



Trans-Carotid Artery Revascularization

How I do it

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DISCLOSURE

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- **Consultant / Advisory Board:** Silk Road Medical
- **Speakers Bureau:** Silk Road Medical



A Victim of the Endovascular Revolution





What about cerebrovascular disease?



What about cerebrovascular disease?



- Over 135,000 carotid artery revascularizations per year
- 90% are performed on asymptomatic disease
- 11% are catheter-based interventional procedures



Choice of revascularization



- Carotid Endarterectomy (CEA) is safe and effective
- Carotid artery stenting (CAS) has some advantages



Choice of revascularization



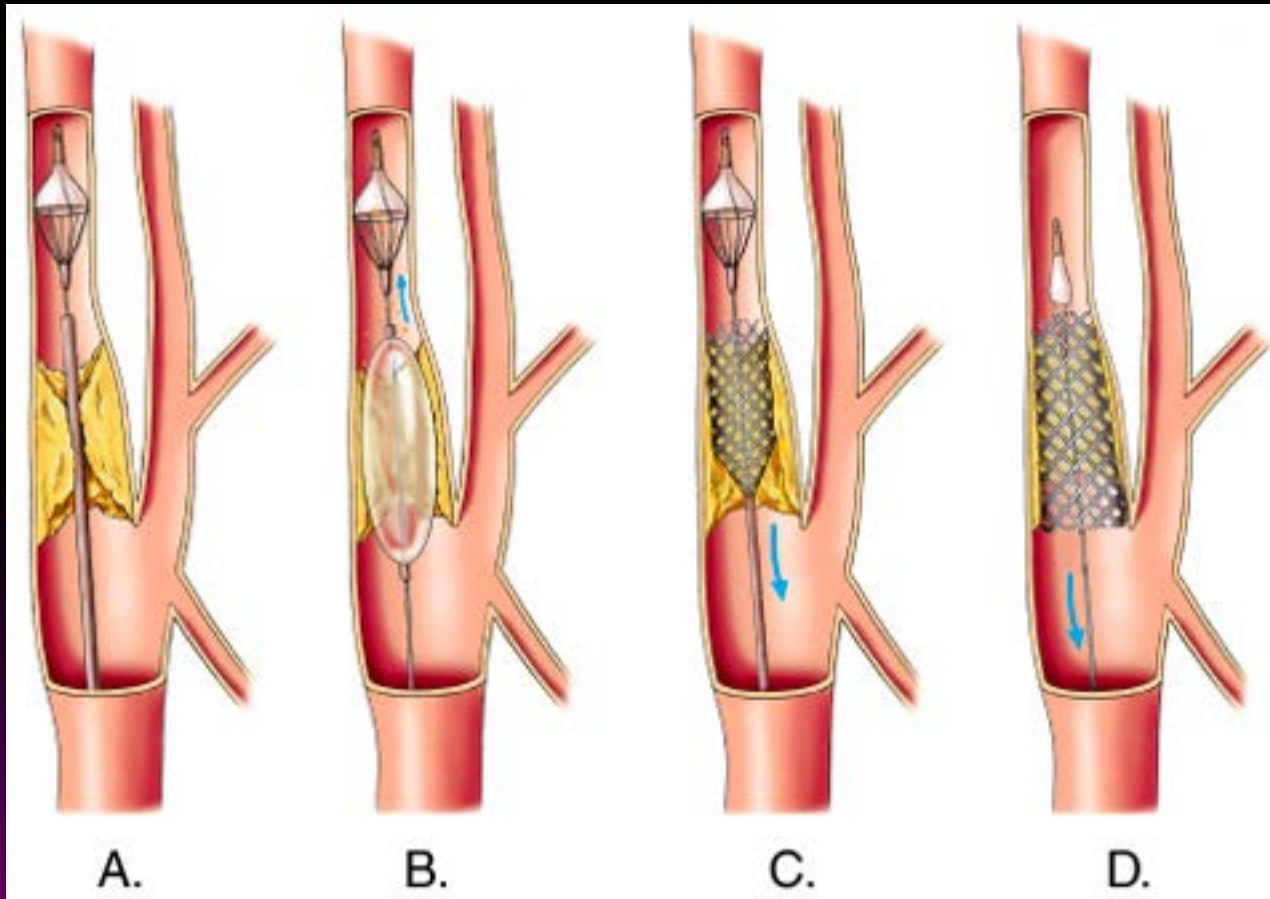
- Some lesions are challenging to treat with CEA
 - High ICA lesions Above C2
- Higher risk anatomical
 - Prior neck dissection (redo CEA)
 - Radiation
 - Contralateral ICA disease or occlusion
 - Contralateral laryngeal nerve injury
 - Tracheostomy



