



Bank of America Healthcare Conference Investor Presentation

# Forward Looking Statement

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**Commercial-stage company** that has established an **entirely new**, minimally invasive **procedure** with potential to become the **standard of care** in a multi-billion \$ market



# TCAR for Stroke Prevention

>1,700  
Q1 US Procedures  
(<5% market penetration<sup>1</sup>)

>10,000  
WW Procedures

\$59-61M  
2019 Exp. Revenue  
(71-77% YoY growth)

Figures as of 05/08/2019

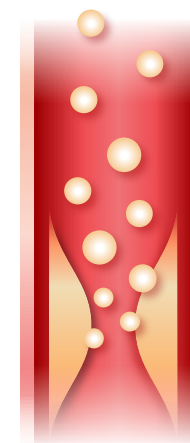
<sup>1</sup> Represents Q1 annualized figure relative to total carotid procedures in 2018 of 168k

Relentless Focus on Patient Outcomes  
Every patient.  
Every day.

# Carotid Artery Disease –

33% of Ischemic Strokes

Cause of stroke:



Plaque fragments  
break off and move to brain

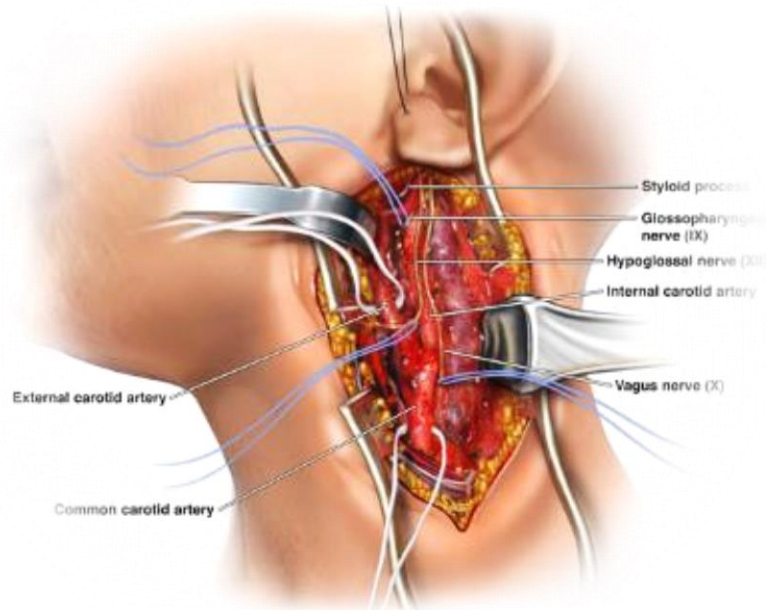
Current Prevalence

**4.3M** people in US have carotid stenosis

# A Dated Standard of Care

## Carotid Endarterectomy

65 years

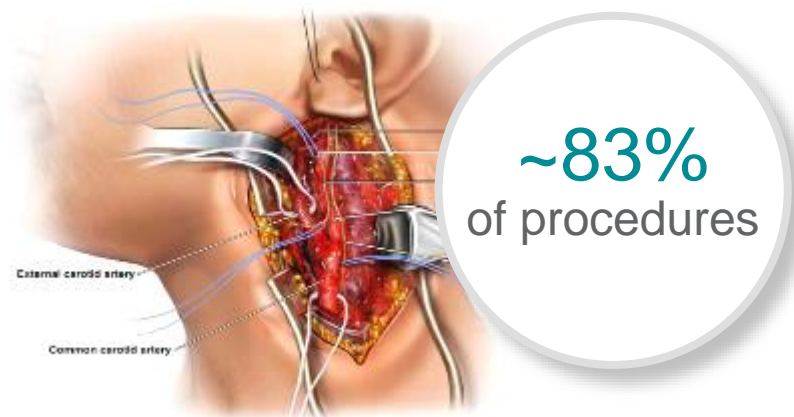


Major Adverse Events  
Collateral Damage

↓ Hospital Economics  
↓ Accountable Care

# “CAS: An Unacceptable Tradeoff”

## **SURGICAL:** Carotid Endarterectomy (CEA) 65 years



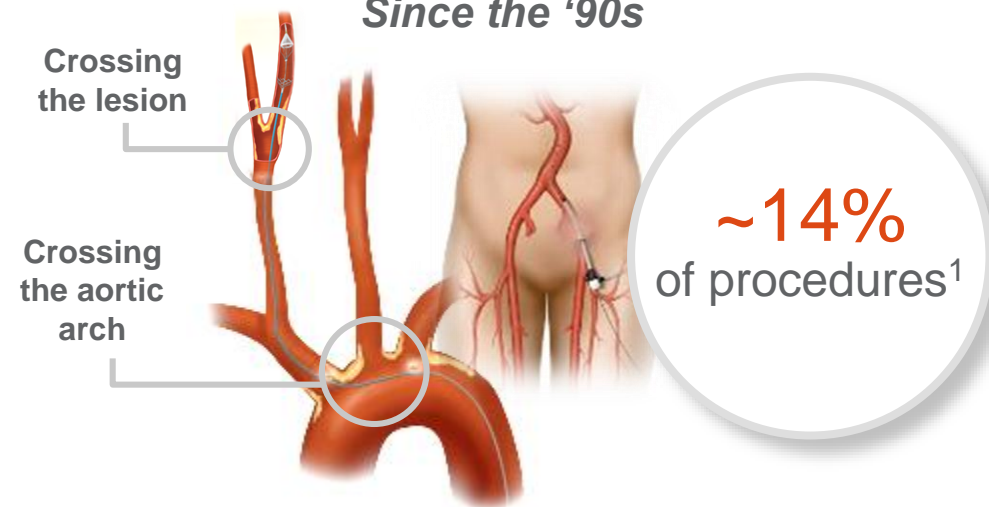
