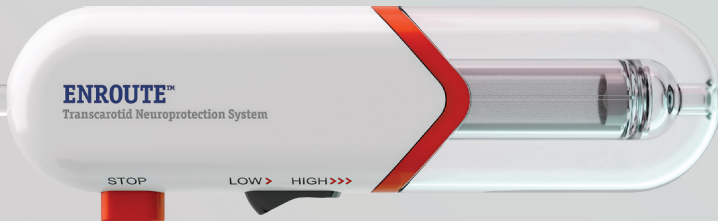


**ENROUTE™**  
Transcarotid Neuroprotection System



| One powerful switch

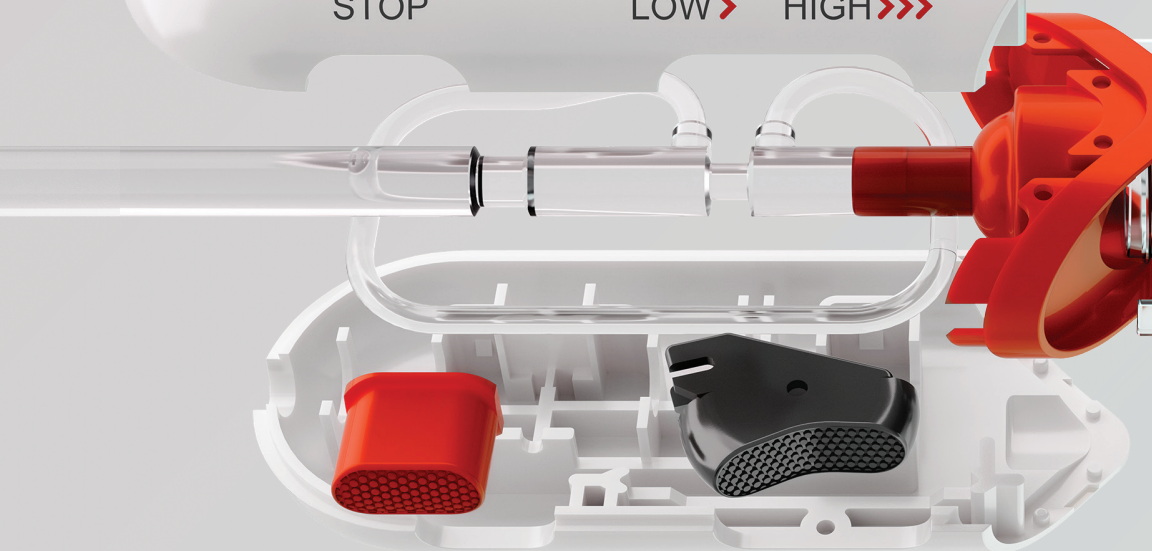


Minimally invasive TCAR therapy  
with the neuroprotection of CEA.