Trans-Femoral carotid stenting



- Lesion must be crossed before embolic protection is in place

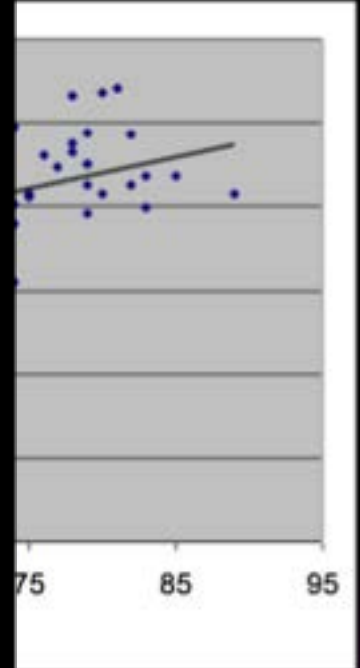




Trans-Femoral carotid stenting



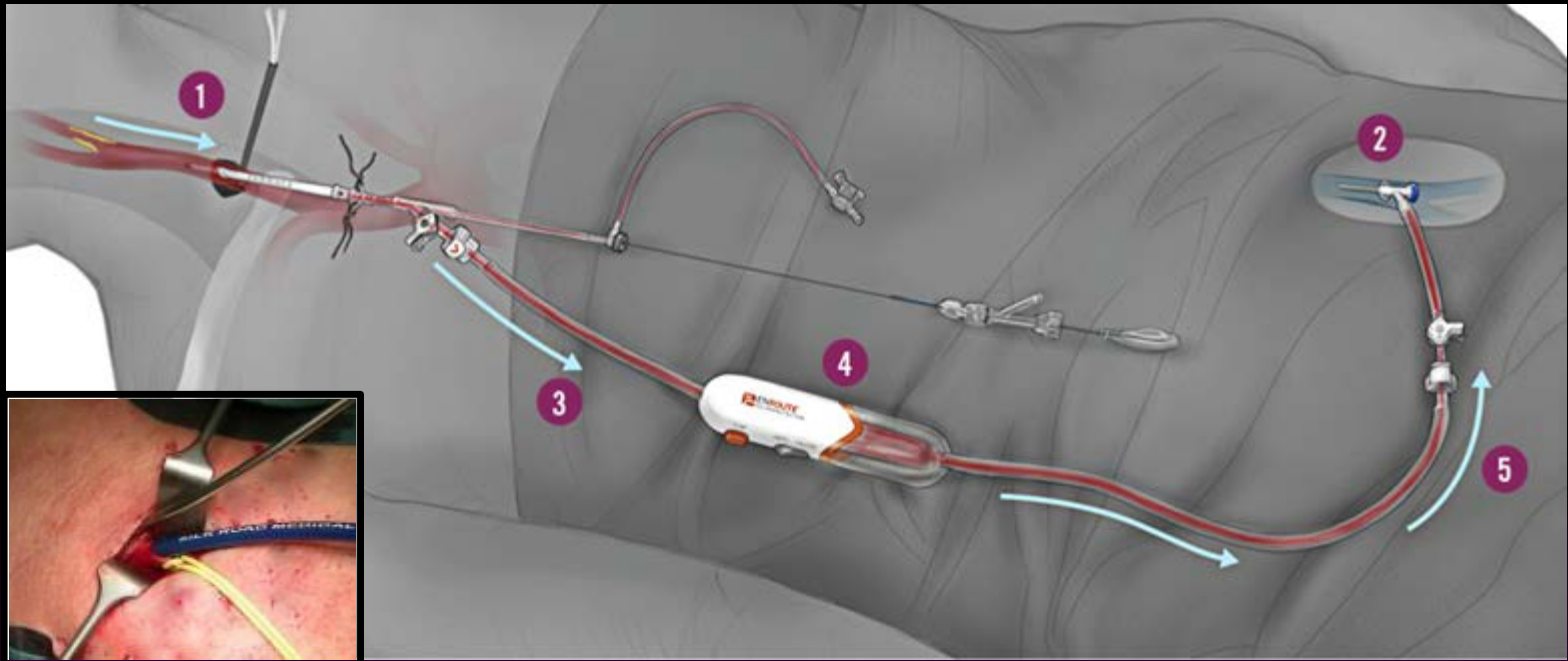
