

**DEPARTMENT OF VETERANS AFFAIRS**

**Justification and Approval (J&A)**

**For**

**Other Than Full and Open Competition (>\$150K)**

**Acquisition Plan Action ID:** VA259-17-AP-2999

1. **Contracting Activity:** Department of Veterans Affairs, NCO 19 for the Grand Junction VA Medical Center. Purchase request #575-17-1-892-0005.
2. **Nature and/or Description of the Action Being Processed:** This procurement is for a new firm-fixed-price contract for the purchase of brand name Stryker Digital Capture System Ultra (SDC Ultra) arthroscopic surgery kits. In accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501. The equipment in question for replacement has an average of 4 years past estimated end of useable life per VISTA records (some as much as 6 years) and has been identified as directly attributable to outage during use during surgery resulting in delays and possible degradation of the quality of patient outcomes due to EPERS reports filed with Patient Safety, here. With scopes, instruments and resection equipment actually inside the patient during surgery the nurses are being asked to “jiggle the wires” to make the equipment work. We have been asked to make this as high a priority acquisition as possible to avoid having to put Orthopedic arthroscopic surgery on stand down due to patient safety concerns.
3. **Description of Supplies/Services Required to Meet the Agency’s Needs:** The arthroscopic surgery kits are used in arthroscopic surgeries. These surgeries are a minimally invasive procedure on a joint in which an examination and treatment of damage is performed. During the procedure an arthroscope, an endoscope is inserted into the joint through a small incision. The ability to use only a small incision allows for a shorter recovery time and increases patient safety. The kits consist of multiple components including, but not limited to: a base system with autoclave arthroscopes, arthroscopy pumps, and cannula pumps. The anticipated lead time is 15-45 days ARO.
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;

FAR13.5 Simplified Procedures for Certain Commercial Items: The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(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):** From November 2014 to present, the Grand Junction Surgery team has been participating in trial evaluations of multiple arthroscopic kit manufacturers. The trials included kits from Olympus America, Stryker Orthopedics, Smith and Nephew Orthopedics, and Arthrex. Each kit was used in actual surgeries for a period no less than three (3) weeks. During the trials the VA surgical providers found the Stryker product to be superior in handling capabilities, tissue manipulation and resection, visualization, reduction in trauma to the patient tissues, more easily controlled hemostasis of bleeding, and more efficient resulting in decreased surgical and anesthesia time while providing improved patient outcomes. The instruments were of a superior design, the resection equipment more efficient, the irrigation capabilities easier to control resulting in less tissue infiltration by irrigation/reduction in postoperative edema which resulted in increased patient safety and shortened recovery times.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** The Grand Junction VA Medical Center Surgery team evaluated kits from four different manufactures, listed above in #5, during actual surgeries to find the system that best meets their needs. The brand name solicitation will be posted on [www.fbo.gov](http://www.fbo.gov) to encourage SDVOSB competition.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The final contract price will be considered fair and reasonable through competition between distributors. Solicitation will be posted on [www.fbo.gov](http://www.fbo.gov).
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** The Grand Junction VA Medical Center Surgery team evaluated kits from four different manufactures, listed above in #5, during actual surgeries to find the system that best meets their needs. From market research conducted on [www.vip.vetbiz.gov](http://www.vip.vetbiz.gov), multiple SDVOSB vendors are able to provide the required items.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** A comparative trial was conducted inclusive of what the orthopedic providers determined, from their past clinical/surgical experience and following research of their own throughout a field of their peers. The VAMC trialed products from four vendors whom were projected to be the leading companies in this field of surgical specialty, with the majority of market share in this line of product and the most promising variety of state of the art and industry standard technology and support systems to offer. Stryker is the sole manufacturer of the Digital Capture System Ultra (SDC Ultra).
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** AMD in Florida.
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 required:** In future acquisitions, new evaluations of multiple manufacturer's products will be conducted. This will allow the surgery team to re-evaluate which manufacturer's kits meet their needs. A complete solicitation will be posted for the chosen manufacturer's name brand item.