VIA ELECTRONIC TRANSMISSION

December 14, 2007

Steve Phurrough, M.D., M.P.A.
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Dr. Phurrough,

We, the undersigned societies, are writing to formally request reconsideration of the national coverage decision for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting (CAG-00085R3). The benefit categories for carotid stenting are inpatient hospital services and physician services. Our organizations represent a broad group of physicians and specialties involved in patient care and treatment of carotid artery disease, including stenting, endarterectomy and medical therapy. Specifically, we are requesting that the following patient population be added to the current CAS coverage policy:

> *"Patients who are at high risk for carotid endarterectomy (CEA) due to defined anatomic factors, and who have either symptomatic carotid artery stenosis of 50-69% (or greater) or asymptomatic carotid artery stenosis of ≥80%."*

While CMS recently reevaluated coverage of CAS for all high surgical risk patients and concluded with a decision to not expand coverage, CMS did not specifically consider the subset of patients who are at high risk for surgery due to anatomic factors. In the June 2007 CAS Stakeholders Meeting organized by CMS, this specific group was discussed; the rationale for considering this population of patients separately, along with the need for such patients to have access to CAS therapy, was also discussed.

We define 'anatomic factors' as follows:

a) Previous CEA with recurrent stenosis
b) Prior radiation therapy to neck
c) Previous ablative neck surgery (e.g., radical neck dissection, laryngectomy)
d) Surgically inaccessible carotid lesion, located above cervical vertebra C2
e) Common carotid artery lesion below the clavicle
f) Contralateral vocal cord palsy
g) Presence of tracheostomy stoma
h) Contralateral internal carotid artery occlusion
i) Immobile neck
j) Severe tandem lesions

There is compelling clinical rationale and need for patients in the anatomic group defined above to have access to CAS. These patients do not have an acceptable surgical option, due to their anatomic conditions, which inherently preclude or severely limit safe surgical access. The surgical literature suggests CEA event rates in this group are significantly higher than that of CAS. Meyer et al at the Mayo Clinic reported the complication rates of patients undergoing repeat CEA and documented a 10.9% perioperative stroke and death rate[1]. More than 90% of the patients were symptomatic in the aforementioned study. Similarly, Das and colleagues reported a 7.6% stroke and death rate at 30 days for patients at the Cleveland Clinic who had a repeat CEA[2]. Roughly half of these patients were symptomatic and the other half asymptomatic. Gasecki and colleagues, reporting on behalf of the NASCET trial group, noted a 14.3% stroke and death rate at 30 days in those patients who also had a contralateral occlusion of the internal carotid artery[3].

Some have raised the issue of whether high surgical risk asymptomatic patients are best treated with medical therapy. This stems from a potential concern about limited life expectancy in an elderly patient population with comorbidities. However, in the group of patients who are at high surgical risk due to anatomic factors (not comorbidity or age), survival can be expected to equal that of a 'standard risk' group, such as that treated in ACAS and ACST. Furthermore, most clinicians would agree that the severity of stenosis (*≥80%)* in the population we are proposing for coverage clearly puts individuals at increased risk for a neurologic event. While there may not be unanimity as to when and whether to revascularize all such patients, those in whom revascularization is deemed appropriate need access to an additional treatment option beyond medical therapy.

Based on enrollment in recent CAS clinical studies, we estimate this population to represent approximately 30% of the overall high surgical risk population. Contemporary registries of CAS in the 'real world' may provide the best estimate of this proportion. In Abbott's CAPTURE, CAPTURE 2 and EXACT studies anatomic patients represented 16, 30, and 13% of all patients enrolled, respectively. For CAPTURE and EXACT, prior CEA was extracted from 'Other Risk' responses and should be considered a low estimate value.

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[1] Meyer FB, Piepgras DG, Sundt TM Jr., et al. Recurrent carotid stenosis. Sundt's Occlusive Cerebrovascular Disease, Second Edition. Philadelphia: WB Saunders; 1994:310-321.

[2] Das MB, Hertzer NR, Ratliff NB, et al. Recurrent carotid stenosis: a five-year series of 65 reoperations. Ann Surg 1985; 202:28-35.

[3] Gasecki AP, Eliasziw M, Ferguson GG, et al., for the North American Symptomatic Carotid Endarterectomy Trial (NASCET) Group. Long-term prognosis and effect of endarterectomy in patients with symptomatic severe carotid stenosis and contralateral carotid stenosis or occlusion: results from NASCET. J Neurosurg 1995; 83:778-782.