**SIGNIFICANT** adverse events



**LOW** 30-day stroke risk

**A Dated Standard of Care**

## **ENDOVASCULAR:** Transfemoral Carotid Artery Stenting (CAS) Since the '90s



**LOWER** adverse events



**HIGHER** (~2x) 30-day stroke risk

**A Niche Procedure**

Source: Modus Health Group 2018

<sup>1</sup> Excludes 2018 TCAR procedures

# A ~\$2.6B Annual US Treatment Opportunity in 2018

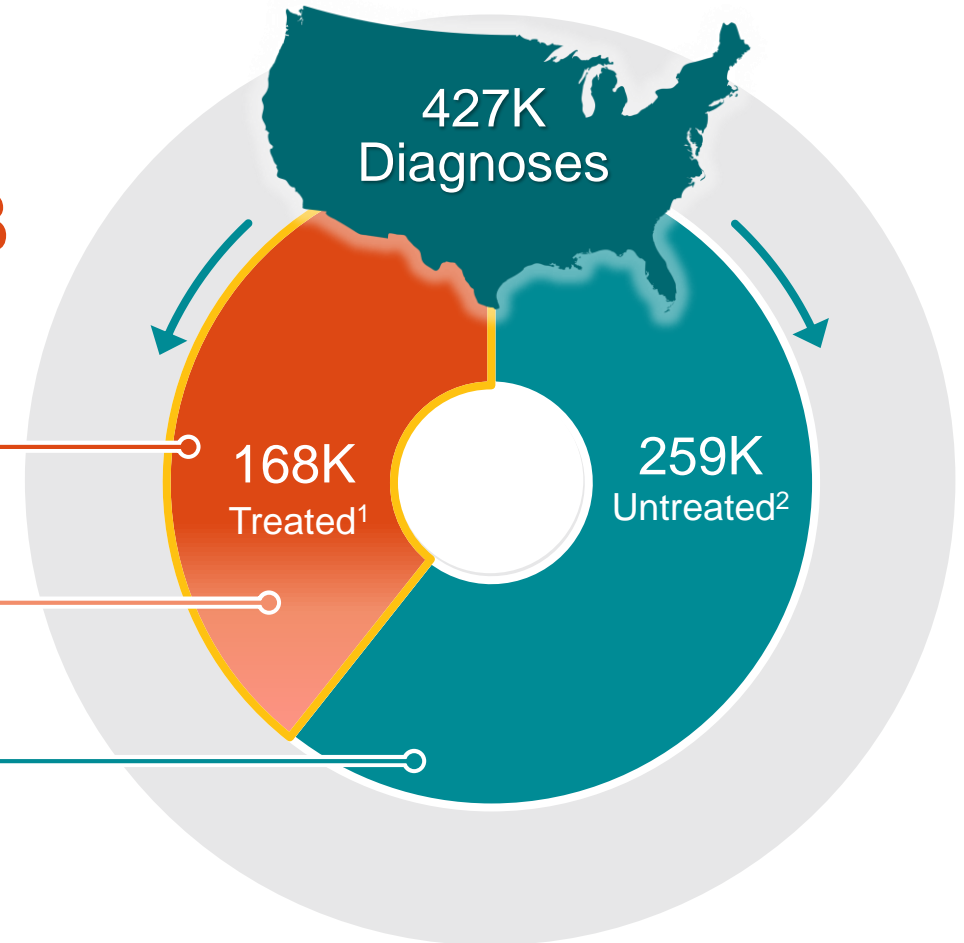
## Greenfield opportunity

**1** **Convert** current procedures  
Established market with suboptimal treatments **\$1.0B**

✓ **\$665M High Surgical Risk, ~2/3 or 111K procedures**

○ **\$340M Standard Surgical Risk, ~1/3 or 57k procedures**

**2** Treat today's **untreated** **\$1.6B**  
TCAR changes risk / reward



A New, Minimally Invasive Procedure with Clinical Advantages

Source: Modus Health Group data for 2017 and 2018; note: US opportunity calculated as procedure volume multiplied by average sales price of each TCAR product (1 unit each)

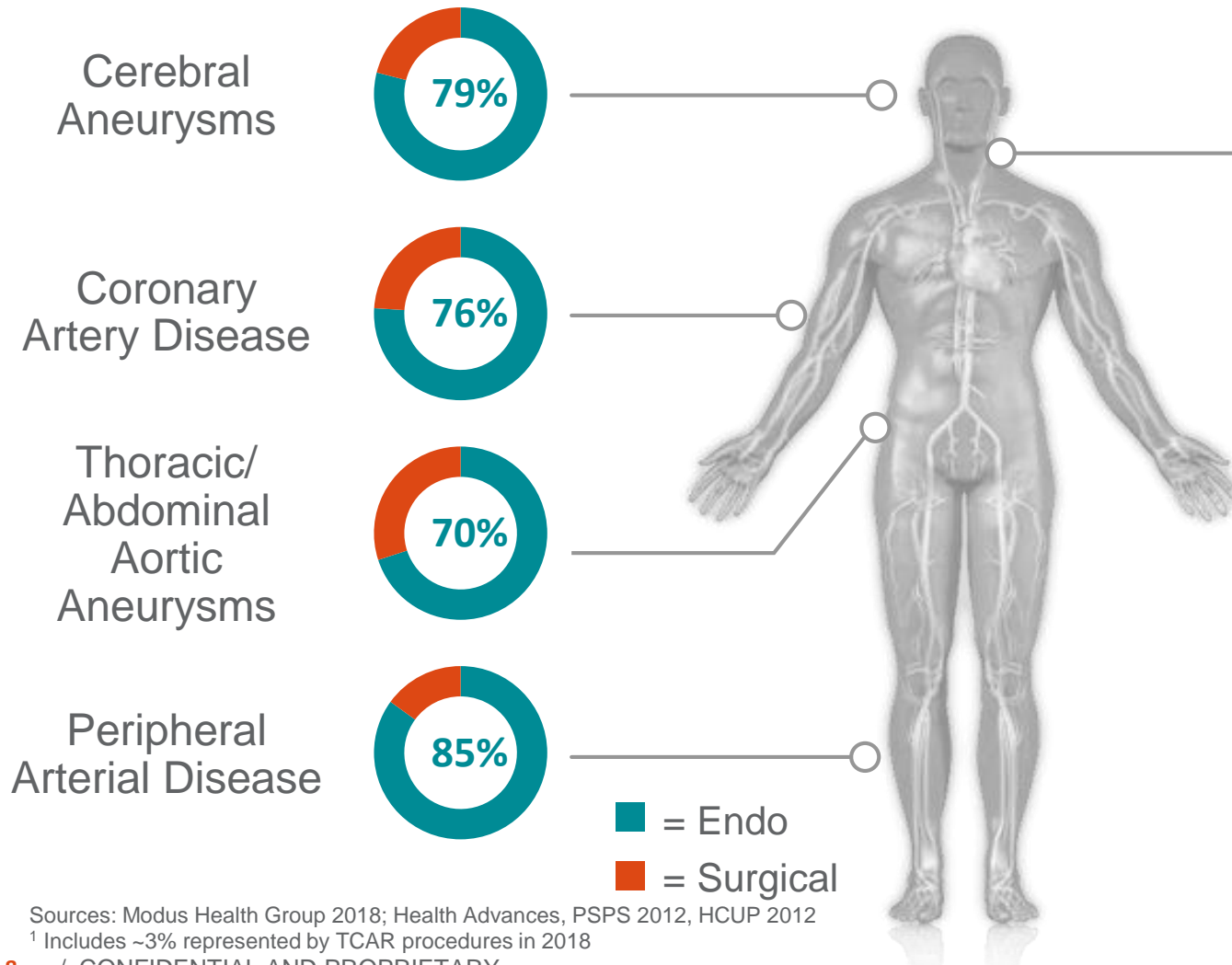
<sup>1</sup> Treated with CEA, CAS, or TCAR; does not include patients who undergo medical management alone; Includes both standard and high surgical risk

<sup>2</sup> Includes patients who receive no treatment or are treated with medical management alone



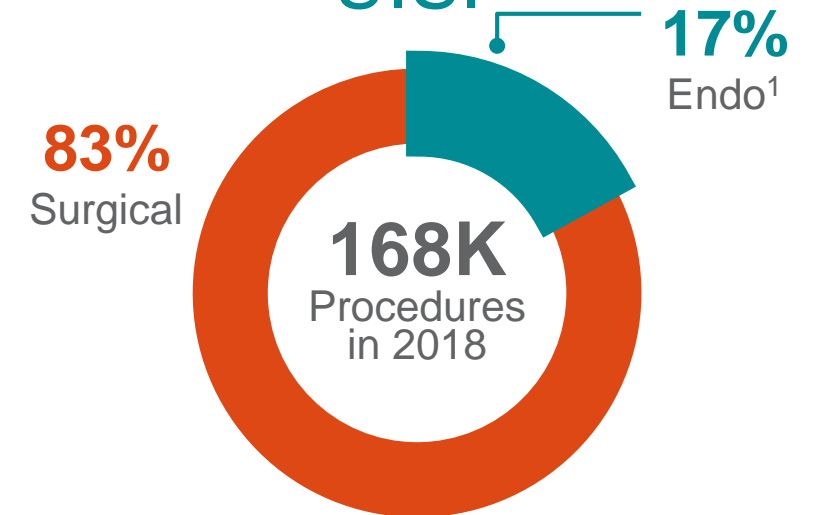
The New Normal:

