

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA261-16-AP-2219

1. **Contracting Activity:** Department of Veterans Affairs, VISN 21, Network Contracting Office, VA Martinez Clinic, 150 Muir Road, Martinez, CA 94553-4668. This justification and approval is for other than full and open competition. 2237 number is 570-16-2-444-0019.
2. **Nature and/or Description of the Action Being Processed:** This is for the purchase of fully integrated micro-invasive arthroscopic and laparoscopic instrumentation for general and orthopedic surgery from one manufacturer, Stryker Corporation, for the VA Central California Health Care System in Fresno, CA.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The VA Central California Health Care System in Fresno, CA, is currently in need of a complete suite of fully integrated micro-invasive arthroscopic and laparoscopic instrumentation in order to continue servicing Veterans with knee and shoulder conditions and other medical conditions. Total estimated value for this one-time purchase is \$680,735.92. Delivery shall be within 30 days after receipt of order.
4. **Statutory Authority Permitting Other than Full and Open Competition:** 41 U.S.C. 1901 in accordance with 13.501(a)(ii):
 - (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;

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for the purchase of arthroscopic equipment for the VA Fresno, in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2.

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):**

VA Fresno is currently in need of a fully integrated suite of micro-invasive arthroscopic and laparoscopic instrumentation to continue servicing Veterans with knee and shoulder conditions and other medical conditions. Video and camera systems will also be utilized for laparoscopic minimally invasive procedures.

VA Fresno has instituted robust new programs, such as orthopedic arthroscopy and the Total Joint Replacement Program, as well as minimally invasive nephrectomy and other complex and advanced laparoscopic programs. The clinic has found that, to continue these programs and to provide our Veterans

with surgical care within the VA Fresno service territory, the VA needs to obtain a suite of surgical equipment. If the VA is unable to obtain this equipment, Veterans would have to continue traveling as far as San Francisco and Palo Alto to obtain these surgical services. The VA Fresno's current equipment is either non-functional or delivers unacceptably poor quality results. These programs will shut down if the hospital does not acquire appropriate equipment in an expedient manner, thereby inconveniencing and possibly negatively impacting our Veterans. It is important to note that, over the past ten years, all of the major product lines of this type of equipment, namely, Olympus, and Stryker have been utilized at the VA Fresno hospital. The following conclusions and requests presented by VA Fresno surgeons are the result of a vast cumulative experience with all the available products on the market, both at VA Fresno clinic and at other VA and DOD hospitals.

Recent experience with previous arthroscopy cannulas, scopes and cameras have been disappointing. For example, several medical equipment pieces of different manufacturers, which are currently owned or were trialed by the VA, have been difficult to make work together in a compatible fashion, as follows:

1. All Olympus lenses, such as the A70941A, move around in the Stryker producing a fuzzy picture. The VA has two older 1188 Stryker cameras, which are two generations from the new cameras, but outperform the Olympus cameras with any of our current lenses. The Olympus camera 7544885-10801601NTSC picture is darker than the Stryker camera 1488-010-001 and does not have the 3-Chip, which allows visualization of the ureteral stent used in complex laparoscopic cases when using the illuminator.

All Olympus cameras, including the 7544885 1080 1601 NTSC, will not fit into the Stryker camera box as the end adapter would not fit into the camera box 1488-010-011. The Fresno VA trialed the 1488-010-011 Stryker camera head, first with the Stryker Illuminator. The Stryker insufflator 0620-040-610 Pneumo Sure XL high Flow has heated tubing which the other companies did not have. The heated tubing allows the patient to stay warmer and keeps the lens from fogging. The Olympus Insufflator UHI-3, among other problems, does not have heated tubing, which helps warm the patient and decreases fogging of the lens when placed inside the patient's cavity. The Olympus ImageSource CV1800 Camera Box, Exera II CV-180, produces a picture, which is too dark to correctly and safely identify the patient's anatomy, both for laparoscopic or arthroscopic surgeries, and surgeons could not visualize the fibers; even after the Olympus service representatives came out to lighten the picture, it was still unsatisfactory.

The 1488 HD 3 CHIP camera Control Unit (CCU) with DVI fiber Output 1488-010-001 by Stryker had a much brighter and clearer picture than the Olympus. (The Arthrex camera, AR-3210-0025 would not work with the 4mm lens). The Olympus Exera II CLV-180 light source is much dimmer than the Stryker light source, and additionally, the fibers, which carry the light and which notify the user of any cracks in the fiber, could not be seen. The Stryker X8000 light source had the advantage over the Olympus Exera ii CLV-180, which was so very dim in laparoscopic cases. The Olympus orthopedic cannulas A70951A and A70941A do not have the in-flow / out-flow cannulas offset, and the water competes going in and out, resulting in poor visualization in the orthopedic joint.