Based on subset analysis of existing published CAS studies previously submitted to CMS, 30 day stroke/death rates for CAS in the anatomic high risk group are comparable to those in the overall high surgical risk group (see Appendix A). For example, in the CAPTURE post market study, anatomic stroke/death rates were 3.1% in the asymptomatic group and 8.6% in the symptomatic patients. This compares to 4.9% and 9.9% stroke/death for all asymptomatic and symptomatic CAPTURE patients, respectively.

Recently released data from the BEACH and CABERNET trials is also encouraging, with 30 day stroke/death rates in the anatomic risk group at 2.9% and 3.9% respectively (Please see Appendicies B & C for more detailed information.)

Please note that patients with adverse surgical conditions, such as those listed in this letter, were not included in the asymptomatic carotid surgical trials because they were known to be at high risk. The subsequent data dovetails nicely with known risks in surgery and a lack of surgical randomized trial data in this group.

We also recommend that CMS's new coverage policy mandate participation in robust data registries such as NCDR's CARE Registry (see: http://www.accncdr.com/webncdr/CarotidStent/Default.aspx). High quality, audited data generated by such registries will help CMS assess the wisdom of our requested coverage expansion and many provide some guidance for future decisions regarding coverage.

Last, we present a brief update on ongoing CAS 'high surgical risk' and 'standard surgical risk' clinical studies in Appendix D. It is important to note that, while not included as new evidence for consideration, second generation CAS post market studies in the high surgical risk population, such as CAPTURE 2 and EXACT, continue to show improved 30 day outcomes over time, as physicians continue to gain experience with the procedure. In particular, high surgical risk CAS outcomes in the non-octogenarian population in these large studies of over 4,000 patients are at or approaching the AHA guidelines of 3% and 6% (for asymptomatic and symptomatic patients, respectively) which were based on standard risk CEA trials.

In conclusion, we urge CMS to expand coverage to include this important subset of patients who have anatomic factors that render them high risk for endarterectomy. There is a strong and compelling clinical need for an additional revascularization option that CMS did not address in its previous coverage decision. Staff contact information for the undersigned organizations are American College of Cardiology - Sergio A. Santiviago, 202.375.6392 ssantivi@acc.org; Society for Cardiovascular Angiography and Interventions – Wayne Powell, 202.375.6341, wpowell@scai.org; Society of Vascular and Interventional Neurology - Dan Tjornehoj 715.381.3440, dtjornehoj@svineuro.org; and Society for Vascular Medicine Denise Baran, 847.480.2961 x295 dbaran@vascularmed.org.

Respectfully submitted,

American College of Cardiology
Society for Cardiovascular Angiography and Interventions
Society of Vascular and Interventional Neurology
Society for Vascular Medicine

cc:
Marcel Salive, MD, MPH - marcel.salive@cms.hhs.gov
Sarah McClain, MHS - sarah.mcclain@cms.hhs.gov
Joe Chin, MD - jchin@cms.hhs.gov
Rosemarie Hakim, PhD, MS - rosemarie.hakim@cms.hhs.gov

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APPENDIX A

ANATOMIC SUBSET ANALYSIS OF EXISTING PUBLISHED STUDIES

TABLE 1 Study Comparison of Safety Events ≤ 30 Days – All Patients

	CAPTURE Final Report (N=4225) Anatomic Patients* (N=694)^^	**CAPTURE Final Report (N=4225) All Patients**
All Patients	N=694 (16.4%)	N=4225
Death, Stroke, MI	4.6% (32/694)	6.1% (259/4225)
Death, Stroke	3.9% (27/694)	5.5% (231/4225)
Death, Major Stroke	1.7% (12/694)	2.6% (111/4225)
Asymptomatic Patients	N=585 (85%)	N=3574 (85%)
Death, Stroke, MI	3.9% (23/585)	5.4% (194/3574)
Death, Stroke	3.1% (18/585)	4.9% (174/3574)
Death, Major Stroke	1.0% (6/585)	2.2% (78/3574)
Symptomatic Patients	N=105 (15%)	N=573 (14%)
Death, Stroke, MI	8.6% (9/105)	11.2% (64/573)
Death, Stroke	8.6% (9/105)	9.9% (57/573)
Death, Major Stroke	5.7% (6/105)	5.8% (33/573)
Patients < 80 years old	N= 560 (81%)	N=3237 (77%)
Death, Stroke, MI	4.1% (23/560)	5.3% (171/3237)
Death, Stroke	3.4% (19/560)	4.6% (148/3237)

