

Attachment 2: Request for Sole Source Memo Format

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, VISN 11, Ann Arbor, MI. Medical Center 506-14-4-025-2950. The estimated cost is \$3,395.00
2. **Nature and/or Description of the Action Being Processed:** This will be a firm-fixed price purchase order of disposable medical supplies for the CSI Orbital Atherectomy System.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** CSI is the only manufacturer and distributor of this unique type of Orbital Atherectomy System indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and stenotic material from artificial arteriovenous dialysis fistulae.
Devive descriptions Diamondback Stealth PAD System is the only atherectomy device that uses an Orbital Sanding mechanism of action that allows for the removal of hard to treat calcified lesions WITHOUT damaging the vessel wall. Stealth devices are used at increasing speeds from Low to Medium to High and with each speed the crown Orbits in a larger diameter allowing the user to use one device (in most cases) to treat above and below the knee with only one device saving the facility money. The average spin times of the device are 2-3 minutes. Stealth has the lowest dissection rates, perforation rates as well as the best long term patency rates of any of the atherectomy devices on the market. We are able to treat from the iliacs to the toes safely and predictably. Our Orbital Sanding allows us to safely sand away the calcified and hard plaque in the lesion and makes a post dilation with a balloon effective at low atmospheres preventing dissections, perforations and barotrauma, in turn preventing the costly use of unnecessary stenting.
Other atherectomy devices use cutting blades that cut into the artery vessel wall increasing the occurrence of perforations and restenosis.
Also the Stealth requires only a 6 french sheath as opposed to other atherectomy devices that require larger sheaths increasing the risk of groin complications from larger sheath size.
1) The device is now powered by electricity instead of nitrogen gas, so no more bulky nitrogen tanks.
2) The device now has computer chips and torque control sensors built into the handles.
3) The device is completely operable from the sterile field table by the physician and requires little to no participation by circulating nurse.
4) Usually only needs to be inserted into patient one time per case. Other devices require multiple removals and reinsertion. This saves time and Fluoro exposure.
5) The actual spinning crown that is coated in real diamond dust is made of tungsten. Much heavier allowing for more efficient sanding and less time to modify the plaque.
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):**

The diamondback Stealth PAD System is the only atherectomy device that uses an Orbital Sanding mechanism of action that allows for the removal of hard to treat calcified lesions WITHOUT damaging the vessel wall.

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

This technology is not available from other sources.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable :** Previous purchases of products that have already been deemed fair and reasonable are: VA25814P0554 for \$3,395.00, VA25512P1296 for \$3,395.00.

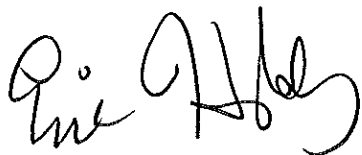
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** This order is for a disposable component to the CSI system already in use at the Ann Arbor VAMC.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** NO

10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** CSI, 651 Campus Drive, St. Paul, MN 55112

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:**
No actions are currently available.

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.



Eric D. Hobbs
Chief, Inventory Management, GIP
VA Ann Arbor, MI



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
Title

Date

Facility

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

Name
Network Contract Manager
VISN/PCA X

Date

Title
Facility

- c. **SAO (If over 650K):** I certify the justification meets requirements for other than full and open competition.

Name
Director
Service Area Office, East

Date

- d. **VHA HCA Review and Approval:** 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 (if over \$12.5 million) or approve (\$650K to 12.5 million) for other than full and open competition.

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

Date

- e. **VA Deputy Senior Procurement Executive Approval (over \$12.5 million but 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.

C. FORD HEARD
Deputy Senior Procurement Executive (DSPE)
Office of Acquisition and Logistics
Department of Veterans Affairs

Date

- f. **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.

Jan R. Frye

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

Date