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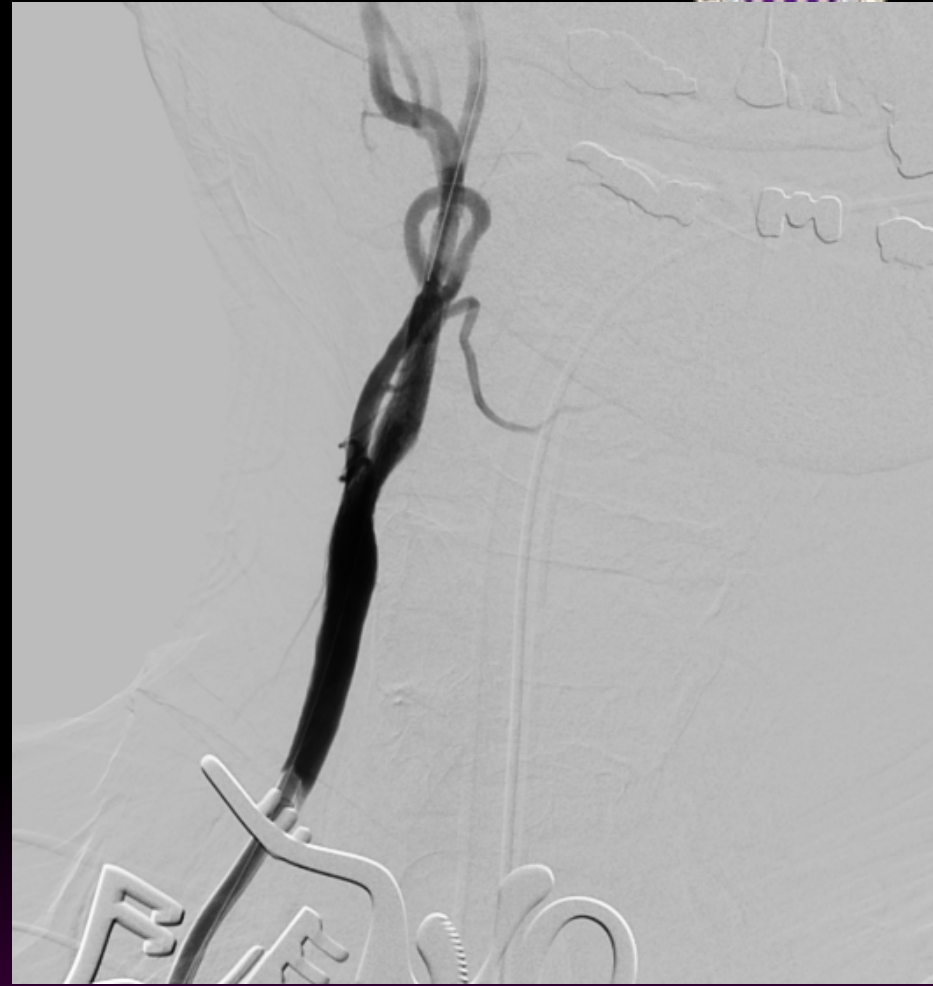


nd aortic



Trans-Carotid artery revascularization (TCAR) for high-risk carotid stenosis







4 weeks

2 weeks



Who is a TCAR candidate?



