



**TVA** | medical

**Transforming Vascular Access  
for Hemodialysis Patients**

HBD East Think Tank– December 7, 2017

Noah Bartsch

Vice President of Clinical & Regulatory  
Affairs

# Introduction

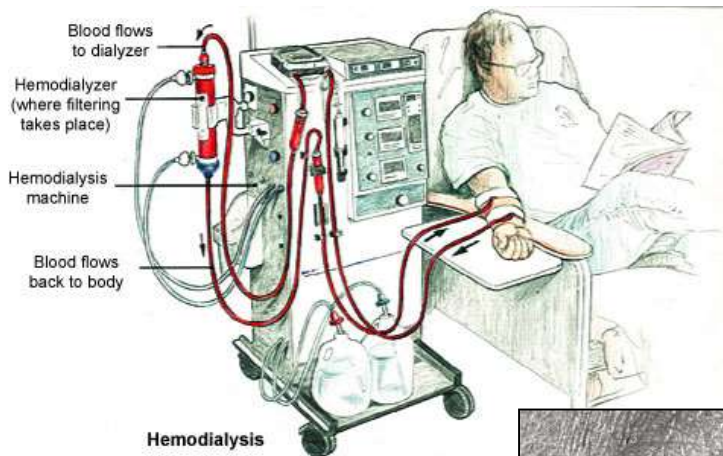
- Joined TVA Medical June 2017
- New to HBD (first meeting)
  
- Biomedical Engineer
- 15 Years Regulatory & Clinical Experience
- USA & International Regulatory Affairs
- Global Clinical Research

# 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

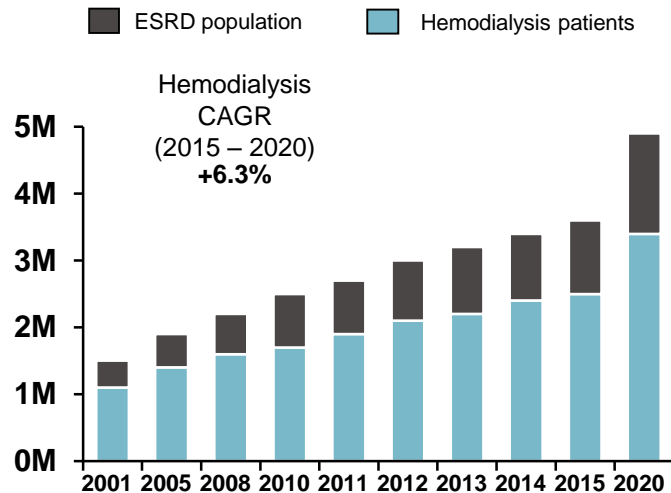
- Open surgery – connect artery & vein
- Blood flows through fistula
- Creates arterialized vein segments
- Allow patient to connect to dialysis repeatedly
- First performed in 1960's
- Standard of care today



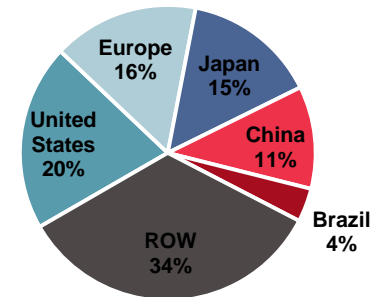
**Patients need working vascular access for dialysis**

# Global Dialysis Access Need

## Expanding Patient Population



## Global Medical Need



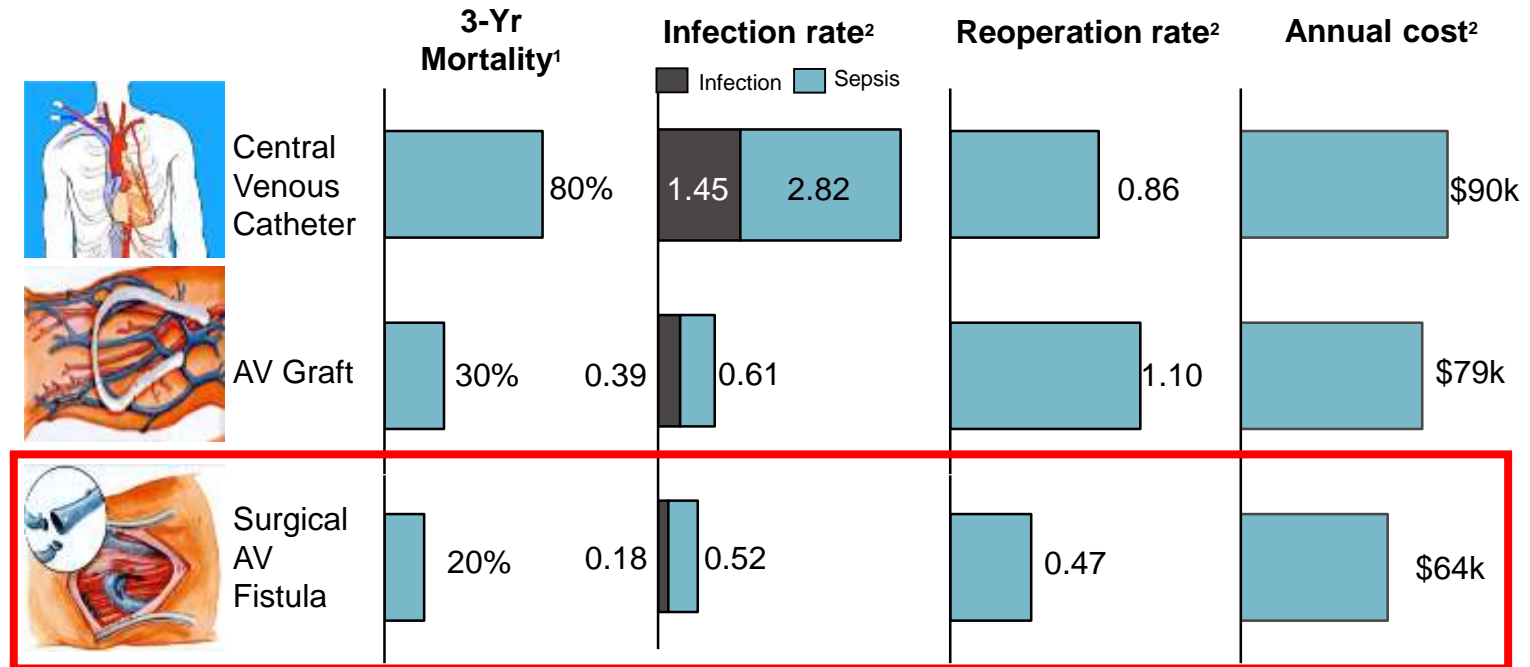
## Growth Drivers

- 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 .  
Liyanaige, et al. Lancet. Epub March 13, 2015. 10.1016/S0140-6736.

