

## DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval  
Under  
Simplified Acquisition Procedures (SAP)  
Simplified Acquisition Threshold (\$3K to \$150K)  
For Restricting Competition under FAR 13.106-1(b)(1) "Single Source"**

**1. Contracting Activity:**

Department of Veterans Affairs, Network Contracting Office (NCO) 20,  
5515 NE 82<sup>nd</sup> AVE Suite 103, Vancouver, WA 98662-6182

**2. Nature of the Action Being Processed:**

This procurement under 2237# 648-14-1-093-3515 for \$33,385.00 for LASER Sheaths and Catheters from the Spectranetics Company to release and remove Intra-Cardiac Pacemaker Leads and other intravascular Plaques, Thrombi, and Scar Tissue. This system will allow us to stop outsourcing the Patients needing this surgery.

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

The Portland Department of Veterans Affairs Hospital proposes to enter into a contract on a basis of other than full and open competition with Spectranetics to supply disposable Sheaths and Catheters to remove Intra-Cardiac Pacemaker Leads and other intravascular Plaques, Thrombi, and Scar Tissue. These items will allow us to direct the energy beam of the LASER to destroy these tissues to release the implanted leads for removal. These items can also be used to direct that energy to clear blocked vessels to avoid larger, more complicated and extensive, invasive procedures.

**4. Statutory Authority Permitting Restriction in Competition:**

The statutory authority for restricting competition under SAP, or Single Sourcing, for acquisitions under \$150,000 or Simplified Acquisition Threshold (SAT) is 41 U.S.C. 253(c), as implemented by FAR 13.106-1(b)(1). The specific reason for restricting competition is **an urgent and compelling need for Spectranetics Sheaths and Catheters to remove failed Intra-Cardiac Pacemaker Leads and other intravascular Plaques, Thrombi, and Scar Tissue.** This justification is where in accordance with FAR 6.001(a), acquisitions conducted under FAR 13 for SAP are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2, IAW the VHA SOP for Other Than Full And Open Competition dated 3-22-2011.

**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 company is the only company on the market that can supply the full line of disposables and the LASER to perform these technically difficult procedures. Acquiring these items will allow us to move these procedures back into the PVAMC. With the ability

to treat Intravascular Lesions we will also help some patients avoid Cardiac (Open Heart) Surgery or in some cases repeat surgeries

**6. Description of Efforts Made to Ensure that Offers are Solicited from As Many Potential Sources as Deemed Practicable IAW FAR 13.104:**

The Contracting Specialist has researched for other vendors who can supply other lasers and catheters on GSA, vetbiz, SBA However, none were found as the manufacturer is the sole source capable of providing the product.

**7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable – IAW FAR 13.106-3 (a) (vii):**

In accordance with FAR 13.106-3(2)(vii) The anticipated cost is considered fair and reasonable due to the cost the Portland VA is spending to send our Veterans out to get the release and to remove Intra-Cardiac Pacemaker Leads and other intravascular Plaques, Thrombi, and Scar Tissue. This is presently costing the Portland VA hospital an average \$15,000.00 per Patient to outsource them, as well as the cost of their post-operative care. At this time we send 6-8 veterans out a year, but the number is constantly growing.

**8. Description of the Market Research Conducted and the Results, or Statement of Reasons Market Research was not Conducted (FAR 10):**

Market research was done to determine the availability of similar sets from other manufacturers. No set was found that filled all the functional needs, as well as the compatibility requirement with our current set.

**9. Any Other Facts Supporting the Restriction of Competition:**

There is no other company on the market that can offer the complete line of disposables and the LASER to perform these difficult lifesaving procedures. We are outsourcing these Patients at a cost of \$15,000.00 each and then taking over their Post-Op Recovery Care.

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

None

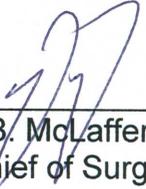
**11. Statement of Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making Subsequent Acquisitions for the Supplies or Services Required:**

None

**12. Requirements Certification - IAW FAR 6.303-2(c):**

I certify that the requirement outlined in this justification is a bonafide 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.

  
\_\_\_\_\_  
Name: R.B. McLafferty, M.D.  
Position: Chief of Surgery

12/30/13  
\_\_\_\_\_  
Date

**13. Approvals IAW VHA SOP 3.22.11:**

- 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: Traci Montero  
Contracting Specialist  
NCO 20 Supply Team B Acquisitions Team

\_\_\_\_\_  
Date

- b. **NCM/PCM/DESIGNEE:** 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 for other than full and open competition.

\_\_\_\_\_  
Name: Andres Arredondo  
Contracting Officer  
NCO 20 Supply Team B Acting Manager

\_\_\_\_\_  
Date