.

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.

How Supplied

Packaging

The WavelinQ™ EndoAVF System is supplied STERILE and intended for single use only. Catheters are considered sterile only if the pouch is undamaged and unopened. The outer surfaces of the carton and pouch are NON-STERILE and must not be placed in the sterile field. Open the pouch using aseptic techniques so that its inner contents are delivered to the sterile field. The WavelinQ™ catheters are sterilized with ethylene oxide gas.

Storage

Store the WavelinQ™ EndoAVF System in a cool, dark, dry place. Do not expose to organic solvents, ionizing radiation, or ultraviolet light.

Additional Equipment

Vessel Access

- Ultrasound machine and ultrasound probe
- Two (2) 5 Fr introducer sheaths
- Two (2) 0.014" (0.356 mm) guidewires
- 4 Fr guide catheter (as needed)
- Tourniquet or blood pressure cuff
- Anticoagulant medication, as needed
- Vasodilator medication, as needed

Electrode Activation

- Electrosurgical Unit: TVA or BD ESU-1
- Electrosurgical Pencil
  - Must have a 3 prong universal connector that interfaces with an ESU-1
  - Must have a minimum Rated Accessory Voltage of 700V and a yellow button that activates the generator.
- Ground Pad
  - Must have a universal connector that interfaces with an ESU-1
  - Must be rated to disperse a minimum of 60W for 2 seconds
- Arm Restraint
  - TZ Medical Arm Board (CZ-400-TVA) and Fixation Straps (TVA-MC-2)

Note: While exhaustive, this equipment list is not meant to cover all possible scenarios.

Instructions For Use

Once the WavelinQ™ catheters are removed from their packaging, ensure all subsequent procedures are performed in a sterile field.

Inspection Prior to Use

1. Before removing the WavelinQ™ EndoAVF System from its packaging, carefully inspect the packaging for any evidence of damage. If there is evidence of damage, do not use the WavelinQ™ EndoAVF System.

Equipment Setup

2. The procedure should be performed in an angiography room and carried out under X-ray control.
3. Patient preparation and sterile precautions should be the same as for any percutaneous transcatheter procedure. The medication is decided by the physician, including anesthesia and precautions to reduce pain, clotting, and vasospasm during the procedure according to latest scientific guidelines and with respect to the individual patient.
4. Place ESU on a flat secure surface located near operative field making sure that the Ground Pad and Electrosurgical Pencil cabling have sufficient length to be connected during subsequent procedural steps.
5. Turn on ESU. Ensure the **Cut T** mode is illuminated, the power setting LED display reads **60 W**, and the maximum activation time of **0.7 SEC** is set in the time LED display.
6. Place ground pad on patient following standard guidelines for electrosurgical patient grounding and insert ground pad plug into ESU. Confirm indicator light changes from red to green ensuring appropriate patient contact.
7. Turn off ESU until ready for energy delivery in order to prevent inadvertent activation.

WavelinQ™ EndoAVF System Procedure

Vascular Access

8. Identify the vascular access location during pre-procedure planning. The arterial and venous access location may include upper arm access (brachial artery/vein) or venous wrist access (ulnar vein or radial vein).
9. Prepare the vascular access location with sterile preparation per hospital protocol.
10. Administer anesthesia or conscious sedation per hospital protocol.
11. Secure the patient's procedure arm in a restraint to prevent arm movement.
12. Use tourniquet or blood pressure cuff to facilitate vessel access as required per standard protocol.
13. Under ultrasound guidance, gain percutaneous access to target vein with a puncture needle. Devices can be introduced from an upper arm access (brachial vein) for the parallel configuration or from venous wrist access (ulnar vein or radial vein) for the antiparallel configuration.
14. Introduce a guidewire into the vein through the needle and advance an adequate length to facilitate introducer sheath insertion. A microintroducer sheath may be used to first confirm intraluminal position of guidewire.
15. Insert a 5 Fr sheath into the vein over the guidewire.
16. Inject contrast media and perform a venogram to assess appropriateness of vessel anatomy for procedure. Limit the dose of contrast depending on the patient's residual renal function. Alternate contrast methods may be used at the discretion of physician.
17. Under ultrasound guidance, gain access to the brachial artery with a puncture needle and introduce a guidewire.
18. Insert a 5 Fr sheath into the artery over the guidewire. Using physician discretion, administer anticoagulant and vasodilator intravenously.
19. Insert a 0.014" guidewire into the artery and deliver to the target AVF creation site.
20. Insert a 0.014" guidewire into the vein and deliver to the target AVF creation site.
21. Orient fluoroscope perpendicular to the target artery and vein using guidewires, ultrasound or contrast as guidance.
22. Remove tourniquet or blood pressure cuff (if applied).

Preparation of the Catheters

23. Carefully inspect the WavelinQ™ EndoAVF System pouch for any evidence of damage to the sterile barrier. If there is evidence of damage, do not use the WavelinQ™ EndoAVF System.
24. After inspection of the pouch, carefully peel open the pouch and transfer the sterile WavelinQ™ EndoAVF System to sterile field using standard transfer precautions.

AVF Creation

25. Remove the arterial catheter from the packing card and inspect for damage. Evaluate the distal end of the catheter. If it is suspected that the sterility or performance of the catheter has been compromised, the catheters should not be used.
26. Advance the arterial catheter over the 0.014" wire and insert through the arterial sheath, taking care not to kink the distal magnet arrays. Under fluoroscopic guidance, advance the catheter to the target AVF location.
27. Rotate the arterial catheter until the illumination of the rotational indicator is maximized and the concave surface of the backstop is pointed at the venous wire. See Figure 1 for catheter cross-section.
28. Remove the venous catheter from the packing card:
    a) Removing the plug and cable bundle from the card tabs
    b) Unclip the venous handle and then slide the catheter out of its containment tube. Refer to image of WavelinQ™ EndoAVF System catheters and packaging in "Device Description" section above. Do not remove the yellow hemostasis valve crosser.
29. Inspect the venous catheter for damage. If it is suspected that the sterility or performance of the catheter has been compromised, the catheter should not be used.

30. The hydrophilic coating on the catheters does not need to be hydrated or wiped prior to use.
31. Advance the venous catheter over the 0.014" wire until the yellow hemostasis valve crosser encounters the hemostasis valve of the introducer sheath. Grasp and insert the yellow hemostasis valve crosser through the hemostasis valve until it stops in the sheath hub. Grasp the proximal end of the yellow valve crosser and advance the catheter simultaneously through the yellow crosser and the sheath. Fluoroscopically inspect the electrode after venous catheter insertion to confirm proper electrode form. If the electrode appears deformed, gently remove venous catheter and inspect. If upon direct visual inspection the electrode appears damaged, replace the venous catheter. If venous catheter is removed and requires reinsertion, reposition the yellow valve crosser over the electrode prior to advancing through the hemostasis valve.

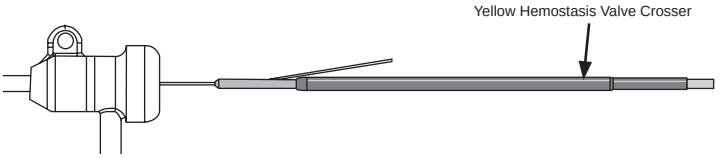

Figure 6. Venous Catheter & Valve Crosser, Pre-insertion

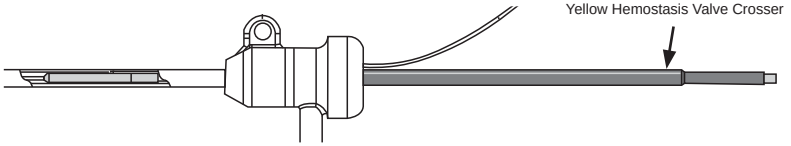

Figure 7. Venous Catheter & Valve Crosser, Post-insertion

32. Under fluoroscopic guidance, advance the venous catheter towards the target location until the distal magnets of the venous catheter begin to engage the first proximal magnets of the arterial catheter. In this location, pause to rotate the venous catheter until the illumination of the rotational indicator is maximized and the arc of the electrode is pointed at the arterial catheter. Adjust the arterial catheter as needed to confirm that catheters are aligned and prepared for venous catheter advancement. Advance the venous catheter until the arc of the electrode is congruent with concave surface of the arterial backstop. Electrode should appear compressed. Confirm that the distal rotational indicators appear aligned and rotationally similar.
33. Rotate the fluoroscope to visualize the maximum tissue thickness distance between arterial and venous catheters. Confirm that the tissue thickness adjacent to the electrode housing is no greater than the width of the magnet array which is 1mm. If tissue thickness appears greater, adjust catheter position to a thinner tissue segment.
34. With catheters in confirmed activation position, remove cable tie and connect venous catheter plug pin to electrosurgical pencil after removing pre-assembled insert. Fully insert the venous catheter plug pin until there is no metallic surface exposed.
35. Pass the Electrosurgical Pencil and 3 prong universal connector out of the sterile field and connect it to ESU's Monopolar 1 receiver.
36. Retract or remove both 0.014" guidewires from the catheter activation zone. No guidewires should be present between the proximal and distal magnet zones during activation.
37. Ensure tourniquet has been removed (if applied).
38. Do not allow catheters to move in order to minimize chance of misalignment.
39. Using fluoroscopy, verify final catheter and electrode position before energy delivery.