# Endovascular Procedures



**THE LAST FRONTIER:**  
Open to Endo Conversion

## Carotid Artery Disease: U.S.

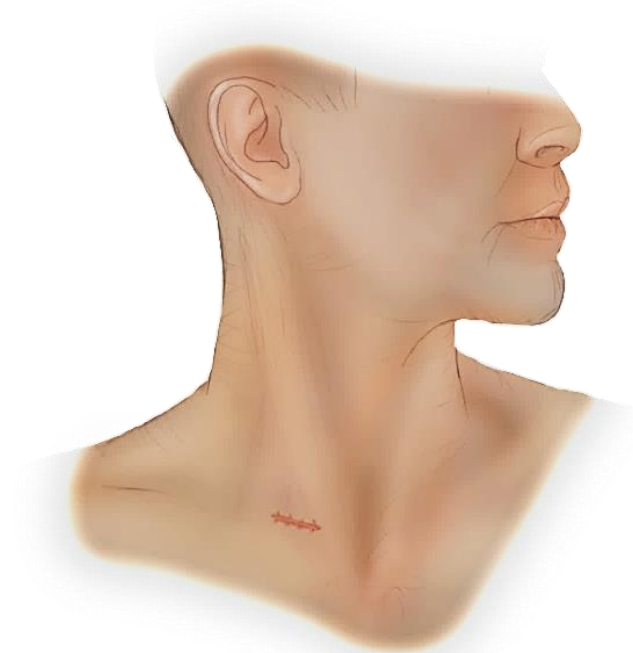


Sources: Modus Health Group 2018; Health Advances, PSPS 2012, HCUP 2012

<sup>1</sup> Includes ~3% represented by TCAR procedures in 2018

# TCAR is the Solution

## TCAR Paradigm Shift: Transcarotid



Minimally Invasive



Avoids Aortic Arch



Avoids Cranial Nerve Plexus



High Rate Flow Reversal Neuroprotection

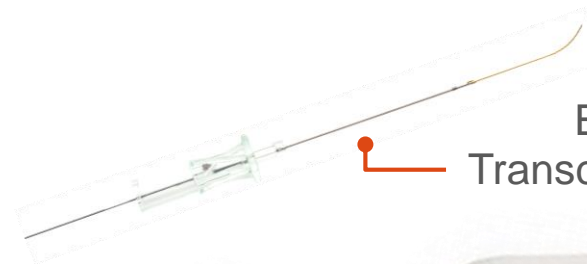
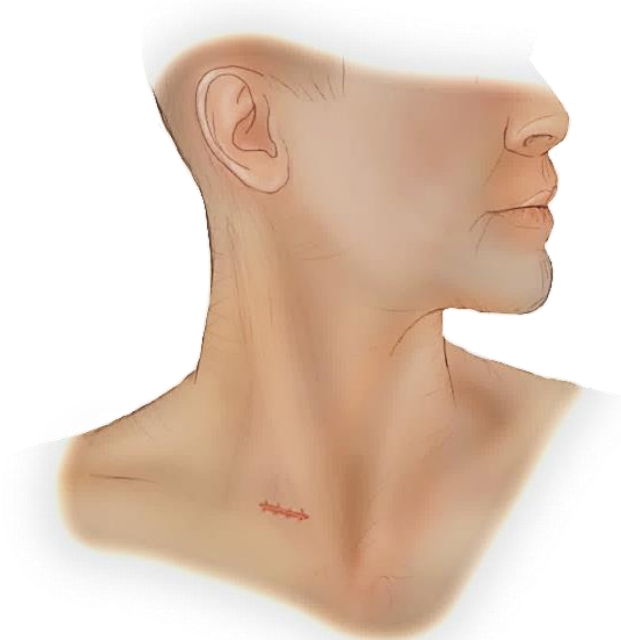


Easy, accurate stenting

TCAR combines advantages from both worlds: **surgical principles** of neuroprotection and game changing **endovascular technology**

# TCAR

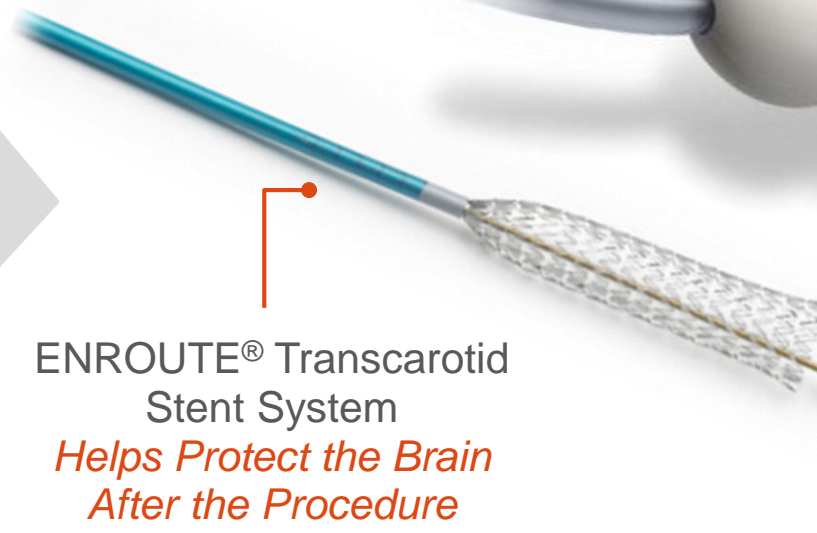
## Carotid-Specific Design, Dedicated Portfolio



ENHANCE®  
Transcarotid Peripheral  
Access Kit



ENROUTE® Transcarotid  
Neuroprotection System (NPS)  
*Helps Protect the Brain  
During the Procedure*

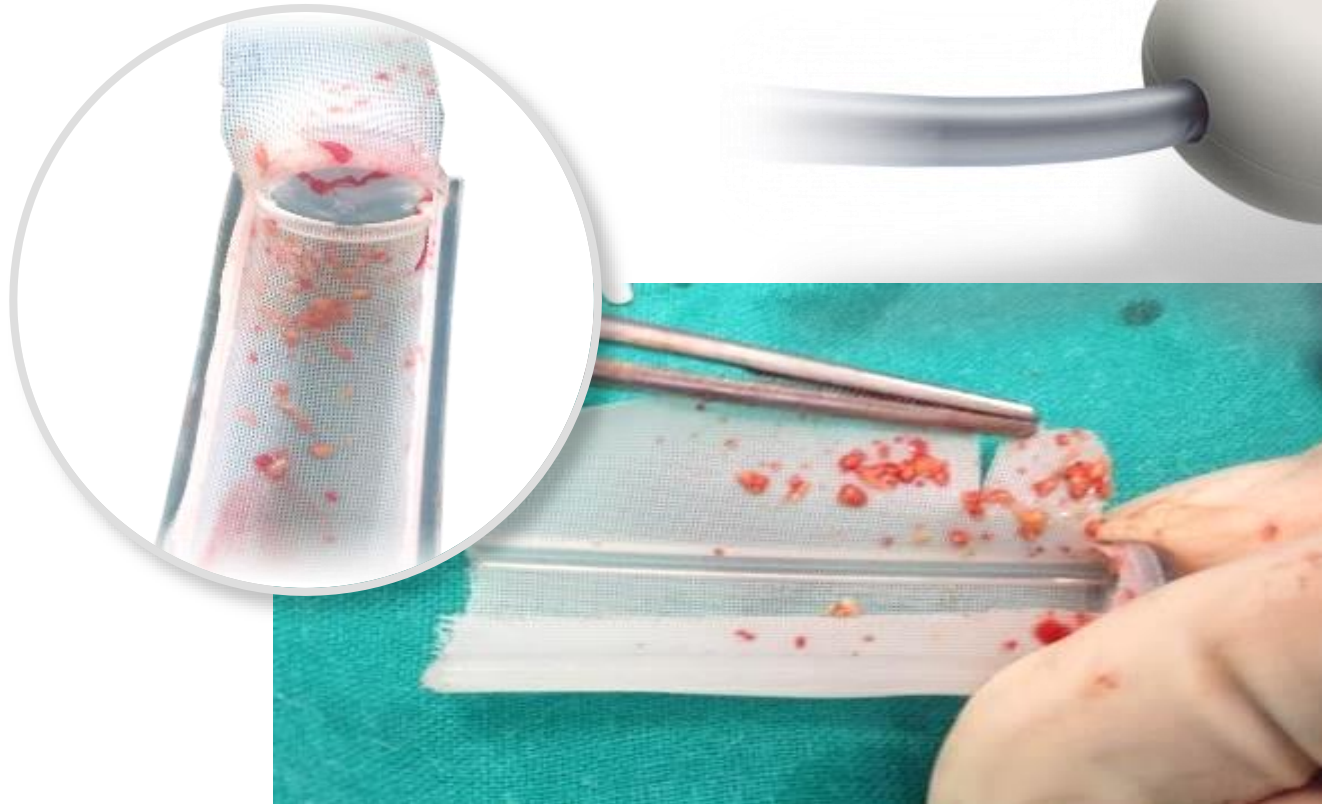


ENROUTE® Transcarotid  
Stent System  
*Helps Protect the Brain  
After the Procedure*