**ENROUTE™**  
Transcarotid Neuroprotection System

STOP

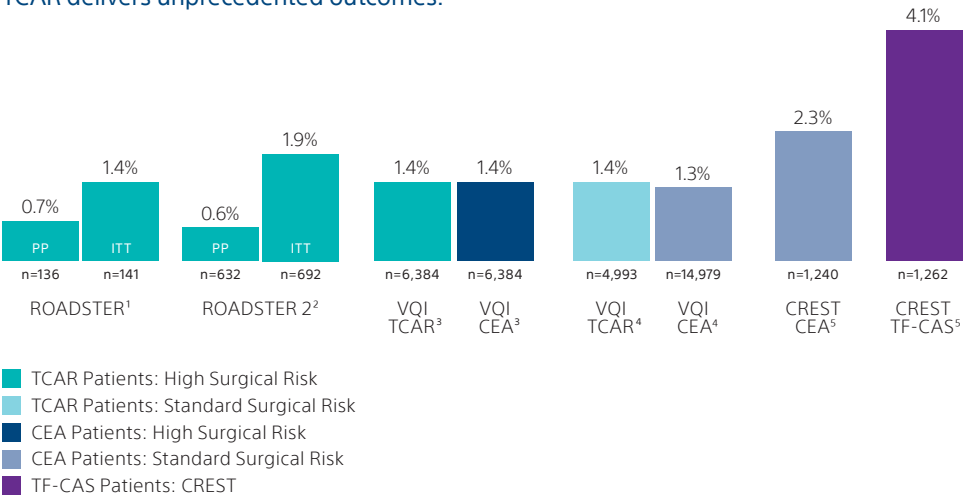
LOW > HIGH >>>



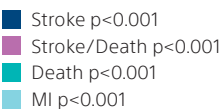
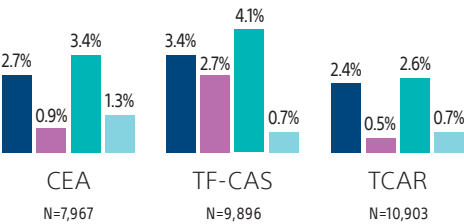
# Less risk. Lasting outcomes.

For a certain population of carotid artery disease patients, endarterectomy is essential. For the others, you could provide the same neuroprotection faster and with fewer risks. That's why a growing network of providers is embracing TCAR by ENROUTE™ as a minimally invasive alternative to carotid endarterectomy (CEA) that's suited for a majority of cases.

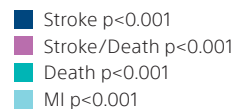
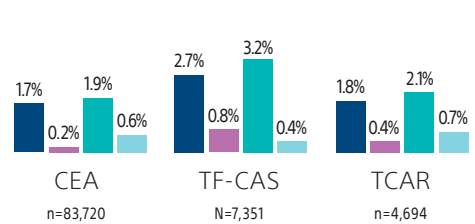
## TCAR delivers unprecedented outcomes.



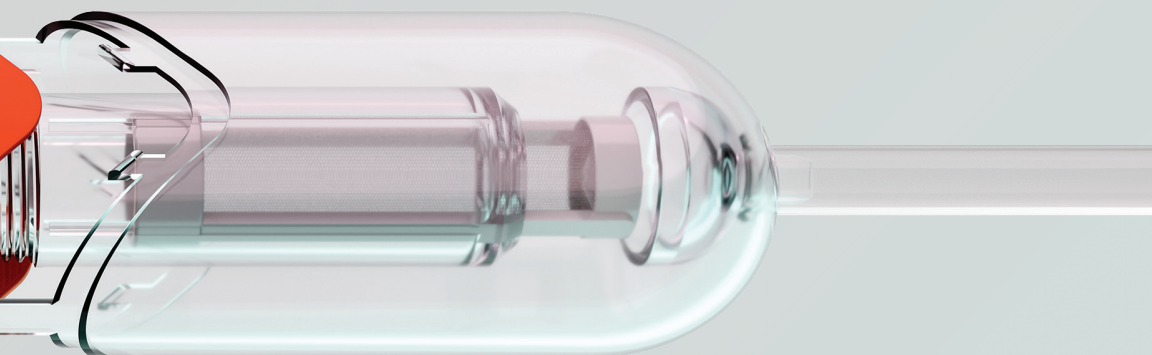
## In HSR patients, TCAR has better outcomes than CEA and TF-CAS.<sup>6</sup>



