ENROUTE®

TRANSCAROTID STENT SYSTEM

Plaque Stabilization Prevents Stroke

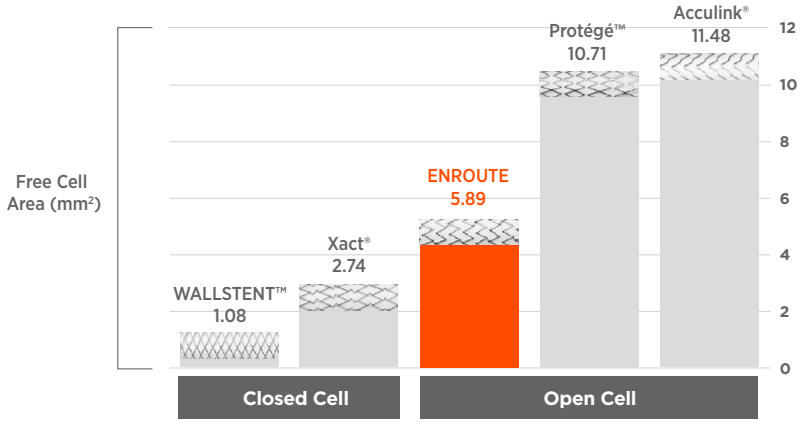
Optimized for TCAR, the ENROUTE Transcarotid Stent System autoconforms to anatomy and delivers long-term plaque stabilization to prevent future strokes.[1]

TCAR Specific Delivery Length

Unlike transfemoral stent systems with lengths long enough for arch navigation, the ENROUTE stent is optimized for transcarotid access with a shorter delivery system for increased precision.

Optimized Cell Design

The ENROUTE stent system is the most "closed" cell of open cell designs,[2] autoconforming to a wide variety of vessel anatomies to provide long-term coverage.



Autoconforming Technology

Made of nitinol, an alloy with low outward expansion forces, the ENROUTE stent system "scaffolds" the plaque without putting unnecessary stress on the native vessel. The stent is offered in both cylindrical and tapered configurations for tailored treatment.


Figure 1

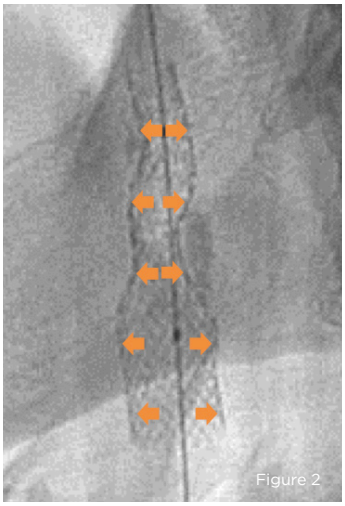


Figure 2

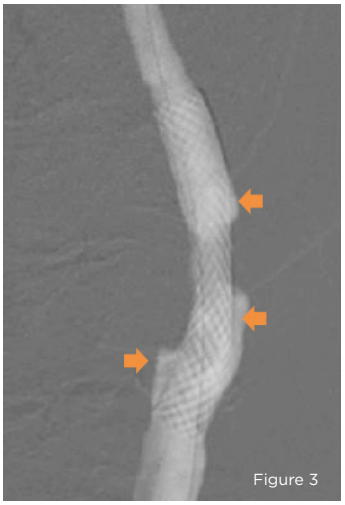


Figure 3

The ENROUTE open cell design allows for each 2mm segment to autoconform independently to the native vessel (Figures 1 and 2). Closed cell stents are more rigid (Figure 3), which can cause malapposition.

Open cell design and autoconforming technology provide durable plaque coverage (Figure 4)


Figure 4

ENROUTE® Transcarotid Stent System

Catalog Number	Diameter x Length (mm)
SR-0620-CS	6 x 20
SR-0630-CS	6 x 30
SR-0640-CS	6 x 40
SR-0730-CS	7 x 30
SR-0740-CS	7 x 40
SR-0830-CS	8 x 30
SR-0840-CS	8 x 40
SR-0930-CS	9 x 30
SR-0940-CS	9 x 40
SR-1030-CS	10 x 30
SR-1040-CS	10 x 40

Catalog Number	Diameter x Length (mm)
SR-080630-TCS	8-6 x 30
SR-080640-TCS	8-6 x 40
SR-090730-TCS	9-7 x 30
SR-090740-TCS	9-7 x 40
SR-100830-TCS	10-8 x 30
SR-100840-TCS	10-8 x 40

Safe and Durable Results

Short Term Stent Outcomes[3,4]

TCAR improves periprocedural safety of stenting with direct carotid access to avoid dangerous arch navigation and robust flow-reversal that ensures protection throughout the procedure. With protection established prior to intervention, the stent can be safely delivered for optimal results.