Death, Major Stroke	1.4% (8/560)	2.0% (66/3237)

- Includes only the most serious event for each patient and includes only each patient's first occurrence of each event.
- ^^ Only 690 patients with symptomatic status available
- * Prior CEA was extracted from 'Other Risk' responses and should be considered an estimated value

TABLE 2 Study Comparison of Safety Events ≤ 30 Days – Non-Octogenarians Only

	CAPTURE Final Report (N=4225) Anatomic Patients* (N=694)^^	**CAPTURE Final Report (N=4225) All Patients**
Asymptomatic Patients < 80 yo	N= 472 (68%)	N=2764 (65%)
Death, Stroke, MI	3.6% (17/472)	4.7% (129/2764)
Death, Stroke	2.8% (13/472)	4.1% (112/2764)
Death, Major Stroke	1.1% (5/472)	1.7% (48/2764)
Symptomatic Patients < 80 yo	N= 84 (12.2%)	N=416 (10%)
Death, Stroke, MI	7.1% (6/84)	9.9% (41/416)
Death, Stroke	7.1% (6/ 84)	8.7% (36/416)
Death, Major Stroke	3.6% (3/84)	4.3% (18/416)

- Includes only the most serious event for each patient and includes only each patient's first occurrence of each event.
- ^^ Only 690 patients with symptomatic status available.
- * Prior CEA was extracted from 'Other Risk' responses and should be considered an estimated value

Appendix B

BEACH: The *B*oston Scientific *E*PI: *A C*arotid Stenting Trial for *H*igh-Risk Surgical Patients

Analytical Method:

Analysis set is ITT population.
Neither BEACH nor CABERNET collected Hypercholesterolemia. BEACH collected hyperlipidemia. Table is labeled accordingly.
"Unfavorable Anatomy" is defined as "Anatomic Risk or Both Anatomic & Comorbid Risks".
Analysis used the latest snapshot from August 2007.
Study not powered to show statistical significance for unfavorable anatomy as defined above (either anatomic risk only or both anatomic & comorbid risks or the combination of the two groups).

BEACH Comorbid Risk Definition:
The patient must fulfill at least ONE of the high risk anatomical OR one of the Class I high risk co-morbid conditions or two of the Class II high risk co-morbid conditions criteria in order to be eligible to participate in the study.

Class I Co-Morbid High Risk (1 to qualify)
1. Congestive heart failure (NYHA Class III/IV).
2. Unstable angina (CCS Class III/IV).
3. Requirement for staged and scheduled CABG or valve replacement post carotid index procedure. The staged procedure must occur >30 days post index procedure.
1. Chronic Obstructive Pulmonary Disease (COPD) manifested with a forced expired volume (FEV $\leq$ 30%).
2. Known severe left ventricular ejection fraction (LVEF $\leq$ 30%).

Class II Co-Morbid High Risk (2 to qualify)
1. Age $\geq$ 75 years.
2. Recent MI (Q-wave and or non Q-wave) >30 days, with any elevation in≤72 hours and CK-MB greater than the local laboratory upper limit of normal values. Note: See General Exclusion Criteria #1.
3. Two or more major diseased coronary arteries with $\geq$ 70% stenosis at the time of index procedure in patients with a history of angina.
4. Requirement for staged and scheduled peripheral vascular surgery, or other major surgeries, [e.g., abdominal aortic aneurysm (AAA)], post carotid index procedure.

BEACH Anatomical Risk Definition:
1. Surgically inaccessible lesions at or above C2 or below the clavicle.
2. Prior neck or head radiation therapy or surgery that included the area of stenosis/repair or ipsilateral radical neck dissection for cancer.
3. Spinal immobility of the neck due to cervical arthritis or other cervical disorders.

4. Restenosis after a previous, or unsuccessful attempt of CEA (≥50% symptomatic, ≥80% asymptomatic).
5. Presence of laryngeal palsy or laryngectomy.
6. Presence of a tracheostoma.
7. Contralateral total occlusion with a qualifying lesion on the ipsilateral side.
8. Bilateral carotid artery disease (Note: Patients were assigned to a bilateral registry).