Figure 8. Activation Position – Parallel Alignment Configuration

40. Hold patient's procedure arm with firm pressure to minimize arm flexion and rotation during energy delivery.
41. Turn on ESU and again ensure the **Cut T** mode is illuminated, the power setting LED display reads **60 W**, and the maximum activation time of **0.7 SEC** is set in the time LED display.
42. While imaging with fluoroscopy, deliver RF energy by firmly pressing and holding the **yellow** cut switch on the electrosurgical pencil until the audible ESU activation tone stops. The electrode should visibly advance and touch the arterial backstop. If electrode does not contact backstop, an additional activation may be administered under the condition that the catheters have not been moved from their original position. Do not activate the device more than 3 times.

Figure 9. Electrode Advanced to Backstop

43. Remove the venous catheter. Remove the arterial catheter.
44. Perform arteriogram via the arterial sheath to confirm AVF creation. Alternate contrast methods may be used at the discretion of physician.

45. Embolization of a brachial vein is recommended at this stage of the procedure to redirect blood flow to the superficial veins and support maturation of the desired target cannulation area. Embolization is recommended during the index procedure for patients who have more than one brachial vein, where a brachial vein is observed to have significant outflow from the AVF. Embolization may not be needed in cases where the brachial vein outflow from the AVF is minimal. Follow manufacturer use and sizing recommendations per embolization device Instructions for Use. Brachial vein embolization could occur in previous steps depending on patient anatomy and physician discretion.
46. Remove the arterial sheath and venous sheath and achieve puncture site hemostasis using manual compression. The arterial access site should provide a bony backstop (the humerus bone) to aid in compression. The operator should hold manual compression using pressure from the hand/fingers directly over the puncture site and maintain pressure for at least 20 minutes. Hemostasis at access sites should be verified with ultrasound.

Device Disposal

WavelinQ™ EndoAVF System components that have been in contact with body fluids are a potential biohazard. Handle and dispose of the catheters and components using acceptable medical practice and all applicable local, provincial, and federal laws and regulations.

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WavelinQ™ EndoAVF System has been previously referred to as the everlinQ™ endoAVF System.

Summary of Supplementary Clinical Information (WavelinQ™ 4F EndoAVF System)

Objective

The WavelinQ™ 4F EndoAVF System was supported by a global analysis ("4Fr Global Analysis") that was designed to aggregate and analyze safety and performance data from the EASE, EASE-2, and EU Study studies of subjects treated with the WavelinQ™ 4F EndoAVF System.

Design

The three 4 Fr endoAVF studies were each prospectively planned and executed. Each study obtained the institutional Ethics Committee approval and all subjects provided informed consent prior to treatment. Data were collected via Case Report Forms and, as of this data freeze, approximately 80% of source documents were monitored. All procedural and post-procedural AEs and reinterventions were collected. Relevant safety events were submitted for independent CEC adjudication. Safety and performance data were collected on all study subjects during the follow-up period and the results reported here are the 6-month results of all available data. The three studies were evaluated for comparability from the perspectives of clinical study operations and statistics to assess whether the clinical studies were poolable.

Global Analysis Data Sources

Comparison and aggregation of the various data sources was possible due to similarities in investigational sites (EASE and EASE-2), study eligibility criteria, medical practice, follow-up procedures, and event adjudication across the studies, as well as use of the same study device; the WavelinQ™ 4F EndoAVF System. Table 1 provides a summary of the data sources used for this analysis.

Table 1. Details of the Studies in the 4 Fr Global Analysis

Data Source	Dates of Index Procedures	Number of Sites (Countries)	Subjects
EASE	May 2016 - November 2016	1 (Paraguay)	32
EASE-2	October 2017 – May 2018	1 (Paraguay)	24
EU Study (4 Fr)	October 2017 - May 2018	6 (3 Germany, 3 United Kingdom)	35
Total Subjects			**91**

Study Populations

The three studies enrolled subjects with chronic kidney disease who need hemodialysis and were candidates for percutaneous AVF creation with the WavelinQ™ 4F EndoAVF System. Subjects from the three studies were aggregated in the Pooled Population for all safety and effectiveness endpoints.

Inclusion/Exclusion Criteria

Eligibility criteria included subjects in need of vascular access for long-term hemodialysis, target artery and vein diameter each ≥2 mm. The core inclusion and exclusion criteria are consistent across the studies, indicating that study subjects enrolled in the three studies were similar with respect to eligibility criteria, baseline clinical and anatomic characteristics, and comorbidities.

Safety Endpoints

The safety endpoints are defined as the proportion of subjects with the following:

1. Significant Events
2. Serious Adverse Events (SAEs)
3. Device-related SAEs
4. Procedure-related SAEs
5. Closure device-related SAEs
6. Coil-related SAEs

Effectiveness Endpoints

The effectiveness endpoints are defined as the proportion of subjects with the following:

1. Procedure Success: Successful endoAVF creation is confirmed via intraprocedural angiography/fistulogram or duplex ultrasound verification performed post-procedure. This definition corresponds to the term "Technical Success" used by others.

2. Time to cannulation: The interval of time from the index procedure to the first successful 2-needle cannulation of the endoAVF.
3. Cannulation success: A successful cannulation of the endoAVF with 2-needles for dialysis. A subject may be called a 'cannulation success' with the first successful 2-needle cannulation of the endoAVF.
4. Primary patency: The interval from the time of access placement until any intervention designed to maintain or reestablish patency, access thrombosis, access abandonment, or the time of measurement of patency (SVS Reporting Standards definition).
5. Modified primary patency: Identical to Primary Patency except that loss was also triggered by reinterventions not directly related to the access circuit; namely coiling or vessel ligation of venous outflow tributaries to encourage flow into the superficial, more easily accessible veins of the upper arm.
6. Assisted primary patency: The interval from access placement to thrombosis or abandonment; not triggered by access circuit interventions performed in the absence of occlusion.
7. Secondary patency: The interval from the time of access placement until access abandonment, lost to thrombosis, or the time of patency measurement including intervening manipulations (surgical or endovascular interventions) designed to reestablish functionality in thrombosed access (SVS Reporting Standards definition).
8. Functional patency: The interval of time from the first 2-needle dialysis utilizing the access until access abandonment (SVS Reporting Standards definition)
9. Functional cannulation: Successful 2-needle access of the endoAVF access circuit with performance of more than 2/3rds of dialysis sessions of at least 120 minutes in duration over a continuous 28-day period. This measure was defined to more aptly measure whether an endoAVF resulted in a working access site for a subject, and is more pertinent to a subject, as opposed to Successful Cannulation, which is limited to completing a single successful 2-needle cannulation.

Compliance

The follow-up compliance is summarized in Table 2. The protocol-specified follow-up duration was 6 months for the EASE and EASE-2 studies and 12 months in the EU Study. Follow-up is complete for EASE but is ongoing for EASE-2 and the EU Study. The analysis presented here (and the corresponding follow-up compliance) is based on all available data and follow-up visits completed through 6-months.

Follow-up intervals for the analyses were constructed to conform to generally accepted intervals, since each study had different follow-up schedules. The intervals in the table include the post-operative period (index procedure through 10 days), 30 days (11 – 45 days), 3 months (46 – 135 days), 6 months (136 – 210 days). Subjects were withdrawn when they exited a study due to an unsuccessful index procedure, abandonment or failure of the endoAVF, death, exit due to adverse event, investigator decision, or loss to follow-up. The breakdown of subject disposition is provided in Figure 12.

Table 2. Follow-Up Compliance

Visit Data	EASE	EASE-2	EU	Pooled
Enrolled Subjects	32	24	35	91
Post-Operative (0-10 Days)				
Eligible Subjects	32	23	34	89
Subjects Not Eligible	0	1	1	2
Follow-Up Not Done in Eligible Subjects	0	0	3	3
Follow-Up Visit Within Window	32	23	31	86
Follow-Up Visit Compliance	100.0%	100.0%	91.2%	91.2%
30-Day (11 – 45 Days)				
Eligible Subjects	29	23	30	82
Subjects Not Eligible	3	1	5	9
Follow-Up Not Done in Eligible Subjects	5	2	2	9
Follow-Up Visit Within Window	24	21	28	73
Follow-Up Visit Compliance	82.8%	91.3%	93.3%	89.0%
3-Month (46 – 135 Days)				
Eligible Subjects	25	21	30	76
Subjects Not Eligible	7	3	5	15
Follow-Up Not Done in Eligible Subjects	10	3	1	14
Follow-Up Visit Within Window	15	18	29	62
Follow-Up Visit Compliance	60.0%	85.7%	96.7%	81.6%
6-Month (136 – 210 Days)				
Eligible Subjects	23	10	22	55
Subjects Not Eligible	9	14	13	36
Follow-Up Not Done in Eligible Subjects	1	3	5	9
Follow-Up Visit Within Window	22	7	17	46
Follow-Up Visit Compliance	95.7%	70.0%	77.3%	83.6%

Eligible subjects are all subjects who are enrolled by snapshot date and either had a follow-up visit or are past due for their follow-up visit.

