

**DEPARTMENT OF VETERANS AFFAIRS**

**Justification and Approval**

**For**

**Other Than Full and Open Competition**

1. **Contracting Activity:** This Justification for Other Than Full and Open Competition is prepared by the Department of Veterans Affairs Network Contracting Office 6 (NCO 6) on behalf of the Veterans Affairs Medical Center Asheville, NC in support of Purchase Request No. 637-14-996-0442.
2. **Nature and/or Description of the Action Being Processed:** This justification provides the rationale for soliciting by other than full and open competition for Stryker orthopedic implant trays. A firm fixed price Purchase Order will be awarded on a sole source basis to Stryker Corp with delivery 15 days after receipt of order (ARO).
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** Orthopedic implant trays are required for urgent or emergent cases performed in the operating room. Attached is a list of required implants. The estimated value of the proposed action is \$251,091.00
4. **Statutory Authority Permitting Other than Full and Open Competition:**
  - (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):** Stryker is currently the only vendor used at the Asheville VAMC for fracture orthopedic implants. The purpose of purchasing additional trays is to create a redundancy in the event an item becomes contaminated. Redundancy of trays is required by National Surgical Office and is the standard of care. One set of Stryker fracture implant trays are currently used in the operating room therefore a redundant set of fracture tray implants are needed. Stryker trays are needed in order to make all items the same; in the event one item is used from the tray the identical backup item is used from the redundant tray alleviating concern during surgical procedures as to whether or not items are compatible or appropriate. Other vendor trays have been identified; but, to provide a higher quality of care for Veterans, the same vendor, Stryker, needs to be utilized so that all fracture implant trays are the same. During the case, surgeons need to be assured that all implants are compatible with each other and that the procedure for using every implant is the same. Stryker is the vendor of the current implant trays on station and should be used for purchasing the back-up implant trays to provide compatibility and consistency.

The Food and Drug Administration (FDA) require medical devices sold in the U.S. to carry a unique code to help monitor safety issues with the device. The use of standardized implants will help quickly identify patients who have received problematic implants. Stryker orthopedic implants are proprietary to Stryker; they do not permit resell of orthopedic implants. Accordingly, the Stryker orthopedic implants is the only brand capable of meeting the need without the Asheville VAMC experiencing substantial duplication of cost not expected to be recovered through completion.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Stryker is the sole proprietor of Stryker brand orthopedic implants; there are no distributors for the Stryker brand implants.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** A determination of fair and reasonableness will be determined by comparison of prices paid for similar equipment and prices paid for previous purchases for the same equipment.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research has identified sources available to sell Stryker brand equipment; however, there are no distributors permitted to resell Stryker orthopedic implants.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** Redundant fracture implant trays are the standard of care of orthopedic surgery. Utilizing 2 different vendors to accomplish this may increase the amount of time a patient is under general anesthesia and can cause increased confusion while in the operating room. Currently the station has Stryker Implant Trays on stations and the need for a duplicate or redundant implant tray is required by National Surgical Office. Utilizing Stryker as the back-up implant tray is requested due to compatibility with current trays and increased patient care.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**
  - Stryker Corp, 4100 E Milham Ave, Portage, MI 49002-9704
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:** For future requirements and subsequent acquisitions of this type, in order to overcome any barriers to competition, market research will be used as a guide to determine whether or not the market for competition exists. The appropriate procurement strategy will then be determined and followed. The contracting agency will continue to monitor the market for the inception of other companies capable of meeting the requirement.

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.

\_\_\_\_\_  
Deena Roten  
Program Specialist - Surgery  
Asheville - 637

\_\_\_\_\_  
Date

13. **Approvals in accordance with FAR 6.304**

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

\_\_\_\_\_  
*Jennifer Copanza*  
JENNIFER J. ESPARZA  
Contracting Officer  
Network Contracting Office 6

\_\_\_\_\_  
9/24/14  
Date

- b. **NCO 6 Quality Assurance Compliance Review (required \$3K and above):**

\_\_\_\_\_  
JEFFERY A. BENTON  
Quality Assurance and Compliance Officer  
Network Contracting Office 6

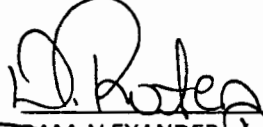
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Date

- c. **NCM/PCM/Designee (Required \$3K and above):** I certify the justification meets requirements for other than full and open competition.

\_\_\_\_\_  
*Jennifer Copanza*  
JENNIFER J. ESPARZA  
Commodities Team Lead  
Network Contracting Office 6

\_\_\_\_\_  
9/24/14  
Date

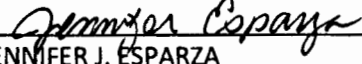
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PAM ALEXANDER Deena Rosten  
Title Program Specialist - Surgery  
Facility - Asheville - 6037

8/14/14  
Date

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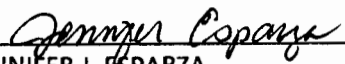
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