DEMOGRAPHICS AND MEDICAL HISTORY

Form CF10

AA1. Patient ID: __ __ __ - __ __ __ __

AA2. Patient acrostic: __ __ __ __ __ __ __ __ __ __

AA3. Date completed __ __/__ __/__ __ __ __ (m m d d y y y y)

A. Demographics

A1. Date of birth	__ __ / __ __ / __ __ __ __ (m m d d y y y y)	
A2. Gender	Male ☐1 Female☐2	
A3. Race **(Select one)**:		
☐1	White/Caucasian	
☐2	Black/African American	
☐3	Native American/Alaska Native	
☐4	Native Hawaiian/Pacific Islander	
☐5	Asian	
☐6	Other	A3a. Specify ______________________________
A4. Ethnicity		
☐1	Hispanic/Spanish/Latino	
☐2	Non-Hispanic/Spanish/Latino	
A5. Height (cm) ___ ___ ___		
A6. Weight (kg) ___ ___ ___.___		

B. Medical History

B1. Etiology of carotid disease - Select primary cause **(Select one)**		
☐1	Atherosclerosis	
☐2	Dissection	
☐3	Fibromuscular dysplasia	
☐4	Radiation	
☐5	Trauma	
☐6	Restenosis	
☐99	Other	B1a. Specify ______________________________

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DEMOGRAPHICS AND MEDICAL HISTORY

Form CF10

AA1. Patient ID: __ __ __ - __ __ __ __

AA2. Patient acrostic: __ __ __ __ __ __ __ __ __ __

AA3. Date completed __ __/__ __/__ __ __ __
m m d d y y y y

Past Medical History **(Select all that apply)**		
☐	B2.	Coronary artery disease (CAD)
☐	B3.	Myocardial infarction (MI)
☐	B4.	Valvular heart disease
☐	B5.	Cardiac arrhythmia
☐	B6.	Congestive heart failure (CHF)
☐	B7.	Hypertension (HTN)
☐	B8.	Diabetes mellitus (DM)
☐	B9.	Stroke (CVA)
☐	B10.	Transient ischemic attack (TIA)
☐	B11.	Amaurosis fugax or Transient monocular blindness (TMB)
☐	B12.	Peripheral vascular disease (PVD)
☐	B13.	Renal failure (Ccr < 30 ml/min or Cr ≥ 3.0 mg/dL)
☐	B14.	Gastrointestinal (GI) ulcer or bleed
☐	B15.	Chronic obstructive pulmonary disease (COPD)/Emphysema/Asthma
☐	B16.	Current or past smoker
☐	B17.	Cancer
☐	B18.	Coagulopathy
☐	B19.	Hyperlipidemia or dyslipidemia

B20. ASA (American Society of Anesthesiology) Grade **(Select one)**	
☐1	I - Normal healthy individual
☐2	II – Mild systematic disease that does not limit activity
☐3	III – Severe systematic disease that limits activity, but is not incapacitating
☐4	IV – Incapacitating systematic disease that is constantly life threatening
☐5	V – Moribund, not expected to survive 24 hours with or without surgery

B21. NYHA (New York Heart Association) CHF class **(Select one)**	
☐0	No cardiac disease.
☐1	I - Patients with cardiac disease, but without resulting limitations of physical activity.
☐2	II - Patients with cardiac disease resulting in slight limitation of physical activity.
☐3	III - Patients with cardiac disease resulting in marked limitation of physical activity.
☐4	IV - Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort.

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PRE-PROCEDURAL DIAGNOSTICS Form CF20

AA1. Patient ID: __ __ __ - __ __ __ __

AA2. Patient acrostic:__ __ __ __ __ __ __ __ __ __

AA3. Date of assessment __ __/__ __/__ __ __ __ (m m d d y y y y)

AA4. Procedure:	CAS ☐1 CEA ☐2
AA5. Target side:	Right ☐1 Left ☐2
AA6. Reimbursement category	CMS-Medicare ☐1 Commercial ☐2 IDE☐3 Post-approval ☐4 Other ☐99

A. Carotid Symptoms

A1. Symptomatology	Symptomatic ☐1 Asymptomatic ☐0
A2. Stroke Ipsilateral	Yes ☐1 No ☐0
A2a. If Yes, indicate time interval	
☐1	≤ 30 days
☐2	1-12 months
☐3	> 12 months
A2b. Modified Rankin Scale ____ (0 - 6) * ***required by CMS for patients with pre-procedural stroke***	
A3. TIA Ipsilateral	Yes ☐1 No ☐0
A3a. If Yes, indicate time interval	≤12 months ☐1 >12 months ☐2
A4. Amaurosis fugax or TMB Ipsilateral	Yes ☐1 No ☐0
A4a. If Yes, indicate time interval	≤12 months ☐1 >12 months ☐2

