

ENROUTE™ Transcarotid Neuroprotection System

Roadster Study Clinical Summary

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INTRODUCTION

A prospective, single-arm, multicenter clinical trial was performed to evaluate the use of the ENROUTE™ Transcarotid NPS during TCAR procedures performed in patients considered to be at high risk for complications from carotid endarterectomy.

METHODS

141 high surgical risk patients (Symptomatic $\geq$ 50% stenosis; Asymptomatic $\geq$ 70% stenosis) were enrolled in 18 sites. In the pivotal cohort, 26% were symptomatic. Primary endpoint was the composite of all stroke MI and death at 30 days post-procedure. Secondary end points included CNI, 30-day stroke/death and procedural success.

RESULTS

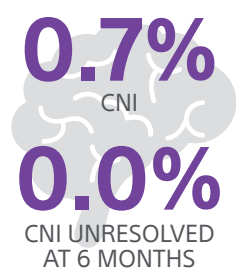
The all-stroke rate in the ITT group was 1.4% (2 of 141), stroke and death was 2.8% (4 of 141), and stroke, death and MI was 3.5% (5 of 141). There were no major strokes. One patient (0.7%) experienced postoperative hoarseness from potential cranial nerve injury, which completely resolved at the 6-month follow-up visit. Technical success was 99% (140 of 141) with mean procedure time of 74 minutes. Local anesthesia was used in 53% of cases.

CONCLUSIONS

The results of the ROADSTER trial demonstrate that the use of the ENROUTE Transcarotid NPS is safe and effective at reducing stroke during TCAR. The overall stroke rate of 1.4% is the lowest reported to date for any prospective, multicenter clinical trial of CAS.

PER PROTOCOL (n=136)		INTENT TO TREAT (n=141)	
0.7%	All Stroke	1.4%	All Stroke
1.5%	Death	1.4%	Death
0.7%	MI	0.7%	MI
2.2%	Stroke/Death	2.8%	Stroke/Death
2.9%	Stroke/Death/MI	3.5%	Stroke/Death/MI

Cranial Nerve Injury Rates



Transcarotid Efficiency Reverse Flow Time



Procedure Time Mean



Local Anesthesia Use in ITT Group



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. TheraSphere is a registered trademark of Theragenics Corporation used under license by Boston Scientific Medical Device Limited, a wholly owned indirect subsidiary of Boston Scientific Corporation. **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 device 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 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, PROTEGE® 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. **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 (CNVI) • 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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