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ENROUTE™ Transcarotid Stent System

Plaque Stabilization Reduces Stroke Risk

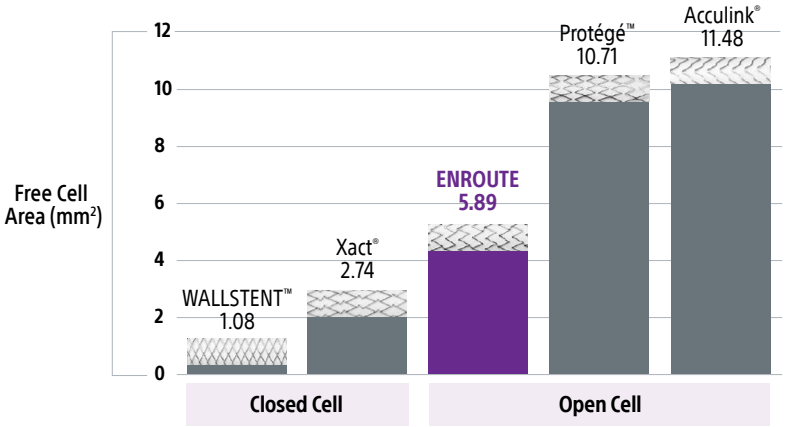
Optimized for TCAR, the ENROUTE Transcarotid Stent System autoconforms to anatomy and delivers long-term plaque stabilization to prevent future strokes.[1]

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

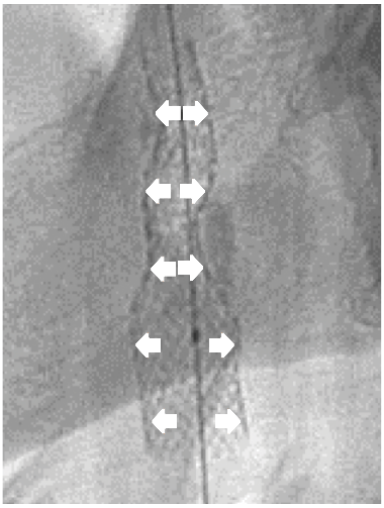


Figure 2

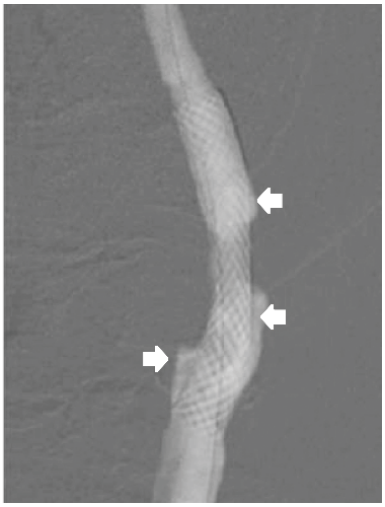


Figure 3

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 < .00	96.9%[1]

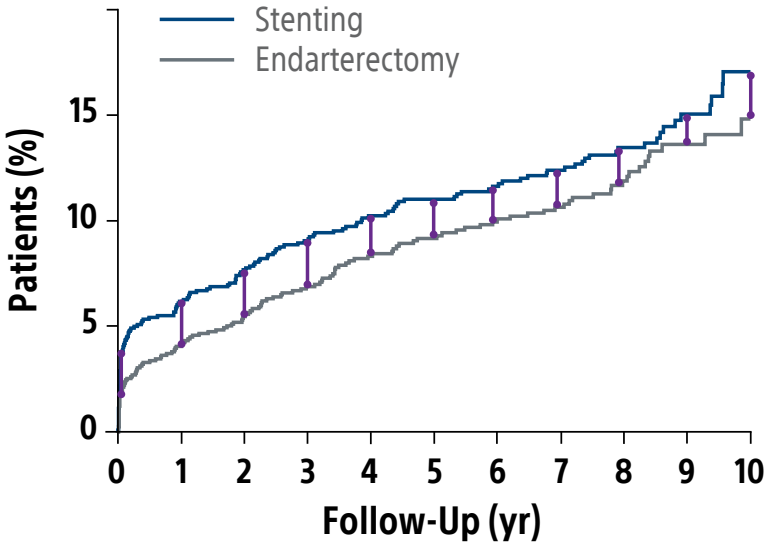
Long-Term Stent Outcomes[5]

After the first 30 days, event rates for a transfemoral stent and CEA are 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 Stenting With 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