B. CMS Qualifying High Risk Factors

B1. Physiologic **(Select all that apply)**		
☐	B1a.	None ***(if checked go to B2)***
☐	B1b.	NYHA CHF Class III/IV
☐	B1c.	LVEF < 30%
☐	B1d.	Unstable angina
☐	B1e.	Recent MI (within 30 days)
☐	B1f.	Other from approved IDE CAS trials
☐	B1g.	Other, Specify ____________________
B2. Anatomic **(Select all that apply)**		
☐	B2a.	None ***(if checked go to C1)***
☐	B2b.	Recurrent stenosis
☐	B2c.	Radical neck dissection
☐	B2d.	Contralateral occlusion
☐	B2e.	Prior radiation to neck
☐	B2f.	Contralateral laryngeal nerve injury/palsy
☐	B2g.	High anatomic lesion (C2 or higher)
☐	B2h.	Other from approved IDE CAS trials
☐	B2i.	Other, Specify ____________________

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AA1. Patient ID: __ __ __ - __ __ __ __

AA2. Patient acrostic:__ __ __ __ __ __ __ __ __ __

AA3. Date of assessment __ __/__ __/__ __ __ __
m m d d y y y y

C. Pre-Procedure Medications

Has the patient been on any of the anticoagulants/antiplatelets below for at least 3-days pre-procedure? **(Select all that apply)**		
☐	C1.	None *(if checked go to D1)*
☐	C2.	Aspirin
☐	C3.	Ticlopidine
☐	C4.	Clopidogrel
☐	C5.	Other antiplatelet

D. Baseline Doppler Ultrasound and/or Angiogram

D1. Was Baseline Ultrasound done?	Yes ☐1 No ☐0 *(if No go to D4)*
D2. Ipsilateral carotid artery stenosis (%)	
☐1	< 50 %
☐2	50-69 %
☐3	70-79 %
☐4	≥ 80 %
☐5	Total occlusion
D3. Does contralateral carotid artery have ≥70% stenosis determined by ultrasound?	Yes ☐1 No ☐0

D4. Was Baseline Angiogram done?	Yes ☐1 No ☐0 *(if No go to E1)*
D5. Ipsilateral carotid artery percent stenosis ___ ___ ___ % (NASCET method)	
D6. Does contralateral carotid artery have ≥70% stenosis determined by angiogram?	Yes ☐1 No ☐0

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PRE-PROCEDURAL DIAGNOSTICS Form CF20

AA1. Patient ID: __ __ __ - __ __ __ __

AA2. Patient acrostic:__ __ __ __ __ __ __ __ __ __

AA3. Date of assessment __ __/__ __/__ __ __ __
m m d d y y y y

E. Head CT Scan or MRI

E1. Was head CT or MRI done?			Yes ☐1 No ☐0 *(if No go to F1)*
E1a. Type of exam			CT ☐1 MRI ☐2
E2. Were results normal? Yes ☐1 *(if Yes go to F1)* No ☐0 *(if No Complete E3a –i)*			
E3. CT/MRI results **(Select all that apply)**			
☐	E3a	Tumor	
☐	E3b.	Arteriovenous Malformation (AVM)	
☐	E3c.	Brainstem infarct	
☐	E3d.	Cerebral infarct	E3d1. Right ☐1 Left ☐2 Bilateral ☐3
☐	E3e.	Cerebellar infarct	E3e1. Right ☐1 Left ☐2 Bilateral ☐3
☐	E3f.	Intracranial hemorrhage	
☐	E3g.	Other	

F. Neurological Exam

	Normal	Abnormal	Not Done
F1. Cranial Nerves	☐1	☐2	☐3
F2. Motor Exam	☐1	☐2	☐3
F3. Sensory Exam	☐1	☐2	☐3
F4. NIH SS	☐1	☐2	☐3
F4a. If Abnormal, enter NIH SS score:		__ __	
F5. Modified Rankin Scale	Not Done ☐	Score (0-6) ___	