Not eligible subjects are not eligible for the analysis because they have exited the study, or they have not reached the end of the follow-up visit window and are not yet exited or determined to have missed the visit. Subjects were withdrawn when they exited a study due to an unsuccessful index procedure, abandonment or failure of the endoAVF, death, exit due to adverse event, investigator decision, or loss to follow-up. The breakdown of subject disposition is provided in Figure 12.

Follow-Up Visit Compliance is the number of subjects who had follow-up visits within the window divided by total number of eligible subjects in the window.

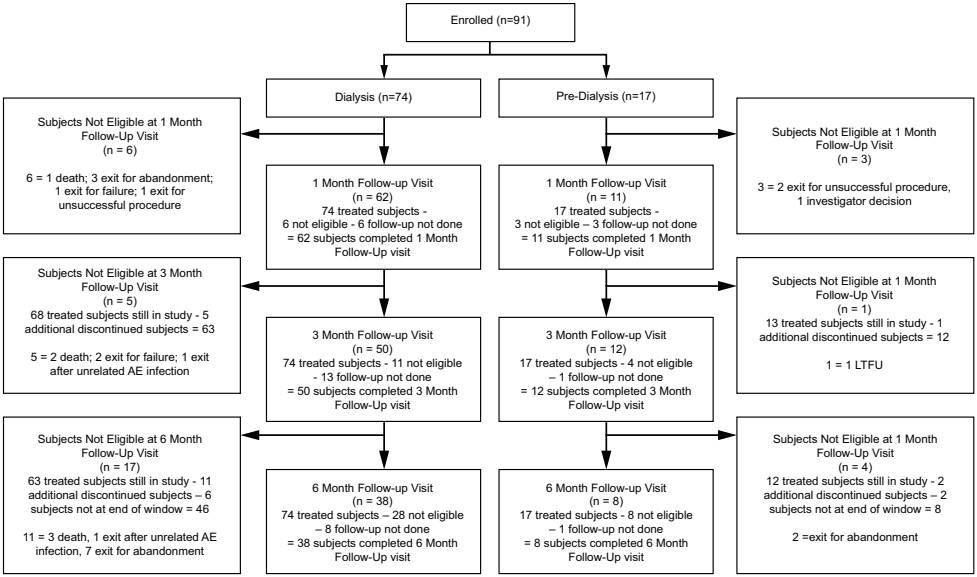


Figure 10. Breakdown of Subject Disposition

Demographics

Demographics for the Pooled Population and each individual study Population are provided in Table 3 below.

Table 3. Demographics and Baseline Characteristics

Characteristic	Statistic	EASE (N=32)	EASE-2 (N=24)	EU Study (N=35)	Pooled (N=91)
Gender					
Male	n/N (%)	31/32 (96.9%)	18/24 (75.0%)	27/35 (77.1%)	76/91 (83.5%)
Female	n/N (%)	1/32 (3.1%)	6/24 (25.0%)	8/35 (22.9%)	15/91 (16.5%)
Age					
	Mean ± SD	50.9±12.9	49.0±11.1	60.5±16.3	54.1±14.7
	Min, Max	21.0-71.0	25.0-65.0	27.0-85.0	21.0-85.0
	Median	52.0	50.5	65.0	55.0
	IQR	46.5,59.5	42.0,57.0	52.0,73.0	47.0,65.0
Race*					
Caucasian	n/N (%)	0/32 (0.0%)	0/24 (0.0%)	24/35 (68.6%)	24/91 (26.4%)
Black	n/N (%)	0/32 (0.0%)	0/24 (0.0%)	0/35 (0.0%)	0/91 (0.0%)
Asian	n/N (%)	0/32 (0.0%)	0/24 (0.0%)	4/35 (11.4%)	4/91 (4.4%)
Indian	n/N (%)	0/32 (0.0%)	0/24 (0.0%)	4/35 (11.4%)	4/91 (4.4%)
Other	n/N (%)	0/32 (0.0%)	0/24 (0.0%)	1/35 (2.9%)	1/91 (1.1%)
Not Reported	n/N (%)	32/32 (100.0%)	24/24 (100.0%)	2/35 (5.7%)	58/91 (63.7%)
Ethnicity					
Not Hispanic or Latino	n/N (%)	0/32 (0.0%)	0/24 (0.0%)	35/35 (100.0%)	35/91 (38.5%)
Hispanic or Latino	n/N (%)	32/32 (100.0%)	24/24 (100.0%)	0/35 (0.0%)	56/91 (61.5%)
Height (cm)					
	Mean ± SD	170.4±9.6	165.7±11.7	171.5±7.8	169.6±9.8
	Min, Max	152.0-189.0	140.0-186.0	150.0-188.0	140.0-189.0
	Median	170.0	165.0	170.0	170.0
	IQR	164.5,177.0	157.5,172.0	167.0,175.0	164.0,175.0
Weight (kg)					
	Mean ± SD	75.6±13.0	65.8±16.2	83.7±22.8	76.1±19.3
	Min, Max	54.0-114.0	30.0-109.0	53.0-168.9	30.0-168.9
	Median	73.5	63.1	77.3	73.4
	IQR	64.9,81.0	55.0,74.5	70.0,93.3	64.2,82.0

Table cont. next page

Table 3. Demographics and Baseline Characteristics

Characteristic	Statistic	EASE (N=32)	EASE-2 (N=24)	EU Study (N=35)	Pooled (N=91)
BMI					
	Mean ± SD	25.9±3.1	24.1±3.0	28.6±8.1	26.5±5.8
	Min, Max	20.7-32.6	17.7-31.5	16.7-57.8	16.7-57.8
	Median	25.3	23.6	27.8	24.8
	IQR	23.5,27.2	22.5,25.9	23.9,32.6	23.4,28.4
Systolic BP					
	Mean ± SD	163.5±26.0	161.5±35.0	142.6±21.4	154.9±28.5
	Min, Max	120.0-250.0	84.0-248.0	109.0-212.0	84.0-250.0
	Median	160.0	160.5	141.0	150.0
	IQR	146.5,178.5	145.0,187.5	125.0,158.0	140.0,169.0
Diastolic BP					
	Mean ± SD	102.2±19.3	107.0±18.9	73.8±9.6	92.5±21.9
	Min, Max	45.0-140.0	60.0-142.0	50.0-90.0	45.0-142.0
	Median	100.5	106.5	71.0	90.0
	IQR	90.0,111.5	98.5,123.0	69.0,83.0	74.0,109.0

**Race was not entered in EASE or EASE-2 subjects; rather, only ethnicity was specified, and all subjects were Hispanic. The Pooled data for race comprise only EU Study subjects.*

Procedural Characteristics

The procedural characteristics for the Pooled Population and each individual study Population are show below in Table 4. Characteristics include endoAVF location, arm, access sites, and access and target vessel diameters.

Table 4. Procedural Characteristics

Parameter	EASE (N=32)	EASE-2 (N=24)	EU Study (N=35)	Pooled (N=91)
endoAVF Location				
Ulnar-Ulnar	12/32 (37.5%)	19/24 (79.2%)	35/35 (100.0%)	66/91 (72.5%)
Radial-Radial	20/32 (62.5%)	5/24 (20.8%)	0/35 (0.0%)	25/91 (27.5%)
Arm				
Right	7/32 (21.9%)	7/24 (29.2%)	8/35 (22.9%)	22/91 (24.2%)
Left	25/32 (78.1%)	17/24 (70.8%)	27/35 (77.1%)	69/91 (75.8%)
Access Artery*				
Radial	19/32 (59.4%)	6/24 (25.0%)	0/35 (0.0%)	25/91 (27.5%)
Brachial	9/32 (28.1%)	2/24 (8.3%)	6/35 (17.1%)	17/91 (18.7%)
Ulnar	4/32 (12.5%)	16/24 (66.7%)	29/35 (82.9%)	49/91 (53.8%)
Access Vein				
Radial	17/32 (53.1%)	2/24 (8.3%)	0/35 (0.0%)	19/91 (20.9%)
Brachial	13/32 (40.6%)	5/24 (20.8%)	24/35 (68.6%)	42/91 (46.2%)
Ulnar	2/32 (6.3%)	12/24 (50.0%)	10/35 (28.6%)	24/91 (26.4%)
Access Vein Diameter (mm)				
Mean ± SD	3.0±0.8	3.5±0.5	NR	3.2±0.8
Range	1.6-4.7	2.0-4.5	NR	1.6-4.7
Median	2.9	3.5	NR	3.4
IQR	2.3,3.7	3.1,3.8	NR	2.7,3.8
Access Artery Diameter (mm)				
Mean ± SD	3.2±1.1	4.6±0.8	4.7±0.9	4.2±1.2
Range	1.4-5.9	3.2-6.2	3.3-7.4	1.4-7.4
Median	2.8	4.8	4.7	4.3
IQR	2.4,4.1	4.1,5.0	4.0,5.3	3.5,5.0
Target Vein Diameter (mm)				
Mean ± SD	2.7±0.8	3.4±0.8	2.7±0.5	2.9±0.8
Range	1.6-4.8	2.0-4.9	1.8-3.7	1.6-4.9
Median	2.7	3.6	2.5	2.7
IQR	2.1,3.2	3.0,3.9	2.3,3.1	2.3,3.4
Target Artery Diameter (mm)				
Mean ± SD	3.0±0.7	3.9±0.8	3.8±0.7	3.6±0.8
Range	1.9-4.6	2.6-5.5	2.1-5.8	1.9-5.8
Median	2.9	4.0	3.8	3.6
IQR	2.5,3.6	3.6,4.3	3.2,4.4	2.9,4.1

