Update On The everlinQ® Percutaneous Fistula Device

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Disclosures

Becton Dickinson- Bard
WL Gore Inc.

everlinQ® endoAVF System is now 

WAVEDLINQ™ EndoAVF System

WAVEDLINQ™ 6F EndoAVF System

Dual catheter system utilizing RF energy to create a fistula without an open surgery

What does a WAVEDLINQ™ 6F EndoAVF look like?

Histology and gross anatomy demonstrates minimal vessel trauma of the RF-based WAVEDLINQ EndoAVF

• Well-healed endoAVF tract with organized, mature fibrous remodeling
• Lining of endoAVF tract well covered in endothelial cells

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

WAVEDLINQ™ 6Fr EndoAVF Procedure

Arterial Catheter Advanced to AVF Site
Where is a WavelinQ™ 6F EndoAVF created?

- Basilic vein
- Perforator
- Cephalic vein

WavelinQ™ EndoAVF Creation Site

EndoAVF Fistulogram

Cephalic vein
Perforator

Ulnar Artery and Vein

WavelinQ™ EndoAVF

WavelinQ™ EndoAVF Global Meta-Analysis

Data current as of August 2017 and pooled from 28 sites in Canada, Australia, Germany, UK, Netherlands, Paraguay and Switzerland

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<th>Study</th>
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Pooled Efficacy Analysis Population
N=125 (excluded 4Fr patients)

Pooled Safety Population
N=125

*Collected to assess procedural success and safety outside of a clinical study. Represents the number of cases where adequate data could be collected to evaluate procedural safety and effectiveness.

WavelinQ™ EndoAVF Global Outcomes

- 2-needle Cannulation at 6 months
  - Pooled Study Population n = 157
  - 75%

- Primary Patency
  - Cumulative Patency

- Intervention
  - Balloon angioplasty of anastomosis: 7
  - Balloon angioplasty, general: 6
  - Device/Thrombectomy: 1
  - Subsequent vein embolization: 19
  - Stent: 11
  - Transposition: 6
  - Surgical AVF/AVG: 4
  - Thrombin injection of pseudoaneurysm: 4
  - Open surgical repair: 6
  - Not specified procedures: 3
  - Total Interventions: 55
  - % of patients requiring an intervention: 24% (38/157)

WavelinQ™ EndoAVF Expanded Anatomic Options for Creation

- Forearm Radiocephalic
- WavelinQ™ EndoAVF Ulnar-Ulnar
- Ellipsys™ EndoAVF or Surgical Gracz
- Upper Arm Brachiocephalic
- Upper Arm Transposed Brachiocephalic

WavelinQ™ EndoAVF Has Been Used to Provide More Options to Create a Functional Fistula

- Primary Access Creation
  - First option to provide a patient with a functioning fistula
- Secondary Option to RCAVF
  - Provided to patients that are ineligible for or have a failed RCAVF
- Alternative to Surgery
  - Patients that refuse surgical AVF creation
- Conditioning Fistula
  - Pre-dilates or “plumps” undersized veins for future surgical AVF
- 2-Stage Brachial Vein Transposition
  - Ulnar-Ulnar location arterializes a long segment of brachial vein for a second stage elevation
Future Development:
WAVELINQ™ 4Fr EndoAVF System

Enables multiple procedural access options, including from the wrist, and is currently being used in the EU market.

Access Site
endoAVF Creation Sites
Access Sites
Ulnar Artery – Ulnar Vein
Radial Artery – Radial Vein

Summary

- WAVELINQ™ EndoAVF System creates a functional fistula without open surgery
- Multiple WAVELINQ™ EndoAVF System clinical studies have demonstrated:
  - 75% two-needle cumulative cannulation success at 6 months
  - 79% cumulative patency at 12 months
  - Few interventions required to mature/maintain the endoAVF
- WAVELINQ™ EndoAVF System adds additional anatomic options to the treatment algorithm for patients to receive a functional fistula