

TCAR

TransCarotid Artery Revascularization

**Driven by
Stroke
Prevention**

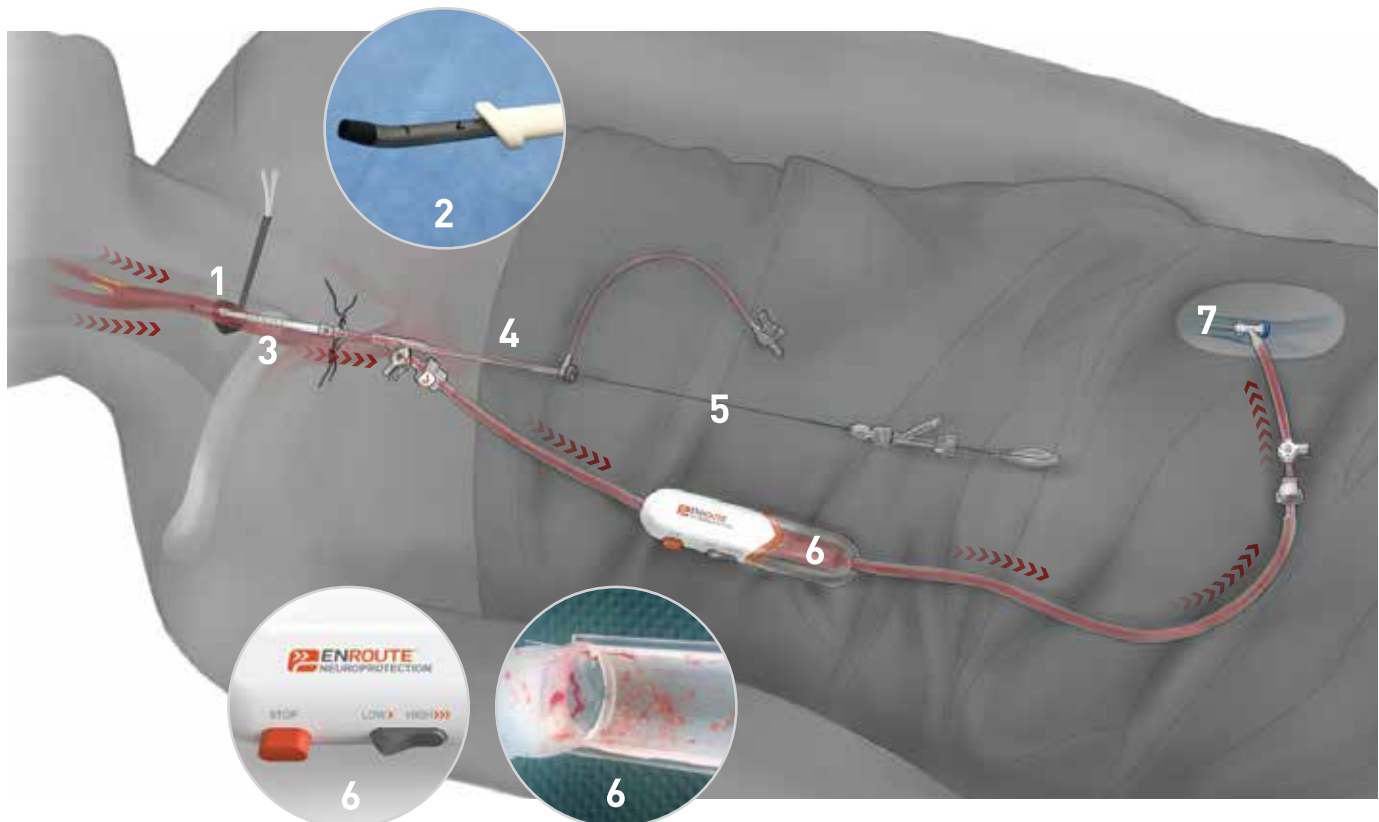


SILKROAD 
MEDICAL®

ENROUTE®

Transcarotid Neuroprotection & Stent System

1. 035" extra support guidewire, dilator and Uber Flex™ arterial sheath designed in combination for **atraumatic vessel entry**.
2. Angled-tip Uber Flex™ arterial sheath maintains coaxial position in lumen for **smooth interventional device delivery** and **optimized flow reversal**.
3. Uber Flex™ arterial sheath includes outer stopper with suture grooves and hub eyelets for **sheath stability**.
4. Extended working channel for interventional device delivery **enhances transcarotid ergonomics** away from image intensifier.