Table 1. Baseline Characteristics – BEACH Intent-to-Treat

Characteristic	N=480
Mean Age	70.9±9.3 (480) (41, 92)
Age ≥80	17.5% (84/480)
Symptomatic	23.3% (112/480)
Male	65.2% (313/480)
Prior CEA	40.6% (195/480)
Diabetes Mellitus	33.8% (162/480)
Hypertension	89.4% (429/480)
Hyperlipidemia	86.5% (415/480)
CHF	21.7% (104/480)
Unfavorable Anatomy	67.5% (324/480)
Current Smoker	17.5% (84/480)
PVD	44.2% (212/480)

Numbers are % (x/n) for binary variables and mean±SD (n) (min,max) for continuous variables.

Table 2. 30-Day Outcomes – BEACH Intent-to-Treat

30-Day Outcomes By Subgroup	All Patients	Anatomic Risk Only & Combined Anatomic Risk Only + Both Anatomic & Comorbid Risk Subgroups	
		Patients with Anatomic Risk Only	Anatomic Risk Only + Both Anatomic & Comorbid Risks
All Patients	N=480	N=281	N=324
Death/Stroke/MI	5.6%	2.9%	3.4%

		(27/478)	(8/279)	(11/322)
	Death/Stroke	5.0% (24/478)	2.9% (8/279)	3.4% (11/322)
Death/Major Stroke	2.7% (13/478)	1.1% (3/279)		1.2% (4/322)
Asymptomatic, all ages, ≥80% stenosis	**N=365**	**N=202**		**N=235**
Death/Stroke/MI	5.0% (18/363)	1.5% (3/200)		2.6% (6/233)
Death/Stroke	4.4% (16/363)	1.5% (3/200)		2.6% (6/233)
Death/Major Stroke	2.8% (10/363)	0.5% (1/200)		0.9% (2/233)
Symptomatic, all ages, ≥50% stenosis	**N=112**	**N=78**		**N=88**
Death/Stroke/MI	8.0% (9/112)	6.4% (5/78)		5.7% (5/88)
Death/Stroke	7.1% (8/112)	6.4% (5/78)		5.7% (5/88)
Death/Major Stroke	2.7% (3/112)	2.6% (2/78)		2.3% (2/88)
<80 years old	**N=396**	**N=245**		**N=279**
Death/Stroke/MI	4.1% (16/394)	2.1% (5/243)		2.9% (8/277)
Death/Stroke	3.8% (15/394)	2.1% (5/243)		2.9% (8/277)
Death/Major Stroke	2.5% (10/394)	1.2% (3/243)		1.4% (4/277)

Numbers are % (x/n).
Baseline % stenosis values are site-reported and from angiography.

Appendix C

CABERNET: *C*arotid Artery Revascularization Using the Boston Scientific EPI FilterWire EX/EZ™ and the EndoTex NexStent™

Analytical Method:

Analysis set is ITT population.

Neither study collected Hypercholesterolemia. CABERNET collected dyslipidemia. Table is labeled accordingly.

"Unfavorable Anatomy" is defined as "Anatomic Risk or Both Anatomic & Comorbid Risks".

Analysis used the latest snapshot from August 2007.

Study not powered to show statistical significance for unfavorable anatomy as defined above (either anatomic risk only or both anatomic & comorbid risks or the combination of the two groups).

CABERNET Comorbid Risk Definition:

The patient must fulfill at least ONE of the high risk anatomical OR one of the Class I high risk co-morbid conditions or two of the Class II high risk co-morbid conditions criteria in order to be eligible to participate in the study.

Class I Co-Morbid High Risk (1 to qualify)

1. Unstable angina (rest pain with ECG changes).
2. Known severe left ventricular dysfunction, LVEF <30%.
3. Congestive heart failure (CHF) - New York Heart Association Functional Class III or IV.
4. Dialysis dependent renal failure.
5. Severe pulmonary disease (COPD) with either:
   - FEV1 <50% predicted or
   - chronic oxygen therapy or
   - resting PO2 of ≤60 mmHg or
   - baseline 50%.≥hematocrit

Class II Co-Morbid High Risk (2 to qualify)

1. Patient is ≥ 75 years of age.
2. Myocardial infarction within previous 6 weeks.
3. Requires staged coronary artery bypass surgery, cardiac vascular surgery, peripheral vascular surgery, or abdominal aortic aneurysm repair.
4. Two or more proximal or major diseased coronary arteries with ≥70% stenosis that have not or cannot be revascularized.

