

**DEPARTMENT OF VETERANS AFFAIRS
NY HARBOR HEALTHCARE SYSTEM**

Justification and Approval For Other Than Full and Open Competition

2237 Transaction Number: 630-13-1-111-0001

Contracting Module ID: VA243-13-AP-3200

1. Contracting Activity:

Department of Veterans Affairs
VISN 3-NCO 3
130 Kingsbridge Road, Bronx, NY 10468

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

Spectranetics manufactures and markets the only Excimer Laser system and disposable catheters for the treatment of peripheral and coronary arterial disease and lead extraction and management.

Photoablation is the use of light to breakdown, vaporize and remove matter. The Spectranetics CVX-300 Excimer Laser facilitates photoablation via a variety of Spectranetics catheters to remove binding scar tissue surrounding cardiac pacemaker ICD leads. The Spectranetics CVX-300 excimer laser in conjunction with proprietary optical fiber catheters is the only excimer laser system approved for use in the removal of cardiac pacemaker and defibrillator leads. An excimer laser produces pulsed bursts of ultraviolet (UV) light energy that are capable of vaporizing plaque and calcium into tiny particles, the majority of which are smaller than a red blood cell, that are easily absorbed into the bloodstream. This energy is transmitted along flexible glass fibers encased in catheters, which can be passed through arteries and veins. The UV light energy is then focused on the blockages that need to be treated.

The Excimer CV laser is currently on site in the NY VA O.R. and has been used on an ongoing basis by the cardiac surgeons since January 2008. The excimer laser is a critical piece of equipment that must remain on-site for the safety of cardiac surgery patients. The OR Manager and the Chief of Cardiothoracic surgery have confirmed the continued need for this equipment for patient care. Both have also advised that it is more economical to lease this laser than to purchase it and it is absolutely necessary for patient care. NYHHS is the VISN 3 referral center for Cardiothoracic Surgery.

The Spectranetics CVX-300® Excimer Laser System was specifically designed for tissue ablation in modern medical treatment facilities. Its compact size and mobility allow the CVX-300® to easily be moved from a cardiovascular catheterization laboratory to an operating room to a special procedures suite. Once situated in the clinical area, the unit is quickly prepped and readied for the laser ablation application using a simple, easy to follow routine.

The Spectranetics CVX-300® Excimer Laser (Class 4 laser) produces a pulsed ultraviolet laser beam at a wavelength of 308 nanometers for the removal of unwanted intravascular tissue through photo-ablation. Rather than simply bypassing or remodeling a blockage, the excimer laser beam breaks the intermolecular and intramolecular bond of the obstruction.

The system is user-friendly, mobile and requires low maintenance. The warm-up time on the system is only 5 minutes and is quickly ready for use. The Spectranetics CVX-300® is microprocessor controlled allowing for simple, automatic calibration of all catheter devices. Company field service engineers perform complete routine maintenance for the system. Gases are not required to be stored at the hospital.

Requirements

Spectranetics CVX-300

The Spectranetics CVX-300® Excimer Laser System is currently on site in the NYHHS Operating Room and has been used on an ongoing basis by the Cardiothoracic Surgeons since January 2008.

Spectranetics CVX-300 Excimer Laser System Product Specifications

Active Medium: • *XeCl, Pulsed Laser System*

Wavelength: • *308 nm*

Pulse Width: • *125ns - 200 ns, FWHM*

Long Gas Life: • *Minimum 3 months gas shelf life.*

Computer Controlled:

- *Automatic Catheter Recognition*
- *Automated Calibration*
- *Automatic Energy Management*
- *Adjustable Energy and Repetition Rate without removing the catheter from the patient*

- *Service Lamp is automatically illuminated approximately two weeks before service is required.*

