

## 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)

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

11. Facility provider number
12. E-mail address
13. Patient's Medicare ID number
14. Patient's date of birth
15. Date of procedure
16. Patient is symptomatic (Y/N)
17. Patient meets high surgical risk criteria (Y/N)
18. Modified Rankin scale score if patient had stroke
19. % stenosis by angiography
20. % stenosis of 2<sup>nd</sup> lesion by angiography (if applicable)
21. Embolic Protection used (Y/N)
22. Any complications (Y/N)

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 **0938-1011 (Expires XX/XX/XXXX)**. This is a mandatory information collection. The time required to complete this information collection is estimated to average 11 hours 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. **\*\*\*\*\*CMS Disclaimer\*\*\*\*\*Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact Sarah Fulton at sarah.fulton@cms.hhs.gov.**