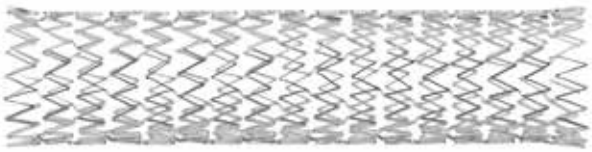
TCAR *TransCarotid Artery Revascularization*

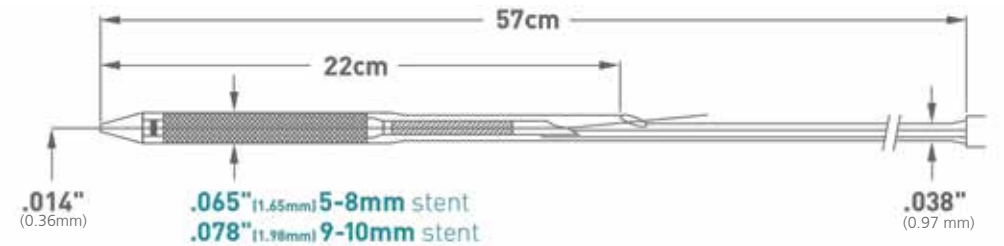
ENROUTE®
TRANSCAROTID STENT SYSTEM

Stroke Prevention through Plaque Stabilization

The ideal carotid stent should provide long-term plaque stabilization. The ENROUTE stent system was selected to preserve the great clinical outcomes of a TCAR procedure.

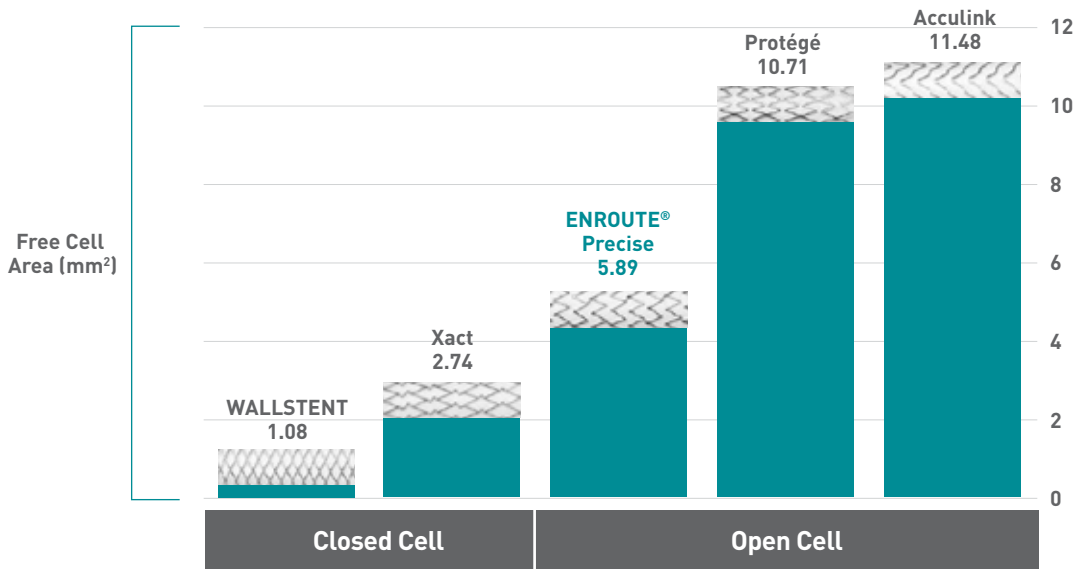


A Cordis Precise™ stent on a transcarotid delivery system



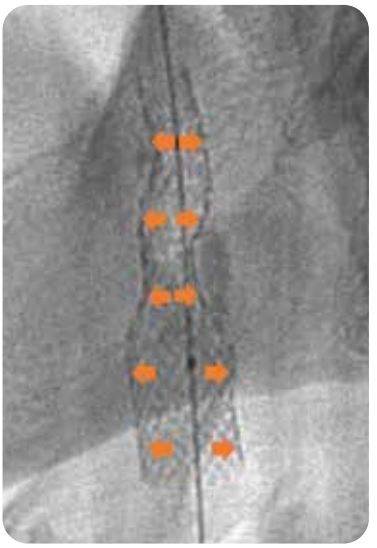
Optimized Cell Design

Despite the lack of any conclusive evidence[1], there's a vigorous debate about the merits of closed cell vs open cell, or lesion coverage vs vessel conformance. Similar to the TCAR procedure itself, the ENROUTE stent takes a best of both world approach, using a stent that is the most "closed" of open cell designs.



