First Time Data Release: EU & Canada Post-Market Multi-Center Experience of WavelinQ™ EndoAVF

Robert Jones

Interventional Radiologist

Birmingham, United Kingdom

Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

☒ Consulting BD, WL Gore

EndoAVF Background

Wee et. al A systematic review, meta-analysis, and meta-regression of the efficacy and safety of endovascular arteriovenous fistula creation JVS 2019 1-9

- **Meta analysis: 7 Studies with 300 Patients**
  - 97.5% Technical Success
  - 89.27% 90-Day Maturation Rate
  - 91.99% 6 Month Patency
  - 85.71% 12 Month Patency
  - 5.46% Procedure-related complications

Current endovascular AVF systems appear to be effective and safe. However, given the lack of head-to-head comparative analyses with surgical AVF creation, superiority cannot be established.

EndoAVF Background

Inston et al. WavelinQ Created Arteriovenous Fistulas versus Surgical Radiocephalic Arteriovenous Fistulas? A Single-Centre Observational Study JVA 1-6 2019

Matched Comparative Analysis	WavelinQ N=30	Surgical AVF N=40
Technical Success	96.7%	92.6%
Primary Patency at 6 Months	65.5%	56.5%
Secondary Patency at 6 Months	75.8%	66.7%

WavelinQ™ EU/Canada Post Market Study

Objective:

Collect data in an observational study on outcomes of endovascular fistula creation using the WavelinQ™ EndoAVF[1] in the post-market setting where the system is available for use.

Design[2]:

Prospective, Multicenter

N=100

13 International Sites

Independent Analysis:

Duplex Ultrasound Core Lab

Clinical Events Committee

1. Previously EverlinQ endoAVF System
2. NCT 02682420

WavelinQ™ Clinical Program

	FLEX	NEAT	EASE	EU Post-Market	EASE-2	CONNECT-AV	Global Study
Device	6F	6F	6F and **4F**	6F and **4F**	**4F**	**4F**	**4F**
Fistula Location	Ulnar-Ulnar	Ulnar-Ulnar	Ulnar-Ulnar Radial-Radial	Ulnar-Ulnar Radial-Radial	Ulnar-Ulnar Radial-Radial	Ulnar-Ulnar Radial-Radial	Ulnar-Ulnar Radial-Radial
Study Type	-Single center -Multiple operators -Prospective -Single-arm	-Multi-center -Prospective -Single-arm	-Single center -Multiple operators -Prospective -Single-arm	-Multi-center -Prospective -Single-arm	-Single center -Multiple operators -Prospective -Single-arm	-Multi-center -Prospective -Single-arm	-Multi-center -Prospective
Number of Patients	33 Patients	60 Patients (+20 Roll-in)	32 Patients	100 Patients	24 Patients	~250 Patients	~100 Patients
Location	Paraguay	Canada, Australia, New Zealand	Paraguay	Germany, UK, Canada	Paraguay	United States	Europe, Canada, Asia
Status	Rajan et al. Percutaneous Creation of an Arteriovenous Fistula for Hemodialysis Access JVIR 2015; 26:484-490 (FLEX)	Lok et. al Endovascular Proximal Forearm Arteriovenous Fistula for Hemodialysis Access: Results of the Prospective, Multicenter Novel Endovascular Access Trial Am J Kidney Dis 2017;70(4):486-497	Berland et alEndovascular Creation of Arteriovenous Fistulae for Hemodialysis Access with a 4Fr Device: Clinical Experience from the EASE Study Annals of Vascular Surgery	Completed	Completed	In protocol finalization	In protocol finalization