Standard CMS coverage for CAS:

Symptomatic high surgical risk with cervical carotid stenosis > 70%

Who is a TCAR candidate – Requires registry data entry



Symptomatic with cervical carotid stenosis > 50% ;
Asymptomatic > 80% and one of the following:

Physiologic high risk

- Age ≥ 75
- CHF, EF $\leq 35\%$
- ≥ 2 diseased coronaries
- Unstable angina
- MI within 6 weeks
- Abnormal stress test
- Need for open heart surgery
- Need for major surgery (including vascular)
- Uncontrolled DM
- Severe Pulmonary disease

Anatomic high risk

- Prior head or neck surgery
- Prior neck radiation
- Restenosis s/p CEA
- Surgically inaccessible lesion
- Laryngeal palsy
- Contralateral CN injury
- Contralateral ICA occlusion
- Tandem lesions
- Bilateral stenosis needing treatment.



Who is a TCAR candidate?

Relative contraindications:

Anatomy

- Clavicle to carotid bifurcation distance < 5cm
- Heavy calcium and plaque burden in the CCA
- Stenosis or occlusion of CCA
- Surgically inaccessible CCA



How I Do it: Patient selection



1. Everyone gets a CTA head + neck
 - a. CCA origin evaluation
 - b. Intracranial collateralization
 - c. Tortuosity and accessibility of CCA
 - d. Accurate clavicle – CCA distance
2. Avoid heavy CCA disease
3. Assess anesthesia risk
 - a. If low risk for GA and open contralateral ICA, do it
4. Be wary of severe COPD
 - a. Pneumothorax is a risk!
5. Recent stroke, tolerance of flow reversal



How I Do it: Pre-operative management



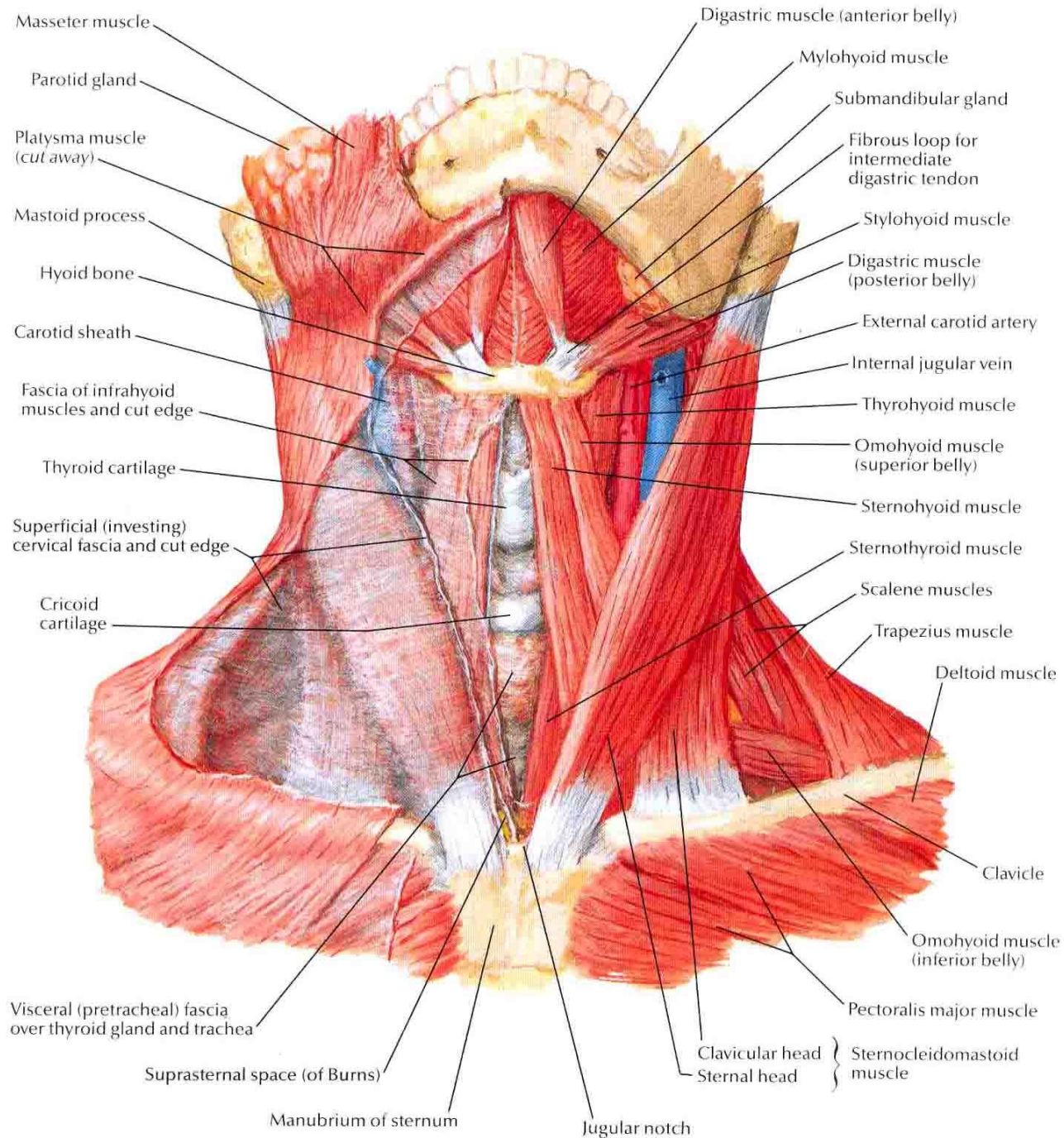
1. Everyone gets dual anti-platelet + statin (minimum 5d pre-op)
 - Including ASA+Plavix morning of procedure
2. If on anticoagulation, hold prior to operation +/- bridge.
3. Standard pre-surgical preparation and labs
4. Medical pre-op evaluation for high risk medical patients.
5. Thorough neurovascular exam



