

#### Transforming Vascular Access for Hemodialysis Patients

HBD East Think Tank– December 7, 2017

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## Introduction

- Joined TVA Medical June 2017
- New to HBD (first meeting)

- Biomedical Engineer
- 15 Years Regulatory & Clinical Experience
- USA & International Regulatory Affairs
- Global Clinical Research



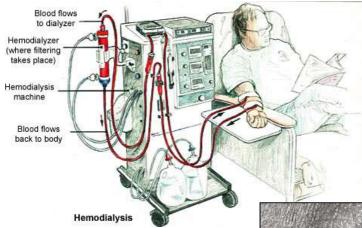
## Disclaimer

The everlinQ endoAVF System is not available for use in Japan or the United States.



### **Global Dialysis Access Need**

#### Hemodialysis Treatment 3-4 hours 3 times/week



#### **Surgical AV Fistula**

- Open surgery connect artery & vein
- Blood flows through fistula
- Creates arterialized vein segments
- · Allow patient to connect to dialysis repeatedly
- First performed in 1960's
- Standard of care today

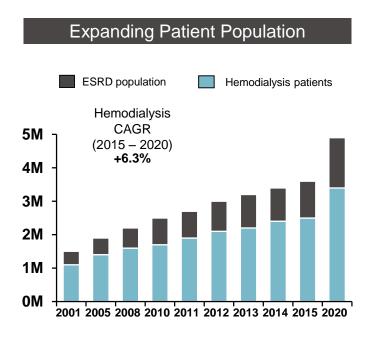




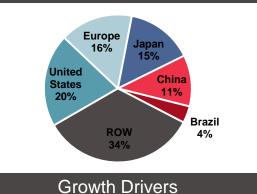
#### Patients need working vascular access for dialysis



### **Global Dialysis Access Need**



#### Global Medical Need



#### Increasing rates of hypertension and diabetes

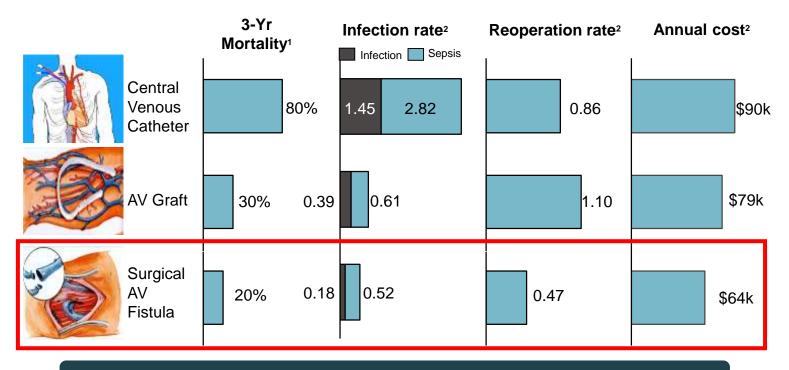
- High correlation to cardiovascular disease
- Hemodialysis availability improving globally
- · Increased focus on cost effective care delivery

#### >2.5 M hemodialysis patients require vascular access

USRDS 2009 Annual Report . Liyanage, et al. Lancet. Epub March 13, 2015. 10.1016/S0140-6736.



## **Current Dialysis Access Options**



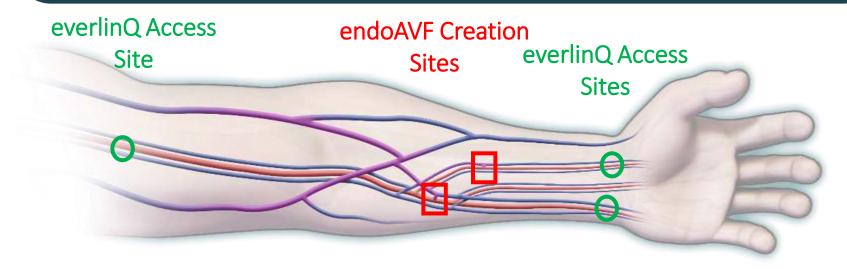
#### Surgical AV fistulas = preferred method of vascular access

1. Woo K., et al. Influence of Vascular Access Type on Sex and Ethnicity-Related Mortality in Hemodialysis-Dependent Patients. Perm J 2012 Spring;16(2):4-9. Mortality is reported at 3 years. 2. USRDS Annual Report 2011 (2007 data). Reoperation rate includes only angioplasty for AVF and AVG, and CVC replacement for CVC. Complication rates are reported per patient-year. Complication rates are calculated as the number of events (from Medicare claims) divided by the time at risk, which is censored at death, change in modality, change in payment status, or the placement of a different type of access.