Table cont. next page

Table 4. Procedural Characteristics

NR- Not Reported
IQR- Interquartile range
Categorical variables are tabulated as n/N.
** Although arterial access was performed using the brachial artery, radial artery, and ulnar artery, device safety and performance via radial artery and ulnar artery 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.*

Safety Results

The Global Analysis of the WavelinQ™ EndoAVF (4 Fr) aggregate safety data is summarized in Table 5. The Pooled Population comprises aggregated data from the 91 subjects enrolled in the three 4 Fr studies. Adverse events were site-reported and reviewed by an independent Medical Monitor and the Clinical Events Committee (CEC). The Investigators reported all events that, in their opinion, were related to the device, to the index procedure, to other subsequent procedures that were in any way related to the index procedure (e.g. reinterventions), or to the access circuit. As well, all deaths were reported.

In total, 22.0% (20/91) of the 4 Fr endoAVF subjects experienced a significant event. These including stenosis, occlusion, thrombosis, and pseudoaneurysm of the access circuit and/or endoAVF, as well as one subject with abandonment of the endoAVF after a cannulation induced brachial artery injury.

SAEs were reported in 26.4% (24/91) of the Pooled Population. Of these events, 18/24 (75.0%) were unrelated to the device and unrelated to the procedure and included 6 unrelated deaths, 3 unrelated infections, 3 access circuit stenoses, 2 access circuit thromboses, 1 access circuit false aneurysm, 1 endoAVF thrombosis, 1 endoAVF stenosis, and 1 myocardial infarction. There were 3 device-related SAEs reported in the studies (3/91, 3.3%) and included 1 thrombosis of the endoAVF, 1 stenosis of the endoAVF, and 1 access circuit false aneurysm. There were 5 procedure related SAEs reported in 5.5% (5/91) of the Pooled Population and included 2 endoAVF stenoses, 1 access circuit hematoma, 1 access circuit false aneurysm, and 1 endoAVF thrombosis. None of the SAEs were related to the method of arterial access for the procedure. There were no reports of Unanticipated Adverse Device Effects (UADEs).

Based on numerical comparisons, the safety outcomes demonstrate an improved safety profile of the subject device compared to the predicate device in terms of device-related and procedure-related SAEs. Only 6.6% (6/91) of the subject device cohort experienced a device- or procedure-related SAE compared to 12.0% (15/125) of the predicate device cohort. The subject device cohort was free of access-related SAEs compared to 5.6% of the predicate device cohort. There were no coil-related SAEs in the subject device cohort, as with the predicate device cohort.

Table 5. Principal Safety Endpoints of the 4 Fr Studies

Endpoint	EASE (N=32)	EASE-2 (N=24)	EU Study (N=35)	Pooled (N=91)
Safety Endpoints (through last follow-up)				
Significant Event*	4/32(12.5%)	4/24(16.7%)	12/35(34.3%)	20/91(22.0%)
SAE (including unrelated events)	7/32(21.9%)	6/24(25.0%)	11/35(31.4%)	24/91(26.4%)
Device-Related SAE	0/32(0%)	2/24(8.3%)	1/35(2.9%)	3/91(3.3%)
Procedure-Related SAE	1/32(3.1%)	1/24(4.2%)	3/35(8.6%)	5/91(5.5%)
Closure Device-Related SAE	0/32(0%)	0/24(0%)	0/35(0%)	0/91(0%)
Coil-Related SAE	0/32(0%)	0/24(0%)	0/35(0%)	0/91(0%)

This summary table is intended to provide standalone results for the most important study endpoints.

The safety endpoints are tabulated on a per-subject basis and represent the number of subjects who experienced at least one event of the specified category over the duration follow-up.

SAE- Serious Adverse Event as adjudicated by the CEC, reported at any time during follow-up.

**Significant Events were classified by the independent Medical Monitor and included device or procedure-related adverse events that either a) could be limb-threatening if not promptly identified or treated, or b) required additional therapy to reestablish patency of the endoAVF access circuit, irrespective of whether they met the criteria for an SAE.*

Effectiveness Results

A summary of the effectiveness outcomes is tabulated in the main summary Table 6 below. Procedural Success[1], defined as the successful creation of an endoAVF with blood flow confirmed intraoperatively by fistulography or postoperative duplex ultrasonography, was achieved in 96.7% (88/91) of the Pooled Population.

Cannulation Success was defined as 2-needle access and hemodialysis through the endoAVF. Cannulation Success was calculated for all subjects and for the subset of those who were on dialysis at the time of enrollment. Using Kaplan-Meier (K-M) point estimates at month 6, the cannulation success rate was 67.5% ± 5.9% for all subjects and 84.9% ± 5.3% for subjects in the dialysis subset[2]. Compared to the results for the predicate device, the 6 month cannulation success rate was 78.4% ± 4.8% for all subjects and 78.4% ± 4.8% for subjects in the dialysis subset.

Primary, Assisted Primary, and Secondary Patency were defined according to the Society of Vascular Surgery (SVS) reporting standards. Rates were determined using the K-M point estimates at month 6. The SVS reporting standards advocate K-M curves to estimate patency. K-M methodology is particularly important in the hemodialysis population, where medical comorbidities cause a relatively high rate of censoring from mortalities, missed visits, and other events unrelated to the fistula. For these reasons and noting that loss of patency can occur at any time rather than at discrete follow-up visits, K-M estimates and Standard Errors (SE) were utilized to express patency.

Primary Patency was achieved in 72.4% ± 5.2%. at 6 months. Corresponding rates for Assisted Primary and Secondary Patency were each 77.3% ± 5.0%. As an additional measure of patency, a modification of the SVS-defined Primary Patency rate was used. This measure, Modified Primary Patency, was identical to Primary Patency except that loss was also triggered by reinterventions not directly related to the access circuit; namely coiling or vessel ligation of venous outflow tributaries to encourage flow into the superficial, more easily accessible veins of the upper arm[3]. Modified Primary Patency was achieved in 69.7%(±5.4%)at 6 months in the Pooled Population.

At 6 months, 46/55 eligible subjects in the Pooled Population completed follow-up within the window, while 36 subjects were not eligible. Not eligible subjects were not eligible for the analysis because they exited the study, or they have not reached the end of the follow-up visit window and are not yet exited or determined to have missed the visit. Table 2 and Figure 12, shown previously, illustrate follow-up compliance and subject disposition.

[1] This definition is analogous to the term "Technical Success" that others have used.
[2] The dialysis subset is the cohort of subjects who were enrolled on hemodialysis or initiated hemodialysis at any point in follow up
[3] Loss of Modified Primary Patency was not triggered by coiling or surgical outflow vein ligation performed during the index procedure. Only secondary interventions were included in the definition of Modified Primary Patency.