# Current Dialysis Access Options



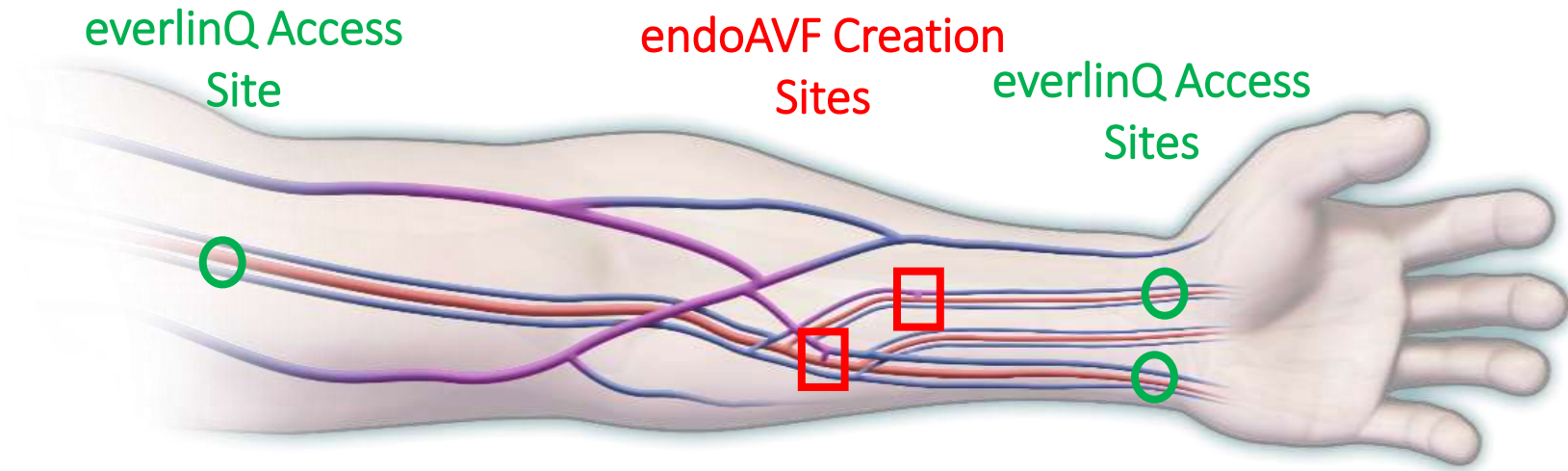
**Surgical AV fistulas = preferred method of vascular access**

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.

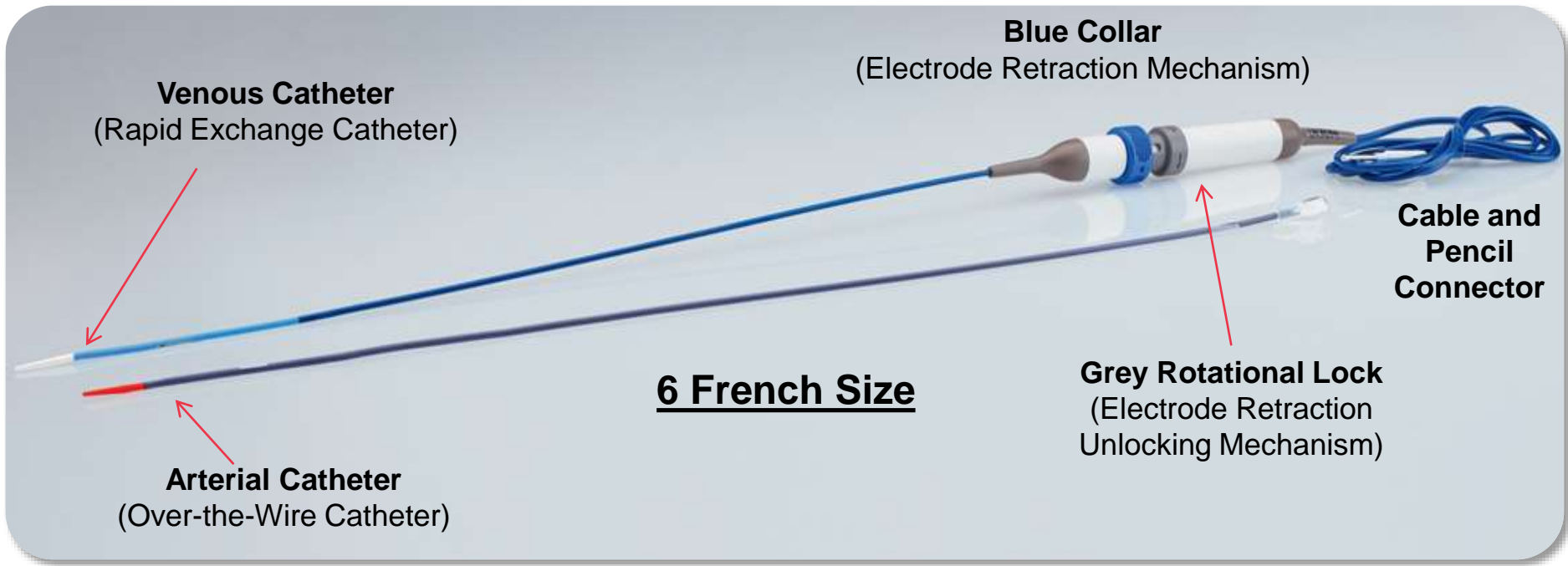
2. USRDS Annual Report 2011 (2007 data). Reoperation rate includes only angioplasty for AVF and AVG, and CVC replacement for CVC. Complication rates are reported per patient-year. Complication rates are calculated as the number of events (from Medicare claims) divided by the time at risk, which is censored 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.