How I Do it: Intra-operative management



1. Hybrid OR team
2. Standard CEA neck prep + bilateral groin prep
3. Propofol sedation for cut-down portion with local anesthesia +/- Cervical block
4. Keep a chest tube set up ready
5. TCAR time-out prior to CCA access
 - Adequately heparinized ACT > 250
 - BP elevated
 - Glycopyrrolate 0.2mg IV
 - Neuro checks







How I Do it: Intra-operative management



6. Limited initial cervical angiogram
 - confirm lesion, ICA patency
 - mark the screen for sheath delivery

7. Insert sheath under fluoro
 - Stabilize the stiff wire and distal CCA
 - negative traction on the CCA with umbi tape

8. Initiate “passive” flow reversal and perform definitive cervical and intracranial angiograms

9. Clamp proximal CCA
 - repeat neuro checks
 - check flow reversal



How I Do it: Intra-operative management



10. Pre-dilate with a 3-4mm rapid exchange balloon
11. Stent – sized to the CCA.
 - Enroute self-expanding open cell non-tapered
 - Err on the side of too long
 - cover the external if needed
12. Post dilate if needed (typically 5mm)
13. One minute of flow reversal



How I Do it: Intra-operative management



14. Repeat cervical angiogram
15. Unclamp. Repeat intracranial angiograms
16. Neuro checks
17. Reverse heparin
18. Close platysma, skin. No drain



How I Do it: Post-operative management



1. ICU overnight
2. Arterial line with BP control
3. ASA + Plavix + Statin
4. Discharge POD 1



Roadster 2: Clinical Trial



1. Single arm, prospective observational study
2. 600 patients to be enrolled.
 - 70% of enrollees at new sites from R1
3. Inclusion: Asymptomatic $> 80\%$ stenosis, Symptomatic $> 50\%$ stenosis with at least one high risk criteria. Life expectancy > 3 years
4. Exclusion: stroke in evolution, proximal carotid stenosis or prior stent, alternative source of cerebral embolus (Afib).



Roadster 2: High Risk Criteria



Parameter	n=486
Age \geq 75	41.4%
Female	33.7%
Symptomatic	24.9%
Both Physiologic & Anatomic Risk Factors	26.8%
Top 3 Physiologic Risk Factors	
Age \geq 75 Years (17.9% as sole criterion)	42.0%
Hx of CAD (\geq 2 vessel disease)	14.7%
COPD	5.6%
Top 3 Anatomic Risk Factors	
High Cervical Stenosis	25.4%
Restenosis after CEA	20.0%
Hostile Neck	17.0%



Roadster 2: Procedure Details



Parameter	ROADSTER 1 n=219	ROADSTER 2 n=486
ROADSTER 1 Operators	100%	17.9%
New TCAR Operators	76.2%	82.1%
Enrollment by New Operators	65.3%	70.0%
Skin-to-Skin Time (median)	70 mins	69 mins
Reverse Flow/Clamp Time (median)	9 mins	9 mins
Tolerance to High Flow	98.6%	98.6%
Tolerance to Low Flow	100%	100%



