

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition (>\$150K)

1. **Contracting Activity:** Department of Veterans Affairs, Network Contracting Office 16, Michael E. DeBakey VA Medical Center (MEDVAMC), 580 Houston, Texas; Transaction **580-15-4-028-0483**

2. **Description of Action:**

Request approval to limit competition to a single OTSB manufacturer/source. This action will be an Unrestricted Sole Source Open Market procurement leading to the award of a new Firm Fixed Price Contract for Commercial Items.

This transaction is an EMERGENCY request for the purchase of specialized Vascular Guidewire Catheters in the EP/Cath Lab. Due to the delay in the award of the IDIQ for these products and recent addition of these cases, additional items are needed. These items are needed immediately in order to save patient lives. Majority of these cases are "Interfacility Consults" (IFC) in which the patient is traveling from out of town to have procedure done. This is a true emergency and is actually a sole source because there is only one vendor.

The Perclose A-T 6F SMC System is indicated for the percutaneous delivery of suture for closing the common femoral artery access site of patients who have undergone diagnostic or interventional catheterization procedures using 5 to 8F sheaths. The Perclose A-T 6F SMC System reduces the time to hemostasis, ambulation (10 feet) and discharge in patients who have undergone diagnostic or interventional catheterization procedures without complicating clinical conditions This device is compatible with the interventional cardiology OCT imaging machine owned by the MEDVAMC.

3. **Description of Supplies or Services:**

The Perclose A-T 6F SMC System for closing the common femoral artery access site of patients who have undergone diagnostic or interventional catheterization procedures using 5 to 8F sheaths. The Total Value of this acquisition is estimated to be \$279,650.00 A list of the line items required to deliver the capability of this system under our current workload is itemized below:

Description	Unit Price	Qty	Ext. Price
Perclose Proglide Catheter	\$2,590.00	50	\$129,500.00
Vascular Balanced Middle Guidewire	\$ 425.00	10	\$ 4,250.00
Asahi Prowater Catheter 0.14 300cm	\$ 475.00	20	\$ 9,500.00
Asahi Prowater Catheter 0.14 190	\$ 475.00	20	\$ 9,500.00
Asahi Catheter 300cm	\$ 725.00	10	\$ 7,250.00
Guidewire Endo 300cm Radioplaque	\$ 475.00	15	\$ 7,125.00
Guidewire Ashai	\$ 725.00	10	\$ 7,250.00
Fiedler XT Catheter	\$ 725.00	10	\$ 7,250.00
Hydrophilic Coated Catheter	\$ 725.00	15	\$ 10,875.00
Guidewire 180cm Straight Asahi	\$ 95.00	70	\$ 6,650.00

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Attachment 3: Request for Sole Source Justification Format >\$150K

Guidewire Fielder	\$ 95.00	50	\$ 4,750.00
Miraclebros 4.5 Straight Tip	\$ 675.00	10	\$ 6,750.00
Miraclebros 12 300cm	\$ 725.00	10	\$ 7,250.00
Asshi Miracle 190cm	\$ 725.00	10	\$ 7,250.00
Pro 12 Catheter	\$ 725.00	10	\$ 7,250.00
Pro PTCA 300cm	\$ 725.00	10	\$ 7,250.00
Sion 300cm	\$ 725.00	10	\$ 7,250.00
180cm Guidewire	\$ 725.00	10	\$ 7,250.00
Hi Torque Pilot 200	\$ 85.00	50	\$ 4,250.00
Torque Pilot 200	\$ 85.00	50	\$ 4,250.00
Iron Man Guidewire	\$ 85.00	50	\$ 4,250.00
Whisper MS Guidewire	\$ 85.00	50	\$ 4,250.00
Hi Torque Guidewire 300cm	\$ 85.00	50	\$ 4,250.00
	\$ 85.00	50	\$ 4,250.00
TOTAL AMOUNT:			\$279,650.00

4. Statutory Authority:

(X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy
Agency Requirements per FAR 6.302-1;

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

This transaction is an EMERGENCY request for the purchase of specialized Vascular Guidewire Catheters in the EP/Cath Lab. Due to the delay in the award of the IDIQ for these products and recent addition of these cases, additional items are needed. These items are needed immediately in order to save patient lives. Majority of these cases are "Interfacility Consults" (IFC) in which the patient is traveling from out of town to have procedure done. The Perclose A-T 6F SMC System is indicated for the percutaneous delivery of suture for closing the common femoral artery access site of patients who have undergone diagnostic or interventional catheterization procedures using 5 to 8F sheaths. The Perclose A-T 6F SMC System reduces the time to hemostasis, ambulation (10 feet) and discharge in patients who have undergone diagnostic or interventional catheterization procedures without complicating clinical conditions This device is compatible with the interventional cardiology OCT imaging machine owned by the MEDVAMC.