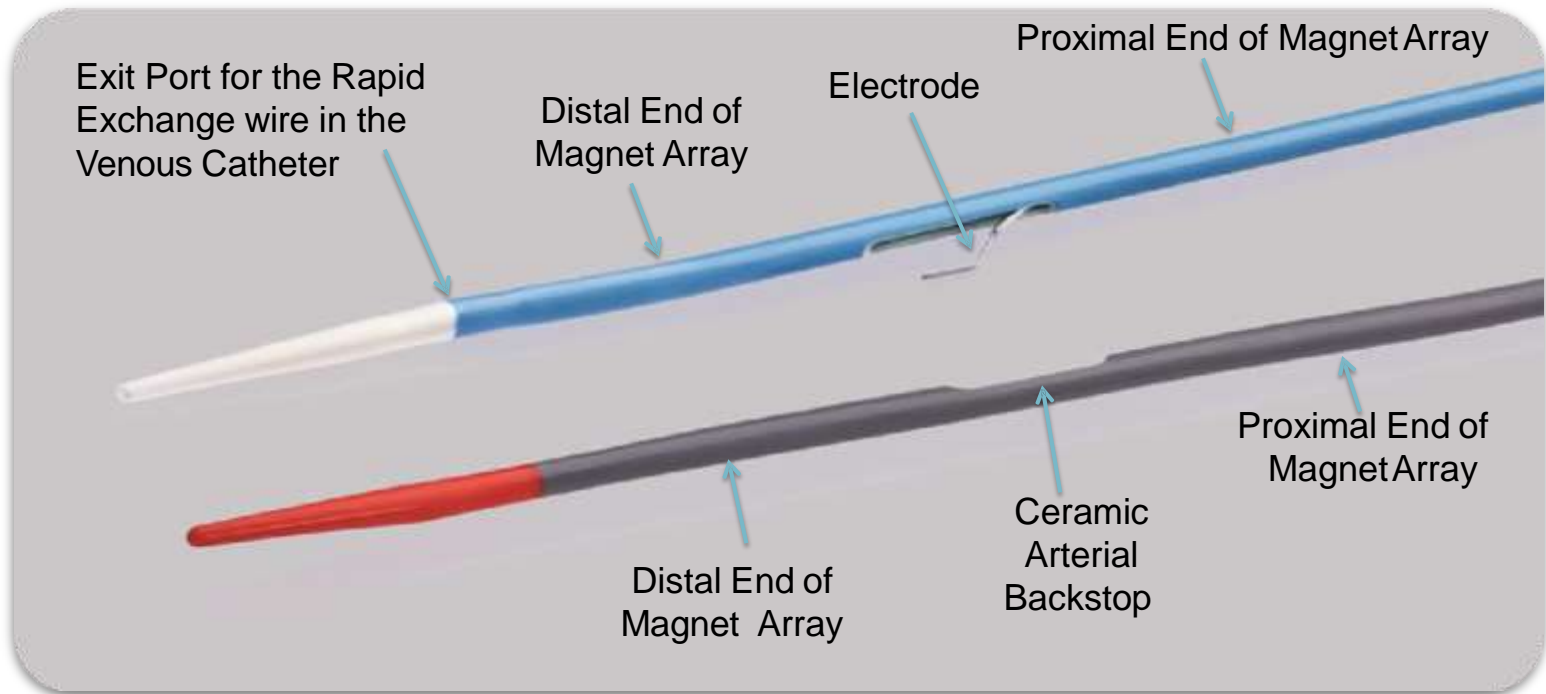


# everlinQ 6 - System

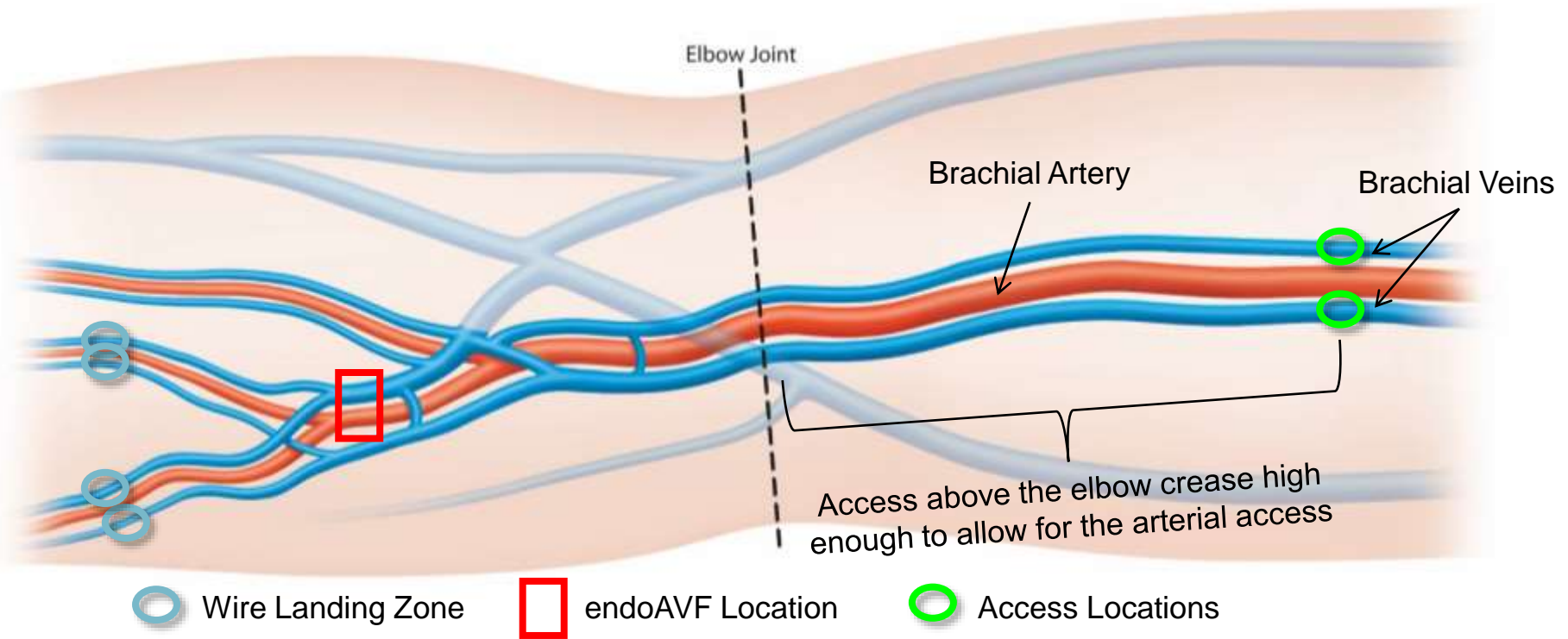




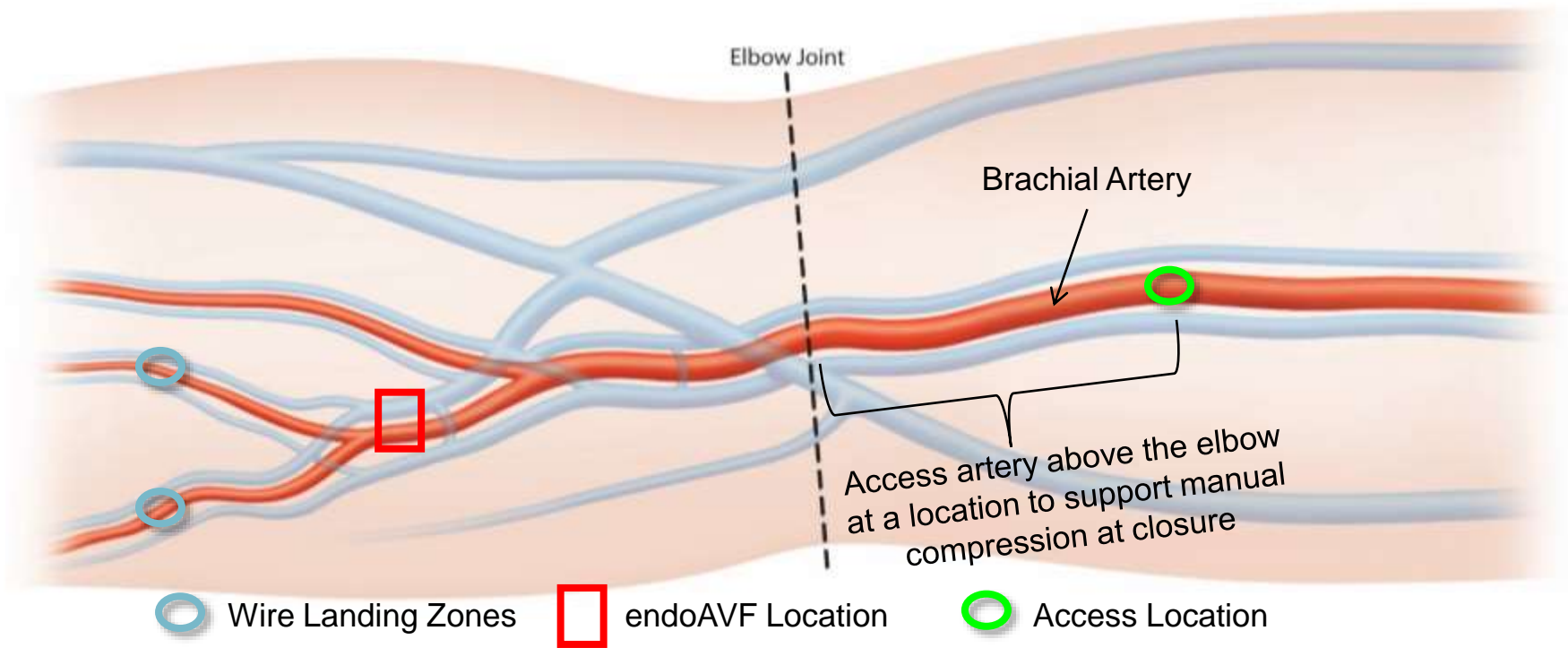
# everlinQ 6 - Catheters



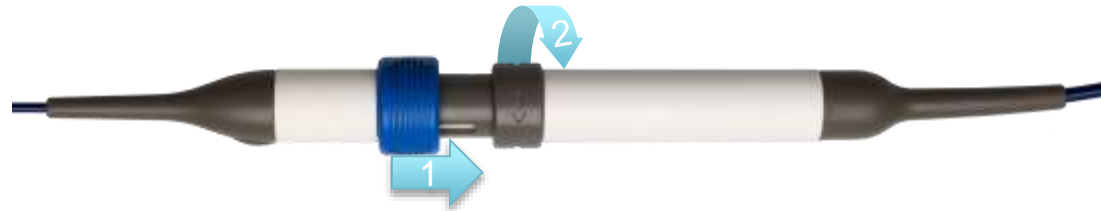
