

NCO 7 SYNTHES SCREW REMOVAL SYSTEM PROCUREMENT  
BIRMINGHAM VAMC

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

521-12-2-233-0138

1. **Contracting Activity:** Department of Veterans Affairs, Network Contracting Office (NCO) 7, 700 S. 19<sup>th</sup> Street, Birmingham, AL 35233. This is a NCO 7 procurement justification for other than full and open competition. The solicitation number associated with this procurement is VA247-12-I-0319.
2. **Nature and/or Description of the Action Being Processed:** This is a request for other than full and open competition for the procurement of a set Synthes Broken Screw Removal Set purchased from American Medical Depot, 4380 NW 135<sup>th</sup> Street, Miami, FL 33054, AMD Proposal #: VABIRMI-SY020812-1.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** This request is for a comprehensive set of instruments to remove broken and/or damaged screws with a diameter of 1.5mm to 7.3mm from a patient when the routine means is not possible. This set includes the 60 line items listed below:

Items Number	Description	Qty
999071965	1 LARGE HANDLE WITH QUICK COUPLING	1
999072984	2 SMALL UNIVERSAL CHUCK WITH T-HANDLE	1
999071954	3 COUNTERSINK FOR 4.5MM CORTEX SCREWS	1
999071951	4 HANDLE WITH MINI QUICK COUPLING, STAINLESS STEEL	1
999073209	5 NARROW SCREW REMOVAL PLIERS	1
999114333	6 DRILL SUCTION DEVICE	1
999114328	7 2.5MM DRILL SLEEVE CLIP-O N FOR 03.607.110	1
999114329	8 3.5MM DRILL SLEEVE CLIP-O N FOR 03.607.110	1
999114330	9 4.0MM DRILL SLEEVE CLIP-O N FOR 03.607.110	1
999114331	10 4.8MM DRILL SLEEVE CLIP-O N FOR 03.607.110	1
999114332	11 6.0MM DRILL SLEEVE CLIP-O N FOR 03.607.110	1
999114938	12 GRAPHIC CASE FOR SCR REMO VAL SET	1
999066957	13 STRAIGHT SHARP HOOK	1
999066958	14 AO COUPLING EXTENSION SHAFT	1

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999066959	15 SMALL SCREW REMOVAL FORCEPS	1
999066960	16 LARGE SCREW REMOVAL FORCEPS	1
999066955	17 4.0MM CARBIDE DRILL BIT EXTENSION	1
999066956	18 6.0MM CARBIDE DRILL BIT EXTENSION	1
999114874	19 2.4MM STARDRIVE SCREWDRIVER SHAFT	1
999023728	20 BLADE SCREWDRIVER ORTHO MANDIBULAR 2MM SHORT	1
999121643	21 BLADE SCREWDRIVER 1.5MM MINI QUICK COUPLING STARDR	1
999077923	22 1.3MM SCREWDRIVER BLADE	1
999114334	23 2.4MM CRUCIFORM SCREWDRIVER SHAFT 100MM	1
999114867	24 CONICAL EXTRACTION SCREW FOR 3.5MM SCREWS	1
999114335	25 4.0MM HEX SCREWDRIVER SHAFT 100MM	1
999114337	26 T40 STARDRIVE SCREWDRIVER SHAFT 100MM	1
999114336	27 T25 STARDRIVE SCREWDRIVER SHAFT 100MM	1
999087166	28 CONICAL EXTRACTION SCREW	1
999071835	29 CONICAL EXTRACTION SCREW FOR LARGE SCREWS	1
999071812	30 HOLLOW REAMER COMPLETE FOR 6.5MM & 7.0MM SCREWS	1
999071828	31 HOLLOW REAMER-COMPLETE 4.5MM SCREWS	1
999071814	32 EXTRACTION BOLT FOR 6.5MM & 7.0MM SCREWS	1
999071831	33 EXTRACTION BOLT FOR 4.5MM SCREWS	1
999072060	34 LARGE HEXAGONAL SHAFT	1
999072057	35 STARDRIVE SCREWDRIVER T25/SELF-RETAINING 165MM	1 1
999072055	36 STARDRIVE SCREWDRIVER QC/T15	1
999071809	37 HOLLOW REAMER COMPLETE FOR 3.5MM & 4.0MM SCREWS	1
999071811	38 EXTRACTION BOLT FOR 3.5MM & 4.0MM SCREWS	1
999072043	39 SMALL HEXAGONAL SHAFT	1
999071834	40 CONICAL EXTRACTION SCREW FOR 2.7MM &	1
999072041	41 1.5MM/2.0MM CRUCIFORM SHAFT, SELF - 1 Ea. RETAINING	
999072040	42 1.3MM CRUCIFORM SHAFT, SELF- 1 Ea. RETAINING	
999072039	43 1.0MM CRUCIFORM SHAFT, SELF- 1 Ea. RETAINING	
999072084	44 CRUCIFORM SCREWDRIVER SHAFT	1
999071832	45 CONICAL EXTRACTION DEVICE FOR THREADED WASHERS	1
999071833	46 CONICAL EXTRACTION SCREW FOR 1.5MM &	1
999072083	47 CANNULATED DRIVER FOR THREADED WASHERS F/3.0MM	1
999071822	48 HOLLOW REAMER-COMPLETE 2.0MM SCREWS	1