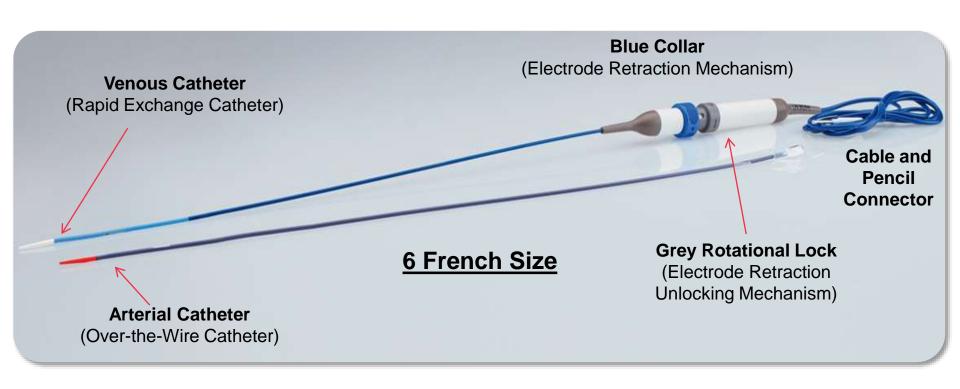
## everlinQ endoAVF

The everlinQ platform is designed to offer patients a minimally invasive endovascular procedure designed to create a working arteriovenous fistula & enable hemodialysis. Called the endoAVF – the everlinQ platform is designed to allow for multiple endovascular access sites & fistula locations to provide physicians an additional option in order to place the right fistula in the right patient.