# everlinQ 6 - Brachial Vein Access



# everlinQ 6 - Brachial Artery Access

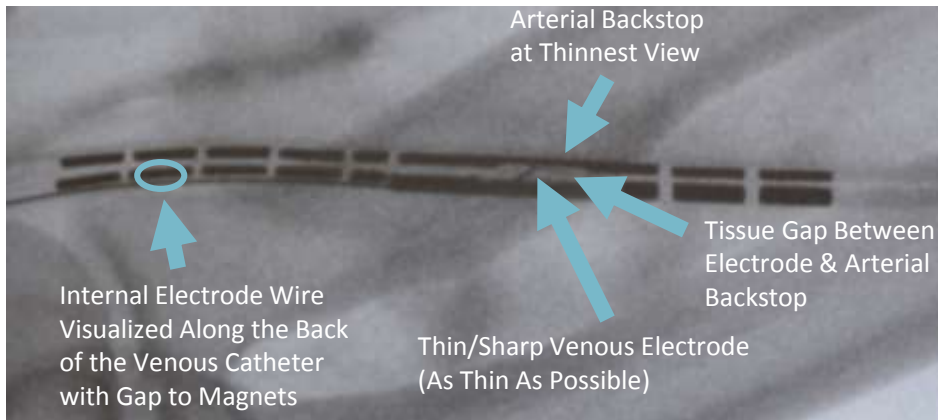


# everlinQ 6 – Electrode & Alignment

