

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

Contracting Activity: Department of Veterans Affairs, VISN 04

Lebanon VA Medical Center

1700 S. Lincoln Ave

Lebanon, PA 17042

Purchase Request #: TBD

Nature and/or Description of the Action Being Processed: The proposed action is a firm-fixed price contract for three (3) Total Joint Surgical Instrument Kits required to perform total knee/shoulder/hip replacement surgeries.

Description of Supplies/Services Required to Meet the Agency's Needs: The Lebanon VA Medical Center (VAMC), has a requirement for three (3) Zimmer brand name total joint surgical instrument kits. These instrument kits are used for total knee/shoulder/ hip replacement surgeries performed at the Lebanon VAMC. All instruments and accessories must be compatible with Zimmer brand equipment currently in use. The Lebanon VAMC stocks and uses Zimmer implants, and requires Zimmer brand instruments to assure compatibility with the prosthetic devices that are used. The instrument set shall be brand new and in original packaging. Sterilization and processing instructions are required upon delivery. See attached listing for each Total Joint Surgical Instrument Kit.

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; **BRAND NAME REQUIREMENT**
- ☐ () (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;

Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

In accordance with FAR 6.302-1, there is only one responsible source and no other supplies or services will satisfy agency requirements. The proposed source is the manufacturer Zimmer. Total joint surgical instrument kits can be supplied by any of the manufacturer's distributors.

PERSONA CPS1 & CPS2 Kits:

These persona knee sets will be an augment to the Persona sets already owned by the VA. Compatibility must be maintained for use of the Implant. The addition of these CPS items will allow for inter-op changes between varying levels of constraint. Previous to now, and/or with other systems, in order to do this a completely different set of trial femurs and polys would be necessary. They will now be incorporated into one concise set negating the need for approx. 7 loaner trays for each case.

SHOULDER/ HIP KIT 001:

The hip items:

These items maintain compatibility's with existing sets already on the shelf at the VA Lebanon. Moreover, the ZB sets allow for implantation of a dual mobility construct while using epoly and OPTION ceramic heads. This feature is unique to the ZB implant system.

The shoulder items:

This set will allow for complete inter-op conversion to/from total shoulder and reverse total shoulder. The ZB comprehensive shoulder is the only implant(and corresponding instrument system) that allows for complete conversion in this manner. Please note: this includes the humeral side as well as the glenoid side.

Typically, every shoulder implanted needs to have the opposite kind on back-up.
Every total shoulder needs to be backed up with a reverse
Every reverse needs to be backed up with a total.

These instruments allow us to essentially do all of the above with once set, needing no redundancies on hold.

Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable: Market research was conducted for this requirement. Market research identified an SDVOSB authorized distributor for Zimmer brand surgical instruments.

Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable: The anticipated cost will be considered fair and reasonable based on current market research. The Government considers purchase history and comparison to similar products in the market. The Firm-Fixed-Price (FFP) for this Period of Performance requirement will be compared to comparable requirements and price lists for similar efforts.

Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted: The following Market research conducted:

- Communication with the Manufacturer about Distributors
- VIP Search for SDVOSB
- NAICS Search for vendors
- Informal Quotes
- Verify SAM Registration

Results of market research: This is a new requirement, therefore Agency Inventories and Excess from Other Agencies is N/A. DLA is the wholesale source. We do not have an agreement with DLA, therefore that source is N/A.

The following searches produced no results: Agency inventories and excess, UNICOR, Ability One, NAC, GSA Advantage, FSS, GWAC, Multi Agency Contracts, BPAs, FPDS and similar identical acquisitions within VISN04. Similar purchases were found for Hip Instruments.

The Surgery Care Line is requiring a brand name of Zimmer for this purchase. They provided an informal vendor quote, which is a Small Disabled Veteran Owned business (information listed and attached below). This company, Era Health, LLC (dba Veterans Healthcare) is on GSA, and has a GSA Contract for medical instruments; however, this set of instruments is not covered by their GSA contract.

The requirement is for a brand name to the manufacturer, Zimmer.

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

Market researched determined the following reasons that only the Zimmer brand total joint instrument kits will satisfy the requirement are as follows:

- 1) The surgical instruments must be compatible with the Zimmer shoulder/knee/hip implants used by the Lebanon VAMC.
- 2) The shoulder/knee/hip instruments are being added to surgical instruments already in use by practicing physicians.
- 3) The surgeons are already familiar with the Zimmer shoulder/knee/hip instrument sets, and consistency among the utilized instrumentation is important for patient safety as well as cost-effective treatment of surgical patients.
- 4) The additional surgical instruments will allow the Lebanon VAMC to provide care to Veterans with minimal delay by increasing the number of surgeries that can be performed in the expanded surgical facilities while maintaining consistency of instrumentation.

Listing of Sources that Expressed, in Writing, an Interest in the Acquisition: None.

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: The Government will continue to stay knowledgeable in the industry of total joint surgical instrument requirements by conducting periodic market research.

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.

Joanne Mitchell, RA
Name

Title Surg Operations Mgr
Facility

03-20-18
Date

1. **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.

AMANDA SAUNDERS
CONTRACTING OFFICER
Facility

Date 3/19/18

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

Name
Network Contract Manager
VISN/PCA X

Date

Title
Facility