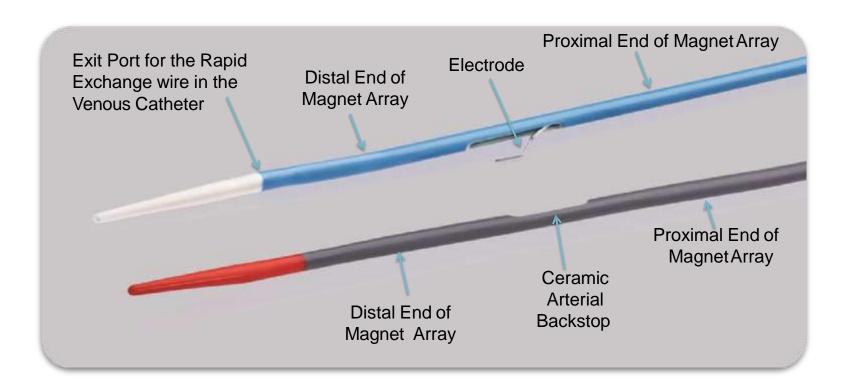


#### everlinQ 6 - System



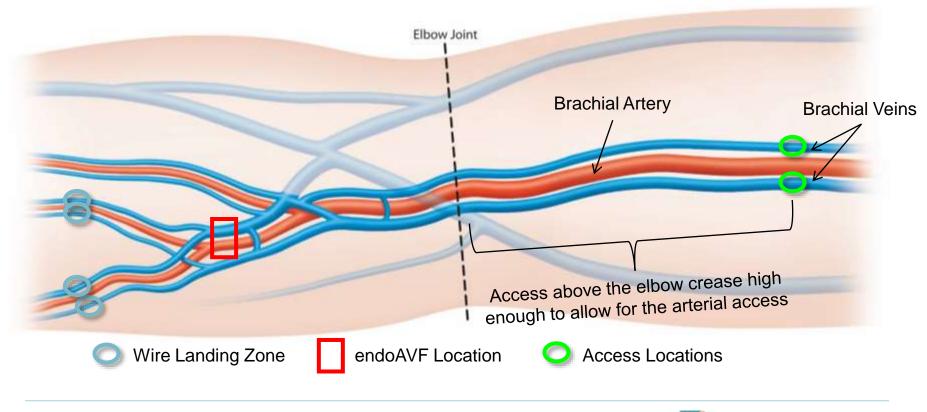


#### everlinQ 6 - Catheters



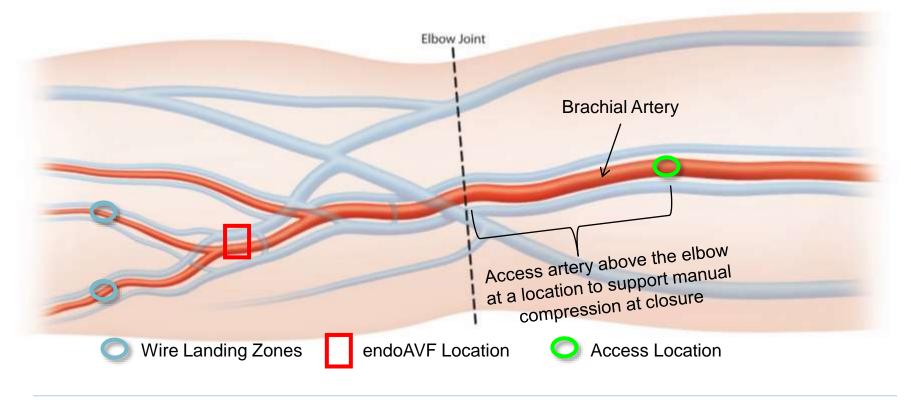


#### everlinQ 6 - Brachial Vein Access



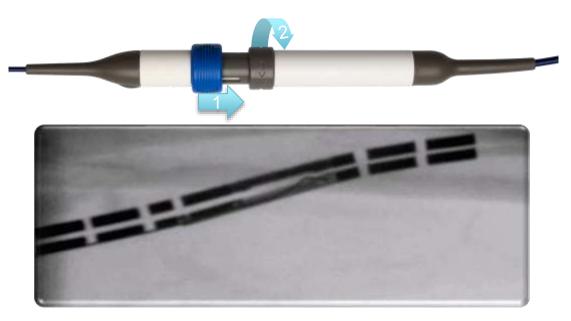


#### everlinQ 6 - Brachial Artery Access

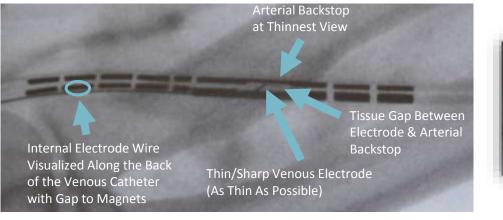


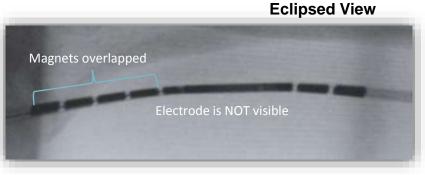


### everlinQ 6 – Electrode & Alignment



Catheters Aligned -Visual check – use magnet spacing and Arterial Backstop -Remove guidewires and deploy electrode





