

Attachment 2: Request for Sole Source Memo Format

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. Contracting Activity: Network 23 Contracting Office (NCO 23) – Iowa City, 1303 5th St, Suite 300, Coralville, IA. 52241. 636-13-3-4647-0111.

2. Nature and/or Description of the Action Being Processed: The proposed acquisition is for a fixed price purchase order for STRYKER neurosurgical instruments for use in the Surgical/OR department in Iowa City.

3. Description of Supplies/Services Required to Meet the Agency's Needs: 343 Neurosurgical STRYKER INSTRUMENTS-(Stryker Spine instrumentation for cervical, thoracolumbar and minimally invasive surgery for Neurosurgery and Orthopedic Spine surgery.) Estimated cost: \$289,865.38. Anticipated date of Delivery: 9/15/2013.

4. Statutory Authority Permitting Other than Full and Open Competition: 41 USC §253(c) (1), as implemented by FAR 6.302-1.

- (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):

-Reflex Hybrid is a low profile anterior cervical plate with large graft windows and proprietary one-step locking mechanism. The product is unique in its locking ring technology for fast insertion and secure locking of screws, and is also has a low profile of to reduce to dysphasia seen in patients. The system has a wide variety of screw lengths, with options to allow for more or less angulation to better meet the needs of individual pathologies.

-Anchor-C is a unique cervical interbody cage with internal fixation. The cage has a large graft volume for best fusion rates, self-locking screws for ease of use, and unique instrumentation to meet differing and difficult patient anatomy. Anchor-C is the only solution because it can meet the needs of nearly any patient anatomy due to large sizing options, it has intuitive instrumentation designed to streamline the procedure, and has been shown to have the strength of traditional anterior cervical plating options while adding the potential to decrease operative time and post-operative complications.

-The Navigator inter-body device offers a unique method of insertion, allowing the surgeon to "steer" the cage into the desired position to provide the best support and opportunity for fusion. It has a large offering of heights, footprints, and lordotic options, making it the best solution for a large population of patients and pathologies.

-The PEEK material allows for a biocompatible material with a large graft volume to optimize fusion rates, while also being radiolucent to aid in optimal placement of the cage and post-operative imaging. These cages are versatile and can be used in both open and minimally invasive procedures.

- Minimally Invasive: The ES2 MIS system is unique as it is the only system that has 15mm of reduction built into the blades of each screw, allowing for reduction of the rod in fewer steps and less time in the operating room. ES2 has also become more comprehensive in accepting several rod diameters for specific surgeon or patient anatomies. ES2 is also build to work seamlessly with the Navigation from Stryker Spine, which will increase accuracy when placing screws, potentially reducing the amount of fluoroscopy exposure to the surgeon, staff, and patient, while also decreasing the chance of mis-placed screws, resulting in bring backs to the operating room.

-This instrumentation has been utilized successfully at the VA Iowa City and continues to be the choice of surgeons performing these types of surgeries.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable: Market research was not conducted. We currently use and have STRYKER instrumentation at our facility. Our neurosurgical surgeons USE STRYKER instrumentation and implants as a standard of care. Using STRYKER which we already have will relieve issues within the facility from SPS (RME) to the OR, decontamination to sterilization as well as surgical tray set up and issuance. We CANNOT have a "mixture" of neurosurgical instrumentation.

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

The Contracting Officer will make a fair and reasonable determination by using one of the following methods:

1. Comparison of proposed prices received in response to the solicitation.
2. Comparison of previously proposed prices and previous Government and commercial contract prices with current proposed prices for like items.
3. Use of parametric estimating methods/application of rough yardsticks to highlight significant inconsistencies that warrant additional pricing inquiry.
4. Comparison with competitive published price lists, published market prices of commodities, similar indexes, and discount or rebate arrangements.
5. Comparison of proposed prices with independent Government cost estimates.
6. Comparison of proposed prices with prices obtained through market research for the same or similar items.
7. Analysis of pricing information provided by the offeror.

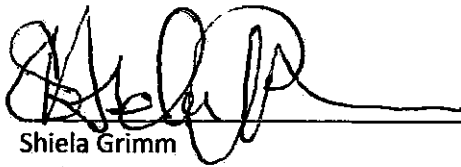
8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted: Market research was not conducted.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition: This is highly specialized Neurosurgical instrumentation equipment. Other vendors simply cannot meet our needs from a product availability standpoint. The surgeons are trained using and very comfortable with the Stryker products over competitive products resulting in better efficiency in the operating room and allowing for better patient outcomes. Using other equipment will have a direct negative impact on patient care.

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

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: None, there are no other vendors that can provide the service for the equipment. When and if the Neurosurgical surgeons request a change based on patient care a competitive process will be initiated.

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.




Shiela Grimm
Staff Nurse, OR
Iowa City VA Healthcare System

6/14/13
Date

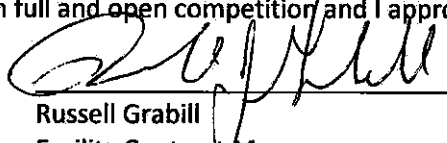
1. Approvals in accordance with FAR 6.304

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


Contracting Officer
NCO 23 - Iowa City

6/18/13
Date

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


Russell Grabill
Facility Contract Manager
NCO 23 - Iowa City

6/18/13
Date

- b. **SAO (If over 500K):** I certify the justification meets requirements for other than full and open competition.

N/A

Name

Date

Director
Service Area Office, East

- c. **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.

N/A

Name
Chief Procurement and Logistics Officer
VHA Head of Contracting Activity (HCA)

Date

- d. **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.

N/A

C. FORD HEARD
Deputy Senior Procurement Executive (DSPE)
Office of Acquisition and Logistics
Department of Veterans Affairs

Date

- e. **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

N/A

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

Date