TCAR®

The **Less Invasive Standard** in
Stroke Prevention

SILKROAD MEDICAL®

Most Vascular Procedures Primarily **Use a Less Invasive Approach, EXCEPT** for **Carotid Artery Disease**

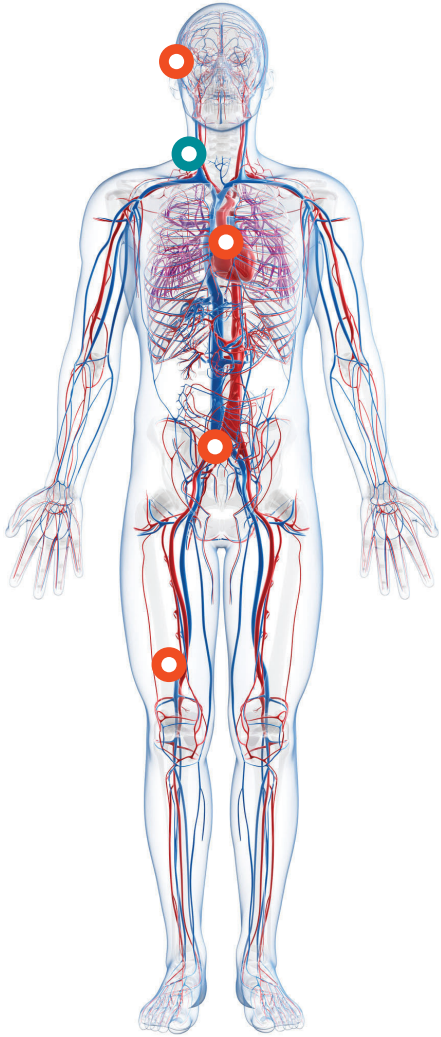
Cerebral Aneurysms **79%**

Carotid Artery Disease **25%**

Coronary Artery Disease **76%**

Thoracic/Abdominal Aortic Aneurysms **70%**

Peripheral Arterial Disease **85%**



TCAR is the Carotid Artery Disease Treatment that Allows for:

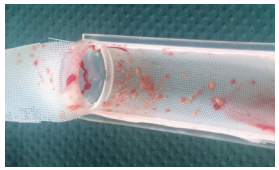
- Speedier Recovery
- Less OR Time
- Ability to use Local Anesthesia
- Less Morbidity (scarring, nerve damage)
- Greater Cost Effectiveness

The TCAR® System

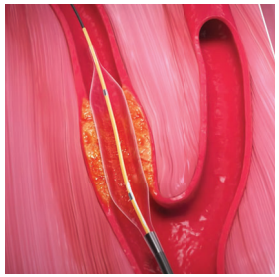
The TCAR system is designed to provide **safe, easy, and reproducible** results, regardless of physician experience.

- With its direct transcarotid approach, TCAR is able to deliver a carotid stent safely to the lesion by:
  - Eliminating the need to cross the aortic arch
  - Providing reverse flow neuroprotection prior to engaging the lesion
  - Eliminating the need for distal filter insertion and alignment in the ICA

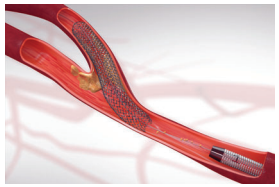
- TCAR's reverse flow neuroprotection system provides robust reverse flow to capture and remove any debris that may become dislodged from the lesion during the procedure