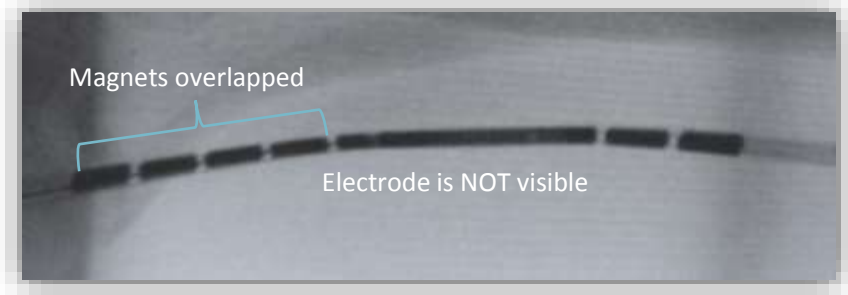


## Catheters Aligned

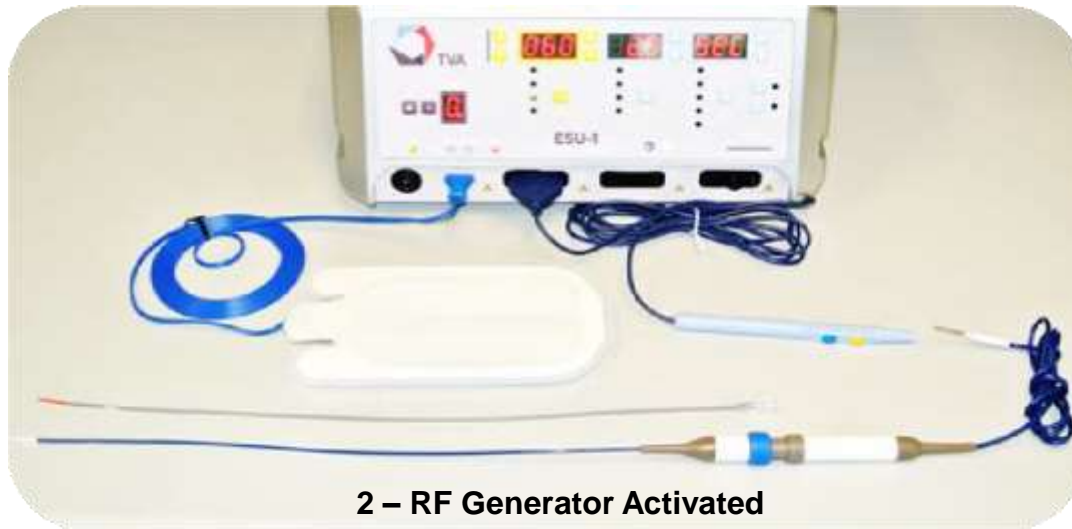
- Visual check – use magnet spacing and Arterial Backstop
- Remove guidewires and deploy electrode



