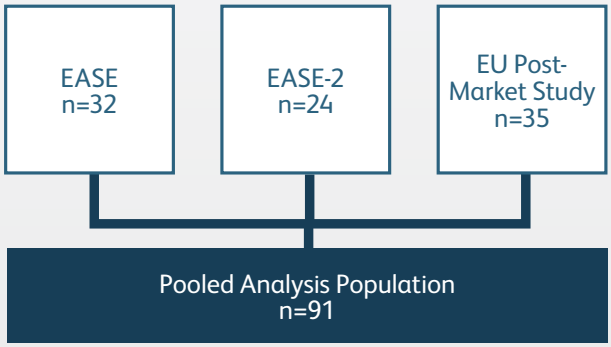
Global Data Analysis

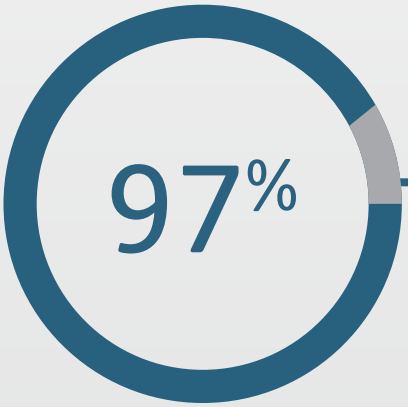
Objective: To aggregate and analyze safety and performance data from the EASE, EASE-2 and EU Study where subjects were treated with the WAVELINQ™ 4F EndoAVF System.

Analysis Design

- Data pooled in November 2018 from 7 sites across 3 studies within Germany, United Kingdom, and Paraguay.
- Enrolled subjects had chronic kidney disease and were in need of hemodialysis (including pre-dialysis patients) and were anatomically suitable for endoAVF creation.

See the WAVELINQ™ 4F EndoAVF System Instructions for Use for more details on the design of the global analysis along with the speciÃc details of each of the studies included in the analysis.

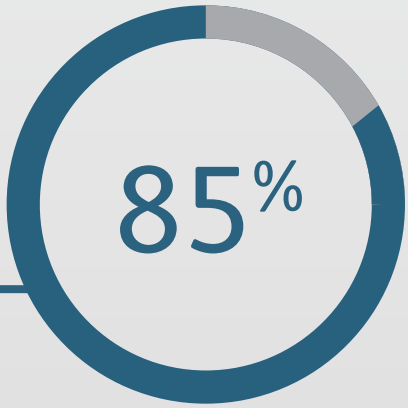




Procedure Success
n=91

Procedure Success: Successful endoAVF creation confirmed via intraprocedural fistulog aphy or by duplex ultrasound performed post-procedure

Cannulation Success (Dialysis Subset): Successful 2-needle cannulation and dialysis through the endoAVF



2-Needle Cannulation Success
at 6 months
n=74*

WavelinQ™
EndoAVF System

*Includes subjects who were enrolled on hemodialysis or initiated hemodialysis at any point in the follow up.

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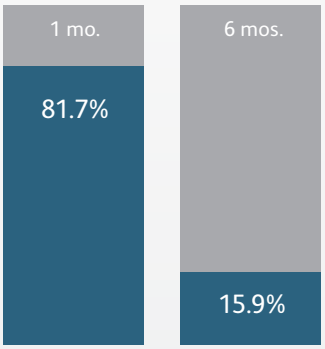
Usability

CVC Initiation & Exposure

In pre-dialysis patients, only **16%** (4/25) initiated dialysis with a CVC through 6 months



In dialysis patients, CVC exposure dropped from 81.7% (49/60) at 1 month to **15.9%** (7/44) at 6 months

	Pooled Studies
Median Time to Cannulation, Months	1.5 [IQR 1.1,2.0]
Mean Time to Cannulation, Months	2.0 (±1.6)

Time To Canulation: 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.

Reintervention	Effectiveness (n = 91)
Therapeutic embolization (Coiling)	5
Balloon angioplasty	10
Stent	2
Thrombectomy and Thrombolytic Therapy	4
Transposition	5
Surgical AVF/AVG	6
Other	1
Total Interventions	**33**
% of patients with 0 interventions	**78%**

Interventions: Secondary procedures performed after the index procedure.