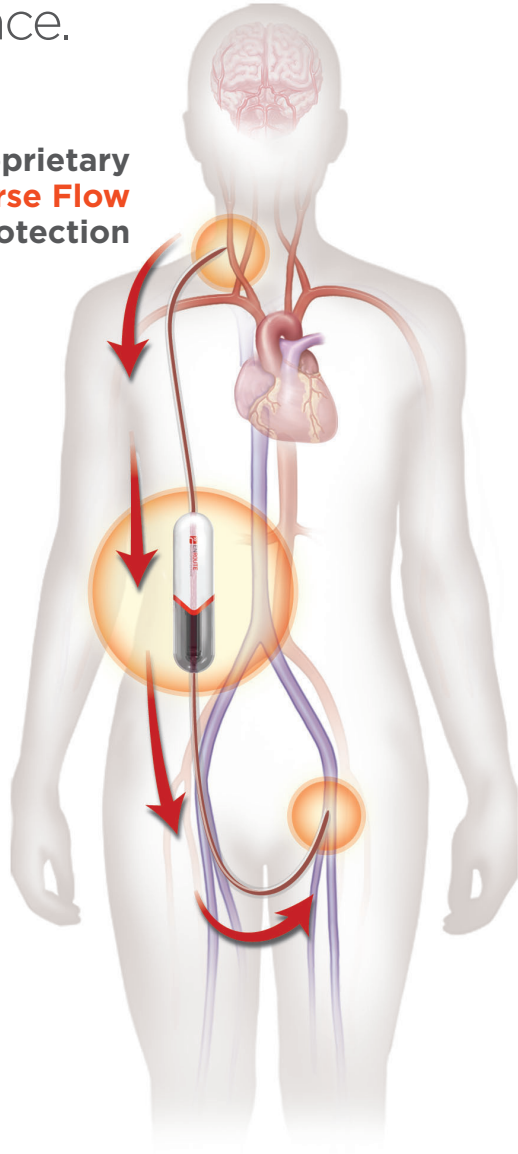
- The ENROUTE Enflate® balloon is a specialty balloon designed for the TCAR procedure. With a short working length and sizes optimized for use with the ENROUTE stent, it is designed specifically to make the TCAR procedure even more efficient and predictable.



- The ENROUTE® Transcarotid Stent Delivery System optimizes working area with its short, 57cm system length and also helps to minimize stored energy to deliver the carotid stent safely and efficiently



Proprietary Reverse Flow Neuroprotection



For additional information on the TCAR procedure, please visit silkroadmed.com/healthcare-professionals/tcar-how-it-works/

Consistent Freedom from Stroke

98.7% *
PROOF[1]
(N=75)

98.7% †
TCAR vs TFCAS[3]
(N=3286)

98.6% †
TCAR for HSR (VQI-TSP)[5]
(N=6384)

ROADSTER[2]
(N=136)
99.3% *
ITT=98.6%

ROADSTER 2[4]
(N=632)
99.4% *
ITT=98.1%

TCAR for SSR (VQI-TSP)[6]
(N=5066)
98.6%

TCAR Freedom from Stroke in Real World Patients[5]

Reproducible, consistent

IN-HOSPITAL OUTCOMES	CEA (N=6384)		TCAR (N=6384)
Stroke-Free Rate	**98.6%**	P = 0.88	**98.6%**
Freedom from Stroke+Death Rate	**98.4%**	P = 0.94	**98.4%**

1. Alpaslan A, et al. Transcarotid Artery Revascularization With Flow Reversal. *J Endovasc Ther.* 2017 Apr;24(2):265-270.
2. 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.
3. Schermerhorn ML, et al. Association of Transcarotid Artery Revascularization vs Transfemoral Carotid Artery Stenting With Stroke or Death Among Patients With Carotid Artery Stenosis. *JAMA.* 2019 Dec 17;322(23):2313-2322.
4. 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.
5. 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. Epub ahead of print.
6. Liang P, et al. Expansion of Transcarotid Artery Revascularization to Standard Risk Patients for Treatment of Carotid Artery Stenosis. Oral presentation at the Vascular Annual Meeting; August, 2021; San Diego, CA.

* At 30 days
† In-hospital

Stent Safety and Durability[1]

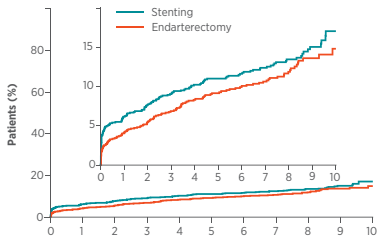
When delivered safely, long-term outcomes are equivalent to CEA

CREST: 10 Year Results[2]

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

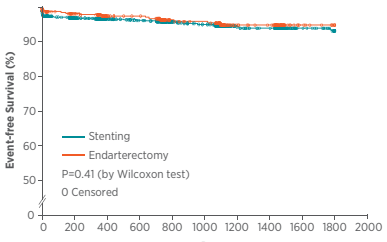
Inset shows data on extended Y –Axis (any stroke)

ACT1: 5 Year Results[3]

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



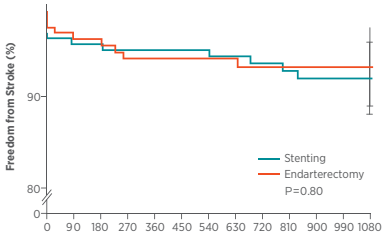
Days	0	1–365	366–730	731–1095	1096–1460	1461–1825
Number at Risk						
Stenting	1089	1068	865	730	541	363
Endarterectomy	364	355	287	244	180	112