## Eclipsed View



# everlinQ 6 – Electrode & Activation

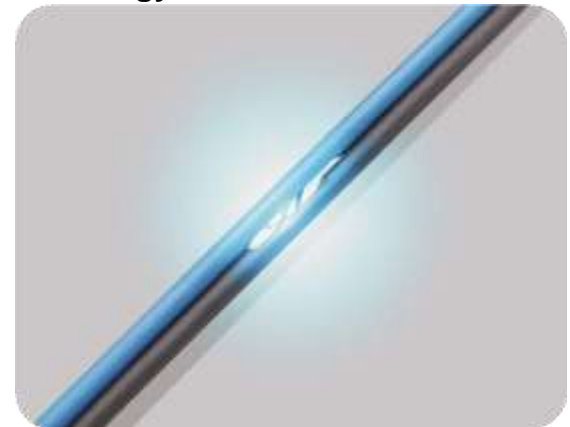


2 – RF Generator Activated

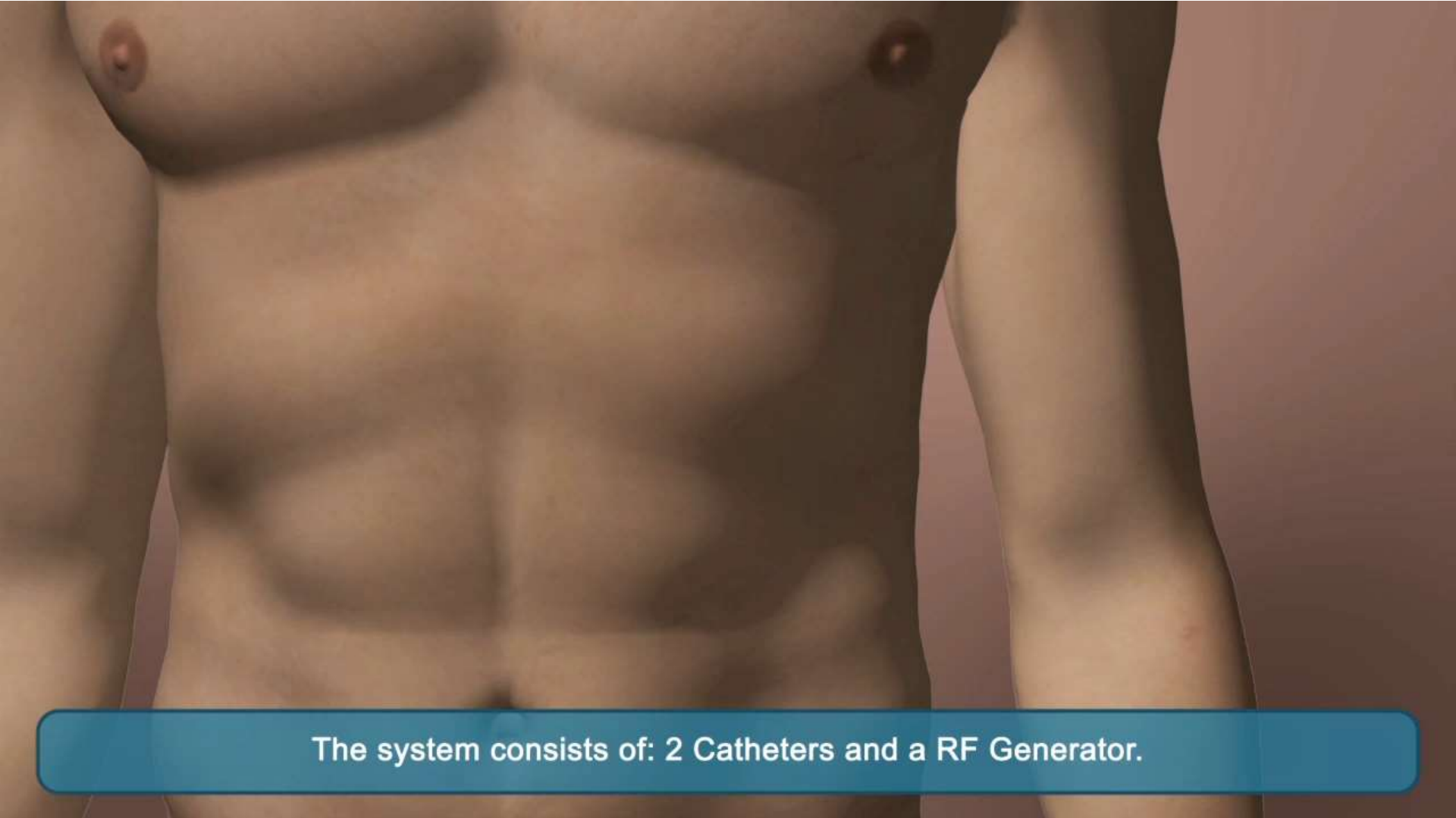
1 - Catheters Aligned & Electrode Deployed



3 – Energy Delivered & Fistula Created



# everlinQ endoAVF Procedure



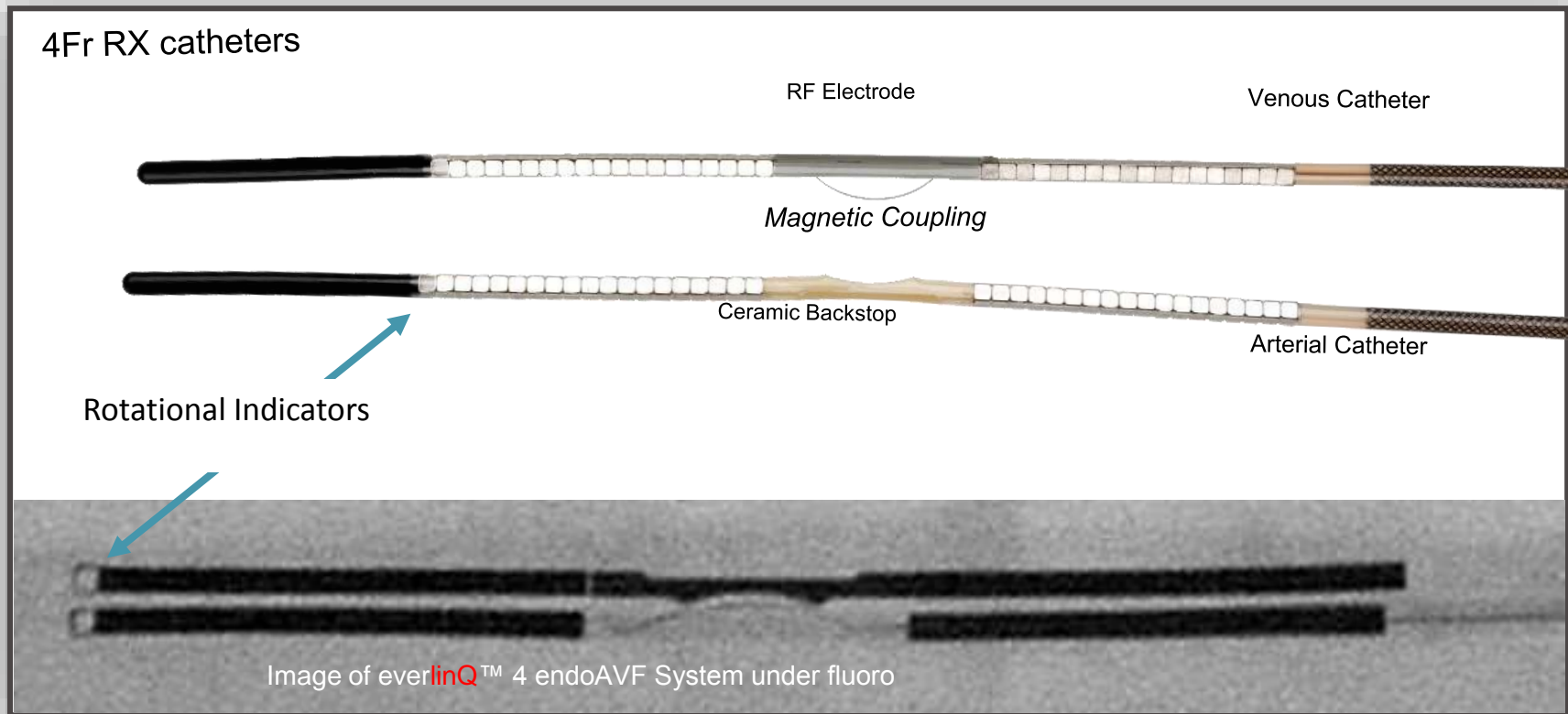
The system consists of: 2 Catheters and a RF Generator.