Finally, the in-flow / out-flow cannula of the Olympus is not offset. This design flaw prevents adequate removal of the fluid, and the picture inside the joint is not as clear as the Stryker in-flow / out-flow cannula. During the trial the Stryker proprietary in-flow / out-flow cannula 0747-031-650 outperformed the Olympus and Arthrex orthopedic cannulas AR-3370, AR-3375-4006. The Stryker 5.0mm X 10 FT clear case Fiber optic light cable outperformed the Olympus light cords both in performance and that you can tell at all times if the light fibers are broken or in good repair with the Stryker light cord, 0233-050-064.

2. Arthrex requested that the VA Fresno trial their Synergy UHDA 4K Imaging platform, tablet controller and StarFish AR-3200-0020, AR-3200-1007, and AR-3370-006. However this company has no method of ureteral stenting capabilities, as they do not manufacture ureteral stenting equipment and they could not connect to the Stryker Illuminator, because it is proprietary and cannot be visualized with the Arthrex system. Surgeons would not be able to utilize the Arthrex system for laparoscopic colectomies (removing cancerous tumors

from the colon) because it lacks the capability of lighted stents during the operation to guide the surgeon away from dissecting into these organs. The General and Urologic surgeons determined the Stryker InfraVision Illuminator 220-180-521, was the best solution to visualize the ureters during laparoscopic surgery. Neither Olympus nor Arthrex have any method for lighted ureteral stents during laparoscopic or endoscopic procedures. The light notifies the surgeon of the structure. The Dual Wave arthroscopy pump AR-6480 and the Continuous Wave II arthroscopy pump AR-6475S were trialed and not as convenient to use as the Stryker pump Cross fire2 Console 0475-100-000, which is combined with the RF generator, making it more desirable than the Arthrex equipment. The Stryker unit 0747-031-650 is an in-flow/out-flow cannula which is part of the instrumentation, which is proprietary in design.

Other companies are designing off-types, which do not function as well as the Stryker in-flow / out-flow and, in our tests, added additional time to the surgery. The surgeons trialed the Arthrex radiofrequency ablaters as the CoolCut 90 AR-9803-90 and preferred the Stryker radiofrequency ablaters because they prefer the Stryker Crossfire 2 console 0475-100-000. Troubleshooting has been difficult, as representatives from various companies are not always available at the same time or not at all. The major concern is that poor quality of images, foggy video, problems with couplers, and image stability would affect the safe and efficient performance of surgical procedures, and eventually, indirectly affect patient safety.

The VA has also encountered situations where coupling devices have been loose whenever the Olympus lenses were used and moved randomly and independently with serious safety and quality issues. Stryker has developed all stages of the laparoscopic and arthroscopic procedures to optimize the equipment for these types of cases. Based on the collective research and experience of VA Fresno surgeons, no small or large business manufacturer, with the exception of Stryker, has the capability to make the fully integrated micro-invasive suite required by this hospital for both general surgery and orthopedic surgery.

Currently, VA Fresno utilizes a mix of various fiber optic cameras and video systems at the hospital and has experienced delays in the procedure for lack of adapters or of equipment that do not fit exactly into another brand of equipment, resulting in extended surgery times, also from having to change out the cameras due to a lack of clear visualization of anatomy. Unfortunately, when operating on living patients, for equipment to fit pretty well is not good enough. Having a mixture of equipment with optic cameras and video systems also increases the risk of reduced quality surgical care. Standardization of the suite of arthroscopic and laparoscopic equipment and instrumentation leads to higher quality outcomes. Lack of standardization reduces the quality, through confusion in trying to locate adapters to complete a case, when timely completion is truly of the essence. Instead of focusing on the patients before surgery, the nursing staff often has to find ways to adapt other systems into a video tower. VA surgeons have had the opportunity to work with different products and have unanimously requested the Stryker equipment.

VA Fresno surgeons have had prior experience both in this and other hospitals with Stryker brand equipment. They have seen a significant improvement in several key aspects of surgery, such as video quality, imaging capability, ergonomics, ability to maintain adequate pressures within the joint space and smooth and instance communication between the devices that allowed for fine-tuning of pressures. Surgeon controls were also comfortably and ergonomically placed with onscreen as well as voice feedback. Instruments worked well together, and procedures could be completed efficiently and safely. In addition, the surgeons' experiences have received superior customer service and timely product replacement and repairs. Similar feedback is echoed from the Orthopedic, Urologic, ENT and General Surgery sections at VA Fresno. One Stryker video tower was already purchased by the VA Fresno hospital. The surgeons experienced the superior image and control qualities, and there was unanimous request to complete the acquisition of this superior quality instrumentation.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Sources Sought Notice number VA261-16-N-0455 was posted on GSA eBuy, under Source Code 65 II A: A-8BA (Reusable Surgical Hand Instruments), from March 11, 2016, through March 22, 2016. A total of