SAPPHIRE: 3 Year Results[4]

Any Stroke

30-day Stroke Rate: 3.6% CAS vs. 3.1% CEA (P=0.77)[3]

Asymptomatic/Symptomatic High Surgical Risk



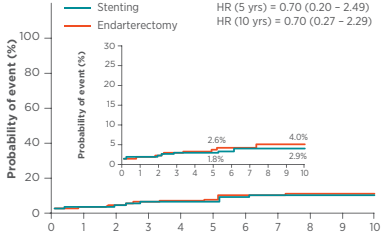
Number at Risk							
Stenting	167	154	145	135	128	111	103
Endarterectomy	166	146	128	113	102	87	77

EVA-3S: 10 Year Results[5]

Any Ipsilateral Stroke beyond 31 Days

30-day Stroke Rate: 9.1% CAS vs. 3.4% CEA

Symptomatic/Standard Surgical Risk

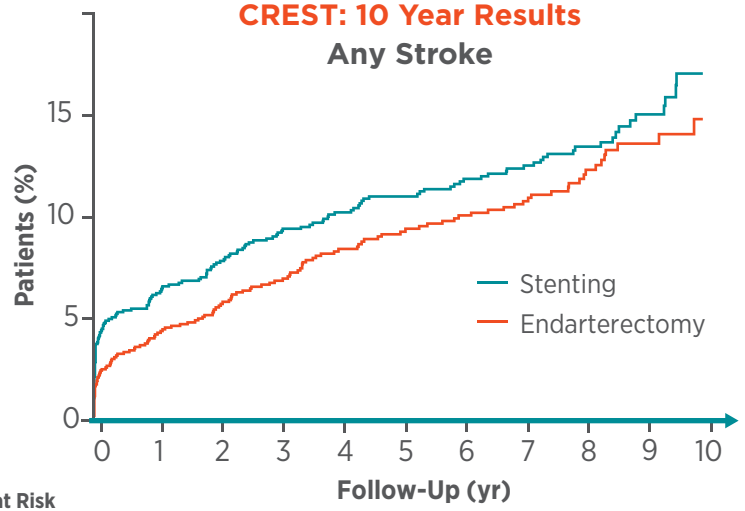


Number at Risk											
Stenting	245	233	224	212	199	185	172	123	83	52	22
Endarterectomy	254	245	236	223	211	194	176	134	85	51	21

After the first 30 days, event rates are similar over 10 years of data.

CREST: 10 Year Results

Any Stroke



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

TCAR is the solution that combines **low periprocedural stroke rates** with benefits of a less invasive procedure.

1. Brott TG, Calvet D, Howard G, et al. Long-term outcomes of stenting and endarterectomy for symptomatic carotid stenosis: a preplanned pooled analysis of individual patient data. *Lancet Neurol.* 2019;18(4):348-356.Brott TG, et al.
2. Brott TG, Howard G, et al. Long-Term Results of Stenting versus Endarterectomy for Carotid-Artery Stenosis. *N Engl J Med.* 2016 Mar 17;374(11):1021-31.
3. Rosenfield K, et al. Randomized Trial of Stent versus Surgery for Asymptomatic Carotid Stenosis. *N Engl J Med.* 2016 Mar 17;374(11):1011-20.
4. Gurm HS, et al. Long-term results of carotid stenting versus endarterectomy in high-risk patients. *N Engl J Med.* 2008 Apr 10;358(15):1572-9.
5. Mas JL, et al. Long-term follow-up study of endarterectomy versus angioplasty in patients with symptomatic severe carotid stenosis trial. *Stroke.* 2014 Sep;45(9):2750-6.

Availability of TCAR Tied to **Improved Center-Level Outcomes**[1]

2021 JAMA Network Open study finds that availability of TCAR at a hospital was associated with a decrease in the likelihood of perioperative MACE† after carotid revascularization

97.7%* TCAR **vs** **97.6%*** CEA

P = 0.91

Overall freedom from MACE was similar between TCAR and CEA

10% Risk Reduction

TCAR adoption reduces risk of MACE by 10% for all carotid interventions compared to centers only offering CEA

† MACE, "Major Adverse Cardiovascular Events," is a composite of in-hospital stroke, myocardial infarction, or death at 30 days after carotid revascularization.