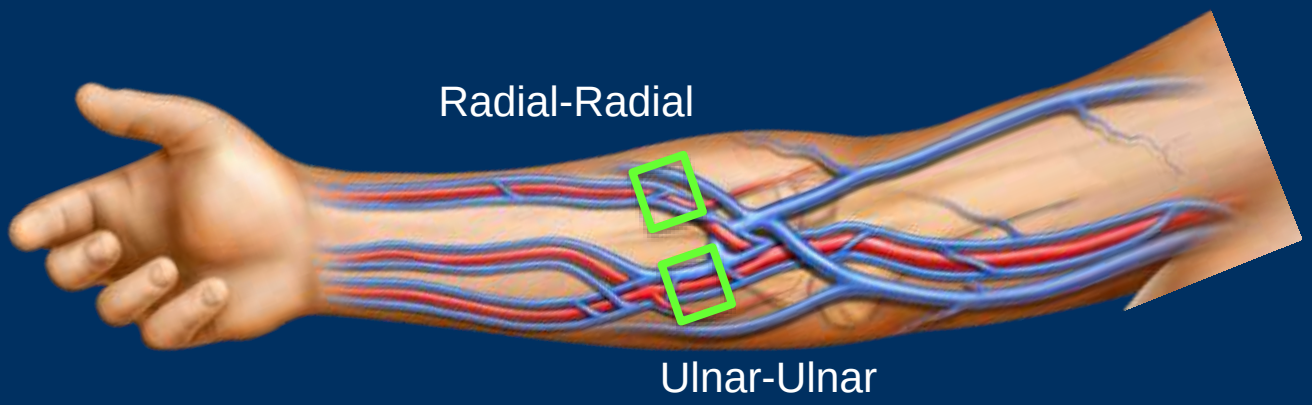
WavelinQ™ EU/Canada Post Market Devices

6F System, N=36

- Radiofrequency (RF)-Based Creation
- Ulnar to Ulnar AVF
- Fluoroscopy Guided

4F System, N=64

- RF-Based Creation
- Ulnar to Ulnar *or* Radial to Radial
- Fluoroscopy Guided



WavelinQ™ EU/Canada Post Market Investigators

PI Name	Country	PI Name	Country
Nicholas Inston		Frank Dellanna	
Mercedeh Kiaii		Urs Benck	
Afshin Tavakoli		Thomas Schmitz-Rixen	
Arne Schwindt		Norbert Weiss	
James Gilbert		Tze Chan	
Ashar Wadoodi		Jan Tordoir	
Dierk Scheinert			

Study Co-Principal Investigators:

- Mr. Nicholas Inston, University Hospitals Birmingham
- Prof. Thomas Schmitz-Rixen, University of Frankfurt

WavelinQ™ EU/Canada Post Market Study Criteria

- ***Key Inclusion Criteria***
  - Adult
  - Chronic dialysis or expected to start within 3 months of creation
  - Target fistula creation ≥2.0mm for artery and vein
  - Allen's test or similar

WavelinQ™ EU/Canada Post Market Study Criteria

- ***Key Exclusion Criteria***
  - Absence of perforator[1]
  - Known central stenosis
  - <1-year life expectancy
  - >50% stenosis in target cannulation outflow vein

1. A perforator is a vein that connects a superficial vein to a deep vein.

WavelinQ™ EU/Canada Post Market Key Baseline Characteristics

Demographic Criteria	N=100	Percent
Gender		
Male	72/100	72%
Female	28/100	28%
Age	60±16.2 (mean)	64 (median)
Race		
Caucasian	70/100	70%
Asian	20/100	20%
Indian	5/100	5%
Other	1/100	1%
Not Reported	4/100	4%
BMI	28.4±7.6 (mean)	26.7 (median)

