

**DEPARTMENT OF VETERANS AFFAIRS**  
**Justification and Approval**  
**For**  
**Other Than Full and Open Competition**

**1. Contracting Activity:** Department of Veterans Affairs, Network Contracting Office 16, Michael E. DeBakey VA Medical Center, Houston, Texas; Transaction 580-14-2-028-0192

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

Request approval to limit competition to a single manufacturer/source. This acquisition will result in the award of a firm fixed price purchase order for commercial items.

This transaction is an **EMERGENCY** request for the purchase of Ensite Velocity Surface Electrode Kit. This order is to replace Electrode kits that were borrowed from the vendor (St. Jude) last week to prohibit delay in care. We are completely out of this product in the Electrophysiology Lab and need this item to replace the product borrowed from an outside facility as well replenish our inhouse supply.

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

**Ensite Velocity Surface Electrode Kit**, (Quantity – 20 Boxes); Product Number 100003331

10 boxes are needed at a cost of \$6,500.00 each. Total estimated cost: \$65,000.00

**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;
- ( X) (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):**

**a. Only One Responsible Source (FAR 6.302-1)**

St. Jude, Inc is the only company capable of providing the supplies and services described in Section III above without the Veteran's Health Administration experiencing substantial

duplication of cost that could not be expected to be recovered through competition and unacceptable delays in fulfilling its requirements.

The Ensite Velocity Surface Electrode Kit is the diagnostic tool in patients for whom electrophysiology studies are indicated. This system is intended to be used in the right atrium of patients with complex arrhythmias that may be difficult to identify using conventional mapping systems alone. In addition, it is intended to display the position of conventional electrophysiology catheters in the heart.

Ensite Velocity Surface Electrode Kit is a mapping system capable to create a three-dimensional and electro-anatomical reconstruction of the heart. The system is based on an electrical field generated by the reference patches applied on the chest of the patient that allows to create a 3-D model of the cardiac chambers. The Navx system also allows real time view of the catheters in the 3-D model of the cardiac chambers without radiation harmful for the patient. This technology has been used successfully for years in the treatment of rhythm disorders such as atrial fibrillation, atrial tachycardia and ventricular tachycardia. Navx mapping system allows the merging of electro-anatomical map derived from trans-catheter mapping with CT scan or cine-MRI or with images obtained by innovative fluorographic technique like Dyna-CT in order to improve the accuracy and details of the anatomical structures of the heart. Prof. Carlo Pappone use this technology since its first version and cooperates with the company for development and improvement of this technology. The system Ensite Velocity is the latest version of this non-fluoroscopic mapping technology, the most updated version in the electrical reconstruction of heart chambers. During high risk procedures, when the patient's heart is too weak every second counts to ensure a safe and positive outcome by saving lives. During a procedure, a catheter is inserted from the femoral artery into the heart and assists the heart with forward flow (the flow is dependent on the size of the catheter).

**b. Unusual and Compelling Urgency per FAR 6.302-2;**

St. Jude is the manufacturer and holds the proprietary right to the Ensite Velocity Surface Electrode Kit. This transaction is an **EMERGENCY** request for the purchase of Ensite Velocity Surface Electrode Kit. This order is to replace Electrode kits that were borrowed from the vendor (St. Jude) last week to prohibit delay in care. We are completely out of this product in the Electrophysiology Lab and need this item to replace the product borrowed from the vendor as well replenish our inhouse supply.

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

Due to Proprietary nature, St. Jude is the manufacturer and it has two authorized small businesses as the distributor of this Electrode Kit; a RFQ will be provided to both small business to submit a quote.

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

Anticipated cost will be considered fair and reasonable and provide the basis for this determination FAR Part 13.106(a) based on competition.

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

The MEDVAMC Cardiology staff is very cognizant of products on the market for these type of electrophysiology cardiology procedures.

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


NA

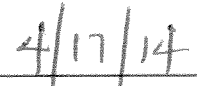
**10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**

See Section VI above.

**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:**

**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.

  
\_\_\_\_\_  
Jeremiah Jackson  
Supervisory Health Systems Specialist  
Michael E. DeBaKey VA Medical Center, Houston, TX

  
\_\_\_\_\_  
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.

\_\_\_\_\_  
Renata Ott  
CONTRACTING OFFICER  
Alexandria VCS

\_\_\_\_\_  
Date

**b. P&C:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

\_\_\_\_\_  
Lonest Bonton  
CHIEF, PURCHASING AND CONTRACTING  
NETWORK CONTRACTING OFFICE 16

\_\_\_\_\_  
Date