Roadster 2: Results in Surgical High Risk Patients

	ROADSTER 1		ROADSTER 2	
	n=203		n=486	
Stroke/Death/MI	6	3.0%	6	1.4%
Stroke	1	0.5%	3	0.7%
Death	2	1.0%	1*	0.2%
MI	3	1.5%	2	0.5%
Stroke/Death	3	1.5%	4	0.9%
Neurological Death	0	0.0%	0	0.0%
CNI (permanent)	0	0.0%	0	0.0%



Conclusions



- TCAR provides a safe and effective method to treat symptomatic and asymptomatic patients with high grade stenosis who are at high risk for CEA
- Direct carotid access with high rate flow reversal allows for treatment of patients traditionally at increased risk for CAS (symptomatic, age ≥ 75)

Appendix A: Roadster 2 inclusion/exclusion



Study Population

Patients with atherosclerotic extracranial internal carotid stenosis (ICA) with or without involvement of the contiguous common carotid artery (CCA) detected by ultrasound.

Symptomatic: greater than or equal to 50% stenosis or

Asymptomatic: greater than or equal to 80% stenosis

Criteria

INCLUSION CRITERIA:

Patient must meet one of the following criteria regarding neurological symptom status and degree of stenosis:

Symptomatic: Stenosis must be >50% as determined by an angiogram and the patient has a history of stroke (minor or non-disabling; NIHSS ≤ 4)

OR Asymptomatic: Stenosis must be >80% as determined by angiogram without any neurological symptoms within the prior 180 days.

Target vessel must meet all requirements for ENROUTE Transcarotid Neuroprotection System and ENROUTE Stent System (refer to IFU for requirements).

Patient has a discrete lesion located in the internal carotid artery (ICA) with or without involvement of the contiguous common carotid artery (CCA).

Patient is ≥ 18 years of age.

Patient understands the nature of the procedure and has provided a signed informed consent using a form that has been reviewed and approved by the Institutional Review Board.

Patient is willing to comply with the protocol requirements and return to the treatment center for all required clinical evaluations.

Patient must have a life expectancy ≥ 3 years at the time of the index procedure without contingencies related to other medical, surgical or endovascular conditions.

Patient meets at least one of the surgical high-risk criteria listed below.

Anatomic High Risk Inclusion Criteria:

A. Contralateral carotid artery occlusion B. Tandem stenoses >70% C. High cervical carotid artery stenosis D. Restenosis after carotid endarterectomy

F. Hostile Necks which the Investigator deems safe for transcarotid access including but not limited to:

I. Prior neck irradiation II. Radical neck dissection III. Cervical spine immobility

Clinical High Risk Inclusion Criteria:

G. Patient is > 75 years of age H. Patient has > 2-vessel coronary artery disease and history of angina of any severity I. Patient has a history of angina

Canadian Cardiovascular Society (CCS) angina class 3 or 4 or

unstable angina

J. Patient has congestive heart failure (CHF) - New York Heart Association (NYHA)

Functional Class III or IV

K. Patient has known severe left ventricular dysfunction

LVEF <30%.

L. Patient has had a myocardial infarction > 72 hours and < 6 weeks prior to procedure.

M. Patient has severe pulmonary disease (COPD) with either:

FEV1 <50% predicted or

chronic oxygen therapy or

resting PO2 of <60 mmHg (room air)

N. Patient has permanent contralateral cranial nerve injury O. Patient has chronic renal insufficiency (serum creatinine > 2.5 mg/dL).

REMINDER: The following is a list of anatomical considerations that are not suitable for transfemoral CAS with distal protection that are NOT contraindications to CAS with proximal protection:

I. Type II, III, or Bovine arch II. Arch atheroma or calcification III. Atheroma of the great vessel origins IV. Tortuous distal ICA V. Tortuous or occluded



Appendix B: Roadster 1

Exclusion Criteria for TCAR ROADSTER 1 trial

- Afib; recent valve or MI; bleeding
- Evolving stroke; neuro disorders
- Occlusion; ostial CCA or intracranial stenosis; string sign; previous stent
- CCA disease at entry site
- <5cm clavicle to bifurcation

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