# everlinQ 4

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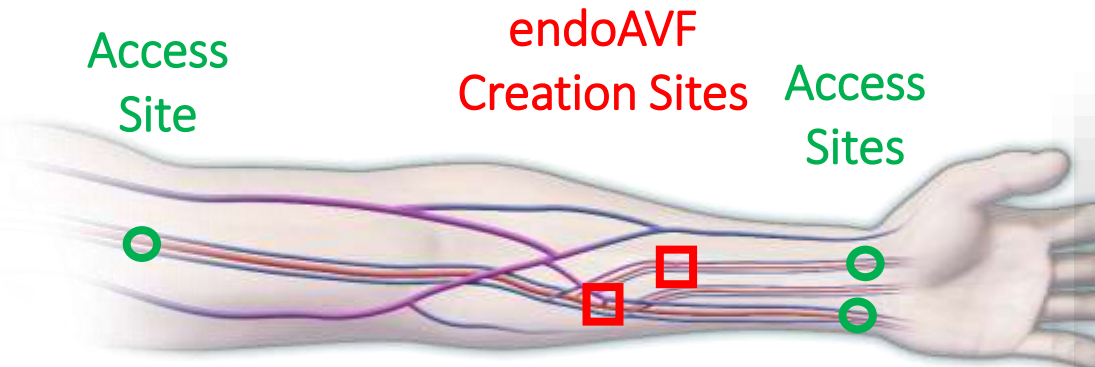
# TVA everlinQ™ 4 endoAVF System

**SMALLER – MORE FLEXIBLE – OPTIMIZED VISUAL INDICATORS**





# everlinQ™ 4 endoAVF System

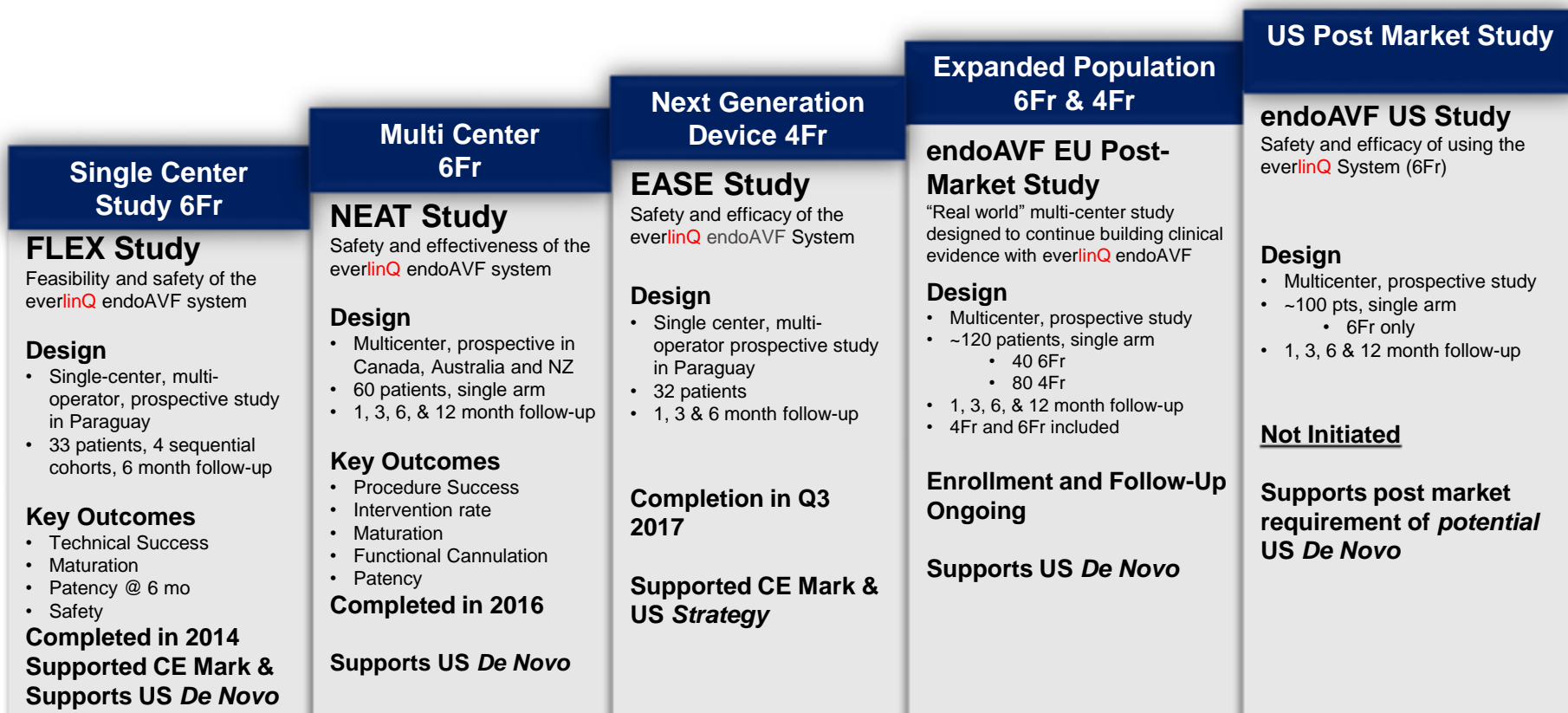


<24 hours post-procedure

## 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



1. J Vasc Interv Radiol 2015; 26:484-490.  
 2. J Vasc Surg 2016; 63(6):7S  
 3. J Am Soc Nephrol 2016; 27:31A

# endoAVF System - Clinical Evidence

**AJKD**  
Original Investigation

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

Charmene E. Lok, MD, MSc,<sup>1,2</sup> Cheong K. Rajan, MD,<sup>1,2</sup> Jason Clement, MD, Mercedes Kral, MD,<sup>2</sup> Ravi Sidhu, MD, MSc,<sup>3</sup> Alan Thompson, MD,<sup>4</sup> George Zullo, Christine D'Amico, MD, MSc,<sup>5</sup> Louise Moxon, MD, MSc,<sup>6</sup> and James Sewak, MD, on behalf of the NEAT Investigators\*

**Background:** Hemodialysis arteriovenous fistulas (AVFs) are traditionally used primarily due to long-term durability, early thrombolysis, and patient acceptability. An endovascular approach to fistula creation without open surgery offers another hemodialysis access option.

