

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: Stryker Universal Trauma Instrument & Implant Set for Cranio-Maxillofacial (Complete Set)

1. **Contracting Activity:** Department of Veterans Affairs, VISN 7, Station 509, Charlie Norwood VA Medical Center, 1 Freedom Way, Augusta, Georgia 30904

Transaction# 509-17-3-921-0003

2. **Nature and/or Description of the Action Being Processed:** This request is for the procurement of one complete set of instruments which are used in the performance of mandibular fracture cases. These sets are exact matches to existing sets that are currently incomplete.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** These sets are exact matches to the instruments and implants currently used at this facility for mandibular fracture cases. To ensure continuity of care and exact matches to existing sets that are incomplete, it is essential to have the exact set.

The cost is estimated at \$240,713.76.

4. **Statutory Authority Permitting Other than Full and Open Competition:** 41 USC §3304(a)(1), as implemented by FAR 6.302-1. Only one responsible source is available because Stryker is the manufacturer of the mandibular fraction set (instruments and implants included) and the set is to serve as a backup to the primary set and therefore must be an exact match.

- (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):** Only one responsible source is available because Stryker is the manufacturer of the mandibular fraction set and the set is to serve as a backup to the primary set and therefore must be an exact match.  
  
Brand-name is requested because the replacement pieces must match the existing set for the set to be useful and therefore requires it to come from the same manufacturer. Since Stryker is the only manufacturer of the requested set, they are the only manufacturer capable of providing the supplies requested. If we are unable to purchase the exact set from the manufacturer to replace missing implants, then the set is a loss and a complete new set would be needed and would result in delays to patient care.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** The manufacturer, Stryker, made known to us that there are two authorized distributors who can meet the needs of the government by direct purchase through these authorized distributors. The suggested vendor is one of the sources and is a SDVOSB. Considering that these sets must be exact matches, the only sources available are those authorized by the manufacturer to supply the needed instrument and implant sets. As a result, no other sources were sought.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The service line has determined that quotes received are fair and reasonable considering the alternative to replacing the entire set and having to outsource patient care services until a replacement set can be tested/trialed and procured.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Efforts were made to contact the manufacturer to identify authorized distributors that might meet socioeconomic goals. The requested instrument and implant sets are open market and not available from any contract sources and are not on contract through the manufacturer or its authorized distributors. Because an exact match is required for continuity of care and consistency in instruments & implants in these sets, no other market research was conducted.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** Surgeons are already using these instruments and implants, they are familiar with them and to ensure continuity of care delivered exact replacement is being sought through the manufacturer which restricts competition.
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:** Due to staff familiarity and success with these instruments and implants, there is no plan at this time to consider alternative products.

Chapter VI: Other Than Full and Open Competition (OFOC) SOP  
Attachment 3: Request for Sole Source Justification Format >\$150K

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.

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Janice Askew  
Assistant Chief Logistics  
Charlie Norwood VA Medical Center

\_\_\_\_\_  
Date

13. **Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP.** *This part if filled out by Contracting Staff as part of the Justification*

- 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.

  
\_\_\_\_\_  
Name: Brigitte Huffin  
Title: Contracting Officer  
Facility: Station 509

9/14/17  
\_\_\_\_\_  
Date

- 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.

  
\_\_\_\_\_  
Name: Laurinda Millage  
Title Branch Chief Supervisor, Services/Commodities  
Facility: Station 509

9/14/2017  
\_\_\_\_\_  
Date