Table 6. Principal Effectiveness Endpoints of the 4 Fr Studies Through 6 Months

Endpoint	EASE (N=32)	EASE-2 (N=24)	EU Study (N=35)	Pooled (N=91)
Procedural Success	32/32 (100.0%)	23/24 (95.8%)	33/35 (94.3%)	88/91 (96.7%)
Time to Successful Cannulation (Months)				
Observations	21	13	15	49
Median [IQR]	1.3[1.1,1.6]	1.1[1.1,1.3]	2.6[2.0,3.6]	1.5[1.1,2.0]
Mean ± SD	1.4±0.5	1.2±0.3	3.4±2.4	2.0±1.6
(Min, Max)	(1.0,3.0)	(0.7,2.0)	(1.1,11.0)	(0.7,11.0)
Endpoint	**EASE**	**EASE-2 (N=24)**	**EU Study (N=35)**	**Pooled (N=91)**
Effectiveness Endpoints (6-month Kaplan-Meier estimates for all time points after the index procedure)				
Cannulation Success (All Subjects) ‡	83.5%(±8.1%)	68.2%(±11.5%)	48.7%(±9.5%)	67.5%(±5.9%)
Cannulation Success (Dialysis Subset)	87.8%(±7.6%)	73.3%(±11.4%)	77.3%(±9.8%)	84.9%(±5.3%)
Functional Cannulation (All Subjects) ‡	85.8%(±7.5%)	78.7%(±16.1%)	37.0%(±9.5%)	61.5%(±6.2%)
Functional Cannulation (Dialysis Subset)	90.0%(±6.6%)	100%(±0%)	60.7%(±12.2%)	78.5%(±6.2%)
Primary Patency	84.1%(±6.5%)	69.5%(±11.8%)	63.3%(±8.9%)	72.4%(±5.2%)
Modified Primary Patency	84.1%(±6.5%)	69.5%(±11.8%)	56.5%(±9.2%)	69.7%(±5.4%)
Assisted Primary Patency	87.3%(±5.9%)	69.5%(±11.8%)	72.6%(±8.4%)	77.3%(±5%)
Secondary Patency	87.3%(±5.9%)	69.5%(±11.8%)	72.6%(±8.4%)	77.3%(±5%)
Functional Patency	100%(±0%)	90.0%(±9.5%)	69.4%(±15.5%)	90.0%(±4.8%)

This summary table is intended to provide standalone results for the most important study endpoints.

‡Cannulation Success and Functional Cannulation are specified in the full dataset (labeled as "All Subjects"), including subjects who undergo endoAVF creation when they are not yet on dialysis. The time to Cannulation Success may be longer and the rate of Cannulation Success and of Functional Cannulation may be reduced at each timepoint since the estimates include subjects who are enrolled before they are on dialysis; thus, the estimate in the total study population is conservative to the extent that there exist endoAVF suitable for cannulation and dialysis although dialysis is not yet required. A second analysis comprises the subset who were enrolled while on dialysis or began dialysis during the study ("Dialysis Subset").

Procedural Success was defined as successful endoAVF creation confirmed via intraprocedural fistulography or by duplex ultrasound performed post-procedure.

The 6-month window is defined as 136 to 210 days. The effectiveness data in this table represent 6-month Kaplan-Meier estimates for all time points after the index procedure.

Time to Cannulation is the time between the index procedure to the first successful endoAVF cannulation. Cannulation Success was defined as successful 2-needle cannulation and dialysis through the endoAVF.

Functional Cannulation is defined as 2-needle access of the endoAVF access circuit with performance of ≥ 2/3rds of ≥ 120-minute dialysis sessions through the endoAVF access circuit over a continuous 28-day period. Functional Cannulation is expressed as the Kaplan-Meier estimate (Standard Error).

Patency definitions are from the Society of Vascular Surgery Reporting Standards document; Sidawy et al. Recommended standards for reports dealing with arteriovenous hemodialysis accesses, J Vasc Surg 2002;35:603-10. Primary patency is the interval of time of 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 is the interval from access placement to thrombosis or abandonment; not triggered by access circuit interventions performed in the absence of occlusion. Secondary patency is the interval of time of access placement until access abandonment, lost 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 is the interval of time from the first 2-needle dialysis utilizing the access until access abandonment.

Patency rates are expressed as Kaplan-Meier estimates (± Standard Error).

Confidence intervals were not adjusted for multiplicity.

Subset Analysis – Brachial, Ulnar, and Radial Arterial Access

The 4 Fr endoAVF System was studied in both a parallel and anti-parallel configuration. The parallel configuration denotes arterial and venous access at the same location with the devices inserted in the same direction. The anti-parallel configuration is used when the artery and vein are accessed at different locations, and the devices are inserted in opposite directions. Although arterial access was performed using the brachial artery, radial artery, and ulnar artery, device safety and performance via radial artery and ulnar artery access has not been fully established. The subset analysis is presented in Table 7, below.

Table 7. Subset Analysis – Access Artery*

	Pooled Population		
	Brachial	**Ulnar**	**Radial**
Subjects	17/91 (18.7%)	49/91 (53.8%)	25/91 (27.5%)
Safety Endpoints (through last follow-up)			
Significant Events	3/17(17.6%)	12/49(24.5%)	5/25(20.0%)
SAE	5/17(29.4%)	15/49(30.6%)	4/25(16.0%)
Device-Related SAE	0/17(0%)	3/49(6.1%)	0/25(0%)
Procedure-Related SAE	1/17(5.9%)	4/49(8.2%)	0/25(0%)
Arterial Access-Related SAE	0/17(0%)	0/49(0%)	0/25(0%)

Table cont. next page

Table 7. Subset Analysis – Access Artery*			
Closure Device-Related SAE	0/17(0%)	0/49(0%)	0/25(0%)
Coil-Related SAE	0/17(0%)	0/49(0%)	0/25(0%)
Effectiveness Endpoints (6-month Kaplan-Meier estimates for all time points after the index procedure)			
Procedural Success	16/17 (94.1%)	47/49 (95.9%)	25/25 (100.0%)
Time to Successful Cannulation (Months):			
N	11	24	14
median [IQR]	1.5[1.1,2.0]	1.7[1.1,2.8]	1.4[1.1,1.6]
mean ± SD	2.3±2.9	2.1±1.2	1.5±0.5
(min, max)	(1.0,11.0)	(0.7,5.4)	(1.0,3.0)
Cannulation Success, 6-Month, All Subjects	71.4%(±12.1%)	62.1%(±8.3%)	82%(±10.7%)
Cannulation Success, 6-Month, Dialysis Subgroup	83.3%(±10.8%)	85.5%(±7.4%)	87.1%(±10.8%)
Functional Cannulation, 6-Month, All Subjects	57.1%(±13.2%)	56.3%(±8.7%)	85.4%(±9.5%)
Functional Cannulation, 6-Month, Dialysis Subgroup	69.2%(±12.8%)	78.9%(±9.2%)	91.7%(±7.8%)
Primary Patency, 6-Month	79.3%(±10.7%)	67.1%(±7.6%)	78.5%(±8.6%)
Modified Primary Patency, 6-Month	79.3%(±10.7%)	62%(±7.9%)	78.5%(±8.6%)
Assisted Primary Patency, 6-Month	79.3%(±10.7%)	74.4%(±7.1%)	82.9%(±7.8%)
Secondary Patency, 6-Month	79.3%(±10.7%)	74.4%(±7.1%)	82.9%(±7.8%)
Functional Patency, 6-Month	78.8%(±13.4%)	88.6%(±7.8%)	100%(±0%)

All effectiveness endpoints except Procedure Success and Time to Cannulation are K-M estimates ± SE.

Confidence intervals were not adjusted for multiplicity.

* *Although arterial access was performed using the brachial artery, radial artery, and ulnar artery, device safety and performance via radial artery and ulnar artery 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.*

Subset Analysis – Radial vs. Ulnar endoAVF

Among the 91 subjects in the Pooled Population of 4 Fr endoAVF subjects, the fistulae were radial-radial (radial artery-to-radial vein) in 25 subjects (27.5%) and ulnar-ulnar (ulnar artery-to-ulnar vein) in 66 subjects (72.5%). The rate of significant events was similar in the two subgroups (20.0% vs 22.7%). Regarding SAEs, there were only 3 device-related SAEs in the entire cohort and these occurred in the ulnar subgroup (3/66, 4.5%). There were only 5 procedure-related SAEs in the entire cohort and these occurred in the ulnar subgroup (5/66, 7.6%). There were no arterial access SAEs in either of the subgroups (0/91, 0.0%).

In sum, the safety after the radial and ulnar endoAVF procedure was similar, as evidenced by comparably low rates of device and procedure-related SAEs. Performance was not different with 4 Fr radial or ulnar endoAVF with the single exception of improved all-subject Cannulation Success in the radial-radial group compared to the ulnar-ulnar group. These results confirm the safety and performance of radial-radial compared to the ulnar-ulnar endoAVF procedure with the 4 Fr endoAVF System. The safety and effectiveness data with the two endoAVF options is presented in Table 8, below.