IN-HOSPITAL OUTCOMES	TCAR (N=6384)	vs	CEA (N=6384)	TCAR (N=3286)	vs	TF-CAS (N=3286)
Stroke-Free Rate	**98.6%**	P = 0.88	**98.6%**	**98.7%**	P = .001	**97.6%**
Freedom from Stroke+Death Rate	**98.4%**	P = 0.94	**98.4%**	**98.4%**	P < .001	**96.9%**

Long Term Stent Outcomes[5]

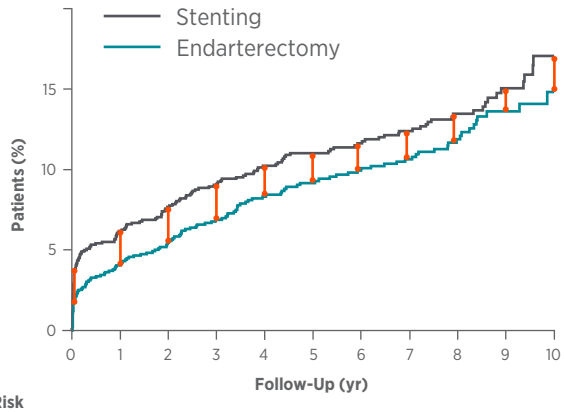
After the first 30 days, event rates for a transfemoral stent and CEA similar over 10 years of data, demonstrating the long-term durability of a stent.

CREST: 10 Year Results

Any Stroke

30-day Stroke Rate: 4.1% CAS vs. 2.3% CEA (P=0.01)

Symptomatic/Asymptomatic Standard Surgical Risk



Number at Risk											
Endarterectomy	1240	1118	1037	945	825	721	676	603	420	234	63
Stenting	1262	1103	1030	957	861	750	714	654	461	257	65

> The stroke rate of **0.6%** after TCAR in the Per Protocol population may be the lowest reported rate after **any carotid intervention.**
>
> – *Stroke.* 2020;51:2620-2629.

1. Kashyap VS, So KL, Schneider PA, et al. One-year outcomes after transcarotid artery revascularization (TCAR) in the ROADSTER 2 trial. J Vasc Surg. 2022 Aug;76(2):466-473.e1. doi: 10.1016/j.jvs.2022.03.872
2. S. Morr. Carotid artery stenting: current & emerging options. Med Devices (Auckl). 2014;7:343–355.
3. Malas MB, et al. TransCarotid Revascularization with Dynamic Flow reversal versus Carotid Endarterectomy in the Vascular Quality Initiative Surveillance Project. Ann Surg. 2020 Sep 15. doi: 10.1097/SLA.0000000000004496.
4. Schermerhorn ML, Liang P, Eldrup-Jorgensen J, et al. Association of Transcarotid Artery Revascularization vs Transfemoral Carotid Artery StentingWith Stroke or Death Among Patients With Carotid Artery Stenosis. JAMA. 2019;322(23):2313-2322. doi:10.1001/jama.2019.18441
5. 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.

ENROUTE® Transcarotid Stent System
PRESCRIBING INFORMATION

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 and standard risk for adverse events from carotid endarterectomy, who require carotid revascularization and meet the criteria outlined below.

	High Risk	Standard Risk
With neurological symptoms	≥ 50% stenosis of the common or internal carotid artery by ultrasound or angiogram	≥ 70% stenosis of the common or internal carotid artery by ultrasound or ≥ 50% stenosis of the common or internal carotid artery by angiogram
Without neurological symptoms	≥ 80% stenosis of the common or internal carotid artery by ultrasound or angiogram	≥ 70% stenosis of the common or internal carotid artery by ultrasound or ≥ 60% stenosis of the common or internal carotid artery by angiogram
Reference vessel diameter	Must be within 4.0 mm – 9.0 mm at the target lesion	
Carotid bifurcation location	Minimum 5 cm above the clavicle to allow for placement of the ENROUTE Transcarotid NPS	

Contraindications

Use of the ENROUTE Transcarotid Stent System is contraindicated in the following patients:

1. Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated.
2. Patients in whom the ENROUTE Transcarotid NPS is unable to be placed.
3. Patients with uncorrected bleeding disorders.
4. Patients with known allergies to nitinol.
5. Lesions in the ostium of the common carotid artery.