1. Columbo JA, Martinez-Camblor P, O'Malley AJ, et al. Association of Adoption of Transcarotid Artery Revascularization With Center-Level Perioperative Outcomes. *JAMA Netw Open.* 2021;4(2):e2037885.

* At 30 days

Efficiencies of a **Less Invasive Approach**

Average Procedure Time[1]

TCAR **73 Mins** vs CEA **121 Mins**

Ability to treat **67% more** patients vs CEA

Procedure Cost

	TCAR	CEA
OR Time (minutes)	73	121
Cost per minute[2]*	$37	$37
Total OR Time Cost	$2,701	$4,477

Reduced OR Cost over CEA: **$1,776**

Local anesthesia is used significantly more often with TCAR vs CEA[3]

Significantly less likely for >1 day stay in hospital[1]

*Based on average procedure cost in national survey data

1. 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. Epub ahead of print.
2. Childers CP, Maggard-Gibbons M. Understanding Costs of Care in the Operating Room. *JAMA Surg.* 2018 Apr 18;153(4):e176233.
3. Malas M. Outcomes of TransCarotid Revascularization with dynamic flow reversal (TCAR) versus carotid endarterectomy (CEA) in the TCAR Surveillance Project. Oral presentation at: Vascular Annual Meeting; June 2019; National Harbor, MD.

Beyond Stroke Prevention

With a less invasive approach compared to CEA, TCAR provides **additional benefits** beyond stroke prevention for patients, physicians, and hospitals.

Patients Prefer Less Invasive Procedures

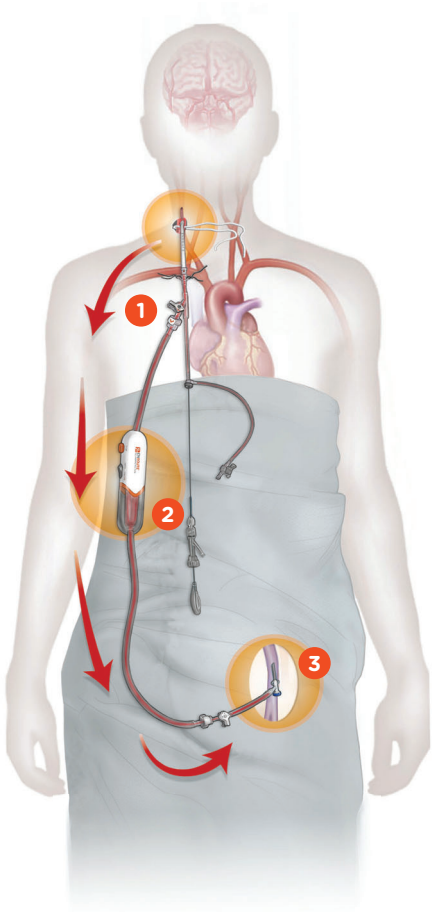
Compared to CEA, TCAR Offers[1]

- **89% Less Risk of CNI**[2]
- **47% Less Risk of MI**
- **Shorter Length of Stay**
- **Shorter Incision Length/Better Appearance**
- **39% Less Risk of Bleeding Requiring Intervention***

1. 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. Epub ahead of print.
2. Liang P, et al. Expansion of Transcarotid Artery Revascularization to Standard Risk Patients for Treatment of Carotid Artery Stenosis. Oral presentation at the Vascular Annual Meeting; August, 2021; San Diego, CA.

* With protamine use

A Dedicated Line of TCAR® Products, Customized for Atraumatic Vessel Navigation and Stent Delivery



ENROUTE® Neuroprotection System

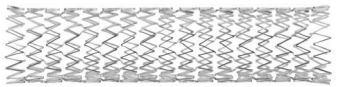
ENROUTE Neuroprotection System includes TCAR dedicated Uber Flex™ arterial sheath, venous sheath and 0.035" extra support guidewire.