Auto-Tapering Conformance

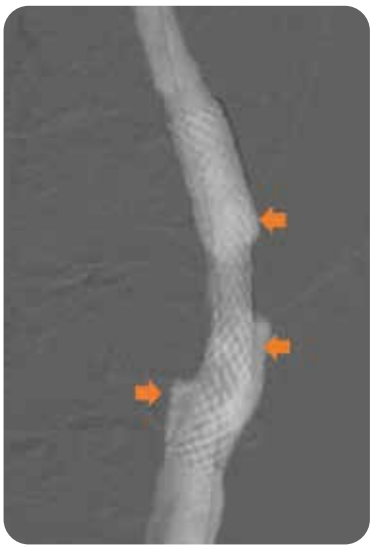
Nitinol is the optimal carotid stent material because of its low outward expansion forces that "scaffolds" the plaque without putting unnecessary stress on the native vessel.



- **Stents are always recommended to be sized at least 1-2mm larger than native vessel**
- **Bifurcation is typically the widest in diameter, so stents often need to go Small – Large – Medium**
- **The ENROUTE hybrid-cell design allows for each 2mm segment to "taper" independently**
- **Studies on possible benefits of tapered stents have been inconclusive[1]**

Lesion Coverage

Free cell area determines coverage, with the smaller the area, the less chance there is for plaque to break loose. But that also assumes ideal stent apposition and consistent hemodynamics, which isn't always the case.



- **The ENROUTE stent has a smaller free cell area than any other open-cell stent[2]**
- **Closed cell stents are more rigid, which can cause mal-apposition and vessel kinks**
- **Free cell area is variable, dependent on the degree of stent expansion – oversized stents will have more metal coverage**

> The overall **stroke rate** of **1.4%** is the **lowest reported to date** for any prospective, multi-center trial of carotid stenting.

J Vasc Surg 2015;62:1227-35

[1] S. Morr. Cartoid artery stenting: current & emerging options. Med Devices (Auckl). 2014; 7: 343–355.

[2] M. Bosiers. Does free cell area influence the outcome in carotid artery stenting? Eur J Vasc Endovasc Surg. 2007 Feb;33(2):135-41

Transfemoral CAS: Long Term Durability but High Peri-Procedural Stroke Risk

Randomized controlled trials with multi-year follow-up show the rate of ipsilateral stroke beyond 30 days is no different between CEA and trans-femoral carotid stenting. In the long term, stenting has been clinically proven to be a durable solution to carotid disease. Most of the stroke risk in stenting is during the peri-procedural period.

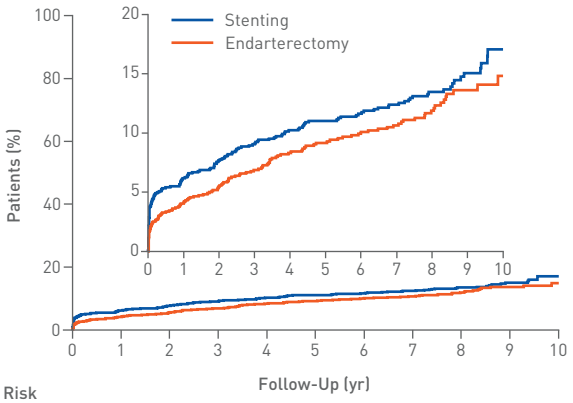
CREST: 10 Year Results

Any Stroke

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

Symptomatic/Asymptomatic Standard Surgical Risk

Brott TG et al. N Engl J Med 2016;374: 1021-31.



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

Inset shows data on extended Y –Axis (any stroke)

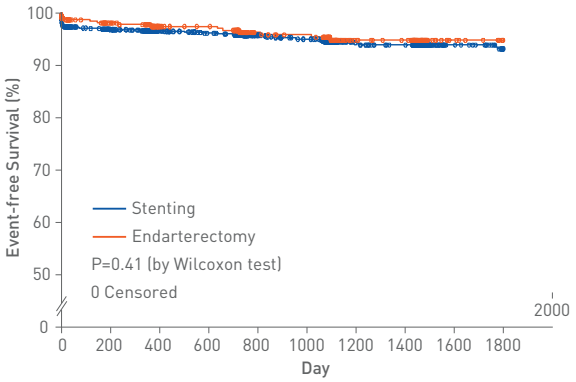
ACT1: 5 Year Results

Freedom from All Stroke Through 5 Years

30-day Stroke Rate: 2.8% CAS vs. 1.4% CEA (P=0.23)

Asymptomatic/Standard Surgical Risk

Rosenfield K et al. N Engl J Med Feb 2016.



