DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A)
For
Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs,
Network 15 Contracting Office
3450 S. 4th St Trwy
Leavenworth, KS 66048
The purchase request 657-14-4-1423-1255, John Cochran VA Medical Center, 915 N. Grand Blvd, St. Louis, MO. 63106

2. **Nature and/or Description of the Action Being Processed:**
This is a request for (Spider FX) embolic protection device and (Turbohawk) atherectomy catheter. The estimated cost of this purchase is $52, 425.00. A firm-fixed price onetime buy is anticipated. The requested supplier is EV3 / Covidien, Inc., 3303 Campus Drive, Plymouth, MN 55441. (800) 716-6700.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The following is proposed: the Logistics department, by maintaining inventory stock, supports the Cardiovascular Lab which has a compelling need for EV3/Covidien products used for patient procedures, performed by the Interventional Cardiologist and Vascular Surgeons at the St. Louis VA. We are requesting the following stock items and to replenish the inventory levels in order to support the Cardiovascular Lab. The following supplies are requested by the physicians in the department:

TURBOHAWK ATHERECTOMY CATHETER, THS-LS-C 15 EACH

The directional atherectomy catheter is a FDA approved plaque excision catheter that uses a tiny directional blade to shave away and remove plaque from inside the artery. The directional atherectomy catheter provides the physician with a frontline plaque excision solution in treating multiple vessel lesions which contributes to: maximum luminal gain, minimizes barotrama , preserves the native vessel for future treatment options, prevents limb loss, and relieves symptoms. Directional atherectomy is effective in the treatment for all plaque morphologies including soft plaque and mild to moderate calcium. The dual jog controls maximizes the apposition force to the vessel wall to ensure consistent cutter contact. A lower profile tapered tip provides ease of delivery. Clinical outcomes have shown diabetics have done better than non- diabetics when treated with directional atherectomy. The clinical studies have also shown that the directional atherectomy limb salvage rate was favorable in comparison to other endovascular and surgical trials, .014 wires 7fr. and 6fr. Directional atherectomy catheters for treatment of all plaque morphologies.

4. **Statutory Authority Permitting Other than Full and Open Competition:** *4*
   (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):** These supplies are used to treat peripheral vascular and coronary artery disease in our patients. These supplies are required in the Cardiovascular Lab by the Interventional Cardiologist and the Vascular Surgeons to repair the circulatory system in the upper and lower extremities, for use in the peripheral vascular arteries and coronaries. These specific items are preferred by the physicians due to the training they and the staff in the cardiovascular lab have received, the exceptional level of success when treating the patients with these items, and FDA approval for the usage of these items for treating peripheral vascular and coronary disease. EV3/Covidien is the only manufacture to provide these products with the specific specifications and performance standards as determined by the physicians performing the delicate treatment of peripheral vascular and coronary disease in our patients. This allows the physicians and the staff to use the products they are proficient with. The use of these particular supplies provides for not only better outcomes but it cuts down on procedure time. When we have longer than normal procedure times, this sometimes results in overtime for the cardiovascular lab staff that has to stay after hours to recover some of these patients. When using these devices, the need for repeat procedures is reduced, thus results in a cost savings for the VA and prevents the patients from having to undergo multiple procedures for the same problem.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** EV3/Covidien is the sole manufacture of these items. Due to the unique needs of each patient, the diversity in the products, dependability, and quality of supplies required, no products will be available from small businesses and these products are available only from the manufacturer.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:**. The requesting service and the Contracting Officer will conduct market research comparable products in the marketplace to determine that the cost to the Government is fair and reasonable.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** EV3/Covidien is the only manufacture and distributor for these specific items requested for purchase for our inventory that satisfy the current requirements of the physicians for patient treatment. We have a similar embolic protection device from Boston Scientific but the staff and physicians are not proficient in the usage of this item nor are they indicated for the usage in the same type of procedures. The embolic protection from Boston Scientific is not FDA approved for use in the peripheral arteries except for the carotids. Currently EV3/Covidien is the only manufacture and distributor for a directional atherectomy catheter. We

have several rotational atherectomy catheters , but these catheters cannot be used in the treatment of all morphologies. The use of these products in our labs helps prevent limb amputations which saves the VA money and keeps the patient from losing a limb.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** For several years, EV3/Covidien has supplied items that been utilized in our lab. These have been used by the physicians in the cardiovascular lab without experiencing any compromising incidents. The St. Louis VA has consistently received products from EV3/Covidien in a timely manner without delay.

10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Covidien /EV 3

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 requirement is currently being researched and reviewed by the Logistics and the NCO for the establishment of a supply contract that would encompass these items.

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.

James D Thorne — 8/19/2014

Name James Thorne — Date
Title Inventory Management
Facility St Louis 657

13. Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP. *This part if filled out by Contracting Staff as part of the Justification*

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

shiela.morrall1@va.gov — Digitally signed by shiela.morrall1@va.gov DN: cn=shiela.morrall1@va.gov Date: 2014.08.18 13:59:36 -05'00'

Name — Date
Title
Facility

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

loyd.jackson@va.gov — Digitally signed by loyd.jackson@va.gov DN: cn=loyd.jackson@va.gov Date: 2014.08.19 15:24:02 -05'00'

Name — Date
NCO/PCO XX Director of Contracting or Designee
Facility

Kay Brundage