Catheter Output Fluence: • 30-60 mJ/mm²*

Maximum Repetition Rate: • 40 pps*

Warm-Up Time: • 5 minutes

Weight: • 650 pounds / 295 kg

Length: • 49 inches / 125 cm

Height: • 35 inch unit / 89 cm

• 6 7/8 inch control panel / 17.5 cm

Width: • 24 1/8 inches / 61.3 cm

Movement and Storage: • *Small, compact, mobile unit*

Power Requirements: • 208 VAC

• 50/60 HZ • Single Phase

• 20 amp

Power Cord Length: • 12-foot / 3.65-meter

Power Cord Plug: • NEMA L6-30R, Hubbell Part#2621,
250VAC-30A, Twist lock

Wall Outlet Receptacle: • NEMA L6-30R, Hubbell Part#HBL2620
250VAC, 30A, Wall mount twist lock

Regulatory Approvals:

- ***The only US FDA-approved multi-purpose cardiovascular laser system***
- *Complies with UL 60601-1, IEC-601, IEC-825, EN-60825*
- *CE Mark Approved*

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

The company is going to lease us with the equipment at the approved rate. This facility will be responsible for the procurement of the disposable catheters. We are requesting this on a multi-year agreement to for the treatment of our veterans.

This type of laser requires very frequent servicing which is included in the rental/service agreement. The vendor will provide regular equipment maintenance for the duration of the agreement.

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):

Not Applicable. Only source based on market research for the required equipment.

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

Sources have been sought out on GSA and FBO and we have received no interest.

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

Purchasing new equipment will far exceed the price of the incumbent leased equipment as the price quoted for a new laser was \$216,000, with the facility not having funds to cover this cost. To purchase the incumbent laser already on site would cost the facility \$50,000 with only a 6 month warranty. After that, continued preventive maintenance and service of the same scope under lease would cost nearly \$30,000 if we were to put these same services under contract. The combined cost of purchase and continued services would far exceed the cost of continuing the lease for the equipment already on site at the hospital which has been quoted as \$30,000 yearly over the next 5 years.

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

Market research was conducted and no comparable products were found in the open market.

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

JUSTIFICATION:

Spectranetics manufactures and markets the only Excimer Laser system and disposable catheters for the treatment of peripheral and coronary arterial disease and lead extraction and management.

The Excimer laser is a critical piece of equipment that must remain on-site for the safety of cardiac surgery patients. The OR Manager and the Chief of Cardiothoracic surgery have confirmed the continued need for this equipment for patient care. Both have also advised that it is more economical to lease this laser than to purchase it and it is absolutely necessary for patient care. The projected lifetime of the Spectranetics CVX-300 Excimer Laser System is estimated to be ten years, providing that the unit is properly stored in a secure place, protected from freezing or extremely high temperatures, and routine maintenance is performed by factory authorized personnel every three to six months as required.

NYHHS is the VISN 3 referral center for Cardiothoracic Surgery.

The Spectranetics CVX-300® Excimer Laser System will enable the VA to offer the "Standard of Care for Cardiothoracic Surgery" for the vaporizing plaque and calcium into tiny particles.

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

None

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:

Facility will be looking to purchase a new laser system within the next few years and will soon be conducting market research on the best laser system available at that time.

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.


Sally Bashker

Name: Sally Bashker
Title: AO/COR Surgical Service
Facility: 630, NYHHS

Date: 8/7/2013

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.

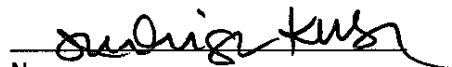


Name Lawrence Unger
Title Contracting Officer
Facility NCO 3

08/28/2013

Date

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



Name
for Network Contract Manager
VISN/PCA 3

Date

Title **Ms. Jadwiga Kustra**
Facility **Deputy NCM**
Network Contract Office 3
SAO East

- c. **SAO (If over 500K):** 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 \$10million) or approve (\$500K to 10 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 \$10 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.

Iris B. Cooper

Date

Deputy Senior Procurement Executive (DSPE)
Office of Acquisition and Logistics
Department of Veterans Affairs

- 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

Date

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