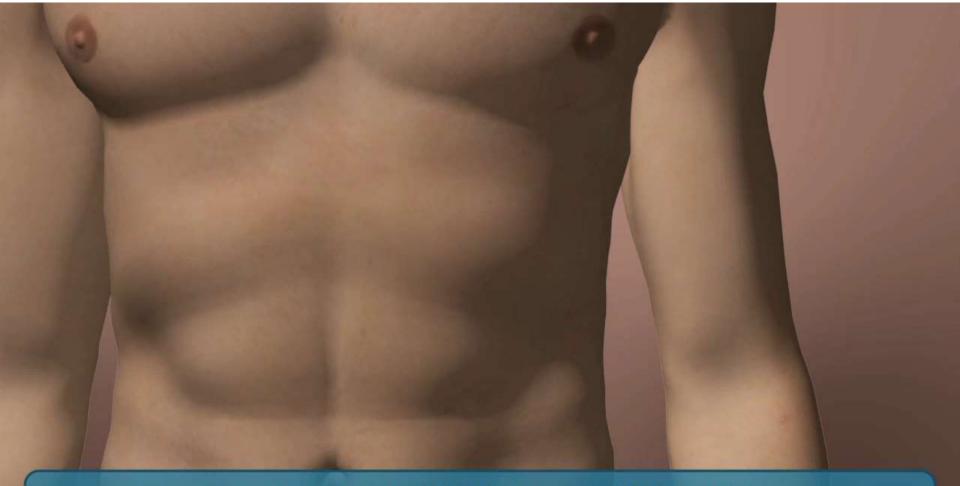


#### everlinQ 6 – Electrode & Activation





## everlinQ endoAVF Procedure



The system consists of: 2 Catheters and a RF Generator.

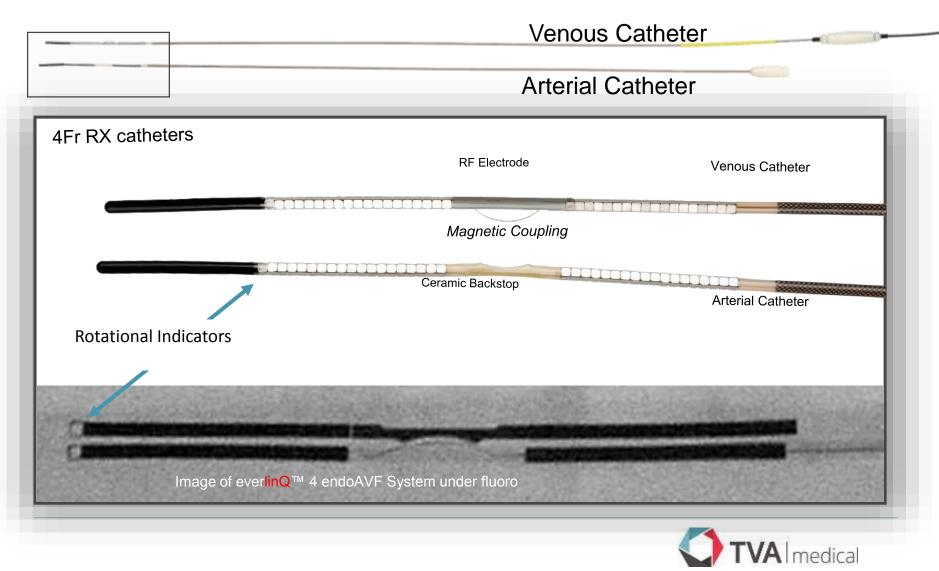


# everlinQ 4

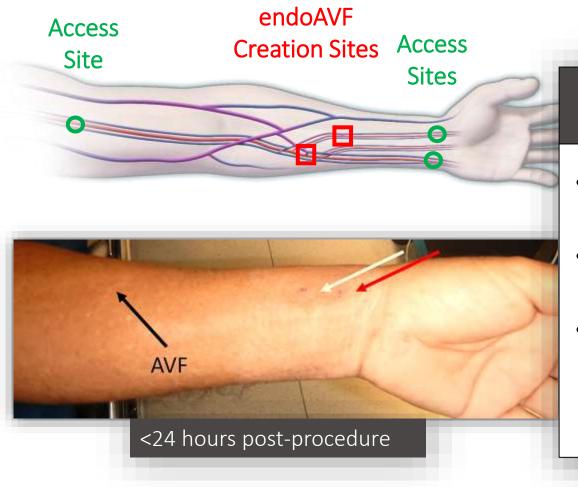


## TVA everlinQ<sup>™</sup> 4 endoAVF System

#### SMALLER – MORE FLEXIBLE – OPTIMIZED VISUAL INDICATORS



## everlinQ<sup>™</sup> 4 endoAVF System



#### 4 Fr System

- Additional creation site for endovascular fistula
- Enables wrist access or upper arm access
- Additional options for patients & physicians