G. Laboratory Results

	G1a.	G1b.
Creatinine	Not Done ☐	__ __ . __ mg/dL

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PROCEDURE - CAS Form CF3A

AA1. Patient ID: __ __ __ - __ __ __ __

AA2. Patient acrostic:__ __ __ __ __ __ __ __ __ __

AA3. Date of Procedure __ __/__ __/__ __ __ __
m m d d y y y y

A. General Evaluation

A1. Date of hospital admission:		__ __/__ __/__ __ __ __ m m d d y y y y
A2. Date of discharge:		__ __/__ __/__ __ __ __ m m d d y y y y
A3. Lesion side:		Right ☐1 Left ☐2
A4. Target Vessel location **(Select all that apply)**		
☐	a. ICA	
☐	b. CCA	
☐	c. ICA/CCA (Bifurcation)	
A5. Name of primary interventionalist		(Drop-down list)
A6. Name of co-interventionalist		(Drop-down list)

B. Target Lesion Angiogram (stenosis as determined by NASCET)

B1. Percent stenosis:		___ ___ ___ %
B2. Thrombus present:		Yes ☐1 No ☐0
B3. Calcification by fluoroscopy:		
☐1	None	
☐2	Little	
☐3	Moderate	
☐4	Heavy	

C. Cerebral Protection Devices/Filters

C1. Was a Cerebral Protection Device/Filter used?	Yes☐1 No☐0
C1a. If No, provide reason:	*(if No provide a reason and go to D1)*
C2. Cerebral Protection Manufacturer/Brand (Drop-down list includes approved devices and "Other" option)	

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AA1. Patient ID: __ __ __ - __ __ __ __

AA2. Patient acrostic:__ __ __ __ __ __ __ __ __ __

AA3. Date of Procedure __ __/__ __/__ __ __ __
m m d d y y y y

D. Stent Deployment

D1. Number of Carotid Stents implanted: _______ *(if none enter 0)*

Enter the first 4 stents inserted:

	a. Manufacturer/Brand (Drop-down list includes approved devices and "Other" option)	b. Stent length (mm)	c. Check if tapered stent	d. Stent diameter (mm)	e. Tapered stent diameter (range mm)
D2. 1st stent		___ ___	☐	___ ___ .___	__ - __
D3. 2nd stent		___ ___	☐	___ ___ .___	__ - __
D4. 3rd stent		___ ___	☐	___ ___ .___	__ - __
D5. 4th stent		___ ___	☐	___ ___ .___	__ - __

E. Intra-procedural Complications **(In angiography or OR suite)**

E1. Did any complications occur during the procedure? **(Select all that apply)**			Yes ☐1 No ☐0 *(if No go to F1)*
☐	E2.	Abrupt closure	
☐	E3.	Spasm requiring treatment	
☐	E4.	Loss of external carotid	
☐	E5.	Embolization (systemic)	
☐	E6.	Embolization (carotid)	
☐	E7.	Thrombosis	
☐	E8.	Occlusive untreated dissection	
☐	E9.	Arrhythmia requiring treatment	
☐	E10.	Hypotension requiring treatment	
☐	E11.	Stroke	E11a. Modified Rankin Scale: ___ (0-6)
☐	E12.	TIA	
☐	E13.	Amaurosis fugax or TMB	
☐	E14.	Seizure	
☐	E15.	Puncture site complications	
☐	E16.	Death *(complete CF50)*	
☐	E17.	Other	E17a. Specify ______________________________

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PROCEDURE - CAS

Form CF3A

AA1. Patient ID: __ __ __ - __ __ __ __

AA2. Patient acrostic:__ __ __ __ __ __ __ __ __ __

AA3. Date of Procedure __ __/__ __/__ __ __ __
m m d d y y y y

F. Immediate Post-procedural Complications

(After leaving angiography or OR suite and before discharge)

F1. Did any complications occur after procedure and before hospital discharge? **(Select all that apply)**			Yes ☐1 No ☐0 *(if No go to G1)*
☐	F2.	Arrhythmia requiring treatment	
☐	F3.	Hypotension requiring treatment	
☐	F4.	MI	
☐	F5.	Stroke — F5a. Major ☐1 Minor ☐2	F5b. Modified Rankin Scale: ___ (0-6)
☐	F6.	TIA	
☐	F7.	Amaurosis fugax or TMB	
☐	F8.	Seizure	
☐	F9.	Puncture site complications	
☐	F10.	Death *(complete CF50)*	
☐	F11.	Other neurological complication	F11a. Specify ____________________
☐	F12.	Secondary carotid intervention	F12a. Specify ____________________
☐	F13	Other	F13a. Specify____________________

G. Results

G1. Immediate result of procedure: (**Select one)**	
☐1	Procedural (technical) success without complications
☐2	Procedural (technical) success with complications
☐3	Procedural (technical) failure – unable to deploy stent
☐4	Procedure terminated for stenosis < 70%
☐5	Procedure terminated due to complication prior to stent deployment