69 vendors received the notice. Only one vendor responded with information: Pacific Monarch Inc., a small business, but the information they provided was for repair and maintenance of surgical equipment, not for purchase of instrumentation. A concurrent Sources Sought Notice (same RFI number) was posted on FBO, from March 14, 2016 through March 22, 2016. Three vendors submitted information: 1) Beacon Point Associates (SDVOSB), a Stryker Corporation dealer; 2) Karl Storz Endoscopy-America (large business), for Karl Storz equipment, but they could not provide all equipment; and 3) AMD Next, or American Medical Depot (small business), another Stryker Corporation dealer.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The anticipated cost will be considered fair and reasonable based on anticipation and verification that costs offered to the VA shall be in line with those extended to similar entities under similar circumstances.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** FAR Part 10 directs that market research be conducted on each acquisition appropriate to the circumstances. See Section 6 above, which describes the efforts taken in obtaining market research and the subsequent results achieved.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** The total cost to purchase the entire suite of fully integrated micro-invasive Stryker arthroscopic and laparoscopic instrumentation on an open market basis, including arthroscopy pumps, electrosurgical cutting and coagulation device and accessories (CrossFire 2 Console,) high definition endoscopic cameras, arthroscopy cannulas, cordless power instruments, smooth or threaded metallic bone fixation fasteners (ICONIX anchor sets), universal anterior cruciate ligament (ACL) instrumentation, ACL workstations, and ACL reconstruction instrumentation (VersiTomic Flexible Reaming System) is currently \$680,735.92.

No manufacturer, other than Stryker, can supply all of the required components for a fully integrated micro-invasive suite for general and orthopedic surgeries at VA Fresno. No other manufacturer sells video equipment has the method of using lighted stents, which stay lighted throughout the entire laparoscopic colectomy, a type of surgery that is frequently perform at VA Fresno; this was the reason why the surgeons at this facility started reviewing other companies' equipment of similar or same technology, because the facility is currently experiencing problems and needs to find a satisfactory method to safely complete these surgeries. Neither Olympus nor Arthrex have any method for providing this equipment. Cook has a lighted stent which VA Fresno has used and, ultimately, it is not acceptable because it failed during a procedure. Stryker has the Illuminator, which worked perfect during the trial and improved safety for the Veteran patient. Out of all the companies that were trialed by VA Fresno surgeons, only Stryker is able to make all of the required equipment and meet the needs of VA Fresno with their fully integrated micro-invasive suite. This purchase also includes surgical drills. VA Fresno trialed the synthes drill and the brassler drill. Both of these drills were too large for the surgeon to handle safely. Stryker has a drill which the surgeons can handle safely.

Without this purchase, the VA would be required to continue referring Veterans to other hospitals inside and outside the VA system for arthroscopic and laparoscopic surgical services, costing the VA significantly more than being able to conduct these same procedures in-house at the VA Fresno hospital. In addition, using multiple manufacturers' instrumentation and equipment would potentially cause compatibility issues and, as a result, reductions in the quality of care to the Veterans.

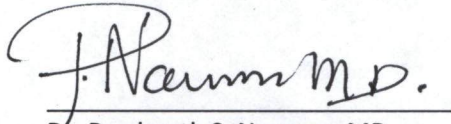
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**

Beacon Point Associates, LLC (SDVOSB)
DUNS # 07-871-7364
21011 Johnson Street, Suite 109
Pembroke Pines, FL 33029
Attn: Tom Summerour/Jeff Summerour
Phone: 954-391-9361 / Fax: 954-210-7361

Email: tom.summerour@beaconpointassociates.com / jeff.summerour@beaconpointassociates.com

AMD Next (American Medical Depot) (small business)
DUNS # 06-272-2038
10315 USA Today Way
Miramar, FL 33025
Attn: Scott Nurik
Phone: 305-364-0888, x6814 / Fax: 305-364-0877
Email: scott.nurik@amdnext.com

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:** Future requirements for this equipment will be re-evaluated for the prospect of finding other manufacturers that can meet the same requirement as the Stryker arthroscopic and laparoscopic equipment and instrumentation. In the meantime, the VA cannot perform all the required procedures in-house without this suite of equipment.
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.



Dr. Prashanth S. Navaran, MD
Chief of Surgical Services
VA Fresno, CA

06/02/2016.
Date

13. **Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP.**

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

Angela Oppenheimer
Contract Specialist / Contracting Officer
NCO 21 / VA Martinez, CA

Date

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

Patricia Benson, Branch Chief, Supply Team II
Director of Contracting - Designee
NCO 21 / VA McClellan, CA

Date