ENROUTE®  
0.014" Guidewire

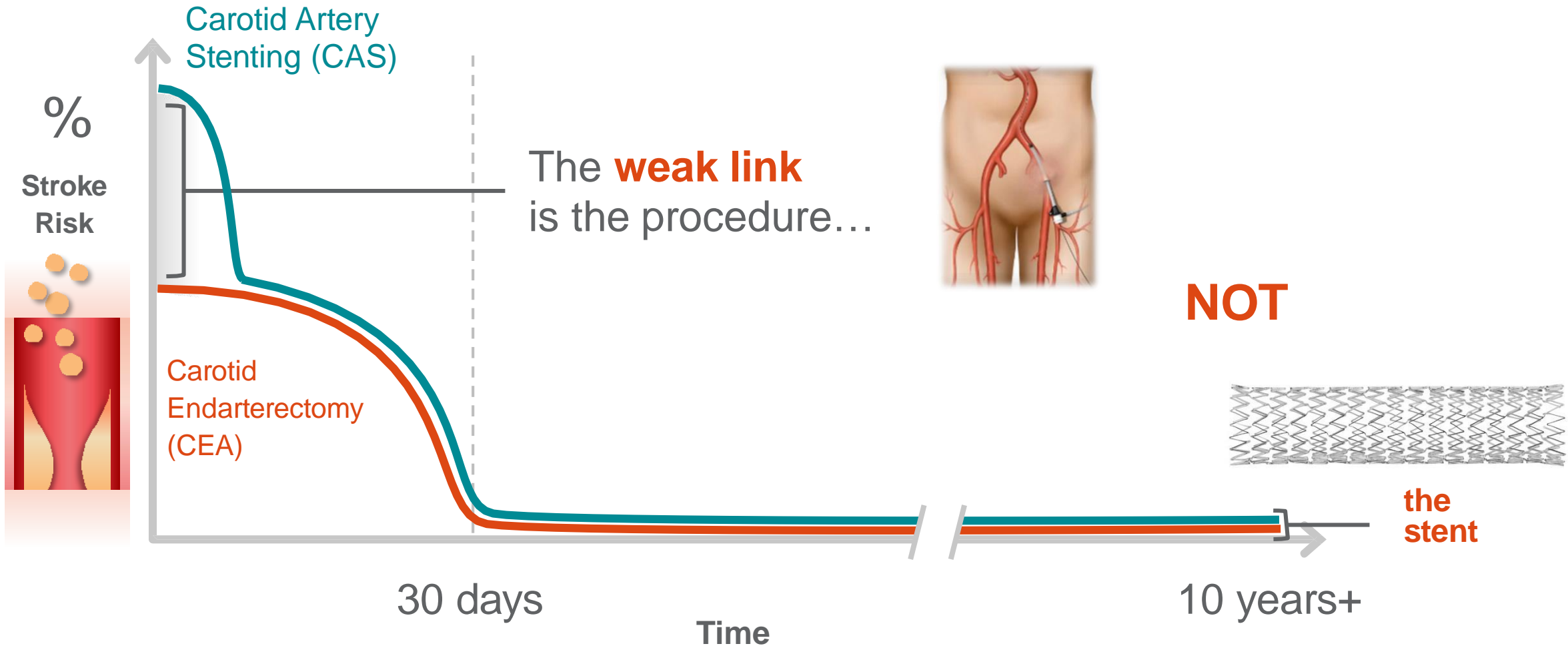
# The proof is in the filter



**>10,000**  
TCAR procedures  
worldwide<sup>1</sup>

<sup>1</sup> As of 05/08/2019

# Proven Stent Durability



Source: CREST 10-year follow-up, N Engl J Med 2016; 374:1021-1031.

# Why Vascular Surgeons Have Adopted TCAR

and are marching towards the standard of care

Growing clinical evidence base

P2P influence & inter/intra specialty competition

Quality initiatives and economic incentives

Better patient and physician experience



# Clinical Trials: 30 Day Stroke

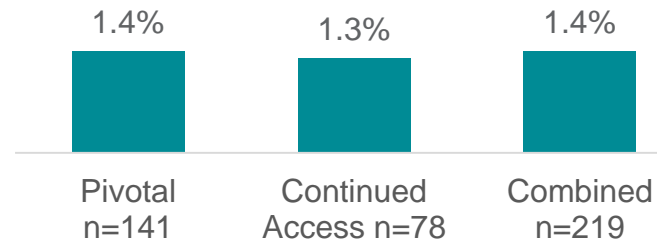
## ROADSTER Trial Design and Purpose

- 1<sup>st</sup> time TCAR in the US
- 1<sup>st</sup> generation NPS
- Supported 510(k) clearance of NPS
- Supported PMA for ENROUTE Stent

### ROADSTER<sup>1</sup>

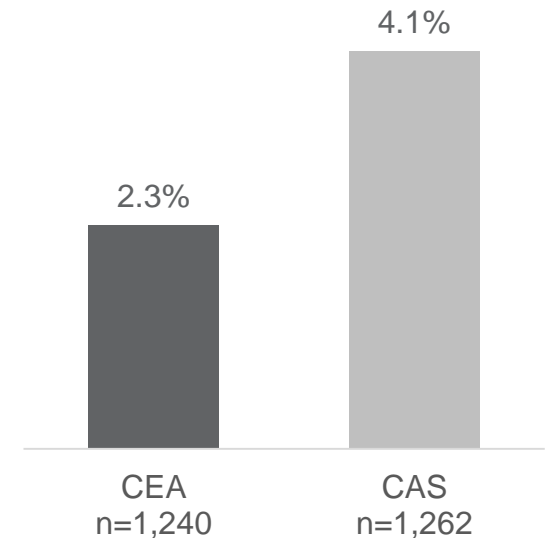
*“The overall **stroke rate of 1.4%** is the **lowest reported to date** for any prospective, multi-center trial of carotid stenting.”*

– J Vasc Surg 2015;62:1227-35



High Surgical Risk

### CREST<sup>2</sup>



Standard Surgical Risk

<sup>1</sup> J Vasc Surg 2015;62:1227-35; ROADSTER outcomes presented on an “intention to treat” basis

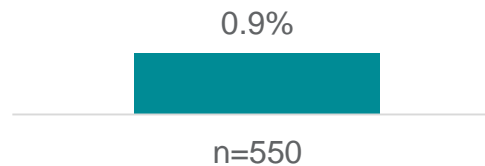
<sup>2</sup> N Engl J Med 2010; 363:11-23

# Real World Registries: 30 Day Stroke

## ROADSTER2 Trial Design and Purpose

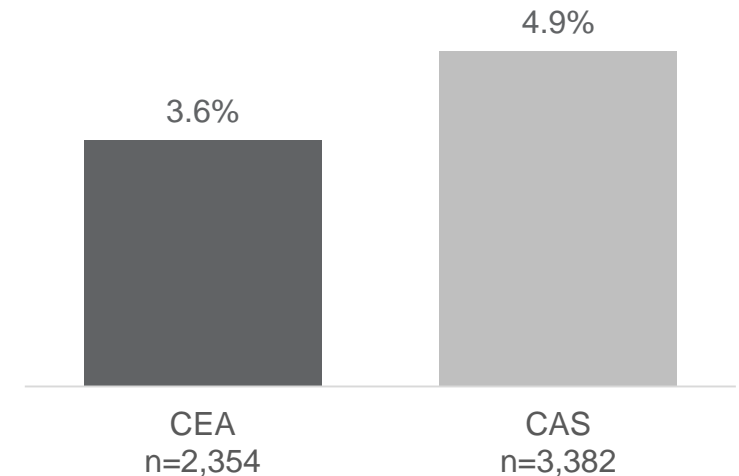
- FDA condition of PMA stent approval
- Evaluate real world usage
- 600+ patient enrollment completed

### ROADSTER2 Interim<sup>1</sup>



High Surgical Risk

### SVS Registry



High Surgical Risk

Silk Road Medical, J Vasc Surg 2013;57:1318-24

SVS: Society for Vascular Surgery

<sup>1</sup>Based on most recent report to the FDA in November 2018; ROADSTER2 outcomes presented on a "per protocol" basis





Unprecedented alignment

**TCAR**



September 2016



*High Surgical Risk: Symptomatic and Asymptomatic*

# TCAR Surveillance Project (TSP)

## TSP Trial Design and Purpose

- Evaluate safety and effectiveness of TCAR vs CEA
- High Surgical Risk patients
- Open-ended
- Funded by SVS and participating VQI hospitals

## VASCULAR ANNUAL MEETING

*“In-hospital Outcomes of TransCarotid Artery Revascularization and Carotid Endarterectomy in the SVS Vascular Quality Initiative”*

*Presented by Dr. Mark Schermerhorn at VAM June 2018 (n=1,182 TCAR and 10,797 CEA)*

