

**DEPARTMENT OF VETERANS AFFAIRS**

**Justification and Approval**

**For**

**Other Than Full and Open Competition**

**Prepared February 22, 2012**

1. **Contracting Activity:** Department of Veterans Affairs, VISN 04 Philadelphia VA Medical Center.  
The purchase request number for this consignment agreement is 642-12-2-912-0245

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

This is a request for other than full and open competition for the procurement of stents on a consignment basis for use by the Interventional Radiologist in the Philadelphia VA Interventional Room for the care of veterans with vascular disease. These prosthetic devices need to be available for routine and emergency care of veterans. The prosthetic devices on the purchase order consist of Cook Medical. The Cook Medical Company is the intended company that carries this inventory.

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

The items on the purchase request are below: Quantity of each stent required for the consignment inventory is two. Some stents require a quantity of three.

Silver Stent:

Sizes .018

|                   |          |     |
|-------------------|----------|-----|
| ZIV5-18-125-7-40  | 2,300.00 | (2) |
| ZIV5-18-125-7-60  | 2,500.00 | (2) |
| ZIV5-18-125-7-80  | 2,500.00 | (2) |
| ZIV5-18-125-8-40  | 2,200.00 | (2) |
| ZIV5-18-125-10-40 | 2,200.00 | (2) |

Sizes .035

|                  |          |     |
|------------------|----------|-----|
| ZIV6-35-80-7-40  | 2,000.00 | (3) |
| ZIV6-35-80-7-60  | 2,100.00 | (3) |
| ZIV6-35-80-7-80  | 2,100.00 | (3) |
| ZIV6-35-80-8-40  | 2,000.00 | (3) |
| ZIV6-35-80-8-60  | 2,100.00 | (3) |
| ZIV6-35-80-8-80  | 2,100.00 | (3) |
| ZIV6-35-80-10-40 | 2,000.00 | (3) |
| ZIV6-35-80-10-60 | 2,000.00 | (3) |
| ZIV6-35-80-10-80 | 2,000.00 | (2) |

|                  |          |     |
|------------------|----------|-----|
| ZIV6-35-125-6-40 | 2,000.00 | (2) |
|------------------|----------|-----|

## Sole Source – Prosthetic Stents – VAMC Philadelphia

|                  |          |     |
|------------------|----------|-----|
| ZIV6-35-125-6-60 | 2,100.00 | (2) |
| ZIV6-35-125-6-80 | 2,100.00 | (2) |
| ZIV6-35-125-7-40 | 2,000.00 | (2) |
| ZIV6-35-125-7-60 | 2,100.00 | (2) |
| ZIV6-35-125-7-80 | 2,100.00 | (2) |

Average Cost: \$99,400.00

The total estimate value of the consignment inventory (48 stents) is 99,400.00. The estimated delivery date is two days after receipt of the order.

The estimated monthly usage will be eight stents at a total monthly cost of approximately 16,800.00, the anticipated annual cost is 201,600.00 a year.

#### **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;

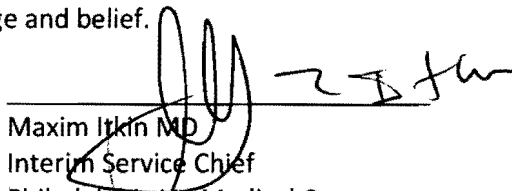
#### **5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition**

**Requires the Use of the Authority Cited Above (applicability of authority):** Interventional Radiology implantable products are specified by the clinical team to meet the unique and comprehensive needs of each Veteran with an identified medical indication. The specific product described above has been determined by the clinical team to be the best product to treat the Veteran patient's medical condition and functional limitations. Substituting an implant with other than that specifically prescribed is beyond the role, competency and professional functions of the Contract Specialist and would be detrimental to the treatment of the Veteran patient. Full and open competition for the above described implant negates the clinician's subject matter expertise as related to the individual Veteran's urgent medical condition requiring priority life sustaining medical treatment for the implanted device. In this case the by-name device(s) is /are the specific prescription and method of treatment for the Veteran-patient.

#### **6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable: Not applicable based on the medical determination described above.**

Sole Source – Prosthetic Stents – VAMC Philadelphia

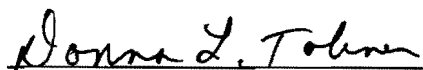
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be fair and Reasonable:** The prices for these implants are comparable to similar devices that have been recently purchased by this facility from other manufactures.
8. **Description of the Market Research Conducted and the Results, or a statement of the Reasons Market Research Was Not Conducted:** Market research was not conducted based on the medical determination described above.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** VAAR 806.302-5(B) (1) allows an exception to full and open competition for prosthetics appliances in accordance with 38 U.S.C.S 8123.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** N/A
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:** Based on the medical determination above, no further actions are contemplated.
12. **Requirements Certification:** (required) 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.

  
Maxim Itkin MD  
Interim Service Chief  
Philadelphia VA Medical Center

12/12/12  
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.

  
Contracting Officer  
Philadelphia VA Medical Center

2/25/2013  
Date

Sole Source – Prosthetic Stents – VAMC Philadelphia

- b. **One Level above Contracting Officer:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief. (This signature may be the VISN NCM if the Contracting Officer and Contracting Supervisor is the same individual.)



Anthony Palma  
Chief, Contracting Section  
Philadelphia, VAMC – 642

12/26/12

Date