H. Neurological Exam (Post-procedure and prior to discharge)

	Normal	Abnormal	Not Done
H1. Cranial Nerves	☐1	☐2	☐3
H2. Motor Exam	☐1	☐2	☐3
H3. Sensory Exam	☐1	☐2	☐3
H4. NIH SS	☐1	☐2	☐3
H4a. If Abnormal, enter NIH SS score:		__ __	
H5. Modified Rankin Scale	Not Done ☐	Score (0-6) ___	

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PROCEDURE - CEA

Form CF3B

AA1. Patient ID: __ __ __ - __ __ __ __

AA2. Patient acrostic:__ __ __ __ __ __ __ __ __ __

AA3. Date of Procedure __ __/__ __/__ __ __ __ (m m d d y y y y)

A. General Evaluation

A1. Date of hospital admission:		__ __/__ __/__ __ __ __ (m m d d y y y y)
A2. Date of discharge:		__ __/__ __/__ __ __ __ (m m d d y y y y)
A3. Lesion side:		Right ☐1 Left ☐2
A4. Type of anesthesia: **(Select One)**		
☐1	General	
☐2	Regional	
☐3	Local	
A5. Thrombus present:		Yes ☐1 No ☐0
A6. Name of primary surgeon		(Drop-down list)
A7. Name of co-surgeon		(Drop-down list)

B. Surgery Information

B1. Arteriotomy patch	Yes ☐1 No ☐0
B2. Shunt used	Yes ☐1 No ☐0

C. Intra-procedural Complications

(In OR suite)

C1. Did any complications occur during the procedure? **(Select all that apply)**			Yes ☐1 No ☐0 ***(if No go to D1)***
☐	C2.	Acute occlusion	
☐	C3.	Cranial nerve injury	
☐	C4.	Stroke	C4a. Modified Rankin Scale:___ (0-6)
☐	C5.	TIA	
☐	C6.	Seizure	
☐	C7.	Technical defects requiring revision	
☐	C8.	Death ***(complete CF50)***	
☐	C9.	Other	C9a. Specify ____________________

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PROCEDURE - CEA Form CF3B

AA1. Patient ID: __ __ __ - __ __ __ __

AA2. Patient acrostic:__ __ __ __ __ __ __ __ __ __

AA3. Date of Procedure __ __/__ __/__ __ __ __
m m d d y y y y

D. Immediate Post-procedural Complications
(After leaving OR suite and before discharge)

D1. Did any complications occur after procedure and before hospital discharge? **(Select all that apply)**		Yes☐1 No☐0 *(if No go to E1)*	
☐	D2.	Arrhythmia requiring treatment	
☐	D3.	Hypotension requiring treatment	
☐	D4.	MI	
☐	D5.	Cranial nerve injury	
☐	D6.	Stroke D6a. Major ☐1 Minor ☐2	D6b. Modified Rankin Scale: ___ (0-6)
☐	D7.	TIA	
☐	D8.	Amaurosis fugax or TMB	
☐	D9.	Seizure	
☐	D10.	Death *(complete CF50)*	
☐	D11.	Other neurological complication	D11a. Specify ______________________
☐	D12.	Secondary carotid intervention	D12a. Specify ______________________
☐	D13.	Other	D13a. Specify ______________________

E. Results

E1. Immediate result of procedure: (**Select one)**	
☐1	Procedural (technical) success without complications
☐2	Procedural (technical) success with complications
☐3	Procedural (technical) failure

F. Neurological Exam (Post-procedure and prior to discharge)

	Normal	Abnormal	Not Done
F1. Cranial Nerves	☐1	☐2	☐3
F2. Motor Exam	☐1	☐2	☐3
F3. Sensory Exam	☐1	☐2	☐3
F4. NIH SS	☐1	☐2	☐3
F4a. If Abnormal, enter NIH SS score:		__ __	
F5. Modified Rankin Scale	Not Done ☐	Score (0-6) ___	

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Vascular Registry

Vascular Registry
CAROTID

CONFIDENTIAL

FOLLOW-UP VISIT

Form CF40

AA1. Patient ID: __ __ __ - __ __ __ __

AA2. Patient acrostic:__ __ __ __ __ __ __ __ __ __

AA3. Date of visit __ __/__ __/__ __ __ __ (m m d d y y y y)