## VEITH SYMPOSIUM<sup>®</sup> Connecting The Vascular Community

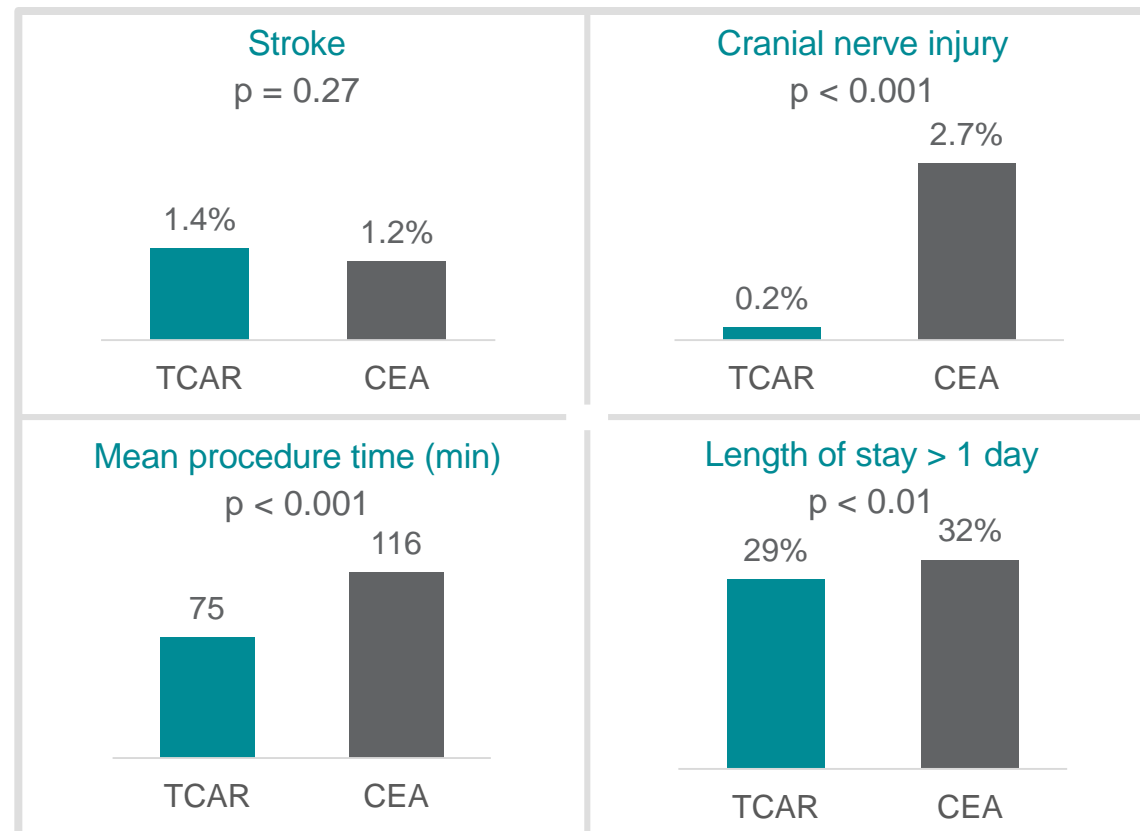
*“Outcomes of TCAR (TransCarotid Artery Revascularization) Compare Favorably with Those of Carotid Endarterectomy (CEA) in Symptomatic and Asymptomatic Patients Despite the Higher Medical Risk of the TCAR Patients: From the SVS/VQI Registry”*

*Presented by Dr. Mark Schermerhorn at VEITH November 2018 (n=2,545 TCAR and 43,114 CEA)*

# In-Hospital Outcomes of the SVS TCAR Surveillance Project

## Key outcomes<sup>1</sup>

- ✓ TCAR showed comparable stroke rates versus CEA **despite older, sicker patients**
- ✓ TCAR displayed 10x lower rates of in-hospital cranial nerve injury
- ✓ TCAR showed a significant reduction in mean procedure time versus CEA
- ✓ TCAR reduced the likelihood of a prolonged hospital stay<sup>2</sup>
- ✓ Simple, efficient procedure improves hospital workflow resulting in economic benefits



Marc Schermerhorn, MD; Patric Liang, MD; Hanaa Dakour Aridi, MD; Vikram Kashyap, MD; Grace Wang, MD; Brian Nolan, MD; Jack Cronenwett, MD; Jens Eldrup-Jorgensen, MD; Mahmoud Malas, MD, MHS - VEITHsymposium, Nov 2018

<sup>1</sup> Outcomes data represent unadjusted, in-hospital outcomes

<sup>2</sup> Prolonged hospital stay denotes stay of greater than 1 day

# TCAR: Established Codes and Payment

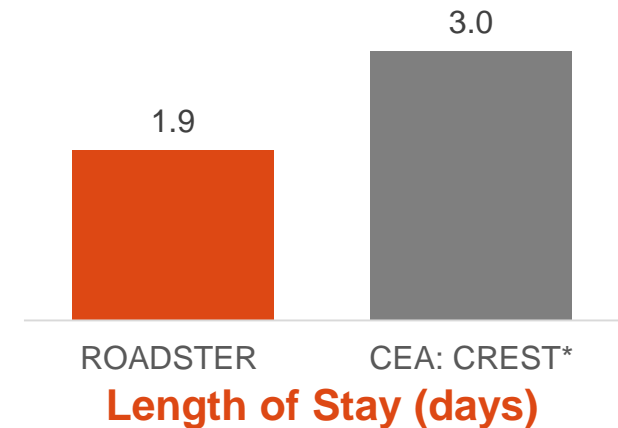
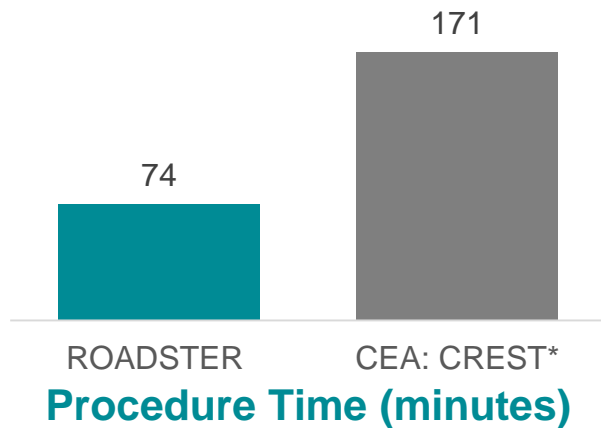
Economic value proposition easily understood by Value Analysis Committees

## Physician: CPT Code

|             |       |                |
|-------------|-------|----------------|
| <b>TCAR</b> | 37215 | <b>\$1,050</b> |
| CEA         | 35301 | <b>\$1,187</b> |

## Hospital: ICD-10 Codes

|             |             |                 |
|-------------|-------------|-----------------|
| <b>TCAR</b> | DRGs 034-36 | <b>\$13,132</b> |
| CEA         | DRGs 037-39 | <b>\$9,048</b>  |

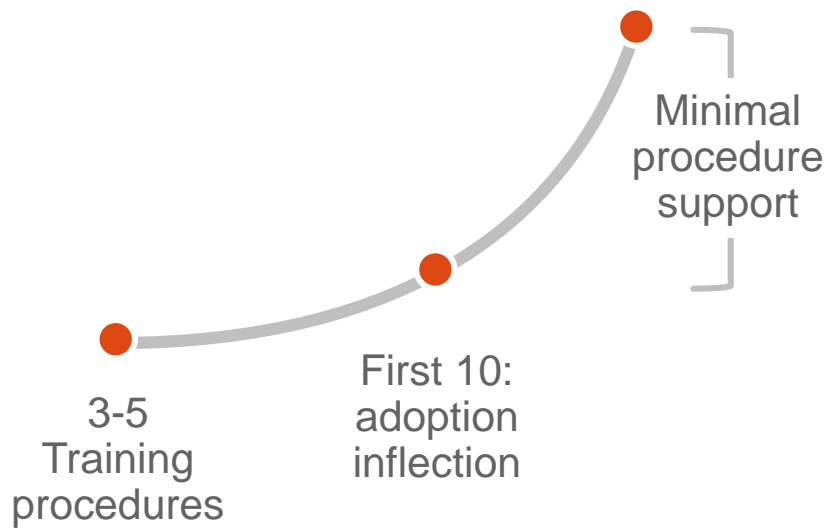


Medicare national average payment levels for CPT and DRG figures in 2019  
 \*Standard Surgical Risk patients (ROADSTER High Surgical Risk)

