

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VAA244-16-AP-7706

1. **Contracting Activity:** Department of Veterans Affairs, NC04, VA Pittsburgh Healthcare System, H.J. Heinz Medical Center. 2237# 595-16-4-021-1410
2. **Nature and/or Description of the Action Being Processed:** Brand Name purchase and Sole Seller - Sole Source award of a firm fixed price Contract, to American Purchasing Services, dba, American Medical Depot (AMD), off the VA Biomet Med/Surgical Prime Vendor Contract V797-P-0262.

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for the award of a Contract, in accordance with FAR Part 13.5 Simplified Acquisition Procedures for certain commercial items.

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

Biomet Orthopedics, LLC Vanguard Total Knee Systems. The Vanguard Total Knee System is composed of 232 specific line items. The set is used to implant prosthetic knee implants.

The total estimated price is \$340,986.

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):**

It is essential to the Government to purchase the Biomet Vanguard Total Knee System Implants and Equipment, since it has all of the following features that are not available in another company's Knee System: (See email from Biomet, dated 9/14/2016, under DP02 in the Procurement Action Briefcase of the eCMS Contract File).

This system allows the use of a porous construct with a vitamin E polyethylene. No other manufacturers system in us combines the both of these items.

Additionally, no other manufacturer's system allows a modular interchangeable tibial keel while remaining fully porous in a primary arthroplasty.

The use of the system will allow the surgeon to implant a polyethylene component that is manufactured and infused with vitamin E.

Further making the system and these items unique, is the fact that the vitamin E polyethylene can be used while maintaining a porous construct to the total joint arthroplasty.

When taken together the porous construct in combination with the vitamin E polyethylene allow for a greater longevity of the implant in the veteran.

As the patient ages the use of this particular implant (porous and E poly) will reduce the need/cost of revision surgery as the patient ages.

It should also be noted, that this particular set of items will allow us to implant the Tibia with an interchangeable keel. In a primary environment, we can move from 40 to 80 mm as the patient's anatomy and bone stock dictates.

The VA must purchase the above items from American Medical Depot, since they are the exclusive Agent for Biomet, and since Biomet is the Sole Seller of the items under #3 above. (See email from Biomet dated, 9/13/2016, under DP02, in the Procurement Action Briefcase of the eCMS Contract File).

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A Notice of Intent to Sole Source will be posted to FBO for 3 days.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The prices quoted by AMD on behalf of Biomet, are deemed fair and reasonable, since AMD has indicated that the quoted prices for the needed items, are less than the prices for the same items on their Commercial Price List.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:**

Written confirmation was obtained from Biomet, stating they are the Sole Source for the needed items, and that AMD is their exclusive Agent.

Information was obtained from Biomet to justify the brand name purchase.

A Query of the VetBiz Website using the Keywords Biomet and NAIC Code 339112 revealed no results.

A Query of the GSA Advantage Website, using the word Biomet Vanguard Total Knee System revealed no results.

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

This system is used for total knee replacements with a focus of benefits for the younger Veteran population. We currently have been requesting the vendor to provide us with the necessary trays on an "as needed basis", however, these requests are becoming more frequent. As this occurs, it becomes more challenging for the vendor to supply. By purchasing this system, the facility will then reduce the number of different systems from 3 to 2 which would prove to be a benefit to both the SPS department and the operating room staff in reducing the total number of trays needed to perform 1 surgical procedure and by reducing the variability in the systems required. Any deviation from this request could cause a situation where the veteran may not be able to have the best implant for his/her Total knee replacement. Due to the volume of total knee replacements two sets are required.

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: N/A

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.

Name: Joanne Hettel
Title: RN, Acute Care
Facility: Lebanon VA Medical Center

Date

13. Approvals in accordance with the [VHAPM, Volume 6, Chapter VI: OFOC SOP](#).

- 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: Ronald Mazzei
Title: Contract Specialist/Contracting Officer
Facility: H.J. Heinz

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: Elizabeth R. Morin
Branch Chief Commodities Team
Facility: Coatesville

Date