Table 8. Subset Analysis – Radial and Ulnar AVF		
	Pooled Population	
	Radial	**Ulnar**
Subjects	25/91(27.5%)	66/91(72.5%)
Safety Endpoints (through last follow-up)		
Significant Events	5/25(20%)	15/66(22.7%)
SAE	5/25(20%)	19/66(28.8%)
Device-Related SAE	0/25(0%)	3/66(4.5%)
Procedure-Related SAE	0/25(0%)	5/66(7.6%)
Arterial Access-Related SAE	0/25(0%)	0/66(0%)
Closure Device-Related SAE	0/25(0%)	0/66(0%)
Coil-Related SAE	0/25(0%)	0/66(0%)
Effectiveness Endpoints (6-month Kaplan-Meier estimates for all time points after the index procedure)		
Procedural Success	25/25 (100.0%)	63/66 (95.5%)
Time to Successful Cannulation (Months):		
N	13	36
median [IQR]	1.3[1.1,1.6]	1.6[1.1,2.2]
mean ± SD	1.4±0.5	2.2±1.9
(min, max)	(1.0,3.0)	(0.7,11.0)
Cannulation Success, 6-Month, All Subjects	78.8%(±11.8%)	64.3%(±6.8%)
Cannulation Success, 6-Month, Dialysis Subset	86.5%(±11.3%)	84.7%(±6.0%)
Functional Cannulation, 6-Month, All Subjects	84.2%(±10.2%)	56.6%(±7.2%)
Functional Cannulation, 6-Month, Dialysis Subset	91.3%(±8.3%)	75.7%(±7.4%)
Primary Patency, 6-Month	77.6%(±8.9%)	70.9%(±6.2%)
Modified Primary Patency, 6-Month	77.6%(±8.9%)	67.2%(±6.4%)

Table cont. next page

Table 8. Subset Analysis – Radial and Ulnar AVF		
Assisted Primary Patency, 6-Month	82.2%(±8.1%)	75.9%(±5.9%)
Secondary Patency, 6-Month	82.2%(±8.1%)	75.9%(±5.9%)
Functional Patency, 6-Month	100%(±0%)	85.6%(±6.8%)

All effectiveness endpoints except Procedure Success and Time to Cannulation are K-M estimates ± SE.

Confidence intervals were not adjusted for multiplicity.

Conclusion

The aggregate data presented herein confirm the safety and performance of the WavelinQ™ 4F EndoAVF System for the creation of AVF for hemodialysis access. The data for the WavelinQ™ 4F EndoAVF System provides evidence of the safety and performance of the device for the creation of either a radial-radial fistula or an ulnar-ulnar AVF.

Summary of WavelinQ™ 6F EndoAVF System Clinical Information

Objective

The WavelinQ™ 6F EndoAVF System was previously studied in a global analysis (Global Analysis Plan). The Global Analysis Plan was designed to aggregate and analyze safety and effectiveness data from the FLEX, NEAT, EU PMCF and EASE studies and commercial cases sources where subjects were treated with the WavelinQ™ 6F EndoAVF System.

Design

Prospective Study Data

The FLEX, NEAT, EU PMCF and EASE studies were each prospectively planned and executed. Each study obtained the required institutional ethics approvals and all subjects provided informed consent prior to treatment. Data were collected via Case Report Forms and were independently monitored. As the studies were conducted at different points in time and in different geographic regions, the mechanics of data collection varied. The FLEX and EASE studies utilized hard copy case report forms (CRFs) with subsequent transfer to a database. The NEAT and EU PMCF studies utilized electronic data capture (EDC) with electronic case report forms. Inclusion criteria required subjects to need vascular access for long-term hemodialysis with target vein diameter ≥ 2 mm, target artery diameter ≥ 2 mm, and ≤ 2 mm between target artery and vein. Relevant safety events were submitted for independent CEC adjudication. All procedural and post-procedural AEs and secondary procedures were collected. Procedure success and patency effectiveness data were collected during the follow-up period; 6-month follow-up for FLEX and EASE and 12-month follow-up for NEAT and EU-PMCF.[4]

[4] The commercial data source does not have a specified follow-up period. This data was collected without a study protocol, given the commercial nature of the data.

Commercial Data

The Commercial data source was collected and reported by treating physicians from open-label commercial use of theWavelinQ™ 6F EndoAVF System . The physician reported data utilizing a form generated by TVA Medical based on the guidance of in-country regulatory counsel to specifically conform to applicable privacy regulations. The form was designed to specifically exclude any information that could be deemed to be personal data (i.e., any information relating to a living individual that identifies him or her or makes he or she reasonably capable of being identified).

Global Analysis Data Sources

Table 9 below presents the general characteristics of each study in the Global Analysis.

Table 9. Details of the Data Sources

Data Source	Device	# Sites (Countries)	Total Subjects	Subjects in Pooled Analysis*	
				Safety	Effectiveness
FLEX	6Fr	1 (Paraguay)	33	33	33
NEAT	6Fr	5 (Canada) 1 (Australia)	60	60	60
EASE	4Fr	1 (Paraguay)	32	NI	32
EU-PMCF	6F	5 (Germany) 3 (England)	32	32	32
COMM- All	6Fr	4 (England) 16 (Germany) 1 (Netherlands) 1 (Switzerland)	79	NI	NI
COMM- Cannulation data collected			45	NI	NI
Total Subjects			**236†**	**125**	**157**

NI – Not included in the pooled data set

COMM– Commercial cases. The COMM-Cannulated cases comprise the subset of COMM cases.

**EASE subjects were not included in the Pooled Safety Population, since the 4Fr system is a different product from the other data sources which used the 6Fr system. No COMM subject was included in the Pooled Safety or Effectiveness Populations, since baseline data was unavailable in the commercial cases; precluding pooling.*

†The total number of subjects is less than the sum of the column, since the COMM – Cannulated subject cohort is a subset of the COMM group.

Inclusion/Exclusion Criteria. A comparison of eligibility criteria across studies is provided below.

	FLEX	NEAT	EU-PMCF	EASE
Geography	PY	CA, AU	DE, GB	PY
Size of System	6Fr	6Fr	6Fr	4Fr
Inclusion Criteria				
Eligible for AVF	Yes	Yes	Yes	Yes
Age	Yes	Yes	Yes	Yes

Table cont. next page

Inclusion/Exclusion Criteria. A comparison of eligibility criteria across studies is provided below.

	FLEX	NEAT	EU-PMCF	EASE
Kidney failure	Yes	Yes	Yes	Yes
Target AVF distance	Yes	Yes	No	No
Target vein diameter	Yes	Yes	Yes	Yes
Target artery diameter	Yes	Yes	Yes	Yes
Life Expectancy	Yes	Yes	Yes	Yes
Exclusion Criteria				
Informed Consent Required	Yes	Yes	Yes	Yes
Significant baseline conditions	Yes	Yes	Yes	Yes
Central vein stenosis > 50%	Yes	Yes	Yes	Yes
Hypercoagulable state	Yes	Yes	Yes	Yes
Planned/prior procedure < 30 days	Yes	Yes	Yes	Yes
Target vessel abnormality	Yes	Yes	Yes	Yes
Pregnancy	Yes	Yes	Yes	Yes
Known bleeding diathesis	Yes	Yes	Yes	Yes
Immunosuppression	Yes	Yes	Yes	Yes
Documented history of drug abuse	Yes	Yes	Yes	Yes
Body mass index	Yes	Yes	No	No
Contrast/Sedation/Anesthesia	No	Yes	Yes	Yes

PY- Paraguay, CA- Canada, AU- Australia, DE- Germany, GB- United Kingdom,
AVF- Arteriovenous fistula

Safety and Effectiveness Endpoints

The safety and effectiveness endpoints for the WavelinQ™ 6F EndoAVF System were the same as those for the WavelinQ™ 4F EndoAVF System and are defined above.

Compliance

The follow-up compliance is summarized in Table 10. The protocol-specified follow-up duration was 12 months in the NEAT and EU-PMCF studies and 6 months in FLEX and EASE. Subjects were withdrawn when they exited a study due to abandonment of the endoAVF, successful renal transplantation, or if the subject withdrew consent voluntarily. Of the 123 subjects in the Pooled population 109 (88.6%) attended the 6 month follow-up visit. Of the eligible 53 subjects with pre planned 12 month visits, 49 (92.5%) attend the 12 month visit.

Table 10. Follow-Up Compliance

Follow-Up Interval[1]	NEAT (N=60)	FLEX (N=33)	EU-PMCF[4] (N=32)	EASE (N=32)	Pooled[2] (N=157)
Follow-Up Duration	12 Months	6 Months	12 Months	6 Months	NA
Postoperative (0-10 Days):					
Eligible Subjects	60/60 (100.0%)	33/33 (100.0%)	32/32 (100.0%)	32/32 (100.0%)	157/157 (100.0%)
Death[5]	0/60 (0.0%)	1/33 (3.0%)	0/32 (0.0%)	0/32 (0.0%)	1/157 (0.6%)
Withdrawal[3]	1/60 (1.7%)	0/33 (0.0%)	5/32 (15.6%)	1/32 (3.1%)	7/157 (4.5%)
Within the Visit Window	58/60 (96.7%)	32/33 (97.0%)	25/32 (78.1%)	31/32 (96.9%)	146/157 (93.0%)
30-Days (11 – 45 Days)					
Eligible Subjects	59/60 (98.3%)	32/33 (97.0%)	26/32 (81.3%)	31/32 (96.9%)	148/157 (94.3%)
Death[5]	1/59 (1.7%)	2/32 (6.3%)	0/26 (0.0%)	1/31 (3.2%)	4/148 (2.5%)
Withdrawal[3]	0/59 (0.0%)	0/32 (0.0%)	2/26 (7.7%)	2/31 (6.5%)	4/148 (2.5%)
Within the Visit Window	57/59 (96.6%)	30/32 (93.8%)	22/26 (84.6%)	24/31 (77.4%)	133/148 (84.7%)
3-Months (46 – 135 Days)					
Eligible Subjects	58/60 (96.7%)	30/33 (90.9%)	24/32 (75.0%)	26/32 (81.3%)	138/157 (87.9%)
Death[5]	1/58 (1.7%)	1/30 (3.3%)	3/24 (12.5%)	3/26 (11.5%)	8/138 (5.8%)
Withdrawal[3]	2/58 (3.4%)	0/30 (0.0%)	3/24 (12.5%)	2/26 (7.7%)	7/138 (5.1%)
Within the Visit Window	55/58 (94.8%)	28/30 (93.3%)	18/24 (75.0%)	13/26 (50.0%)	114/138 (82.6%)
6-Months (136 – 270 Days)					
Eligible Subjects	55/60 (91.7%)	28/33 (84.8%)	18/32 (56.3%)	22/32 (68.8%)	123/157 (78.3%)
Death[5]	0/55 (0.0%)	0/28 (0.0%)	0/18 (0.0%)	1/22 (4.5%)	1/123 (0.8%)
Withdrawal[3]	2/55 (3.6%)	0/28 (0.0%)	0/18 (0.0%)	0/22 (0.0%)	2/123 (1.6%)
Within the Visit Window	53/55 (96.4%)	23/28 (82.1%)	11/18 (61.1%)	22/22 (100.0%)	109/123 (88.6%)
12-Months (271 – 390 Days)					
Eligible Subjects	53/60 (88.3%)	NA	NA6	NA	53/60 (88.3%)