# Easy-to-Learn Procedure

with Many Physicians Trained

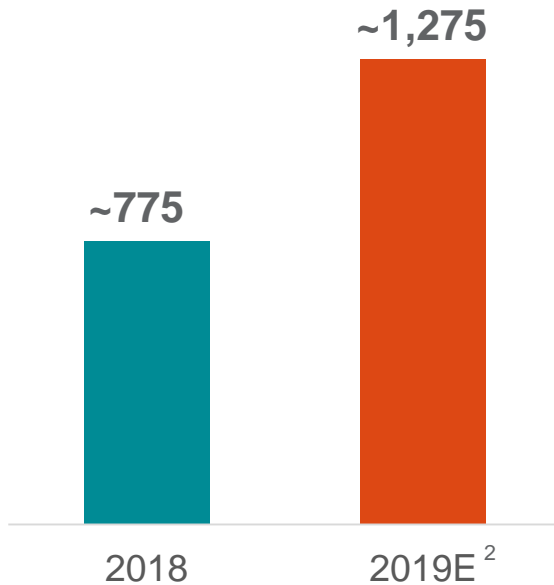
## Indicative Short Learning Curve



# Commercial Strategy: Efficient Go-to-Market

## Concentrated Market

~2,750 physicians perform  
~80% of procedures<sup>1</sup>

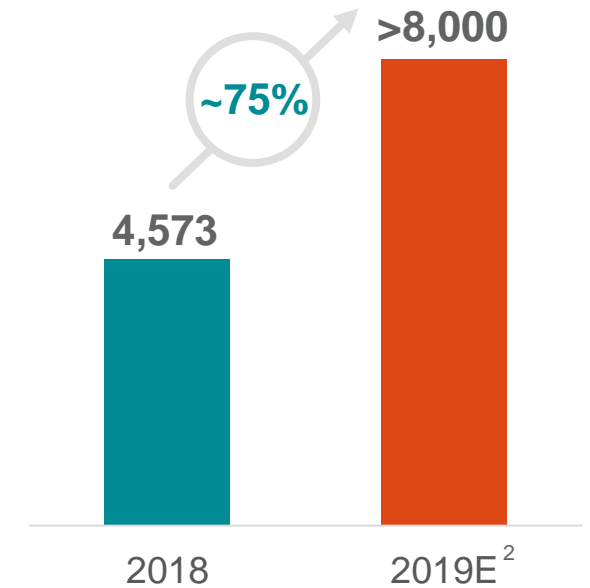


PHYSICIANS TRAINED

## Clinically-Focused Direct Sales Force

**Concentrated**  
hospital base and  
procedure volume  
drives **efficient**  
coverage model

## Growing Adoption



U.S. PROCEDURES

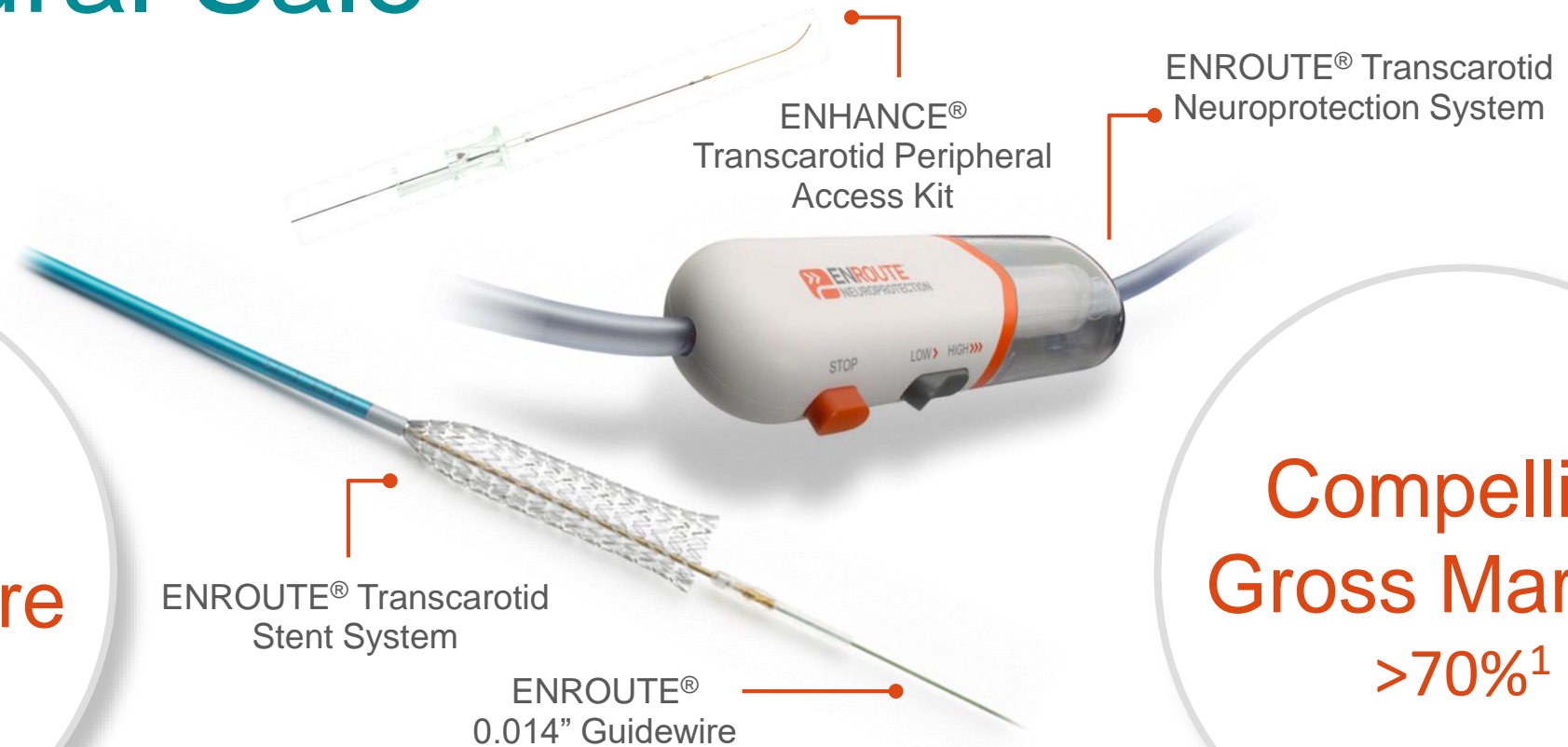
<sup>1</sup> Data as of 12/31/18 (Source: Independent 3rd Party Market Data)

<sup>2</sup> Outlook as of 5/8/2019

# Attractive Business Model

## Procedural Sale

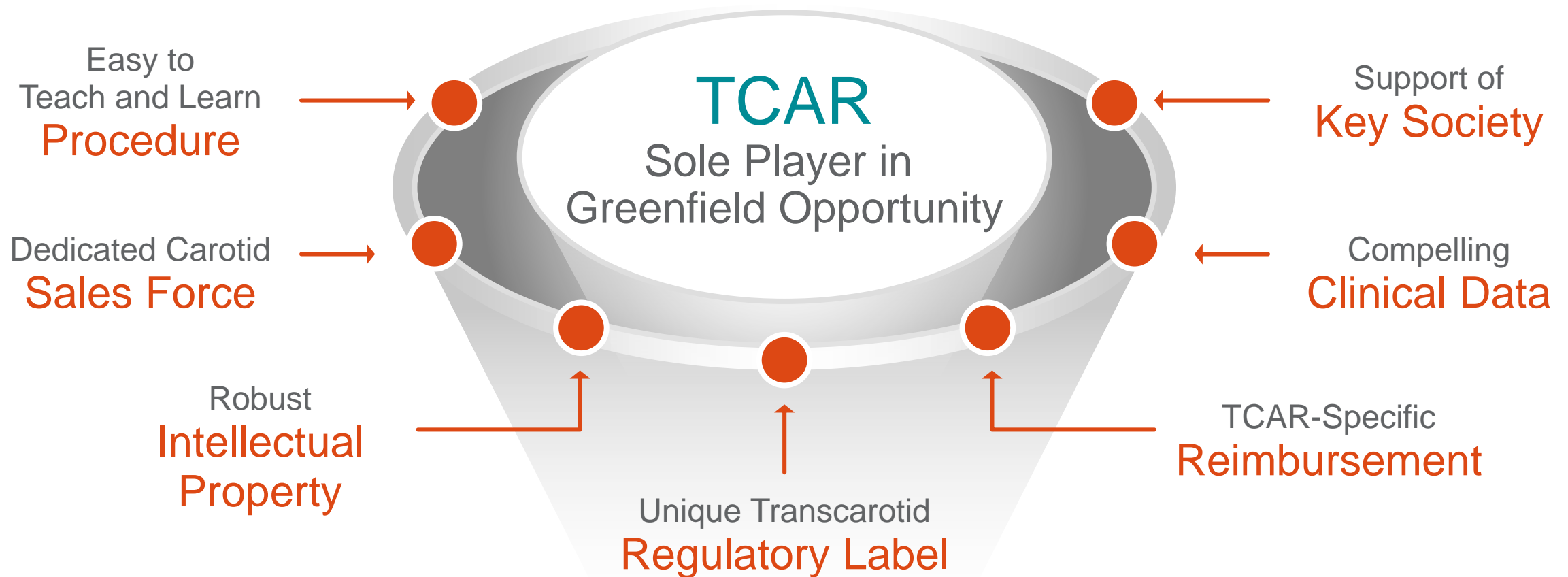
4 Products  
1 Procedure  
**Full Procedure  
ASP**



