


**DEPARTMENT OF VETERANS AFFAIRS**  
**Justification and Approval**  
**For**  
**Other Than Full and Open Competition**

1. **Contracting Activity:** Department of Veterans Affairs, VISN 08, *West Palm Beach* Medical Center
2. **Nature and/or Description of the Action Being Processed:** We are requesting to purchase Kyphon cement for Pain Management Procedures performed in the operating room.  
*Estimated value \$52,059.00*
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** Same as above
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;
  - (x) (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):** In my seven years of performing this procedure I have seen and experienced some complications with the systems from other companies. In my experience Kyphon provides a more complete instrumental kit which facilitates the procedure in a safer manner. Kyphoplasty is a procedure used on spinal fractures during which a small balloon is inserted into the fracture. The balloon is then inflated to create a space that the physician fills with special bone cement. Kyphoplasty is used to stabilize fractures, reduce back pain, and to help restore vertebral height. The Express Curette is a new item which is to be used with the kits during the procedure for scoring and scraping bone. MEDTRONIC is the manufacturer, leader and inventor of the Kyphone Balloon Kyphoplasty. Therefore, it is in the best interest of the government to continue to use Medtronic as the sole provider of the product being requested. This is an acute event, and there is urgency to correct the fracture and in doing so, improving the quality of life and functions of the patient and preventing further use of medical facility resources in being misused. This request was submitted on 8/16/2012, we have no control of when a patient is arriving with a fracture and because of the possibility of this happening we must be ready to take action for urgency of care.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:**  
A market survey was conducted to determine if any sources other than MEDTRONIC can provide the required services. In my research I search for sources using GSA Advantage, Google, and looked into VISTA and found that no other sources were identified.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:**  
Research in VISTA contract files indicated that MEDTRONIC SPINAL & BIOLOGICS has been used in the past and their prices indicate no dramatic change, therefore, I believe that MEDTRONIC's price represents a Fair and Reasonable Price.
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 to identify alternative service providers as well as complete alternatives to MEDTRONIC's treatment of vertebral compression fractures only compatible with Kyphon Express Access Tools Offering and it was determined that no alternatives currently exist.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** Currently, there are no other sources

available that can meet the needs of the requesting service for the purchase of a device that only the manufacturer can provide according to my market research. For this reason the medical staff will use the services of MEDTRONIC.


10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** In my market research no other sources were found but Medtronic which is the sole manufacturer and sole provider of the device to be purchased.
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:** The VA will continue to search for alternate sources of this service in future requirements and will compete them to see if more sources can be found. In the near future we are planning to turn this type of requirement into a contract due to the urgency and recurring need.
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.

  
 John Melendez-Benabe, MD  
 Section Chief Pain Management Clinic  
 West Palm Beach VA Medical Center

8/20/12  
 Date

13. **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.

  
 Name  
 Contracting Officer  
 Facility

8/24/12  
 Date

- b. **Product Line Supervisor (PLS):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

  
 Name CHRISTOPHER Murphy  
 Contracting Supervisor  
 Facility

8/24/2012  
 Date

- c. **DNCM/NCM**: (SAT to \$500,000) I certify the justification meets requirements for other than full and open competition.

\_\_\_\_\_  
Mitchell Thomas  
Network Contract Manager  
VISN 8

\_\_\_\_\_  
Date

- d. **SAO**: I certify the justification meets requirements for other than full and open competition.

\_\_\_\_\_  
Jeff Ryan  
Director  
Service Area Office, East

\_\_\_\_\_  
Date

- e. **VHA HCA Review and Approval**: (over \$500,000) I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and recommend approval (over \$50 million), approve (up to \$ 50 million) for other than full and open competition.

\_\_\_\_\_  
HCA  
Chief Procurement and Logistics Officer  
VHA Head of Contracting Activity (HCA)

\_\_\_\_\_  
Date

- f. **VA Deputy Senior Procurement Executive Approval (over \$10 not exceeding \$50 million)**: I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

\_\_\_\_\_  
Iris B. Cooper  
Deputy Senior Procurement Executive (DSPE)  
Office of Acquisition and Logistics  
Department of Veterans Affairs

\_\_\_\_\_  
Date

- g. **VHA Senior Procurement Executive Approval (over \$50 million)**: I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

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Jan R. Frye

Date

Deputy Assistant Secretary for Acquisition and Logistics  
Senior Procurement Executive (SPE)  
Department of Veterans Affairs