

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

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-XXXX**. The time required to complete this information collection is estimated to average (**XX hours**) or (**XX minutes**) per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.