## In SSR patients, TCAR and CEA have better outcomes than TF-CAS.<sup>6</sup>



# Reverse the flow. Advance the treatment.



## 39%

less risk of  
bleeding requiring  
intervention<sup>3\*</sup>

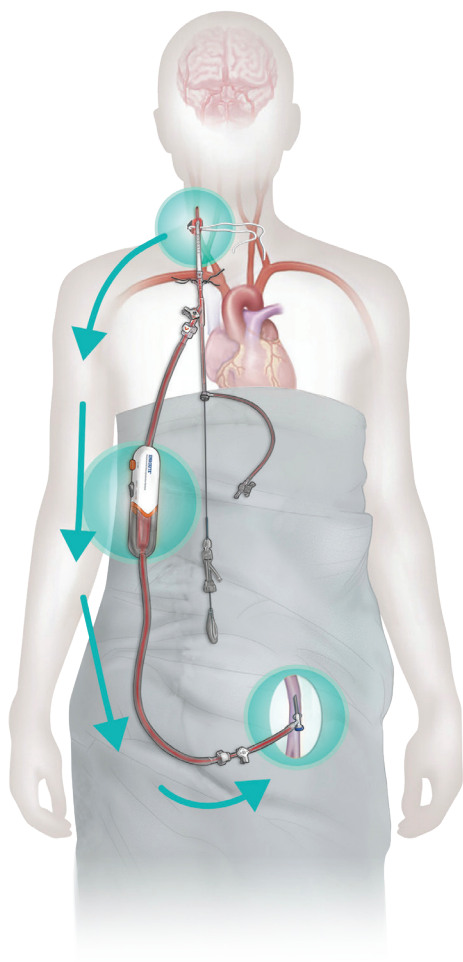
## Local Anesthesia

is used  
significantly more  
often with TCAR  
by ENROUTE<sup>TM 3</sup>

## 85%

less risk of CNI<sup>3,4</sup>

<sup>\*</sup>with protamine use



The ENROUTE Transcarotid Neuroprotection System maintains neuroprotection throughout the procedure.

## Let's break this down.

The TCAR by ENROUTE™ system is the first and only transcarotid artery revascularization (TCAR) therapy with Reverse Flow Technology, to protect the brain, minimize the risk of nerve damage and reduce both procedure and recovery time.

### Direct Transcarotid Approach

Avoids crossing the arch to mitigate risk of causing harmful emboli to break free and cause stroke vs. TF-CAS.

Small incision minimizes scarring and reduces the risk of nerve damage.

### Temporary Flow Reversal

Pressure gradient creates blood flow reversal.

Establishes neuroprotection before lesion is crossed.

ENROUTE ENFLATE™ balloon prepares vessel for stent.

### Embolic Debris Is Captured

Reduces intraprocedural stroke risk.<sup>6</sup>

Blood is returned via sheath in femoral vein.

### Transcarotid Stent Is Placed

Contains plaque to prevent future strokes.

### Procedure Time<sup>1,3</sup>

CEA

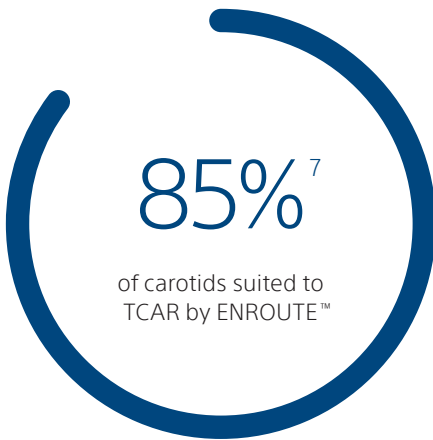
121 minutes

TCAR by ENROUTE

73 minutes

# Who is eligible

Carotid artery disease is on the rise. With 150,000 new cases in the US each year, more carotid treatments mean more strokes\* are prevented. While endarterectomy accounts for about 70% of carotid procedures, TCAR by ENROUTE™ is an equally safe alternative for everyone else.



## Symptomatic

Neurological symptoms

SSR; Stenosis  $\geq$  50-70%\*\*

HSR; Stenosis  $\geq$  50%

## Asymptomatic

SSR; Stenosis  $\geq$  60-70%\*\*

HSR; Stenosis  $\geq$  80%

# Patient selection & medication

## Anatomical Requirement

Typically assessed initially by ultrasound in surgical position.

- CCA  $\geq$  5cm in length
- CCA  $\geq$  6mm in diameter
- Clear CCA (free from significant disease)
- ICA  $\geq$  4mm &  $\leq$  9mm in diameter (reference)

## Suggested Medication

$\geq$  3 days prior to procedure or overnight loading dose.