A. Follow-up evaluation type

This follow-up visit was performed to evaluate: **(Check all that apply)**				
☐	A1.	CAS on the Right side	A1a. If checked, Date of procedure	__ __/__ __/__ __ __ __ (m m d d y y y y)
☐	A2.	CAS on the Left side	A2a. If checked, Date of procedure	__ __/__ __/__ __ __ __ (m m d d y y y y)
☐	A3	CEA on the Right side	A3a. If checked, Date of procedure	__ __/__ __/__ __ __ __ (m m d d y y y y)
☐	A4	CEA on the Left side	A4a. If checked, Date of procedure	__ __/__ __/__ __ __ __ (m m d d y y y y)

B. Endpoint Evaluation (since last evaluation)

B1. Clinical outcome measures **(Select all that apply)**				
☐	B1a.	Stroke	B1a1. Major ☐	B1a2. Minor ☐
B1a3. Date of stroke__ __/__ __/__ __ __ __ (m m d d y y y y)			B1a4. Modified Rankin Scale ___ (0-6)	
☐	B1b.	TIA	B1b1. Single ☐	B1b2. Multiple ☐
		B1b3. Date of TIA	__ __/__ __/__ __ __ __ (m m d d y y y y)	
☐	B1c.	Amaurosis fugax or TMB		
		B1c1. Date of TMB	__ __/__ __/__ __ __ __ (m m d d y y y y)	
☐	B1d.	Myocardial infarction	B1d1. Q wave ☐	B1d2. Non Q wave ☐
		B1d3. Date of MI	__ __/__ __/__ __ __ __ (m m d d y y y y)	

B2. Procedure-related outcome measures **(Select all that apply)**			1. Side		
			Right	Left	Bilateral
☐	B2a.	Residual stenosis	☐1	☐2	☐3
☐	B2b.	Re-stenosis (> 50% restenosis by ultrasound)	☐1	☐2	☐3
☐	B2c.	Target vessel re-do revascularization	☐1	☐2	☐3
☐	B2d.	Target lesion re-do revascularization	☐1	☐2	☐3
☐	B2e.	Stent migration/deformation	☐1	☐2	☐3
☐	B2f.	Distal embolization	☐1	☐2	☐3

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FOLLOW-UP VISIT Form CF40

AA1. Patient ID: __ __ __ - __ __ __ __ AA2. Patient acrostic:__ __ __ __ __ __ __ __ __ __

AA3. Date of visit __ __ /__ __/__ __ __ __
m m d d y y y y

B3. Was repeat carotid duplex ultrasound performed?			Yes ☐1 No ☐0 *(if No go to B6)*
☐	B4.	Right side % stenosis	B4a. < 50%☐1 50-69%☐2 70-79%☐3 ≥ 80%☐4 Total occlusion ☐5
☐	B5.	Left side % stenosis	B5a. < 50%☐1 50-69%☐2 70-79%☐3 ≥ 80%☐4 Total occlusion ☐5
B6. Was repeat angiogram performed?			Yes ☐1 No ☐0 *(if No go to C1)*
☐	B7.	Right side % stenosis	B7a. ___ ___ ___ %
☐	B8.	Left side % stenosis	B8a. ___ ___ ___ %

C. Neurological Exam

	Normal	Abnormal	Not Done
C1. Cranial Nerves	☐1	☐2	☐3
C2. Motor Exam	☐1	☐2	☐3
C3. Sensory Exam	☐1	☐2	☐3
C4. NIH SS	☐1	☐2	☐3
C4a. If Abnormal, enter NIH SS score:		__ __	
C5. Modified Rankin Scale	Not Done ☐	Score (0-6) ___	

D. Next anticipated visit (email reminder will be sent to the site)

D1. Do not send a reminder of the next upcoming visit	☐
D2. Date of the next anticipated visit – email reminder will be sent 15 days prior to this date *(if day is unknown enter 01)*	__ __/__ __/__ __ __ __ m m d d y y y y

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Vascular Registry
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TERMINATION Form CF50

AA1. Patient ID: __ __ __ - __ __ __ __ AA2. Patient acrostic:__ __ __ __ __ __ __ __ __ __

AA3. Date of Termination __ __/__ __/__ __ __ __
m m d d y y y y

A. Termination

A1. Reason for termination: **(Select one)**	
☐1	Patient lost to follow-up *(if checked go to A4)*
☐2	Patient died
☐3	Patient transferred back to Primary Care Physician *(if checked go to A4)*
A2. Date of death	__ __/__ __/__ __ __ __ m m d d y y y y
A3. Cause of death	____________________ ____________________
A4. Date of the last visit patient was evaluated	__ __/__ __/__ __ __ __ m m d d y y y y

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