

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval (J&A)
For
Other Than Full and Open Competition (>\$150K)**

Acquisition Plan Action ID: VA243-15-AP-2049

1. **Contracting Activity:** Department of Veterans Affairs, VISN 3 – VA NY/NJ Veterans Healthcare Network, New York Harbor Medical Center

Purchase Request Number- 630-16-1-054-0007

2. **Nature and/or Description of the Action Being Processed:** The Government intends to award a sole source open market BPA to acquire the requested cardiac catheter supplies for the requesting service.

Contract Type: Base+4 (Blanket Purchase Agreement)

Vendor:

SenteHeart, Inc.

300 Saginaw Drive,
Redwood City, CA 94063

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

These supplies are used for cardiac catheterization procedures at New York Harbor.

Product Description	Item Number	Estimated No. of Units/Year
EndoCATH Occlusion Balloon-15mm x 12mm/90cm/0.035"	20-06	4
Lariat Suture Delivery Device Large (40mm)	30-05	4
FindrWIRZ Guide Wire System 0.035"/150cm&0.25"/220cm	40-05	4
SureCut Suture Cutter	50-01	4
Softip Cannula (long)	60-02	4
TenSURE suture puller	80-01	4

Chapter VI: Other Than Full and Open Competition (OFOC) SOP
Attachment 3: Request for Sole Source Justification Format >\$150K

The quantity is estimated to be the every year for each item

YEAR	PRICE
BASE YEAR	\$ 38,000.00
YEAR 1	\$ 39,900.00
YEAR 2	\$ 41,895.00
YEAR 3	\$ 43,989.75
YEAR 4	\$ 46,189.24
TOTAL PRICE	\$ 209,973.99

The estimated delivery dates/periods of performance:

YEAR	PRICE
BASE YEAR	DOA – SEPTEMBER 30,2016
YEAR 1	OCTOBER 1,2016 – SEPTEMBER 30,2017
YEAR 2	OCTOBER 1,2017 – SEPTEMBER 30,2018
YEAR 3	OCTOBER 1,2018 – SEPTEMBER 30,2019
YEAR 4	OCTOBER 1,2019 – SEPTEMBER 30,2020

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):

Per FAR 6.302-1, Only One Responsible Source the items being requested can only be provided
OFOC SOP Revision 04
Original Date: 03/22/11
Revision 04 Date: 10/01/2015

by the manufacturer SenteHeart. These items are needed for cardiac invasive procedures directly related to patient care which are part of a kit that is used. A substitute product would not be in the best interest of the Government because all of the item being requested are needed in order to work synchronously with all of the other individual parts that combine to create the overall kit. SenteHeart Inc. is the sole proprietor for the requested supplies. The use of these supplies in the acquisition is essential to the Government's requirements, thereby precluding consideration of a product manufactured by another company.

All of these supplies, when purchased together, form a "kit". During a Lariat procedure, each item in this "kit" is used to deliver the device during various stages of the procedure. This kit also includes the implanted device as well. It is used to perform a specific procedure called "percutaneous closure of the left atrial appendage", also known as the Lariat Procedure. Closure of the left atrial appendage is indicated in patients with certain heart arrhythmias who cannot take any anticoagulation at all. It is the only FDA-approved device currently available to close the left atrial appendage percutaneously in patients who cannot tolerate any amount of anticoagulation. The only other way to do it is with a surgical approach, but that is generally not done except in cases where the patient is coming anyway for other heart surgery. So we are talking about patients with atrial fibrillation (the abnormal rhythm) who cannot take anticoagulation (blood thinners) and are not going to have heart surgery for another reason – a very specific patient population. There is indeed another type of device for closing the appendage called the WatchMan (a Boston Scientific product) but that is for patients who can tolerate temporary anticoagulation. Lariats are used for patients who cannot tolerate any anticoagulation at all. There is no other product on the market that meets these requirements. The Lariats are not available from any distributors because Lariat sales are strictly controlled in order that only experienced operators implant them. There are no substitutions. There are no "Lariat-like" products or "Lariat-style" devices available from any other manufacturer or distributor. There is currently no national VA contract for SenteHeart. The Manhattan VA has implanted several Lariats at the facility with excellent success. No other VA in the VISN implants these devices; Manhattan is currently the referral center.

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

Sources sought notices were posted on FBO and GSA eBuy on December 5, 2015 with no responses received. The manufacturer confirmed that there are no authorized distributors. The only company capable of providing these products is SenteHeart, Inc., the manufacturer.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:

The anticipated cost is considered fair and reasonable and provide the basis for this determination. As this is the only vendor capable of performing this requirement it is expected that costs will be the same or have some level of cost savings in regards to current pricing with minor increases expected over the life of the four years after the base period is

complete. There are no "Lariat-like" products or "Lariat-style" devices available from any other manufacturer or distributor within this market at this time.

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

Sources sought notices were posted on FBO and GSA eBuy on December 5, 2015 with no responses received. The manufacturer confirmed that there are no authorized distributors. The only company capable of providing these products is SenteHeart, Inc., the manufacturer.

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

The items being requested are being used for invasive Cardiac Catheterization/Electrophysiology Laboratory. Because the items are being used for invasive procedures on our veterans, a substitute product can jeopardize patient care. The benefits outweigh the cost in limiting competition to the specific vendor listed.

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

SenteHeart, Inc.

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:

Actions were taken to overcome barriers for this acquisition. Sources sought notices were posted on GSA eBuy and FBO with no responses. The Government encouraged fair competition, however, the supplies being requested can only provide by the specific vendor listed.

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.

MICHAEL M.
INGINO 425723

Digitally signed by MICHAEL M. INGINO 425723
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Date: 2016.03.02 10:44:46 -05'00'

Michael Ingino
Chief, Logistics
New York Harbor

Date

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.

Nicole M

Howerton 166633

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cn=Nicole M Howerton 166633
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Date: 2016.03.02 15:11:43 -05'00'

Nicole Howerton
Supervisory Contract Specialist
NCO3

Date

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

SHERIN RABADI
174167

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gov, cn=SHERIN RABADI 174167
Date: 2016.03.07 08:35:15 -05'00'

Sherin Rabadi
Division Chief, Division 2
NCO 3

3.7.16

Date