

**DEPARTMENT OF VETERANS AFFAIRS**

**Justification and Approval**

**For**

**Other Than Full and Open Competition**

1. **Contracting Activity:** Department of Veterans Affairs Network Contracting Office (NCO) VISN 21, located at 3801 Miranda Avenue, Palo Alto, CA 94304-1207 proposes to enter into a firm-fixed price contract on the basis of justification for other than full and open competition for the VA Palo Alto Health Care System. The Purchase request number is 640-14-1-163-0011.
2. **Nature and/or Description of the Action Being Processed:** This action limits competition for the acquisition of a COALITION® ACDF Spacer System required for performing anterior cervical procedures.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:**  
The Surgery Department at VA Palo Alto has an urgent requirement for the publication of scientific research paper.

The estimated total price is \$63,495.00

4. **Statutory Authority Permitting Other than Full and Open Competition:** 41 USC §253(c) (2), as implemented by FAR 6.302.2
  - (x) (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):**

VA Palo Alto has been borrowing this system for these procedures and frequently the system is unavailable, creating a requirement for VA Palo Alto to acquire a system. The Coalition cervical system is designed primarily for degenerative anterior cervical pathology. The system is composed of a peek (Polyetheretherketone) interbody spacer combined with a plate that accommodates screws for fixation. The implant is recessed into the disc space and anchored in place using cervical screws. It provides the biomechanical stability of a traditional ACDF (anterior cervical discectomy and fusion). The Coalition system helps to preserve the natural sagittal anatomic profile while providing anterior column support and stability. The procedure is streamlined by low profile instruments which facilitates a less invasive approach through a smaller incision.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable**

This requirement will not be synopsisized as it does not meet the threshold in FAR 6.302-5(a)(2)(ii).

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:**

As this item has been determined to be commercial, cost or pricing data will not be required. Pricing techniques such as are described in FAR 13.106-3(a), will be used to establish price fairness and reasonableness.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:**

Market research was conducted; there are no GSA vendors that can provide this item. A solicitation was posted and no vendors responded. The manufacturer was contacted; this is a trademark item owned by the manufacturer, Globus, who has advised that there is only one open market small business authorized by Globus to acquire this item, however this small business was contacted to provide a quote and the quote was unacceptable due to funding availability. Globus provide a quote that is within the amount of the available funds due to a discount they offer the VA. This is a trademark item, the patent owned by Globus Medical, a large business. The small business quote was \$93K; Globus offers \$63K.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** None.

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


There are no other sources who can meet the need of the government.

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:**

Any delay in the award of this contract for further research for another vendor who can deliver this item/service in a timely manner would result in the VA San Francisco needing to delay surgeries because of the unavailability of the borrowed unit from VASF.

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.

*(This signature is the requestor's supervisor, fund control point official, chief of service, someone with responsibility and accountability)*

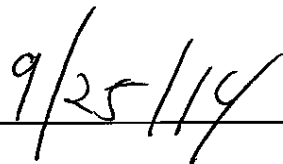


Name William F. Castor

Title : Healthcare Requirements Liaison

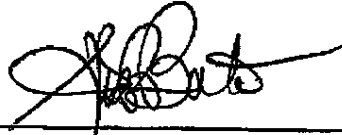
Facility : Palo Alto

Date



**Approvals in accordance with FAR 6.304** This part is filled out by Contracting Staff as part of the Justification

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



Name: Susan Battjer

Title: Contracting Officer

Facility: VA Palo Alto Health Care System

9-25-14

Date

- b. **VISN/PCA QA (Required \$3K and above):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Digitally signed by  
don.neal@va.gov  
DN: cn=don.neal@va.gov  
Date: 2014.09.25 14:53:25  
-07'00'

Name: Don Neal

Title: Chief, Supply Branch 1

Facility: Network Contracting Office (NCO) 21

Date