

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A)  
For  
Other Than Full and Open Competition (>\$150K)

Acquisition Plan Action ID: VA263-17-AP-12384

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1. **Contracting Activity:** Department of Veterans Affairs, NCO 23, St. Cloud VA Health Care System, 4801 Veterans Drive, MN 56303. Organization Activity: Minneapolis VA Health Care System, One Veterans Drive Minneapolis, MN 55417, 618-18-1-4001-0003.
2. **Nature and/or Description of the Action Being Processed:** This procurement is a sole source for the Minneapolis VA Health Care System's Electrophysiology Lab for Biosense Webster Thermocool Smarttouch catheters in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:**  
Thermocool Smarttouch catheters for use with the Carto Mapping System; which provides mapping capability of certain nerve pathways in the heart. These catheters are used during ablation procedures to locate and terminate abnormal rhythms that can be detrimental to the patient.  
  
Delivery Date: On demand delivery through 3/31/2018  
IGCE: [REDACTED]
4. **Statutory Authority Permitting Other than Full and Open Competition:** The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).
5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** The Minneapolis VA Health Care System's Electrophysiology lab currently utilizes a Carto 3D mapping system manufactured by Biosense Webster Inc. The Minneapolis VA requires additional Thermocool Smarttouch catheters for utilization with the system. The new catheters need to be compatible with the existing ablation equipment. No other manufacture's catheters are compatible with the Carto system. The Strategic Acquisition Center awarded a multiple award BPA to Biosense Webster, St. Jude Medical Inc and Boston Scientific. These catheters are not available through the multiple award BPA.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** This is a sole source procurement as no other vendor's catheters are compatible with the Minneapolis VA's Carto System.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** Price is anticipated to be fair and reasonable based on the IGCE and previous purchases.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** VetBiz was searched under NAICS code 339112 which produced 215 results. A search with the keyword "biosense" produced zero results. The Strategic

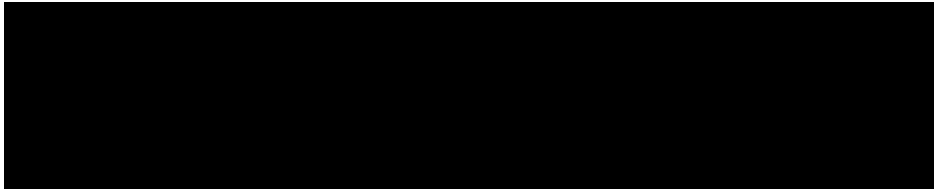
Acquisition Center awarded a multiple award BPA to Biosense Webster, St. Jude Medical Inc and Boston Scientific. Neither St. Jude Medical Inc not Boston Scientific can provide compatible catheters. Biosense Webster has verified that 2 of the items are not available through their BPA. These items have been requested to be added to the BPA but have not yet been added. These 2 items are only available through the open market directly from Biosense Webster, no other vendors are authorized to distribute them.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** NA

10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** NA

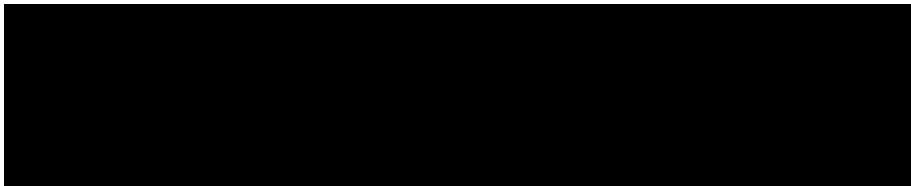
11. **A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:** The government will continue to do market research, and if catheters become available that are compatible with the existing ablation system future procurement will be competed. The current Carto Mapping System has an expected life cycle of 5-7 years and this procurement is for disposable supplies.

12. **Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.



13. **Approvals in accordance with the [VHAPM, Volume 6, Chapter VI: OFOC SOP](#).**

a. **Contracting Officer or Designee's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.



b. **Director of Contracting /Designee (Required over\$150K but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

