

DEPARTMENT OF VETERANS AFFAIRS

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

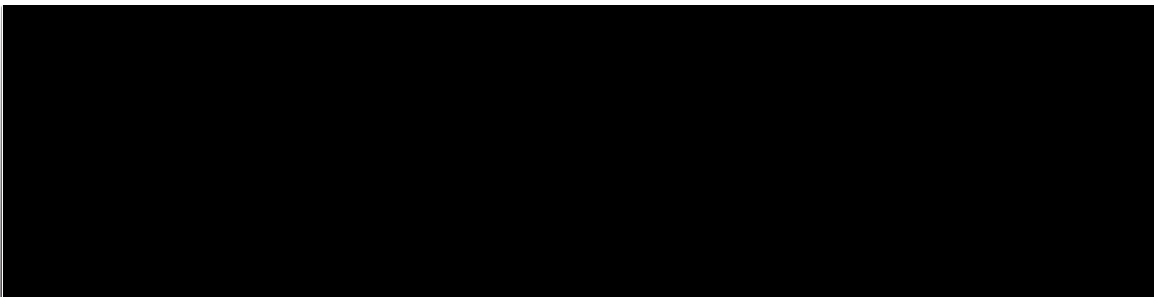
Acquisition Plan Action ID: VA248-18-AP-2397

1. **Contracting Activity:** Department of Veterans Affairs, James A. Haley VA Medical Center (VAMC), NCO-8, Tampa, FL 33637.
2. **Nature and/or Description of the Action Being Processed:** Biosense Webster (Division of Johnson & Johnson) manufactured Electrophysiology (EP) "Smart Touch Slow Flow Ablation Catheters" used for ablation procedures with Johnson & Johnson catheterization equipment. This action is a for an order to be placed against a SAC issued Firm- Fixed Price BPA (VA119-16-A-0066).

FAR13.5 Simplified Procedures for Certain Commercial Items: This sole source procurement is 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 6.302-2.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** This acquisition is for Biosense Webster (Division of Johnson & Johnson) manufactured Electrophysiology (EP) "Smart Touch Slow Flow Ablation Catheters". The estimated value of the resultant contract is \$700,000.
4. **Statutory Authority Permitting Other than Full and Open Competition:**
 - ☒ (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
 - ☐ (2) Unusual and Compelling Urgency per FAR 6.302-2;
 - ☐ (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
 - ☐ (4) International Agreement per FAR 6.302-4
 - ☐ (5) Authorized or Required by Statute FAR 6.302-5;
 - ☐ (6) National Security per FAR 6.302-6;
 - ☐ (7) Public Interest per FAR 6.302-7;
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 James A Haley VA Medical Center exclusively uses Johnson & Johnson catheter equipment; Biosense Webster Ablation Catheters are the only equipment that is compatible with the existing ablation generator equipment. The other companies adaptor cables do not connect to the Biosense Webster generator unit . Biosense Webster is the only organization that provides these catheters; and no other company's equipment is compatible with James A Haley's existing equipment. Accordingly, they are the only firm capable of providing the supplies and services described in Section 3 above without the Veteran's Health Administration experiencing substantial duplication of cost that could not be expected to be recovered through competition and unacceptable delays in fulfilling its requirements.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** There are no other sources available to meet this specific requirement. Biosense Webster, a division of Johnson & Johnson are the sole, manufacturer of the requested catheters. The Biosense Webster ablation catheters and supporting cables cannot be substituted with any other manufacturer's products. These are specialized and manufacturer specific items. In addition, Biosense Webster has provided documentation, dated 3 February 2017, indicating they do not have any distributors of the requested catheters.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The order issued against the BPA as a result of the approval of this justification is considered to be fair and reasonable. The fair and reasonable determination is based off the SAC BPA pricing indicating list price of catheter is \$4800 and the BPA price is \$3669. In addition this pricing is lower than the recently expired BPA (VA248-17-A-0024) pricing of \$3924 each.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** See CO market research report located in ECMS briefcase index P02. In addition further market research was not conducted on this acquisition due to Biosense Webster's lack of qualified distributors.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** The Biosense Webster catheters are embedded with technology that provides physicians with accurate fluid delivery readings and information relating to how much force is being used. Fluid readings are very important to our patient population, and our customer considers this an important safety issue. Furthermore, the CARTO system is currently in use in both of James A Haley's EP rooms, and has extended features for precision mapping of the heart. These catheters are used for Radio Frequency Ablation and for treatment for arrhythmias at James A Haley VAMC. Our customer believes this technology, which is embedded within each catheter and is constantly upgraded, has a positive impact on our patient population. Biosense Webster also provides no-cost inspections and maintenance on our EP equipment.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** None
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:** This justification will be posted within 14 days of award on FEDBizOpps (FBO) for 30 days in accordance with FAR 13.501(a)(1)(iii) allowing interested sources and opportunity to respond.
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.