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 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: • Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated. • Patients in whom the ENROUTE Transcarotid NPS is unable to be placed. • Patients with uncorrected bleeding disorders. • Patients with known allergies to nitinol. • Lesions in the ostium of the common carotid artery. **WARNINGS General Warnings** • 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. • 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. • The long term performance (> 3 years) of carotid stents has not yet been established. • As with any type of vascular implant, infection secondary to contamination of the stent may lead to thrombosis, pseudoaneurysm or rupture. • 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 these instructions). In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted. • Overstretching of the artery may result in rupture and life-threatening bleeding. • 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. • The appropriate antiplatelet and anticoagulation therapy should be administered pre- and post-procedure as suggested in Section 9.1 of these instructions. • In the event of complications such as infection, pseudoaneurysm or fistulization, surgical removal of the stent may be required. **Patient Selection Warnings** Safety and effectiveness of the ENROUTE® Transcarotid Stent System has NOT yet been established in patients with the characteristics noted below. • Lesion Characteristics: o Patients with evidence of intraluminal thrombus thought to increase the risk of plaque fragmentation and distal embolization. o Patients whose lesion(s) may require more than two stents. o Patients with total occlusion of the target vessel. o Patients with lesions of the ostium of the common carotid. o Patients with highly calcified lesions resistant to PTA. o Concurrent treatment of bilateral lesions. • Patient Characteristics: o Patients at low-to-moderate risk for adverse events from carotid endarterectomy. o Patients experiencing acute ischemic neurologic stroke or who experienced a stroke within 48 hours. o Patient has had a recent (<7 days) stroke of sufficient size (on CT or MRI) to place him or her at risk of hemorrhagic conversion during the procedure. o Patients with ipsilateral intracranial or extracranial arterial stenosis greater in severity than the lesion to be treated, cerebral aneurysm > 5 mm, AVM (arteriovenous malformation) of the cerebral vasculature, or intracranial tumor. o Patients with arterio-venous malformations in the territory of the target carotid artery. o Patients with bleeding diathesis or coagulopathies. o Patients with poor renal function, who, in the physician's opinion, may be at high risk for a reaction to contrast medium. o Patients with perforated vessels evidenced by extravasation of contrast media. o Patients with aneurismal dilation immediately proximal or distal to the lesion. o Pregnant patients or patients under the age of 18. • Access Characteristics: o Patients with known internal carotid artery tortuosity that would preclude the use of catheter-based techniques. o Patients with known common carotid or internal carotid artery tortuosity that would preclude the use of catheter-based techniques. o Patients in whom common carotid access is not possible. Risk of distal embolization may be higher if the ENROUTE Transcarotid Stent System cannot be used in conjunction with the ENROUTE Transcarotid NPS during the carotid stenting procedure. **Device Use Warnings** • USE OF A SMALLER THAN INDICATED ACCESSORY DEVICE OTHER THAN THE ENROUTE TRANSCAROTID ARTERIAL SHEATH MAY LEAD TO INTRODUCTION OF AIR INTO THAT DEVICE AS THE STENT DELIVERY SYSTEM IS ADVANCED, WHICH MAY NOT BE REMOVED DURING AIR ASPIRATION. • Ensure that the catheter system is flushed according to the steps outlined in "Introduction of Stent Delivery System" (Section 9.4). Failure to do so could result in air entering the ENROUTE's Transcarotid Arterial Sheath. • Ensure that there is a tight seal between the ENROUTE catheter and the valve for the ENROUTE Transcarotid Arterial Sheath during aspiration. Failure to do so could result in air entering the ENROUTE Transcarotid Arterial Sheath. • The black dotted pattern on the gray temperature exposure indicator found on the pouch must be clearly visible. DO NOT USE THE PRODUCT IF THE ENTIRE TEMPERATURE EXPOSURE INDICATOR IS COMPLETELY BLACK as the pre-programmed stent diameter may have been compromised. • Do not use the device if there are abnormalities in the sterile barrier (e.g., broken seal, torn or breached barrier) or the product. • This device is intended for one-time use only. Do not re-sterilize and/or reuse. Structural integrity and/or function may be impaired through reuse or cleaning. • Do not use the ENROUTE® Transcarotid Stent System after the "Use By" date specified on the package. • Do not use with Ethiodol or Lipiodol* contrast media, which may adversely affect the stent delivery system. *Ethiodol and Lipiodol are Trademarks of Guerbet S.A. • Do not expose the delivery system to organic solvents (e.g., alcohol) as structural integrity and/or function of the device may be impaired. • The stent is not designed for dragging or repositioning. • Once the stent is partially deployed, it cannot be recaptured using the stent delivery system. • As with any type of vascular implant, infection secondary to contamination of the stent may lead to thrombosis, pseudoaneurysm or rupture. • When multiple stents are used, they should be of similar composition. • Long-term outcomes following repeat dilatation of endothelialized stents are unknown. **PRECAUTIONS Stent Handling Precautions** • The ENROUTE Transcarotid Stent System is supplied STERILE and is intended for single use only. DO NOT resterilize and/or reuse the device. • The ENROUTE Transcarotid Stent System is shipped with the Tuohy Borst valve in the OPEN position. Care should be taken not to pre-deploy the stent. The device should be prepped in the tray. (See Section 9.3 of these instructions). • Do not use the ENROUTE Transcarotid Stent System after the "Use By" date specified on the package. • Do not use if the pouch is opened or damaged. • Store in a cool, dark, dry place. **Stent Placement Precautions** • Venous access should be available during carotid stenting in order to manage bradycardia and/or hypotension either by pharmaceutical intervention or placement of a temporary pacemaker, if needed. • When catheters are in the body, they should be manipulated only under fluoroscopy. Radiographic equipment that provides high quality images is needed. • The delivery system is not designed for the use of power injection. Use of power injection may adversely affect device performance. • If resistance is met during delivery system introduction, the system should be withdrawn and another system used. • Prior to stent deployment, remove all slack from the catheter delivery system (see Section 9.4, 4 of these instructions). • Adequate distance must be maintained from the distal tip of the transcarotid access sheath and the proximal edge of the stent to avoid stent delivery within the lumen of the sheath. • When treating multiple lesions, the distal lesion should be initially stented, followed by stenting of the proximal lesion. Stenting in this order obviates the need to cross the proximal stent in placement of the distal stent and reduces the chance for dislodging stents that have already been placed. • Overlap of sequential stents is necessary, but the amount of overlap should be kept to a minimum (approximately 5 mm). In no instance should more than 2 stents overlap. • Fractures of this stent may occur. Fractures may also occur with the use of multiple overlapping stents. Fractures have been reported most often in clinical uses for which the safety and effectiveness have not been established. The causes and clinical implications of stent fractures are not well characterized. Care should also be taken when deploying the stent as excessive force could, in rare instances, lead to stent deformation and/or fracture. **Post Stent Placement Precautions** • Recrossing a deployed stent with adjunct devices must be performed with caution. • In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted. **POTENTIAL PROCEDURE AND/OR DEVICE RELATED 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 • Hypophoshatemia • 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

PI-2028004-AA

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