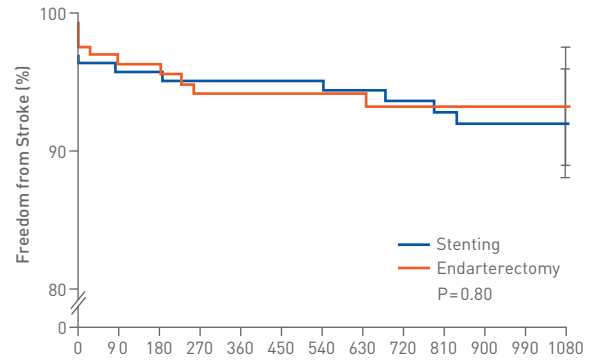
Days	0	1–365	366–730	731–1095	1096–1460	1461–1825
Number at Risk						
Stenting	1089	1068	865	730	541	363
Endarterectomy	364	355	287	244	180	112

SAPPHIRE: 3 Year Results

30-day Stroke Rate: 3.8% CAS vs. 2.7% CEA

Asymptomatic/Symptomatic High Surgical Risk

Gurm HS et al. N Engl J Med 2008;358: 1572-9.



Number at Risk							
Stenting	167	154	145	135	128	111	103
Endarterectomy	166	146	128	113	102	87	77

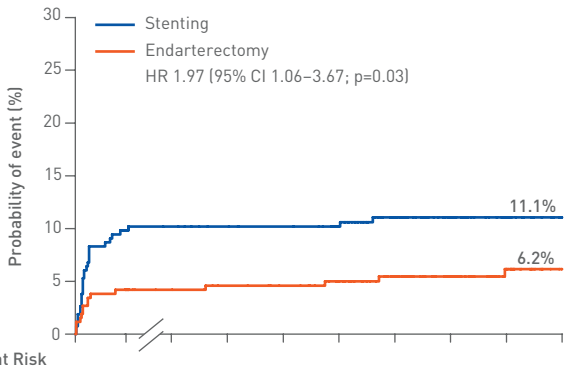
EVA 3S: 4 Year Results

Any Ipsilateral Stroke

30-day Stroke Rate: 8.9% CAS vs. 3.5% CEA

Symptomatic/Standard Surgical Risk

Mas JL et al. Lancet Neurol 2008; 7: 885-892.



Number at Risk										
Stenting	265	239	236	231	228	217	182	151	121	99
Endarterectomy	262	250	246	241	237	227	200	162	131	95

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

1. Patients with neurological symptoms and > 50% stenosis of the common or internal carotid artery by ultrasound or angiogram OR patients without neurological symptoms and > 80% stenosis of the common or internal carotid artery by ultrasound or angiogram, **AND**
2. Patients must have a vessel diameter of 4-9 mm at the target lesion, **AND**
3. Carotid bifurcation is located at 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.

ENROUTE® Transcarotid Stent System Ordering Information

Catalog Number*	Diameter x Length (mm)	Recommended Vessel Size (mm)
SR-0620-CS	6 X 20	4-5
SR-0630-CS	6 X 30	4-5
SR-0640-CS	6 X 40	4-5
SR-0730-CS	7 X 30	5-6
SR-0740-CS	7 X 40	5-6
SR-0830-CS	8 X 30	6-7
SR-0840-CS	8 X 40	6-7
SR-0930-CS	9 X 30	7-8
SR-0940-CS	9 X 40	7-8
SR-1030-CS	10 X 30	8-9
SR-1040-CS	10 X 40	8-9

*Please consult your local sales representative for product availability.

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 these instructions). 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 these instructions.
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. A patient with this device can be scanned safely in an MR system meeting the following conditions:
   - Static magnetic field of 1.5-Tesla or 3-Tesla, only
   - Maximum spatial gradient magnetic field of 4,000 Gauss/cm (40 Tesla/m) or less
   - Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg (Normal Operating Mode).

Under the scan conditions defined above, the ENROUTE Transcarotid Stent is expected to produce a maximum temperature rise of 2.4°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 5 mm from the ENROUTE Transcarotid Stent when imaged with a gradient echo pulse sequence and a 3-Tesla MRI system. The artifact does obscure the device lumen.

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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