1. **Transcarotid Arterial Sheath with Arterial Dilator**
2. **Flow Controller with Filter**
3. **Venous Return Sheath with Venous Dilator**
4. **0.035" Extra Support - J-Tip Guidewire** (not shown)

ENROUTE Enflate® Transcarotid RX Balloon Dilatation Catheter

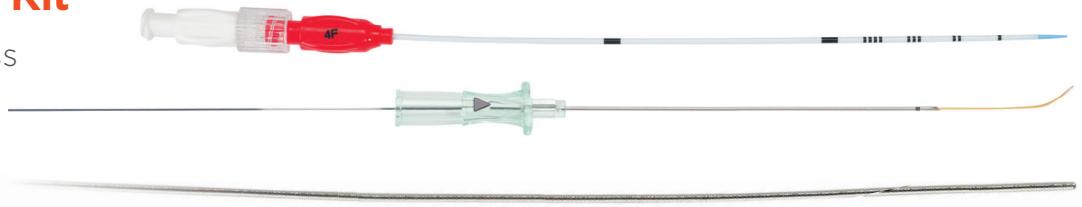
- Non-fluoro visual indicator that aligns the tip of the balloon with the tip of the arterial sheath
- TCAR-specific lengths and diameters
- Short working length designed for transcarotid access

ENROUTE® Transcarotid Stent System



- Ergonomic – Short 57cm delivery system for quick and easy delivery
- Precise – Straight, short path minimizes stored energy for precise stent placement

ENHANCE® Transcarotid Access Kit



- Designed to optimize transcarotid access and interventional device delivery

ENROUTE® 0.014" Guidewire

- Designed for precise lesion navigation in short vessels
- 95cm ergonomic control

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.

General Warnings (cont.)

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).

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.

SILKROAD MEDICAL®

Ordering Information

ENHANCE® Transcarotid Peripheral Access Kit

Catalog Number	Components	Shipped
SR-4F21G7D-MP	- 7cm 21G needle - 50cm 0.018" microwire - 4F 15cm sheath & dilator - 4F stiffened dilator - 20cm extension tube	10/box

Manufactured by Galt Medical for Silk Road Medical distribution.

Indications for Use: These access kits are intended to introduce up to a 0.038" guidewire or catheter into the peripheral vascular system, including the carotid artery, following a small gauge needle stick.

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

ENROUTE® Transcarotid Neuroprotection System

Catalog Number	Components	Shipped
SR-200-NPS	- Transcarotid Arterial Sheath with Arterial Dilator - Venous Return Sheath with Venous Dilator - Flow Controller with Filter - 0.035" Extra Support, J-Tip Guidewire	1 Each

Indications for Use: The ENROUTE Transcarotid Neuroprotection System 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 the appropriate anatomy described below:

- Adequate femoral venous access
- Common carotid artery reference diameter of at least 6mm
- Carotid bifurcation is a minimum of 5cm above the clavicle as measured by duplex Doppler ultrasound (DUS) or computerized axial tomography (CT) angiography or magnetic resonance (MR) angiography

Please refer to Instructions for Use for indications, contraindications, warnings, and precautions.

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

ENROUTE® 0.014" Guidewire

Catalog Number	Shipped
SR-014-GW	5/box

Manufactured by Lake Region Medical for Silk Road Medical distribution.

Indications for Use: The ENROUTE® 0.014" Guidewires are intended for use in the peripheral vasculature.

Caution: Federal (USA) law restricts this device to sale by or on order of a physician.

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

***Please consult your local sales representative for product availability.**

ENROUTE Enflate® Transcarotid RX Balloon Dilatation Catheter

Catalog Number	Balloon Diameter x Length (mm)
SR-4025-BC	4.0 x 25
SR-4525-BC	4.5 x 25
SR-5025-BC	5.0 x 25
SR-5525-BC	5.5 x 25
SR-6025-BC	6.0 x 25
SR-4035-BC	4.0 x 35
SR-4535-BC	4.5 x 35
SR-5035-BC	5.0 x 35
SR-5535-BC	5.5 x 35
SR-6035-BC	6.0 x 35

Indications for Use: The ENROUTE Enflate Transcarotid RX Balloon Dilatation Catheter is intended for percutaneous transluminal angioplasty and post-dilatation of self-expanding stents in the carotid arteries.

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

SILKROAD MEDICAL®

Empowering Physicians & Patients through a Less Invasive Approach to Stroke Prevention

SILK ROAD MEDICAL,INC.
1213 INNSBRUCK DR.
SUNNYVALE, CA 94089
silkroadmed.com

TOLL-FREE: 855.410.TCAR (8227)
MAIN: 408.720.9002
FAX: 408.720.9013
CustomerService@SilkRoadMed.com

AP00499.H