CABERNET Anatomical Risk Definition:

1. Previous carotid endarterectomy with significant restenosis (as defined above for symptomatic or asymptomatic patients).
2. Total occlusion of the contralateral carotid artery.
3. Previous radiation treatment to the neck or radical neck dissection.
4. Target lesion is at or above the second vertebral body (C2) or below the clavicle.

5. Inability to extend the head due to cervical arthritis or other cervical disorders.
6. Tracheostomy or tracheal stoma.
7. Presence of laryngeal nerve palsy.
8. Bilateral carotid artery stenosis as determined by angiography in which both carotid arteries require treatment, as defined as:
    a. Bilateral asymptomatic stenosis ≥60% or,
    b. Bilateral symptomatic stenosis ≥50% or,
    c. Bilateral stenoses, one side with a symptomatic stenosis ≥50% and the other side asymptomatic with a stenosis ≥60%.

Table 1. Baseline Characteristics – CABERNET Intent-to-Treat

Characteristic	N=454
Mean Age	72.5±8.6 (454) (46, 94)
Age ≥80	22.2% (101/454)
Symptomatic	24.2% (110/454)
Male	65.4% (297/454)
Prior CEA	27.5% (125/454)
Diabetes Mellitus	33.0% (150/454)
Hypertension	83.0% (377/454)
Dyslipidemia	69.2% (314/454)
CHF	18.9% (86/454)
Unfavorable Anatomy*	80.4% (365/454)
Current Smoker	18.3% (83/454)
PVD	39.2% (178/454)

Numbers are % (x/n) for binary variables and mean±SD (n) (min,max) for continuous variables.
* Unfavorable anatomy includes patients with bilateral stenosis as defined in inclusion criteria. Some of these patients may also have additional anatomic and/or comorbid risk factors.

Table 2. 30-Day Outcomes – CABERNET Intent-to-Treat

30-Day Outcomes By Subgroup	All Patients	Anatomic Risk Only & Combined Anatomic Risk Only + Both Anatomic & Comorbid Risk Subgroups			
				Patients with Anatomic Risk Only	Anatomic Risk Only + Both Anatomic & Comorbid Risks

All Patients	**N=454**	**N=288**	**N=365**
Death/Stroke/MI	4.0% (18/446)	3.9% (11/284)	4.5% (16/357)
Death/Stroke	4.0% (18/446)	3.9% (11/284)	4.5% (16/357)
Death/Major Stroke	1.8% (8/446)	1.4% (4/284)	1.7% (6/357)
Asymptomatic, all ages, ≥80% stenosis*	**N=284**	**N=171**	**N=222**
Death/Stroke/MI	3.6% (10/278)	2.4% (4/167)	3.7% (8/216)
Death/Stroke	3.6% (10/278)	2.4% (4/167)	3.7% (8/216)
Death/Major Stroke	1.4% (4/278)	0.6% (1/167)	0.9% (2/216)
Symptomatic, all ages, ≥50% stenosis	**N=110**	**N=72**	**N=90**
Death/Stroke/MI	6.4% (7/109)	8.3% (6/72)	7.9% (7/89)
Death/Stroke	6.4% (7/109)	8.3% (6/72)	7.9% (7/89)
Death/Major Stroke	3.7% (4/109)	4.2% (3/72)	4.5% (4/89)
<80 years old	**N=353**	**N=228**	**N=288**
Death/Stroke/MI	2.9% (10/348)	2.2% (5/225)	3.2% (9/283)
Death/Stroke	2.9% (10/348)	2.2% (5/225)	3.2% (9/283)
Death/Major Stroke	1.4% (5/348)	0.9% (2/225)	1.4% (4/283)

Numbers are % (x/n).
*Baseline % stenosis values are site-reported and based on duplex ultrasound findings. When asymptomatic patients with % stenosis values ≥80% as determined by duplex ultrasound and ≥60% as determined by angiogram are considered in the analysis, the N=337, and the percent of Death/Stroke is 3.2%.

APPENDIX D

UPDATE ON ONGOING CAS CLINICAL TRIALS

High Surgical Risk Studies

1. **PROTECT**: Abbott IDE study for approval of the next generation Emboshield Pro embolic protection device used with the Xact stent. Also serves to meet Abbott's FDA PMA approval requirement of three years of patient follow up on the Xact stent. As of October 18, 2007, 157 patients enrolled out of total sample size of 320. No results available.