**Compelling  
Gross Margins  
>70%<sup>1</sup>**

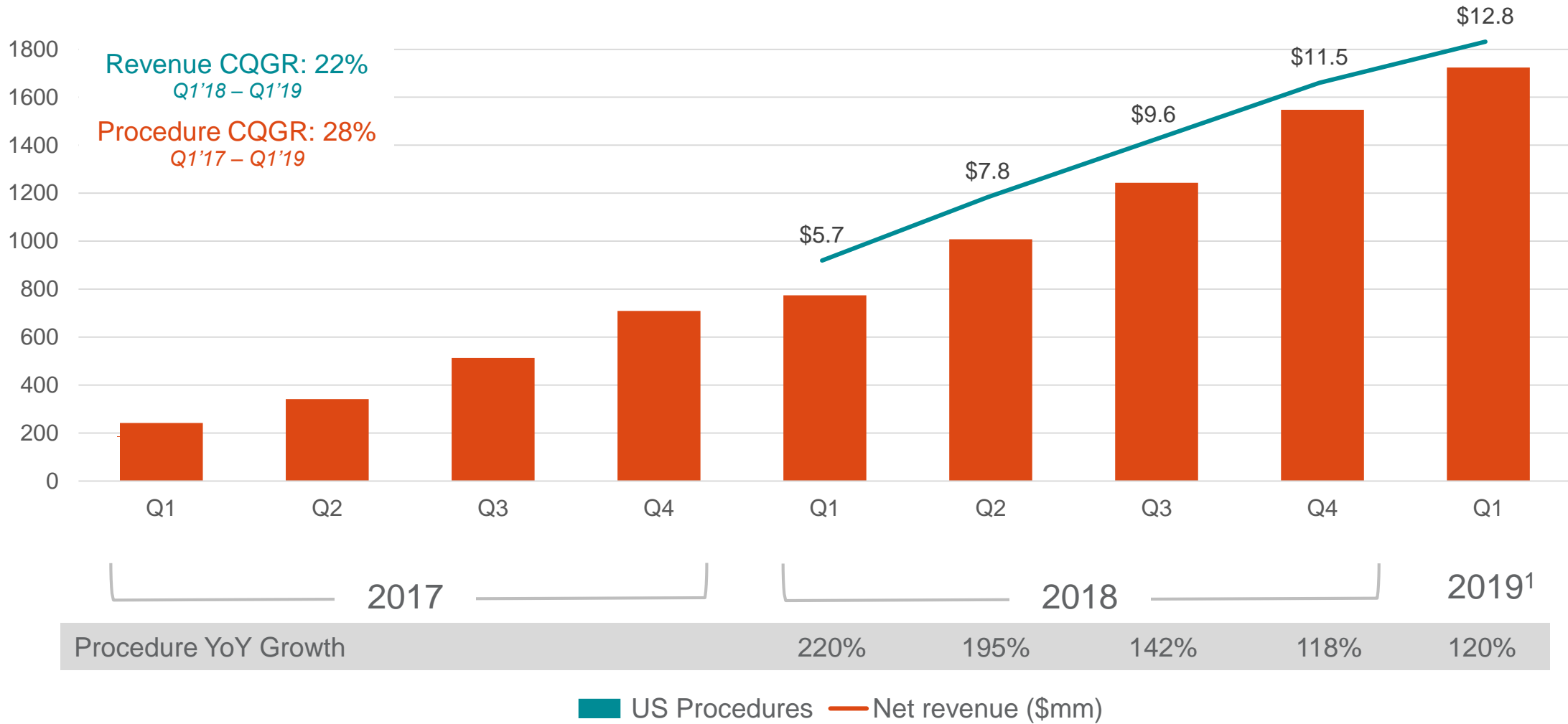
<sup>1</sup> As of 03/31/2019

# Building and Maintaining a Sustainable Competitive Advantage





# Procedure-Driven Ramp

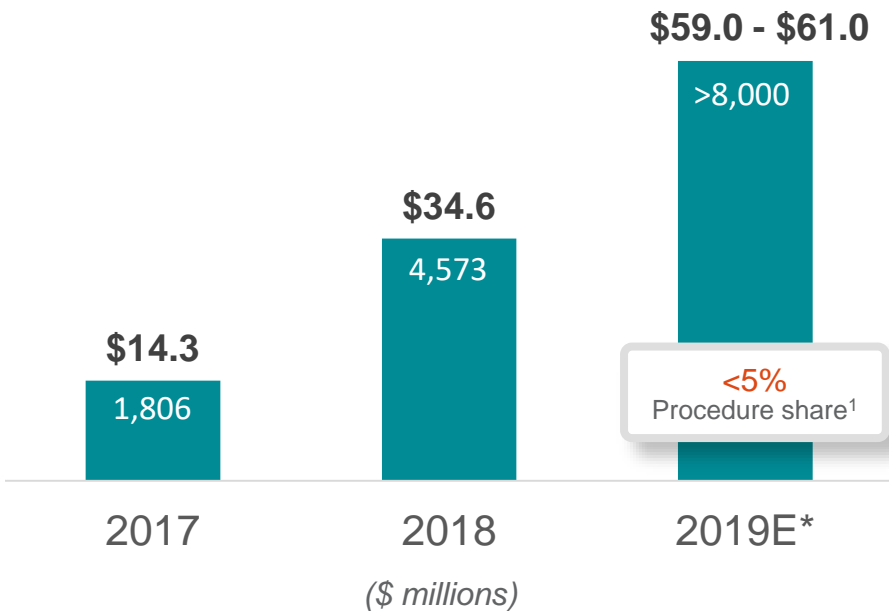


2017 and 2018 procedure metrics and 2018 audited financials  
<sup>1</sup> Q1 2019 procedures and revenue as of 03/31/2019

# Strong Financial Profile

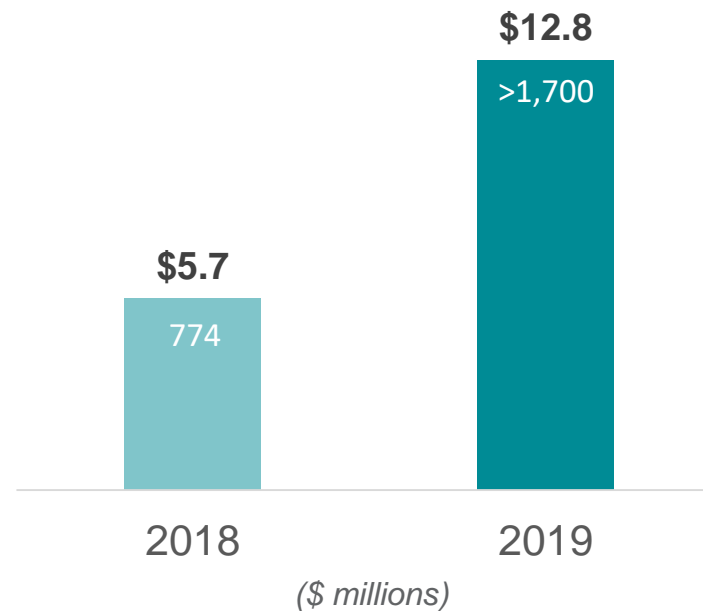
## Annual Results

Revenue CAGR: 105%



## First Quarter Results<sup>2</sup>

Revenue Growth: 124%



## Q1 2019 Performance

- 1Q 2019 revenue growth of 124% year over year
- Increase in gross margin to 74% in 1Q 2019