Table cont. next page

Table 10. Follow-Up Compliance					
Death[5]	1/53 (1.9%)	NA	NA	NA	1/53 (1.9%)
Withdrawal[3]	3/53 (5.7%)	NA	NA	NA	3/53 (5.7%)
Within the Visit Window	49/53 (92.5%)	NA	NA	NA	49/53 (92.5%)

[1] The Follow-Up Intervals in this table are constructed to be contiguous and standardized between the studies evaluated. They do not correspond to prespecifiedwindows in each of the individual study protocols (follow-up windows were specified in the NEAT study protocol alone), nor do they correspond to the windows used to standardize follow-up for the Global Analysis.

[2] Pooled studies include all data sources except COMM (commercial cases).

[3] Withdrawn subjects include those subjects who exited the study due to lack of procedure success, endoAVF abandoned, transplant, or withdrew consent.

[4] NEAT, FLEX, and EASE are completed studies. EU-PMCF is ongoing, with active enrollment and follow-up.

[5] No EU-PMCF subjects had 12-month interval (beginning at day 271) data reported at the time of the data analysis.

Demographics

Demographics for the Pooled population and each individual study population is provided in Table 11 below.

Table 11. Demographics and Baseline Characteristics						
Characteristic	**NEAT (N=60)**	**FLEX (N=33)**	**EU-PMCF (N=32)**	**EASE (N=32)**	**Pooled (N=157)**	**COMM (N=79)**
Gender:						
Male	39/60 (65.0%)	20/33 (60.6%)	21/32 (65.6%)	31/32 (96.9%)	111/157 (70.7%)	NA
Female	21/60 (35.0%)	13/33 (39.4%)	11/32 (34.4%)	1/32 (3.1%)	46/157 (29.3%)	NA
Age:						
Mean ± SD	59.9 ± 13.6	51.0 ± 11.4	63.5 ± 12.7	50.9 ± 12.9	57.0 ± 13.8	NA
Race:						
Caucasian	36/60 (60.0%)	NA	27/32 (84.4%)	0/32 (0.0%)	63/124 (50.8%)	NA
Black	0/60 (0.0%)	NA	0/32 (0.0%)	0/32 (0.0%)	0/124 (0.0%)	NA
Asian	4/60 (6.7%)	NA	4/32 (12.5%)	0/32 (0.0%)	8/124 (6.5%)	NA
Indian	15/60 (25.0%)	NA	1/32 (3.1%)	NA	16/124 (12.9%)	NA
Ethnicity:						
Not Hispanic/Latino	58/60 (96.7%)	0/33 (0.0%)	32/32 (100.0%)	0/32 (0.0%)	90/157 (57.3%)	NA
Hispanic or Latino	2/60 (1.7%)	33/33 (100.0%)	0/32 (0.0%)	32/32 (100.0%)	67/157 (42.7%)	NA
Height (cm):						
Mean ± SD	169.5 ± 11.7	165.0 ± 8.3	165.8 ± 10.6	170.4 ± 9.6	168.0 ± 10.6	NA
Weight (kg):						
Mean ± SD	80.9 ± 21.9	65.8 ± 10.3	81.7 ± 18.5	75.6 ± 13.0	76.8 ± 18.5	NA
BMI:						
Mean ± SD	27.9 ± 6.1	24.2 ± 3.9	29.8 ± 6.8	25.9 ± 3.1	27.1 ± 5.7	NA
Systolic BP:						
Mean ± SD	144.5 ± 22.5	NA	137.7 ± 20.3	163.5 ± 26.0	149.7 ± 25.9	NA
Diastolic BP:						
Mean ± SD	83.4 ± 12.5	NA	72.5 ± 9.2	99.8 ± 18.8	85.8 ± 19.0	83.4 ± 12.5
Target Vein Diameter (mm):						
Mean ± SD	2.5±0.5	NA	3.1±0.8	2.7±0.8	2.7±0.7	NA
Target Artery Diameter (mm):						
Mean ± SD	3.8±0.8	NA	3.7±0.6	3.0±0.7	3.6±0.8	NA

The denominator for each data point varies due to exclusion of subjects with missing data.
NA means data not collected

Safety Results

The Global Analysis of the WavelinQ™ 6F EndoAVF System data is summarized in Table 12 and 13. For each outcome, the data represents the number of subjects experiencing an event divided by the number of subjects in the study. The Pooled Safety Population included subjects treated in the FLEX, EU-PMCF and NEAT studies (6Fr system) (N=125), but did not include subjects in the EASE study (4Fr system) or in the Commercial (COMM) cohort.

Table 12 provides safety outcomes for the pooled 6Fr data (FLEX, EU-PMCF, NEAT) and 4Fr data (EASE). Serious adverse events (SAEs) were defined as an adverse that (1) led to death, (2) led to serious deterioration in the health of the subject, that either resulted in a life threatening illness or injury, or a permanent impairment of a structure or body function, or inpatient or prolonged inpatient hospitalization, or medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or function, (3) led to fetal distress, fetal death or a congenital anomaly or birth defect. In the Pooled Safety population 15/125 (12.0%) subjects reported an unrelated SAE. In addition, 15/125 (12.0%) subjects reported a related SAE. 4/125 (3.2%) subjects reported a device-related SAE, and 15/125 (12.0%) reported a procedure-related SAE. These SAE results reflect CEC adjudicated data.

Closure device-related SAEs occurred in 4.8% of the population (6/125). There were no coil-related SAEs (0/125). There were 8 deaths included as SAEs in the Pooled Safety Population and all were unrelated to the study procedure or device (6.4%, 8/125). Commercial data from outside the US did not indicate any new or different types of risks.

Table 12. Principal Safety and Effectiveness Endpoints of the Studies

	NEAT (N=60)	FLEX (N=33)	EU-PMCF (N=32)	EASE (N=32)	Pooled* (Safety=125)	COMM (N=79)
Safety Endpoints:						
SAE-unrelated	9/60 (15.0%)	4/33 (12.1%)	1/32 (3.1%)	6/32 (18.7%)	15/125 (12.0%)	0/79 (0%)
SAE-related	5/60 (8.3%)	4/33 (12.1%)	6/32 (18.7%)	1/32 (3.1%)	15/125 (12.0%)	3/79 (3.8%)
Device-Related SAE	1/60 (1.7%)	1/33 (3.0%)	2/32 (6.3%)	0/32 (0.0%)	4/125 (3.2%)	1/79 (1.3%)
Procedure-Related SAE	5/60 (8.3%)	4/33 (12.1%)	6/32 (18.8%)	1/32 (3.1%)	15/125 (12.0%)	3/79 (3.8%)
Closure Device-Related SAE	4/60 (6.7%)	0/33 (0.0%)	2/32 (6.3%)	0/32 (0.0%)	6/125 (4.8%)	0/79 (0.0%)
Coil-Related SAE	0/60 (0.0%)	0/33 (0.0%)	0/32 (0.0%)	0/32 (0.0%)	0/125 (0.0%)	0/79 (0.0%)

This summary table is intended to provide standalone results for the most important safety study endpoints. It is also used to present subgroup results later in this document. All results are found in more detailed tables that follow.

The safety endpoints are tabulated on a per-subject basis and represent the number of subjects who experienced at least one event of the specified category over the duration follow-up.

**For all safety endpoints, pooled studies include NEAT, FLEX, and EU-PMCF, and reflect all data from each study. SAE- Serious Adverse Event as adjudicated by the CEC, reported at any time during follow-up.*

Effectiveness Results

A summary of the Effectiveness outcomes is tabulated in Table 13. The Pooled Effectiveness Population comprised subjects treated as part of the FLEX, EU-PMCF, NEAT, and EASE studies (N=157). Subjects treated commercially were not included in this population.