2. **CAPTURE 2 and EXACT**: second generation Abbott post market studies using the Acculink/Accunet and Xact/Emboshield devices, respectively. As of October 17, 2007 over 6,000 patients enrolled between the two studies. Approximately 4000 patients analyzed and presented publicly by Bill Gray, M.D. at the 2007 Scientific Sessions of the Transcatheter Cardiovascular Therapeutics meeting.
Conclusion: stroke/death rates improving vs first generation post market studies. In addition, outcomes in the non-octogenarian population at or approaching the AHA guidelines (see Table 1 below).

TABLE 1: **Study Comparison of Safety Events ≤ 30 Days**

	CAPTURE Final Report (N=4225)	**CAPTURE 2 Interim Report (N=1987)**	**EXACT Interim Report (N=2124)**
All Patients	N=4225	N=1987	N=2124
Death, Stroke	5.5% (231/4225)	3.8% (76/1987)	4.0% (84/2124)
Death, Major Stroke	2.6% (111/4225)	1.4% (28/1987)	1.6% (33/2124)
Symptomatic Patients	N=573	N=197	N=204
Death, Stroke	9.9% (57/573)	8.1% (16/197)	7.4% (15/204)
Death, Major Stroke	5.8% (33/573)	3.6% (7/197)	2.9% (6/204)
Asymptomatic Patients	N=3574	N=1788	N=1917
Death, Stroke	4.9% (174/3574)	3.4% (60/1788)	3.6% (69/1917)
Death, Major Stroke	2.2% (78/3574)	1.2% (21/1788)	1.4% (27/1917)
Symptomatic Patients <80 yo	N= 416	N= 149	N= 165

Death, Stroke	8.7% (36/ 416)	6.0% (9/ 149)	7.3% (12/ 165)
Death, Major Stroke	4.3% (18/ 416)	1.3% (2/ 149)	3.6% (6/ 165)
Asymptomatic Patients <80 yo	N= 2764	N= 1372	N= 1454
Death, Stroke	4.1% (112/2764)	3.1% (42/1372)	3.0% (44/1454)
Death, Major Stroke	1.7% (48/2764)	1.1% (15/1372)	0.9% (13/1454)

***Hierarchical Events-** Includes only the most serious event for each patient and includes only each patient's first occurrence of each event.

3. **CHOICE**: third generation Abbott post market study providing a choice of stent systems, either Acculink or Xact. Currently in early phase of enrollment.

4. **SAPPHIRE Worldwide**: Cordis' post market study of the Precise and Angioguard system. Expected to enroll up to 10,000 patients.

5. **SVS CAS/CEA Registry**: currently enrolling

6. **ACC CARE/NCDR Registry**: currently enrolling

7. **SONOMA**: Boston Scientific post-market study of the NexStent and EPI filter. Currently in early phase of enrollment.

8. **ARMOUR**: Invatec Mo.MA embolic protection study. Enrollment began in September 2007 with expected enrollment of 228 patients.

9. **EMPiRE**: Study of Gore & Associates reverse flow filter with the Parodi-Artery Embolization System (PAES). Currently enrolling with expected enrollment of 320.

10. **EPIC**: Lumen Biomedical Fibernet embolic protection device trial with any approved stent. Currently enrolling with expected enrollment of 254 patients.

11. **VIVA**: Bard study of Vivexx stent. Currently enrolling with expected enrollment of 400 patients.

Normal Surgical Risk Studies

1. **CREST:** NIH and Abbott sponsored randomized study of CAS vs CEA in 'standard risk' asymptomatic and symptomatic patients. Approximately 2100 patients randomized of the 2500 total enrollment. Estimated enrollment completion end 2008, with one year of follow up required on all patients for the primary endpoint and prior to results being made public (estimate: early 2010).

2. **ACT 1:** Abbott sponsored randomized (3:1) CAS vs. CEA study of asymptomatic patients. As of 9/21/07, 360 patients randomized out of 1650 needed.
Lead-in data (N=118) suggests CAS event rates (1.7% stroke/death @30 days) comparable to CEA (presented at VIVA 2007).

3. **ICSS (CAVATAS 2):** International, multicenter, randomized, clinical trial of CAS vs CEA in symptomatic patients. As of July 31, 2007 1298 of 1500 patients randomized.

4. **ACST 2:** international randomized trial of CEA vs CAS in asymptomatic patients. Randomization expected to start November 2007.