Prospective, Multicenter Evaluation of Transcarotid Artery Revascularization (TCAR) in Standard Risk Patients: 30-Day Outcomes of the ROADSTER 3 Study

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Objective

First-ever prospective, multicenter, trial evaluating real world usage of TCAR using the ENROUTE® Transcarotid Stent System (TSS) in conjunction with the ENROUTE® Transcarotid Neuroprotection System (NPS) for the treatment of carotid stenosis in standard surgical risk patients.

Methods

Between 2022–2024, 344 intent-to-treat (ITT) patients were enrolled (320 treated per-protocol (PP)) at 53 US sites. The primary endpoint for this single-arm, post-approval study is a composite of major adverse events (stroke, death, or myocardial infarction (MI)) through 30 days post-procedure, plus ipsilateral stroke from day 31 to 365 post-procedure. The incidence of cranial nerve injury (CNI) within 30 days post-procedure is a key secondary endpoint. Independent neurological assessments are performed for all patients before the procedure, within 24 hours, at 30-days, and at 1-year after TCAR. Events were adjudicated by an independent clinical events committee.

Findings

In the ITT population, 75.3% were less than 75 years of age, 42.7% were female, and 16.3% were symptomatic. Among symptomatic patients, 25.0% experienced a neurologic event within 2 weeks preceding the TCAR procedure. The mean lesion length was 23.3mm, 47.4% had a Type II or Type III aortic arch, and 17.2% of lesions had severe calcification.

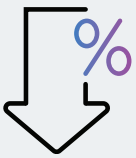
In the ITT population, the rate of stroke/death/MI at 30-days was 0.9% (0.6% PP) with a 30-day stroke rate of 0.9% (0.6% PP, n=2). There were no deaths or MIs through 30-day follow-up. The incidence of CNI within 30 days was 0.6% (0.6% PP); both resolved within 6 months.

Conclusions

These 30-day results of the ROADSTER 3 study demonstrate that TCAR, using the ENROUTE TSS in conjunction with the ENROUTE NPS, is safe and effective in patients at standard risk for adverse events from carotid endarterectomy.

	ITT n=344	PP n=320
Stroke	0.9% (3)	0.6% (2)
Death	None	
MI	None	
Stroke/Death/MI	0.9% (3)	0.6% (2)

CNI 0.6%
Resolved in 6 months

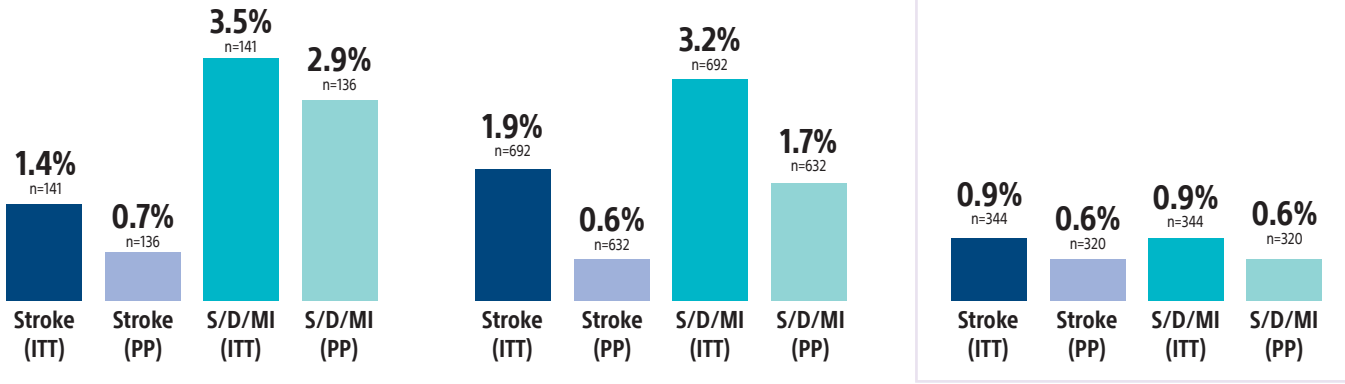


Lowest reported stroke rate in SSR population.*

Parameter	ITT Population		PP Population	
	Symptomatic n=56	Asymptomatic n=288	Symptomatic n=49	Asymptomatic n=271
Death/Stroke/MI	0	1.0% (3)	0	0.7% (2)
Stroke	0	1.0% (3)	0	0.7% (2)

No significant difference based on symptomatic status.

The ROADSTER Trials: Demonstrating Consistent, Low Adverse Event Rates Across All Risk Levels



*Compared to other major carotid intervention trials

1. Kwolek CJ, et al. Results of the ROADSTER multicenter trial of transcarotid stenting with dynamic flow reversal. J Vasc Surg. 2015 Nov;62(5):1227-34
2. Kashyap VS, et al. ROADSTER 2 Investigators*. Early Outcomes in the ROADSTER 2 Study of Transcarotid Artery Revascularization in Patients With Significant Carotid Artery Disease. Stroke. 2020 Sep;51(9):2620-2629.

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 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 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 in tolerance 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**

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 • 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 **PI-2028004-AA**

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