## 2019 Expectations

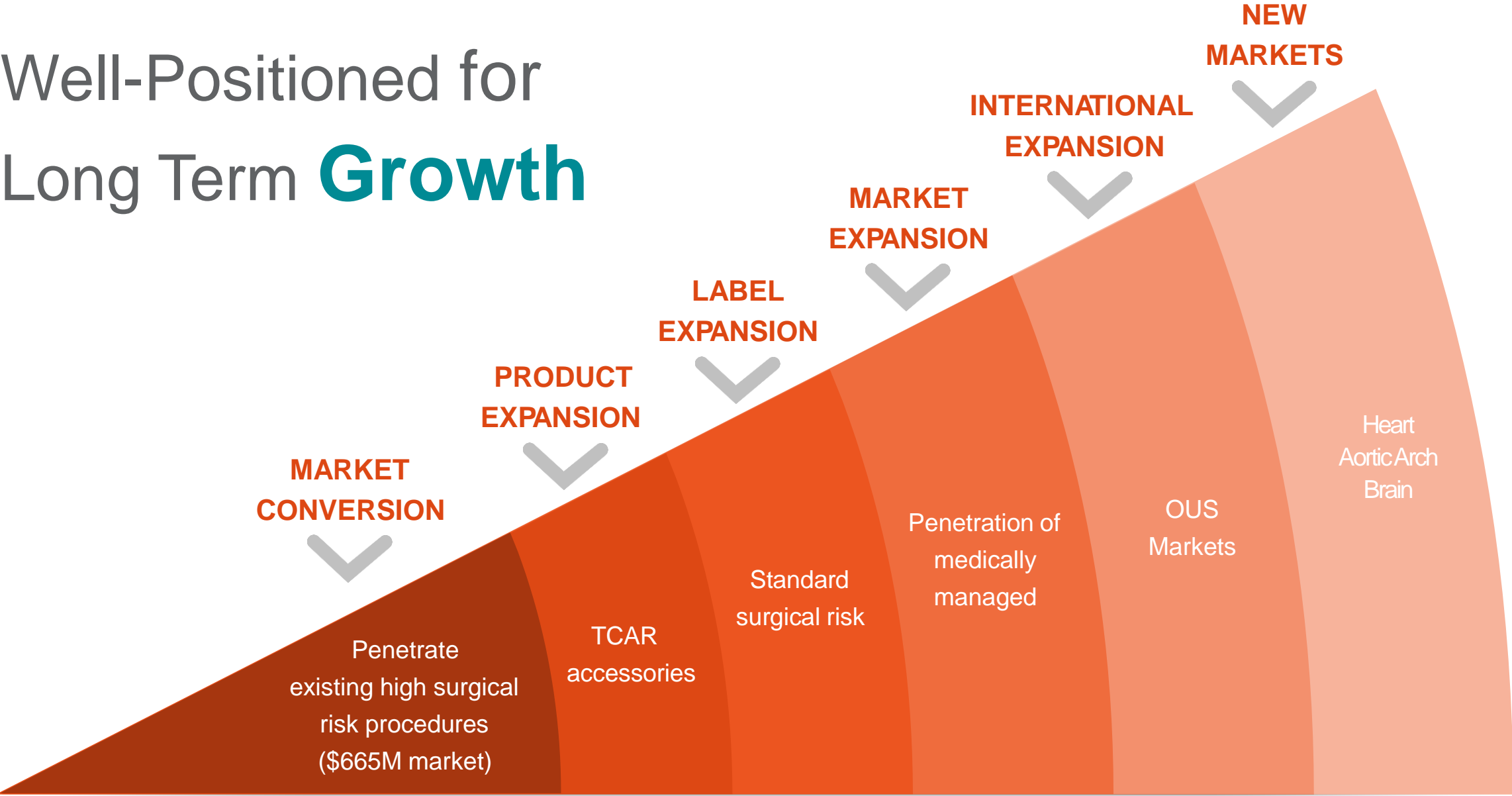
- 2019 annual revenue guidance \$59M - \$61M
- Procedures >8,000
- Physicians trained ~500
- Sales territories to reach ~35

\*As of 05/08/2019

<sup>1</sup> Represents annualized figure relative to total carotid procedures in 2018 of 168k

<sup>2</sup> Three-months ended March 31, 2019 compared to three-months ended March 31, 2018

# Well-Positioned for Long Term **Growth**



# Built For Size and Scale

## Proven Management Team



**Erica Rogers**  
President & CEO

Med360, Visiogen, Boston Sci, Target



**Lucas Buchanan**  
Chief Financial Officer

The Vertical Group, Medtronic, E&Y

|                           |                                 |   |
|---------------------------|---------------------------------|---|
| <b>Andrew Davis</b>       | EVP Global Sales & Marketing    | Medtronic, Acelity, Boston Scientific         |
| <b>Richard Ruedy</b>      | EVP Clinical, Reg, Quality      | Abbott, Nevro, Cardica, Acta                  |
| <b>Alison Highlander</b>  | VP Human Resources              | Roche, SRI, Atomic Tangerine                  |
| <b>Bob Nicholas</b>       | VP Operations                   | Cardiokinetix, Stryker, Concentric, Heartport |
| <b>Tammy Leitsinger</b>   | VP Med Affairs & Prof Education | Cordis, J&J                                   |
| <b>Mark Page</b>          | VP Marketing                    | Arstasis, Flowcardia, Boston Sci              |
| <b>Frances Versprille</b> | VP Commercial Ops & Analytics   | Cordis, Biocompatibles                        |
| <b>Shari Rideout</b>      | VP Quality                      | Vital Connect, Cordis, Carbylan, Depuy/J&J    |

## Investors

WARBURG PINCUS

The Vertical Group 

NORWEST | VENTURE PARTNERS

Janus Henderson  
INVESTORS

 CRG

# A New Era, A New Vascular Category

## ~\$2.6B US MARKET OPPORTUNITY

Carotid artery disease is a **multi-billion dollar category** with **one TCAR player** with the potential to become the **standard of care** for the last endovascular frontier

## COMPELLING CLINICAL DATA

**Safety, effectiveness and clinical advantages** of TCAR have been observed in **multiple clinical trials and post-market studies**

## TCAR-SPECIFIC REIMBURSEMENT

TCAR is **reimbursed under established codes and payment levels** and we are the **only company with transcrotid FDA labeling**

## EFFICIENT COMMERCIAL MODEL

**Concentrated hospital base** and procedure volume combined with **easy-to-learn procedure** drives **efficient coverage model**

## STRONG FINANCIAL PROFILE

**Robust commercial ramp**, compelling gross margins and significant operating leverage potential



APPENDIX

# Silk Road: Robust IP with Long Runway

United States



OUS



|                      |    |    |
|----------------------|----|----|
| Issued Patents       | 34 | 13 |
| Pending Applications | 20 | 20 |

## Transcarotid devices and methods related to:

- Transcarotid-specific devices and methods for percutaneous and mini-open exposures
- Flow reversal
- Flow control and filtration
- Short interventional devices
- Access and vessel closure devices
- Transcarotid TAVR and aortic arch procedures
- Transcarotid neurovascular procedures

**High-Quality IP  
Claims Include:**



# TCAR Surveillance Project (TSP)

## TSP Trial Design and Purpose

- Evaluate safety and effectiveness of TCAR vs CEA
- High Surgical Risk patients
- Open-ended
- Funded by SVS and participating VQI hospitals

## Key patient demographics

| Baseline characteristics | TCAR N=2,545 | CEA N=43,114 | P-value |
|--------------------------|--------------|--------------|---------|
| Coronary Artery Disease  | 51%          | 27%          | <0.001  |
| Prior CHF                | 19%          | 11%          | <0.001  |
| Prior PCI                | 28%          | 22%          | <0.001  |
| COPD                     | 29%          | 23%          | <0.001  |

Marc Schermerhorn, MD; Patric Liang, MD; Hanaa Dakour Aridi, MD; Vikram Kashyap, MD; Grace Wang, MD; Brian Nolan, MD; Jack Cronenwett, MD; Jens Eldrup-Jorgensen, MD; Mahmoud Malas, MD, MHS - VEITHsymposium, Nov 2018