Carotid Artery Stenting Data Collection Elements

1. Facility name and address
2. Point-of-contact for questions with telephone number
3. Facility Medicare provider number
4. Facility is an FDA-approved site that enrolled patients in prior CAS IDE trials such as SAPPHIRE and ARCHeR. (Y/N)
5. Facility is an FDA-approved site that is participating and enrolling patients in ongoing CAS IDE trials such as CREST. (Y/N)
6. Facility is an FDA-approved site for one or more FDA post-approval studies. (Y/N)
7. Facility has a clearly delineated program for granting carotid stent privileges and for monitoring the quality of the individual interventionists and the program as a whole. (Y/N)
8. Facility had the necessary imaging equipment, device inventory, staffing, and infrastructure to support a dedicated carotid stent program. (Y/N)
9. Advanced physiologic monitoring must be available in the interventional suite. (Y/N)
10. Emergency management equipment and systems are readily available in the interventional suite. (Y/N)
11. Carotid artery stenting systems with embolic protection devices are FDA approved. (Y/N)

The following elements will be collected for each CAS patient per facility.

12. Date of procedure mm/dd/yyyy
13. Last name
14. First name
15. Medicare ID number
16. Date of birth
17. Gender (1=male, 2=female)
18. Patient is symptomatic (1=yes, 2=no)
19. Patient has angina (1=yes, 2=no)
20. Patient has contralateral occlusion (1=yes, 2=no)
21. Patient meets high surgical risk criteria (1=yes, 2=no)
22. CHF class (Arabic digits)
23. Modified Rankin scale score if patient had stroke
24. Lesion location (left=1, right=2, both=3)
25. Location of stent (left=1, right=2, both=3)
26. Location of lesion within carotid (ICA=1, CCA=2, both=3)
27. % stenosis by angiography
28. % stenosis of 2nd lesion by angiography (if applicable)
29. Device manufacturer (1=Guidant, 2=Cordis, 3=Abbott, 4=Other)
30. Embolic Protection used (1=yes, 2=no)
31. Any complications (1=yes, 2=no)