WavelinQ™ EU/Canada Post Market endoAVF **Maturation**

Maturation at any timepoint	
n/N (%)	83/91 (**91%**)
95% CI	83% - 96%

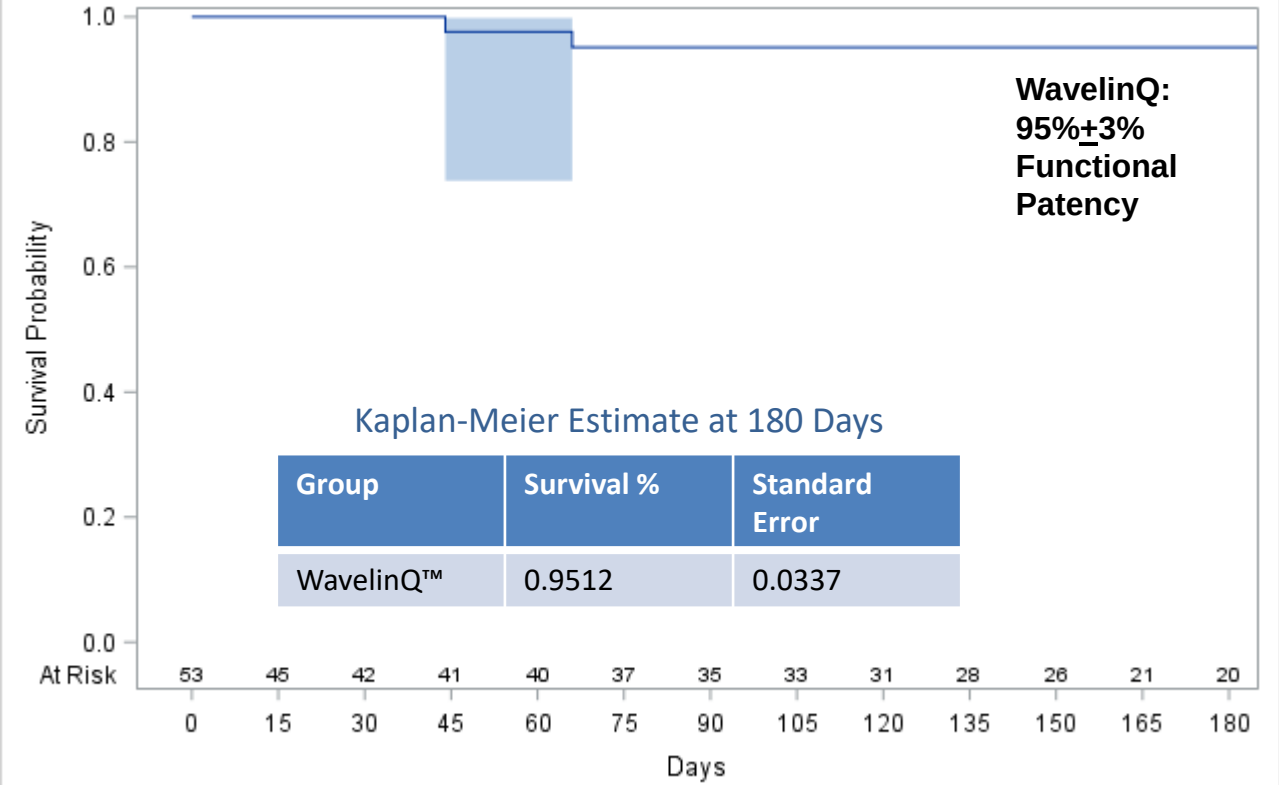
**Maturity is defined as estimated fistula flow ≥500 mL/min with diameter ≥4 mm.*

Interim data, subject to change.

WavelinQ™ EU/Canada Post Market

95% ±3% Functional Patency*

at 6 Months



Kaplan-Meier Estimate at 180 Days

Group	Survival %	Standard Error
WavelinQ™	0.9512	0.0337

Product Limit Survival Estimate with Number of Subjects at Risk

**Functional Patency is protocol defined as "The time period from first endoAVF cannulation (2 needle) to endoAVF abandonment." Functional Patency is calculated for those endoAVF that were successfully cannulated (excluding those that were never cannulated), and failures are those that subsequently become permanently occluded or are otherwise abandoned. The time to loss of Functional Patency is from the time of the first successful cannulation until failure. Thus, Functional Patency is higher than Secondary Patency since it does not include endoAVF that were never successfully cannulated.*

WavelinQ™ EU/Canada Post Market **Reinterventions @ 6 Months**

endoAVF Interventions @ 6mo	n/N	%
Interventions to improve cannulation		
Therapeutic Coil	8/100	8%
Superficialization/Transposition	10/100	10%
Interventions to improve patency		
Balloon Angioplasty	7/100	7%
Stent	1/100	1%
Thrombolytic Therapy	1/100	1%

Interim data, subject to change.

**Excludes those reinterventions that are not related to the endoAVF or access circuit.*

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WavelinQ™ EU& Canada Post Market Summary

- **Real-world, multi-center, reproducible results**
- **95% ±3% Functional Patency**
  - **2 needle cannulation to endoAVF abandonment**
- **Limited need for secondary procedures**
  - **Transposition/superficialization= 10%**
  - **Angioplasty= 7%**

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