5. Shorter length 57cm ENROUTE Transcarotid Stent delivery system **optimizes working area** and reduces stored energy for **precise stent deployment**.
6. Dynamic flow controller **modulates reverse flow rate** and integrated, 200µ filter **captures embolic debris**.
7. Percutaneous Venous Return Sheath **completes the circuit** and returns filtered blood to the patient.

TCAR



Forward

TransCarotid Artery Revascularization

Direct carotid artery access with **robust blood flow reversal** during angioplasty and stenting. Avoids unprotected steps and removes micro and macro emboli throughout the intervention for **CEA-like neuroprotection** in a **less invasive approach**.

SURGICALLY INSPIRED:

- Direct carotid access
- CCA clamp & loop control
- Backbleeding to clear debris



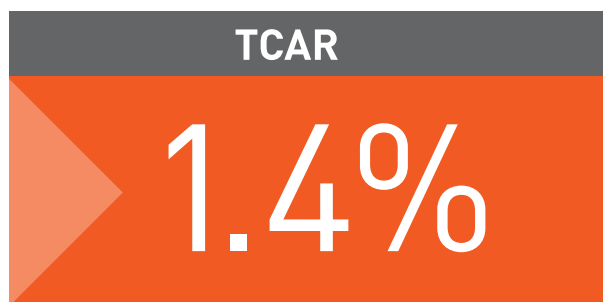
ENROUTE Transcarotid Stent delivery under high reverse flow in TCAR Procedure

Thinking Through Reverse Flow

TCAR Clinical Outcomes

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

> TCAR Stroke Rates in Clinical Trials



HIGH SURGICAL RISK PATIENTS

ROADSTER¹ N=219



STANDARD SURGICAL RISK PATIENTS

CREST² N=1,240

> Real World Stroke Rates in High Surgical Risk Patients

1.4%

TCAR

VQI TSP* N=2,545

3.6%

CEA

SVS Registry³ N=6,370

J Vasc Surg. 2013;57:1318-24

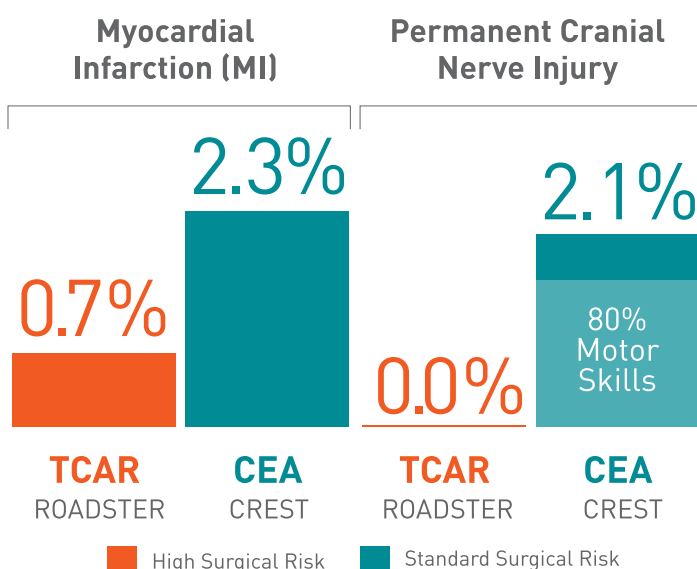
* In-Hospital Outcomes of TCAR and CEA in the SVS-VQI TCAR Surveillance Project - Marc Schermerhorn, MD; Patric Liang, MD; Hanaa Dakour Aridi, MD; Vikram Kashyap, MD; Grace Wang, MD; Brian Nolan, MD; Jack Cronenwett, MD; Jens Eldrup-Jorgensen, MD; Mahmoud Malas, MD, MHS – VEITH Symposium Presentation, November 2018

¹ ROADSTER: J Vasc Surg. 2015 Nov;62(5):1227-34. The Silk Road System for Transcervical Access with Reversal of Flow to Perform TCAR: Results of the ROADSTER Trial - VEITH, 2016

² CREST Trial: N Engl J Med 2010;363:11-23

³ The impact of Centers for Medicare and Medicaid Services high-risk criteria on outcome after carotid endarterectomy and carotid artery stenting in the SVS Vascular Registry - Marc L. Schermerhorn, MD et al.

