

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval For Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, VISN 12, Great Lakes Acquisition Center (0069D), 115 South 84th Street, Milwaukee, WI 53214-1476

2237 Transaction #: 556-13-3-2444-3487

2. **Nature and/or Description of the Action Being Processed:**

Justification and approval for other than full and open competition for the purchase of 3.5/4.0/6.5mm Cannulated Screw Instruments and Implants and restock implants for the James A. Lovell Federal Health Care Center located in North Chicago, IL. This procurement will proceed on a sole source basis with Synthes USA Sales, LLC (DBA) Synthes (780231150).

3. **Description of Supplies/Services Required to Meet the Agency's Needs:**

The Federal Health Care Center in North Chicago, Illinois has a requirement for restocking of surgical equipment to be used by the Orthopedic Surgery Department. The approximate cost is \$186,466.00

Restocking of parts that are compatible with the SYNTHES Surgical Implant Sets now being used at the Captain James A. Lovell Federal Health Care Center located in North Chicago, Illinois.

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):**

The Federal Health Care Center (FHCC) is currently in the process of updated their inventory of the Orthopedic Surgery supplies. The parts requested are direct replacement parts that make up a

surgical implant kit used to surgically reconnect broken bones. The replacement parts are designed to fit the surgical instruments that are included in the kit. The FHCC currently uses the Synthes brand Orthopedic Surgery kits. The implant parts have a unique shaped head that can only be used with the Synthes tools available in the kit. The requested replacement parts are proprietary to the SYNTHES instrument & surgical implant sets. There are no other products that can be substituted for these parts.

These highly specialized kits have power tools and implants and are the only products completely compatible with the station's current inventory. They will allow the station to utilize its current supply of bits, reamers, and other orthopedic supplies.

If another brand were to be used, it would create a substantial duplication of cost to the government that is not expected to be recovered through competition. The cost involved would be to replace all existing kits with new ones due to the unique designs of the tools involved. The surgical team would have to be trained in the proper use, sanitation and care of the new equipment and implants. The unfamiliar equipment would create unacceptable delays in patient care and ultimately put the patient at risk while on the surgical table.

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

Market research was conducted. Items were searched for via the VA's Medical/Surgical Catalog and the GSA Advantage websites. These particular parts were not available. There are no other manufactures or distributors that are able to provide the items for this requirement that are completely compatible with the station's existing tools and equipment. Synthes is the sole manufacturer and distributor of these trademarked products.

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

Price was confirmed with past purchases for the same or similar type equipment and is found to be comparable.

556-A20015, \$176,539.00

556-A10039, \$162,337.00

Contracting Officer (CO) has obtained a copy of current published price list from vendor.

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. Items were searched for via the VA's Medical/Surgical Catalog and the GSA Advantage websites. These particular parts were not available. There are no other manufactures that are able to provide the items for this requirement that are completely compatible with the station's existing tools and equipment.

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

Vendor is sole manufacturer and distributor of these trademarked supplies.

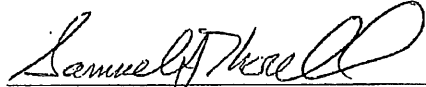
10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

See Section VI above.

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:

None

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.



Samuel J Thorell
Assistant Chief, SPD
FHCC, SPD Department

23 MAY 2013
Date

13. Approvals in accordance with FAR 6.304

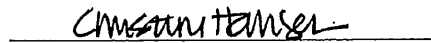
- a. **Contracting Officer's Certification:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.



Richard A. Cable Sr.
Contract Specialist
Federal Health Care Center (556)

6/03/2013
Date

- b. **NCM/PCM:** I certify the justification meets requirements for other than full and open competition.



Christine Hansen
Network Contract Manager
VISN 12

6/21/2013
Date