The Abbott Cardiovascular Catheters and Guidewires are the only known products on the market which can provide the level of patient treatment available. There are no other products known to be compatible with the interventional cardiology OCT imaging equipment currently installed in place at MEDVAMC. This equipment is highly specialized not only in its design but also due to the fact that all our professional staff are trained on its use. Purchasing other products would require a substantial duplication of cost to replace the equipment and re-train the providers and technicians.

There are no existing FSS Contracts or other VA or Government-Wide contracts for supporting this requirement. Many of the required items are proprietary to Abbott Vascular Division and will require procurement by Open Market, Unrestricted, Sole Source methods.

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

The MEDVAMC Cardiology staff is very cognizant of products on the market for these types of interventional cardiology procedures. At this time, Abbott has the only Catheters that are compatible with the MEDVAMC's OCT imaging machine.

A Sources Sought was placed on FedBizOpps in August seeking Small Business capability for this requirement. Only one inquiry was received by email, and that vendor declined to submit a capability statement.

There are no existing FSS Contracts or other VA or Government-Wide contracts for supporting this requirement. Many of the required items are proprietary to Abbott Vascular Division and will require procurement by Open Market, Unrestricted, Sole Source methods.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable: A determination by the contracting officer that the anticipated cost to the Government will be fair and reasonable: Since these items are available commercially and off-the-shelf from Abbott Vascular to Government, private, and non-profit healthcare organizations, pricing can be determined fair and reasonable by commercial price analysis through comparison with prices actually charged to these organizations.

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

A Sources Sought was placed on FedBizOpps in August seeking Small Business capability for this requirement. Only one inquiry was received by email, and that vendor declined to submit a capability statement.

The MEDVAMC Cardiology staff is very cognizant of products on the market for these types of interventional cardiology procedures. At this time, Abbott has the only Catheters that are compatible with the MEDVAMC's OCT imaging machine.

There are no existing FSS Contracts or other VA or Government-Wide contracts for supporting this requirement. Many of the required items are proprietary to Abbott Vascular Division and will require procurement by Open Market, Unrestricted, Sole Source methods.

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

Abbott Laboratories Vascular Division currently has a BPA for use by the VA (VA797N-12-D-0004), however these items have not yet been added.

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

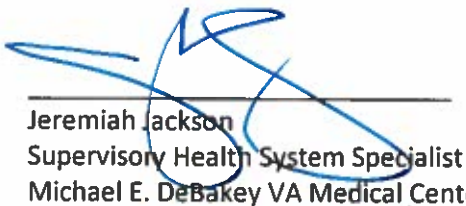
Miller & Dickey Medical Inc., Veteran Owned Small Business contacted us concerning the FBO posting, but declined to offer a capability statement for performing on this requirement.

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 Government will continue to conduct market research to ascertain if there are changes in the market place that would enable future actions to be competed.

We will continue to publicize our requirement for these items, but at this time, there are no interested vendors offering capability statements for performing this requirement.

12. Technical and Requirements Certification: I certify that the supporting data under my cognizance, which are included in this justification, are accurate and complete to the best of my knowledge and belief.

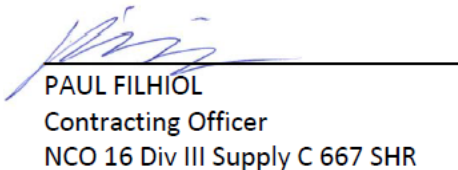

Jeremiah Jackson
Supervisory Health System Specialist
Michael E. DeBakey VA Medical Center, Houston, TX

Date

9/5/15

13. Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP.

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


PAUL FILHIOL
Contracting Officer
NCO 16 Div III Supply C 667 SHR

9/9/2015

Date

- b. **Director of Contracting /Designee (Required \$150K and above):** I certify the justification meets requirements for other than full and open competition.

AARON VILLALPANDO
NCO 16 Director of Contracting (or Designee)

Date