Warnings

General Warnings

1 Only physicians who have received appropriate training for transcarotid stenting and who are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid interventional procedures should use this device.
2. The safety and efficacy of the ENROUTE Transcarotid Stent System have not been demonstrated with embolic protection systems other than the ENROUTE Transcarotid NPS. Use the ENROUTE Transcarotid Stent System only with the ENROUTE Transcarotid NPS.
3. The long term performance (> 3 years) of carotid stents has not yet been established.
4. As with any type of vascular implant, infection secondary to contamination of the stent may lead to thrombosis, pseudoaneurysm or rupture.
5. The stent may cause a thrombus, distal embolization or may migrate from the site of implant through the arterial lumen. Appropriate sizing of the stent to the vessel is required to reduce the possibility of stent migration (see Section 9.3 of the full instructions for use). In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted.
6. Overstretching of the artery may result in rupture and life-threatening bleeding.
7. In patients requiring the use of antacids and/or H2-antagonists before or immediately after stent placement, oral absorption of antiplatelet agents (e.g., aspirin) may be adversely affected.
8. The appropriate antiplatelet and anticoagulation therapy should be administered pre- and post-procedure as suggested in Section 9.1 of the full instructions for use.
9. In the event of complications such as infection, pseudoaneurysm or fistulization, surgical removal of the stent may be required.

Non-clinical testing has demonstrated that the ENROUTE Transcarotid Stent is MR Conditional.

The ENROUTE® Transcarotid Stent in single and overlapped versions at lengths up to and including 75mm is MR Conditional. A patient with the ENROUTE Transcarotid Stent may be safely scanned without a waiting time after implantation under the following conditions. Failure to follow these conditions may result in injury to the patient.

Parameter	Condition
Nominal Values of Static Magnetic Field (T)	1.5T and 3.0T
Maximum Spatial Field Gradient (T/m and gauss/cm)	20 T/m (2,000 gauss/cm)
Type of RF Excitation	Circularly Polarized (CP) (i.e., quadrature-driven)
Transmit RF Coil Information	There are no transmit RF coil restrictions. Accordingly, the following may be used: body transmit RF coil and all other RF coil combinations (i.e., body RF coil combined with any receive-only RF coil, transmit/receive head RF coil, transmit/receive knee RF coil, etc.)
Operating Mode of MR System	Normal Operating Mode
Maximum Whole Body Averaged SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Limits on Scan Duration	Single and overlapped to 75mm conditions can be scanned for 60 minutes of continuous RF exposure (i.e., per pulse sequence or back-to-back sequences/series without breaks)
MR Image Artifact	The presence of this implant produces an imaging artifact. Therefore, carefully select pulse sequence parameters if the implant is located in the area of interest.

Potential Adverse Events

Adverse Events (in alphabetical order) that may be associated with the use of the ENROUTE Transcarotid Stent System when used in conjunction with the ENROUTE Transcarotid NPS include, but may not be limited to (based upon clinical trial data for the PRECISE Stent System and the ANGIOGUARD XP Emboli Capture Guidewire and clinical trial data from the ROADSTER and PROOF studies):

Air embolism, Allergic/anaphylactoid reaction, Anemia, Aneurysm, Angina/coronary ischemia, Arrhythmia (including bradycardia, possibly requiring need for a temporary or permanent pacemaker), Arterial dissection, Arterial occlusion/restenosis of the treated vessel, Arterial occlusion/thrombus, at puncture site, Arterial occlusion/thrombus, remote from puncture site, Arteriovenous fistula, Atelectasis, Atrial Fibrillation, Bacteremia or septicemia, Cerebral edema, Congestive heart failure, Death, Embolization, arterial, Embolization, stent, Emergent repeat hospital intervention, Fever, Gastrointestinal disorders, GI bleeding from anticoagulation/antiplatelet medication, Hallucination, Hematoma bleed, access site, Hematoma bleed, remote site, Hemorrhage, Hyperperfusion syndrome, Hypotension/hypertension, Hypomagnesaemia, Hypophosphatemia, Infection, Intimal injury/dissection, Ischemia/infarction of tissue/organ, Local infection and pain at insertion site, Malposition (failure to deliver the stent to the intended site), Myocardial infarction, Nausea, Oxygen saturation decrease, Pain, Pseudoaneurysm, Rales, Renal failure, Respiratory Infection, Restenosis of the vessel (> 50% obstruction), Rhinorrhea, Seizure, Severe unilateral headache, Stent migration, Stent thrombosis, Stroke, Transient ischemic attack, Transient intolerance to reverse flow, Urinary tract infection, Vasospasm, Venous occlusion/thrombosis, at puncture site, Venous occlusion/thrombosis, remote from puncture site, Vessel rupture, dissection, perforation, Vomiting, Wheezing

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

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