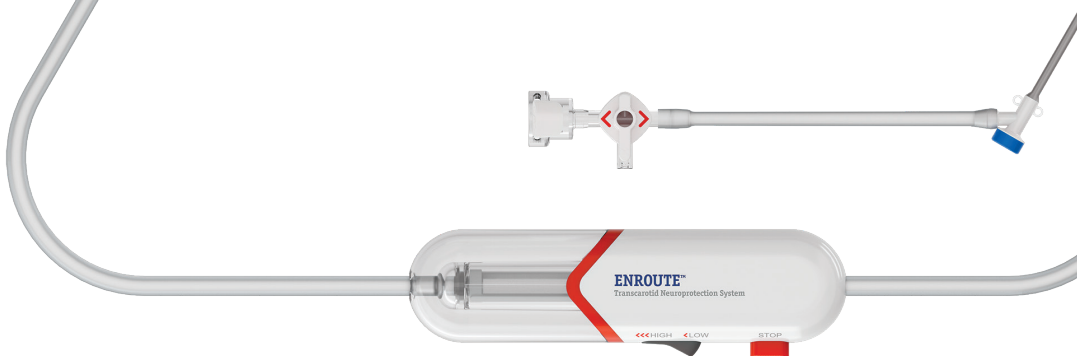
Continue for 30 days post op.\*\*\*

- Plavix (or other P2Y12 Inhibitor)
- Aspirin
- Statin (> 5 days prior or overnight loading dose)

\*from carotid artery disease

\*\*Dependent on diagnostic imaging type; lower bound percentage is in reference to diagnosis via CTA/MRA or procedural angiogram, while upper bound is for diagnosis using ultrasound.

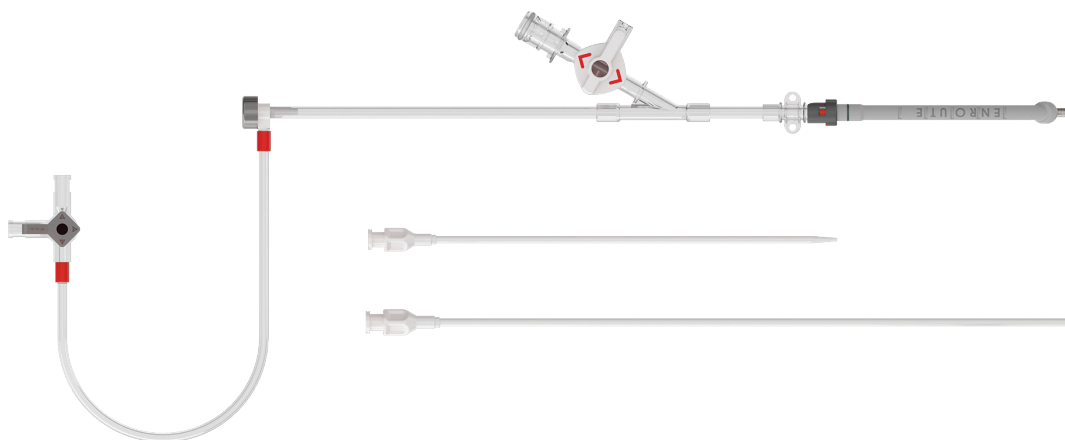
\*\*\*See DAPT White Paper



# One comprehensive TCAR system

Patients prefer minimally invasive procedures with less time on the table, and in the hospital. They face less scarring, have less fear of nerve damage and typically require less general anesthesia.<sup>3</sup> With TCAR by ENROUTE™, you have one comprehensive system to give at-risk patients a faster treatment option that leaves them feeling like themselves again.

See how one switch can make all the difference at [www.bostonscientific.com/enroute](http://www.bostonscientific.com/enroute)





## References

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4. Liang P, Cronenwett J, Secemsky E, et al. Expansion of transcatheter artery revascularization to standard risk patients for treatment of carotid artery stenosis. *JVS.* 2021;74(3):27-28. doi:10.1016/j.jvs.2021.06.048.
5. CREST: Symptomatic/Asymptomatic Standard Surgical Risk Brott TG, et al. Long-Term Results of Stenting versus Endarterectomy for Carotid-Artery Stenosis. *N Engl J Med.* 2016 Mar 17;374(11):1021-31.
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## ENROUTE™ Transcarotid Neuroprotection System