Powerful Reduction in Surgical Morbidity



Less Invasive Procedure



CEA Incision

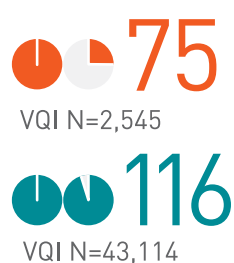


TCAR Incision

Cosmetic result of less invasive procedure.
Local anesthesia can improve recovery time.

TRANSCAROTID EFFICIENCY

OR Time (mins) ● TCAR ● CEA



Length of Stay (mean)



ORDERING INFORMATION

ENROUTE® Transcarotid Stent System		
Catalog Number*	Diameter x Length (mm)	Recommended Vessel Size (mm)
SR-0620-CS	6 X 20	4-5
SR-0630-CS	6 X 30	4-5
SR-0640-CS	6 X 40	4-5
SR-0730-CS	7 X 30	5-6
SR-0740-CS	7 X 40	5-6
SR-0830-CS	8 X 30	6-7
SR-0840-CS	8 X 40	6-7
SR-0930-CS	9 X 30	7-8
SR-0940-CS	9 X 40	7-8
SR-1030-CS	10 X 30	8-9
SR-1040-CS	10 X 40	8-9

*Please consult your local sales representative for product availability.

ENROUTE 0.014" Guidewire	
Catalog Number	Shipped
SR-014-GW	5/box
Components	
95cm 0.014" Guidewire	

Indications for Use: The ENROUTE® Transcarotid Stent System used in conjunction with the ENROUTE Transcarotid Neuroprotection System (NPS) is indicated for the treatment of patients at high risk for adverse events from carotid endarterectomy, who require carotid revascularization and meet the criteria outlined below.

1. Patients with neurological symptoms and > 50% stenosis of the common or internal carotid artery by ultrasound or angiogram OR patients without neurological symptoms and > 80% stenosis of the common or internal carotid artery by ultrasound or angiogram, AND
2. Patients must have a vessel diameter of 4-9mm at the target lesion, AND
3. Carotid bifurcation is located at minimum 5cm above the clavicle to allow for placement of the ENROUTE Transcarotid NPS.

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ENROUTE® Transcarotid Neuroprotection System	
Catalog Number	Shipped
SR-200-NPS	1 Each
Components	
<ul style="list-style-type: none"> • Transcarotid Arterial Sheath* with Arterial Dilator • Venous Return Sheath with Venous Dilator • Flow Controller with Filter • 0.035" Extra Support, J-Tip Guidewire 	

ENHANCE® Transcarotid Peripheral Access Kit		
Catalog Number	Components	Shipped
SR-4F21G7D-MP	7cm 21G needle 50cm 0.018" microwire 4F 15cm sheath & dilator 4F stiffened dilator 20cm extension tube	10/box

Indications for Use: The ENROUTE® Transcarotid Neuroprotection System is intended to provide transcarotid vascular access, introduction of diagnostic agents and therapeutic devices, and embolic protection during carotid artery angioplasty and stenting procedures for patients diagnosed with carotid artery stenosis and who have the appropriate anatomy described below:

- Adequate femoral venous access
- Common carotid artery reference diameter of at least 6mm.
- Carotid bifurcation is a minimum of 5cm above the clavicle as measured by duplex Doppler ultrasound (DUS) or computerized axial tomography (CT) angiography or magnetic resonance (MR) angiography

Please refer to Instructions for Use for indications, contraindications, warnings and precautions.

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.



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