**Study Design & Participants:** Consecutive and non–stage-dependent patients for vascular access creation at 3 centers in Canada, Australia, and New Zealand.

**Intervention:** Using catheter-based endovascular technology and stent-grafting strategy, an AVF was created between larger vessels, resulting in an endovascular AVF (endoAVF).

**Outcomes:** Safety, efficacy, functional stability, and patency endpoints.

**Conclusions:** Safety and acceptability of device-related adverse events, efficacy as primary endovascularly created fistulae, early flow at 100 mL/min, were achieved in 4 weeks for all within 3 months; functional stability of endovascularly created proximal forearm AVFs was durable, primary and cumulative endovascular patency rates were 82% and 54%, respectively.

**Limitations:** Due to the comparative and relative nature of this endovascularly created AVF, this was a single-arm study without a surgical comparison.

**Conclusions:** An endovascularly created proximal forearm AVF using a catheter-based approach without open surgery and with minimal complications. The endovascularly created AVF may be a viable alternative to surgical AVF creation for hemodialysis patients in need of vascular access.

*Am J Kidney Dis. 2016;68:467-477. © 2017 The Authors. Published by Elsevier Inc. on behalf of the Society for Hemodialysis. This is an open access article under the CC BY-NC-ND 4.0 International license.*

**JVA**  
ORIGINAL RESEARCH ARTICLE

## Comparison of post-creation procedures and cost between surgical and an endovascular approach to arteriovenous fistula creation

Yoon Young, Charmene Lok, Ravi Sidhu, James Sewak, Marc Kibicki\*

**Background:** Endovascularly created proximal forearm arteriovenous fistulas (endoAVFs) are increasingly used primarily due to long-term durability, early thrombolysis, and patient acceptability. An endovascular approach to fistula creation without open surgery offers another hemodialysis access option.

**Study Design & Participants:** Consecutive and non–stage-dependent patients for vascular access creation at 3 centers in Canada, Australia, and New Zealand.

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**Clinical Investigation**

## Endovascular Creation of an Arteriovenous Fistula (endoAVF) for Hemodialysis Access: First Results

Charmene Georg Lok<sup>1,2</sup>, Jalla Caroline Lok<sup>1,2</sup>, Mark Wain<sup>3</sup>, Christine Schmitt<sup>4</sup>, Sebastian Wirth<sup>5</sup>, Thomas Hubner<sup>6</sup>, Verena Pothof<sup>7</sup>, Christian Gatzert<sup>8</sup>, Michael Lankau<sup>9</sup>, Ralf-Dieter Hoffmann<sup>9</sup>

**Background:** Hemodialysis arteriovenous fistulas (AVFs) are traditionally used primarily due to long-term durability, early thrombolysis, and patient acceptability. An endovascular approach to fistula creation without open surgery offers another hemodialysis access option.

**Study Design & Participants:** Consecutive and non–stage-dependent patients for vascular access creation at 3 centers in Canada, Australia, and New Zealand.

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**Conclusions:** An endovascularly created proximal forearm AVF using a catheter-based approach without open surgery and with minimal complications. The endovascularly created AVF may be a viable alternative to surgical AVF creation for hemodialysis patients in need of vascular access.

**Abstract**

**Introduction:** Surgical creation of an arteriovenous fistula is the gold standard of vascular access for hemodialysis. Recently, an endovascular approach to upper arm fistula creation (endoAVF) has been developed, which may be an alternative to open surgery. We describe our series of eight cases showing feasibility, early complications and success of this novel treatment option.

**Materials and Methods:** Between July 2015 and February 2016, we created an endoAVF in eight patients. Indications for endoAVF were confirmed by a multidisciplinary committee based upon the evaluation for Chronic Kidney Disease. Patients were suitable for the procedure after a pre-operative ultrasound showed adequate brachial and ulnar vessels and no collateral access system existed. Patient demographics, individual success, total patient evaluation time, complication rates, time to initiation of endoAVF and clinical effectiveness in six months were assessed retrospectively.

**Results:** Creation of endoAVF using the endoAVF endoAVF system (TVA Medical Inc., Austin, TX, USA) was successful in all eight cases. There were no major intraoperative complications and no postoperative complications. Median time to endoAVF initiation was 63 days (range 26-177 days). One patient was lost to follow-up after the first postoperative visit. In the remaining seven patients, hemodialysis was initiated without problems. Primary after 6 months was 100%.

**Discussion:** The endoAVF demonstrated to be feasible and safe for the creation of arteriovenous fistula suitable for hemodialysis access. Further studies with more patients and longer follow-up periods are needed to assess long-term success and comparability to surgical fistula access creation.

**Keywords:** Arteriovenous fistula, Dialysis, End-stage renal disease, Interventional radiology, Endovascular AV fistula, Vascular access, Hemodialysis.

**Abbreviations:**  
AVF Arteriovenous fistula  
endoAVF Endovascular arteriovenous fistula

# Regulatory Update



## everlinQ 6

- *De Novo* 510(k) under FDA review
- Very collaborative process
- Incorporates global clinical evidence/analysis
- Proposal includes USA Post Market Study
- To confirm benefit/risk profile from global analysis in broader USA population

## everlinQ 4

- No formal discussions yet
- Initiate in 2018
- Define clinical data requirements
- Opportunity for clinical strategy development with PMDA/FDA/HBD
- Global Single Protocol Multicenter?

# Regulatory Update



## everlinQ 6

- Complete process with FDA first
- Attend HBD – meet project team & contacts
- Plan for 2018:
- Discuss global clinical evidence with PMDA
- Review USA Post Market plan to meet Japan needs?

## everlinQ 4

- No formal discussions yet
- Initiate in 2018
- Define clinical data requirements
- Opportunity for clinical strategy development with PMDA/FDA/HBD
- Global Single Protocol Multicenter?

**THANK YOU VERY MUCH**

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