

**DEPARTMENT OF VETERANS AFFAIRS**  
**Justification and Approval**  
**For**  
**Other Than Full and Open Competition**  
**Trans#573-13-2-7201-0091**

**1. Contracting Activity:**

Department of Veterans Affairs (VA), Veterans Integrated Service Network (VISN) 08, and Malcom Randall VA Medical Center (VAMC), 1601 SW Archer Rd., Gainesville, FL 32608.

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

Service Area Office (SAO) East intends to award purchase request (PR) number 573-13-2-7201-0091 as a new firm fixed-price (FFP) with Depuy Orthopedics, Inc., 1525A The Greens Way, Jacksonville, FL 32250. The Depuy Cement Removal Set is vitally necessary when performing revisions, replacements and trauma of the lower extremities. The cement removal will be needed for hip and knee surgeries, as well as some shoulder procedures.

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

The Depuy Cement Removal Set consists of ortho curettes, osteotomies, extraction hooks, chisels, shaft extractors, drill bits and cement forceps. The various parts of the set all work in tandem with the current in-house tools and Depuy disposables needed to perform the aforementioned surgeries. Due to the influx of new patients and schedule surgeries, it has become imperative that a second set is procured.

Salient characteristics (description):

Curette, Hooked
Cup Osteotome, 56mm x 80 Deg
Cup Osteotome, 64mm x 80 Deg
Curette, Extraction Sharp
Extraction, Hook 13"
Curved Osteotome, 9mm
Cement Splitter 8 x 13
Flat Osteotome, 8mm x 13"
Prosthesis Shaft Extractor
Guide, Drill w/ Handle
Guide, Shaft for 6mm Drill
Drill, 6mm
Drill, 8mm
Curved Osteotome, 9mmx15" Str Handle
Cement Rongeur, XL Narrow
Cement Forceps
Thin Osteotome, 8mm
Thin Osteotome, 12.5mm

**4. Statutory Authority Permitting Other than Full and Open Competition:**

- (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):**

1. Depuy the only company that offers these types of cement removal kits that are compatible with current in-house surgical Depuy sets instruments, implants and disposables.

2. These instruments are needed because other brands and makes are not compatible with the current operating room configuration. Thus, the salient characteristics listed above are the only products that will fit the existing inventory. Often Depuy loaner sets must be brought into the operating room for use and if they cannot be obtained the procedures are fee-based out to another facility.

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

In accordance with FAR 5.203, a notice that the Government intends to solicit with only one source under the authority of FAR 6.302 will be published with the solicitation.

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

The Malcom Randall VAMC based their Independent Government Estimate (IGE) on historical price data obtained from Depuy as well as an updated quote from Depuy. SAO East reviewed this data and considers the anticipated price fair and reasonable. Attached; please find the most recent quote from Depuy.

**8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:**

Market research reveals that Depuy Prime Vendor has been Identified as the only contractor that can satisfy this procurement request. Joint Venture-T206./904-280-6973. Attached please find an email from Depuy justifying this statement.

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

VA Directive 2009-031

When the agency head has determined in accordance with the agency's standardization program that only specified makes and models of technical equipment and parts will satisfy the agency's needs for additional units or replacement items, and only one source is available.

Facility Director. The Facility Director is responsible for:

Standardization of Reusable Medical Equipment/Instruments (RME) is affected in order to facilitate consistency and efficiency in setup, use, and reprocessing, whether through facility-owned equipment or through a leasing agreement. *NOTE: Exceptions must have the written concurrence of the Chief Consultant, Medical Surgical Services (III).*

Equipment is replaced uniformly throughout the facility, when needed. This is a key component to the standardization process.

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

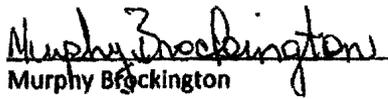
See Section 6 above.

**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:**

Malcom Randall VA Medical Center is unable take any actions to overcome remove barriers to compete for the mentioned cement removal kits; the VA is very specific in its directives to standardize medical equipment and instruments. At this time, Malcom Randall VA Medical Center cannot consider any other possible select companies or other manufactures to supply cement removal kits. These cement removal kits will only fit the operating system which already exists in the operating room inventory. However, Malcom Randall VA Medical Center will continue to conduct market research for any subsequent future procurement requests.

**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.

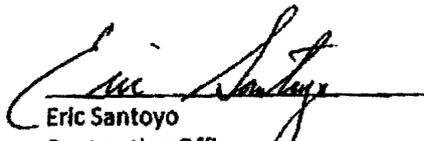
  
Murphy Brockington  
Medical Supply Technician  
Malcom Randall VA Medical Center

6/7/13  
Date:

**Approvals in accordance with FAR 6.304**

**a. Contracting Officer's Certification:**

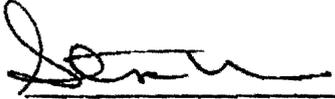
I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

  
Eric Santoyo  
Contracting Officer  
Service Area Office (SAO) East

6/7/2013  
Date

b. **DNCM/NCM:**

I certify the justification meets requirements for other than full and open competition.



Stephanie Goe acting for  
Trevor Martin  
Supervisory Contract Specialist  
Service Area Office (SAO) East

6/7/13

Date