## endoAVF System - Clinical Evidence

		Next Generation	Expanded Population 6Fr & 4Fr	US Post Market Study
Single Center Study 6Fr FLEX Study Feasibility and safety of the everlinQ endoAVF system Design • Single-center, multi- operator, prospective study in Paraguay • 33 patients, 4 sequential cohorts, 6 month follow-up Mey Outcomes • Technical Success	Multi Center 6FrDESESafety and effectiveness of the everlinQ endoAVF systemDesign• Multicenter, prospective in Canada, Australia and NZ• 60 patients, single arm• 1, 3, 6, & 12 month follow-up• 1, 3, 6, & 12 month follow-up• Procedure Success• Intervention rate• Maturation• Functional Cannulation	Next Generation Device 4Fr EASE Study Safety and efficacy of the everlinQ endoAVF System Design • Single center, multi- operator prospective study in Paraguay • 32 patients • 1, 3 & 6 month follow-up Completion in Q3 2017	6Fr & 4Fr endoAVF EU Post- Market Study "Real world" multi-center study designed to continue building clinical evidence with everlinQ endoAVF Design • Multicenter, prospective study • ~120 patients, single arm • 40 6Fr • 80 4Fr • 1, 3, 6, & 12 month follow-up • 4Fr and 6Fr included Enrollment and Follow-Up Ongoing Supports US De Novo	<ul> <li>endoAVF US Study Safety and efficacy of using the everlinQ System (6Fr)</li> <li>Design <ul> <li>Multicenter, prospective study</li> <li>~100 pts, single arm <ul> <li>6Fr only</li> </ul> </li> <li>1, 3, 6 &amp; 12 month follow-up</li> </ul> </li> <li>Mot Initiated <ul> <li>Supports post market requirement of potential US De Novo</li> </ul></li></ul>
<ul> <li>Patency @ 6 mo</li> <li>Safety</li> <li>Completed in 2014</li> <li>Supported CE Mark &amp;</li> <li>Supports US De Novo</li> </ul>	<ul> <li>Patency</li> <li>Completed in 2016</li> <li>Supports US <i>De Novo</i></li> </ul>	Supported CE Mark & US <i>Strategy</i>		

3. J Am Soc Nephrol 2016; 27:31A



#### endoAVF System - Clinical Evidence



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for Hemodialysis Acce

Jonus M. Rice, and William E. Colm.

#### **Original Investigation**

Endovascular Proximal Forearm Arteriovenous Fistula for Hemodialysis Access: Results of the Prospective, Multicent Novel Endovascular Access Trial (NEAT)

Chamaine E. Lok, MD, MSc.17 Dhenrej K. Rapin, MD,17 Jacon Clement, MD Mincedent Klail, MD<sup>1</sup> Revi Schu, MD, MEIC<sup>4</sup> Ken Thomson, MD<sup>1</sup> George Builds Ovidine Dochand, MD, MSc." Louise Most, MD, MSc." and Joanne Senat, MD behalf of the NEAT investigators"

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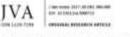
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## **Regulatory Update**



everlinQ 6	<ul> <li>De Novo 510(k) under FDA review</li> <li>Very collaborative process</li> <li>Incorporates global clinical evidence/analysis</li> <li>Proposal includes USA Post Market Study</li> <li>To confirm benefit/risk profile from global analysis in broader USA population</li> </ul>
everlinQ 4	<ul> <li>No formal discussions yet</li> <li>Initiate in 2018</li> <li>Define clinical data requirements</li> <li>Opportunity for clinical strategy development with PMDA/FDA/HBD</li> <li>Global Single Protocol Multicenter?</li> </ul>



## **Regulatory Update**



<ul> <li>everlinQ 6</li> <li>Complete process with FDA first</li> <li>Attend HBD – meet project team &amp; contacts</li> <li>Plan for 2018:</li> <li>Discuss global clinical evidence with PMDA</li> <li>Review USA Post Market plan to meet Japan needs?</li> </ul>
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everlinQ 4	<ul> <li>No formal discussions yet</li> <li>Initiate in 2018</li> <li>Define clinical data requirements</li> <li>Opportunity for clinical strategy development with PMDA/FDA/HBD</li> <li>Global Single Protocol Multicenter?</li> </ul>
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## THANK YOU VERY MUCH