Procedural success, defined as the successful creation of an endoAVF with blood flow confirmed intraoperatively by fistulography or by duplex ultrasound postoperatively, was achieved in 96.8% (152/157) of the Pooled Effectiveness Population. Cannulation Success (the first 2-needle access and hemodialysis through the fistula) was achieved in 82.4% subjects through the 6th month window and in 92.4% of subjects through the 12th month window after the index procedure.[5] The median time to the first successful 2-needle cannulation was 2.1 months after the index procedure. The Kaplan-Meier estimate for Functional Cannulation (All Subjects), defined in Table 6, was 42.4% at the 6th months and 58.9% at 12th months. For dialysis patients only, Function Cannulation was 56.1% and 78.4% at 6 and 12 months, respectively. The reported Kaplan-Meier estimate Primary Patency was 82.7% and 74.8% at 6 and 12 months, respectively. Similar results were observed in the commercial cases, where the corresponding data was available.

Table 13. Principal Effectiveness Endpoints

	NEAT (N=60)	FLEX (N=33)	EU-PMCF (N=32)	EASE (N=32)	Pooled* (Effectiveness=157)	COMM (N=45)
Effectiveness Endpoints:						
Procedural Success	59/60 (98.3%)	32/33 (97.0%)	29/32 (90.6%)	32/32 (100.0%)	152/157 (96.8%)	44/45 (97.8%)
Time to Cannulation (Months)						
Observations	31	25	11	21	88	18
Median [IQR]	3.1 [2.7,5.6]	2.1 [1.9,2.4]	2.4 [1.4,3.4]	1.3 [1.1,1.6]	2.1 [1.6,3.2]	1.7 [0.4,2.9]
Mean ± SD	4.1 ± 2.3	2.2 ± 0.8	3.0 ± 1.9	1.4 ± 0.5	2.8 ± 1.9	2.3 ± 2.3
(Min, Max)	(1.4, 10.7)	(1.1, 4.6)	(1.2, 7.2)	(1.0, 3.0)	(1.0, 10.7)	(0.3, 7.8)
Cannulation Success,6-Month	70.6% (±7.4%)	100.0% (±0.0%)	71.2% (±13.3%)	90.4% (±6.4%)	82.4% (±4.0%)	94.3% (±5.5%)
Cannulation Success,12-Month	86.1% (±6.6%)	NA	100.0% (±0.0%)	NA	92.4% (±3.6%)	100.0% (±0.0%)
Functional Cannulation, 6-Month	36.3% (±6.7%)	88.6% (±7.0%)	63.2% (±13.6%)	85.8% (±7.5%)	42.4% (±6.1%)	NA
Functional Cannulation, 12-Month	53.1% (±7.4%)	NA	100.0% (±0.0%)	NA	58.9% (±6.6%)	NA
Functional Cannulation (dialysis patients) 6-Month+	50.4% (±8.2%)	94.5% (±5.1%)	71.1% (±13.3%)	85.8% (±7.5%)	56.1% (±7.1%)	NA
Functional Cannulation (dialysis patients) 12-Month+	74.2% (±7.9%)	NA	NA	NA	78.4% (±6.7%)	NA
Primary Patency, 6-Month	81.1% (±5.1%)	96.4% (±3.5%)	78.9% (±7.7%)	83.3% (±6.8%)	82.7% (±3.5%)	71.3% (±7.4%)
Primary Patency, 12-Month	73.4% (±5.9%)	NA	78.9% (±7.7%)	NA	74.8% (±4.9%)	63.5% (±8.4%)
Mod Primary Patency, 6-Month	76.5% (±5.5%)	53.6% (±9.4%)	68.4% (±8.8%)	83.3% (±6.8%)	70.5% (±4.0%)	71.3% (±7.4%)
Mod Primary Patency, 12-Month	61.1% (±8.1%)	NA	68.4% (±8.8%)	NA	56.3% (±7.1%)	63.5% (±8.4%)
Assist Prim Patency, 6-Month	84.8% (±4.7%)	96.4% (±3.5%)	82.1% (±7.3%)	86.8% (±6.2%)	85.8% (±3.2%)	71.3% (±7.4%)
Assist Prim Patency, 12-Month	77.2% (±5.6%)	NA	82.1% (±7.3%)	NA	78.2% (±4.7%)	63.5% (±8.4%)
Secondary Patency, 6-Month	86.4% (±4.5%)	96.4% (±3.5%)	82.1% (±7.3%)	86.8% (±6.2%)	86.5% (±3.1%)	70.4% (±7.5%)
Secondary Patency, 12-Month	78.9% (±5.4%)	NA	82.1% (±7.3%)	NA	79.0% (±4.6%)	62.8% (±8.4%)
Functional Patency, 6-Month	96.3% (±3.6%)	100.0% (±0.0%)	100.0% (±0.0%)	100.0% (±0.0%)	98.1% (±1.8%)	95.0% (±4.9%)
Functional Patency, 12-Month	96.3% (±3.6%)	NA	100.0% (±0.0%)	NA	98.1% (±1.8%)	82.3% (±9.3%)

Table cont. next page

[5] The 6 and 12-month timepoints for K-M estimates were calculated at the end of the follow-up windows; 210 and 390 days, respectively.

Table 13. Principal Effectiveness Endpoints

This summary table is intended to provide standalone results for the most important efficacy study endpoints.

The Pooled Effectiveness Population includes those studies plus EASE. The exception is Functional Cannulation, where the pooled dataset is limited to NEAT and EU-PMCF since more extensive cannulation data was available in those studies.

The 6- and 12-month windows are defined as 180 and 360 days ± 30 days, respectively. The data in this table represent events through the end of the respective windows; i.e. 210 days for 6 months and 390 days for 12 months.

NA- Not applicable. Indicates that the data point is beyond the length of follow-up for a study or that the number of evaluable subjects is zero at that time point.

Procedural Success was defined as successful endoAVF creation confirmed via intraprocedural fistulography or by duplex ultrasound performed post-procedure.

Time to Cannulation is the time between the index procedure to the first successful endoAVF cannulation. Cannulation Success was defined as successful 2-needle cannulation and dialysis through the endoAVF.

Functional Cannulation is defined as 2-needle access of the endoAVF access circuit with performance of ≥ 2/3rds of ≥ 120-minute dialysis sessions through the endoAVF access circuit over a continuous 28-day period. Functional Cannulation is expressed as the Kaplan-Meier estimate (Standard Error).

Patency definitions are from the Society of Vascular Surgery Reporting Standards document; Sidawy et al. Recommended standards for reports dealing with arteriovenous hemodialysis accesses, J Vasc Surg 2002;35:603-10. Primary patency is the interval of time of 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 is the interval from access placement to thrombosis or abandonment; not triggered by access circuit interventions performed in the absence of occlusion. Secondary patency is the interval of time of access placement until access abandonment, lost 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 is the interval of time from the first 2-needle dialysis utilizing the access until access abandonment.

Patency rates are expressed as Kaplan-Meier estimates (Standard Error)

Data is site-reported, with independent Medical Monitor classifications and CEC-adjudicated data

** For all effectiveness endpoints except Functional Cannulation, pooled studies include NEAT, FLEX, EU-PMCF, and EASE. The pooled studies for Functional Cannulation excluded FLEX and EASE, since the extent of available cannulation data was less than for the NEAT and EU-PMCF studies.*

†Functional Cannulation, specified in the dialysis subset defined as the cohort of subjects who were enrolled on dialysis or eventually went on dialysis during follow-up. The data include the NEAT and EU-PMCF studies alone.

The 6- and 12-month timepoints were calculated at the end of the follow-up windows, through 210 and 390 days, respectively.

Conclusion

The aggregate data confirms the safety and effectiveness of the WavelinQ™ 6F EndoAVF System for the creation of an autogenous fistula for hemodialysis access. The safety profile is acceptable and the effectiveness of the system, as measured by patency rates, is commensurate with the literature-reported rates for traditional surgically-created AVF. Further, the ability to use the endoAVF access circuit for dialysis over at least a 28-day period (Functional Cannulation) confirms the ability of the endoAVF procedure to provide useable dialysis access circuits for treated subjects.

REF Product Code

LOT Lot Number

Use By

Rx Only Prescription Device

Do Not Reuse

Do Not Resterilize

Contents

Consult Instructions for Use

eIFU indicator Electronic IFU

Keep Away from Heat

Keep Dry

Not Made with Natural Rubber Latex

Do Not Use if Package is Damaged

STERILE EO Sterilized Using Ethylene Oxide

Non-pyrogenic

Manufacturer

Date of Manufacture

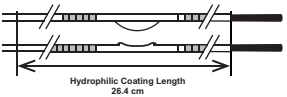
Maximum Guidewire

Minimum Introducer Effective Length

cm Effective Length

D Diameter

Type B label



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