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INTENDED USE/INDICATIONS FOR USE:** The ENROUTE Transcarotid Neuroprotection System (ENROUTE Transcarotid NPS) is intended to provide transcatheter 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 appropriate anatomy described below: • Adequate femoral venous access • Common carotid artery reference diameter of at least 6 mm • Carotid bifurcation is a minimum of 5 cm above the clavicle as measured by duplex Doppler ultrasound (DUS) or computerized axial tomography (CT) angiography or magnetic resonance (MR) angiography. **CONTRAINDICATIONS:** The ENROUTE Transcarotid NPS is contraindicated for use in patients exhibiting the following conditions: • Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated • Patients with unresolved bleeding disorders • Patients with severe disease of the ipsilateral common carotid artery • Uncontrollable intolerance to flow reversal (i.e. pre-conditioning does not result in intolerance to vessel occlusion/flow reversal) **WARNINGS:** • Only physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid interventional procedures should use this device. • Do not advance any part of the ENROUTE Transcarotid NPS if resistance is felt. Stop and assess the cause of resistance. Failure to do so may cause vessel or product component damage. • If excess resistance is encountered during flushing, preparation, or injection of fluids into any of the ENROUTE Transcarotid NPS system components, stop and assess cause of resistance. Failure to do so may result in damage to the product or harm to the patient. • The safety and efficacy of the ENROUTE Transcarotid Neuroprotection System has not been demonstrated with carotid stent systems other than Precise® ProRx Carotid Stent, Acculink® Carotid Stent, Xact® Carotid Stent, PROTÉGÉ® Carotid Stent, Carotid WALLSTENT™ Endoprosthesis and ENROUTE® Transcarotid Stent. • Consider severe disease of the contralateral arteries and ipsilateral posterior arteries which may affect adequate cerebral blood flow during flow reversal. • Systemic antiplatelet and anticoagulation therapy should be used before, during and after the procedure based on hospital and physician preferred protocol. **PRECAUTIONS:** • Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications. • Refer to Instructions for Use supplied with other interventional devices to be used in conjunction with the ENROUTE Transcarotid NPS for their intended uses, contraindications and potential complications. • The ENROUTE Transcarotid NPS is not recommended in patients who cannot tolerate contrast agents necessary for intra-operative imaging. • Common carotid artery and femoral vein size and morphology should be compatible at the respective access site with the 8 Fr. Transcarotid Arterial and Venous Return Sheaths using standard vascular access techniques. • Proper placement of the ENROUTE Transcarotid NPS Sheaths should be monitored and confirmed fluoroscopically. • Monitoring of patients' neurological status during carotid artery stenting procedure is recommended. • The J-tipped wire provided is not intended to be rotated or torqued during use. • Do not withdraw or manipulate the coated wire in a metal cannula or sharp-edged object. • Avoid wiping the wire with dry gauze as this may damage the wire coating. • Avoid using alcohol, antiseptic solutions or other solvents to pre-treat the guidewire as this may cause unpredictable changes in the coating which can affect the wire safety and performance. • Always inspect the guidewire carefully for bends, kinks or other damage prior to insertion or re-insertion. Do not use damaged guidewires. **POTENTIAL PROCEDURE AND/OR DEVICE RELATED ADVERSE EVENTS:** Complications and adverse events can occur when using any embolic protection device in carotid artery stenting procedures. These complications include, but are not limited to: • abrupt vessel closure • allergic reactions • aneurysm • angina/coronary ischemia • arteriovenous fistula • bacteremia or septicemia • bleeding from anticoagulant or antiplatelet medications • bradycardia/arrhythmia and other conduction disturbances • cerebral edema • cerebral hemorrhage • component damage • congestive heart failure • cranial nerve injury (CNI) • death • deployment and retrieval failure • distal embolization • drug reactions • embolism (which includes thrombus, plaque, air, device and/or component) • emergent/urgent endarterectomy • fever • fluid overload • groin hematoma • headache • hemorrhage/hematoma • hemorrhagic stroke • hyperperfusion syndrome • hypertension/hypotension • infection/sepsis • ischemia/infarction of tissue/organ • ischemic stroke • intolerance to vessel occlusion and/or flow reversal • myocardial infarction • pain and tenderness • pseudoaneurysm • reduced blood flow • renal failure/insufficiency • restenosis of the stented artery • seizure • stent deformation • stroke or other neurological complications (e.g., paralysis, paraplegia or aphasia) • surgery required due to device failure • temporary or total occlusion of the artery • thromboembolic episodes • thrombophlebitis • transient ischemic attacks (TIAs) • vascular access complications (e.g., bleeding, vessel damage, pseudoaneurysm and infection) • ventricular fibrillation • vessel spasm, dissection, rupture, or perforation • vessel thrombosis (partial blockage) • unstable angina pectoris. There may be other potential adverse events that are unforeseen at this time. PI-2027808-AA

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