78%

of patients were intervention-free at 6 months post-procedure

Safety

Significant Event Summary† Safety n=91	
Device-Related Serious Adverse Event	3.3%
Procedure-Related Serious Adverse Event	5.5%
Closure-Related Adverse Event	0.0%
Coil-Related Adverse Event	0.0%

Adverse events were site-reported and reviewed by an independent Medical Monitor and the Clinical Events Committee.

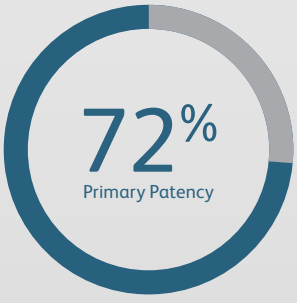
† Signifi ant Event was defined as d vice or procedure-related adverse events that either a) could be limb-threatening if not promptly identified or t eated, or b) required additional therapy to reestablish patency of the endoAVF access circuit; irrespective of whether the event was an SAE. The independent Medical Monitor classified SigniÃ ant Events based on this definition.

Definitions

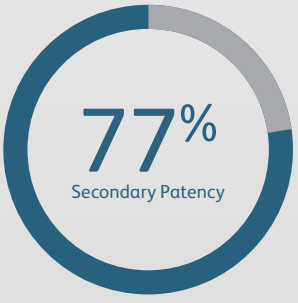
Principal Safety Endpoints (N=91)		
Endpoints	**n (%)**	**Definition**
SigniÃcant Event	20 (22.0%)[1]	Device or procedure-related adverse events that either a) could be limb-threatening if not promptly identiÃed or treated, or b) required additional therapy to reestablish patency of the EndoAVF access circuit; irrespective of whether the event was an SAE.
Serious Adverse Event (SAE)	24 (26.4%)[2]	An event that results in the following: led to death; or led to serious deterioration in the health of the subject, that either resulted in: a life-threatening illness or injury; a permanent impairment of a body structure or a body function; in-patient or prolonged existing hospitalization; medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to body structure or body function; or led to fetal distress, fetal death or a congenital abnormality or birth defect.
Device-related SAE	3 (3.3%)[3]	Related to study device
Procedure-related SAE	5 (5.5%)[4]	Occurred during index procedure
Closure-related SAE	0 (0.0%)	Related to artery closure
Coil-related SAE	0 (0.0%)	Related to either migration of a coil from its intended site of deployment or events that are related to the obstruction of venous outÃow from coil embolization; e.g. sever forearm edema associated with coil occlusion of major venous outÃow channel.

Performance

Patency Rates at 6 months (Kaplan-Meier Estimates)



Primary Patency: 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.



Secondary Patency: 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.

Adverse events were site-reported and reviewed by an independent Medical Monitor and the Clinical Events Committee.

[1] Included 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

[2] Of these, 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 thrombosis, 1 stenosis, and 1 myocardial infarction.

[3] Included 1 thrombosis, 1 stenosis, and 1 access circuit false aneurysm.

[4] Included 2 stenoses, 1 access circuit hematoma, 1 access circuit false aneurysm, and 1 thrombosis

Characteristic	Pooled (n=91)
Sex	
Male	76 (83.5%)
Female	15 (16.5%)
Age	
Years (Mean)	54.1 ±14.7
Race*	
Caucasian	24 (26.4%)
Black	0 (0.0%)
Asian	4 (4.4%)
Indian	4 (4.4%)
Other	1 (1.1%)
Not Reported	58 (63.7%)
Ethnicity	
Not Hispanic or Latino	35 (38.5%)
Hispanic or Latino	56 (61.5%)

Characteristic	Pooled (n=91)
Body Mass Index	
BMI (Mean)	26.5 ±5.8
Key Comorbidities	
Diabetes	48.4%
Hypertension	86.8%
Coronary disease	17.1%
Cerebrovascular disease	2.9%
Peripheral vascular disease	0.0%
On hemodialysis at screening	
Yes	71.4%

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

WavelinQ™
EndoAVF System

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.

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. The safety and performance of this device has not been established for pediatric patients. 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 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.

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

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