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999071823	49 HOLLOW REAMER-COMPLETE 2.7MM SCREWS	1
999071818	50 HOLLOW REAMER-COMPLETE 1.5MM SCREWS	1
999071826	51 EXTRACTION BOLT FOR 2.7MM SCREWS	1
999071821	52 EXTRACTION BOLT FOR 2.0MM SCREWS	1
999071817	53 EXTRACTION BOLT FOR 1.5MM SCREWS	1
999073208	54 FORCEPS FOR BROKEN SCREW REMOVAL	1
999072058	55 LARGE HEXAGONAL WITH T-HANDLE	1
999072213	56 SHARP HOOK	
999073323	57 HOLLOW GOUGE FOR BROKEN SCREW EXPOSURE	1
999072033	58 4.0MM HEXAGONAL SCREWDRIVER	1
999071955	59 HANDLE WITH MINI QUICK COUPLING	1
999071945	60 COUNTERSINK F/3.5MM & 4.0MM CANCELLOUS	1

TOTAL COST: \$25,672.50

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):

The Orthopedic Trauma Instrumentation used at the Birmingham VA Medical Center is 90% Synthes and highly specialized. The Synthes Screw Removal Set contains 60 different surgical instruments which will assist in the removal of orthopedic fixation screw which must be removed from the bone under other than ideal circumstances. These instruments can assist with the removal of broken, embedded and or stripped screw without removing a portion of the bone with the screw. Under these circumstances, without this system, the surgeon would have to use other instruments to cut the bone around the screw(s) to be able to remove them. Any bone lost at the site of an old fracture has the potential to compromise the healing and function for the Veteran patient. The prevention of further bone loss is particularly important if the fraction is a non-union and further surgery and implantation of orthopedic implants is necessary for proper healing of the fracture. The Synthes Screw Removal System will also work with the removal of screws from other vendors. This makes this system the only comprehensive screw removal set on the market that will work in all instances when a surgeon must remove an orthopedic bone plates and screws in less than ideal circumstance.

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

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Customer reviewed the internet for all comprehensive screw removal system designed for the removal of orthopedic bone screws with a diameter of 1.5mm – 7.3mm that are broken, encased in bone or stripped out. What was found was the Shukla Medical Extract-All System. This system is a Universal Intramedullary Nail Extraction System. However our need at the Birmingham VA Medical Center is for the Synthes Screw Removal System. The Synthes Screw Removal System is primarily designed to remove the screws used to fix plates to bones in the stabilization of fractures or corrected deformities. We perform 75% more hardware removals involving plates and screws that we do involving Intramedullary Nails. By market research the Synthes Screw Removal System is the only one of its type on the market.

Intent to Sole Source notice was posted on FBO 7 April 2012 under Solicitation number VA247-12-I-0319. Only one vendor appeared under the FBO "Interested Vendors List" which was "Material Integration, Inc". However several attempts through e-mail and phone were made to contact this vendor with no response. The phone number they provided has been disconnected.

The Synthes Screw Removal System is available American Medical Depot (AMD) who have the following: TIN: 59-233-7158, DUNS: 06-272-2038 and CAGE CODE: OXP01. Their contracts include: SPM2DE-12-D-7602 – ECAT, SP020098H0068 – MEDSURG DAPA, SP020009h0071 – EQUIPMENT DAPA AND SPM2009a8711 – DBPA. AMD is located at 4381 NW 135th Street, Miami, FL 33054. And can be reached at: (305)364-0888, (305)364-0877 (Fax) or sales@american-depot.com. The point of contact for this purchase is Gabriela Vanegas (ext. 6810).

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

The price of the Synthes Screw Removal System totals \$25,672.50 which is considered fair and reasonable. The only means for making a comparison is to compare the pricing to the other instrumentation for the Synthes trays with like instrumentation. However because this is a very unique tray which contains components that are only in this tray it is difficult to make the comparison. One of the obvious costs of not having this system is the prolonged surgery time because we do not have the most appropriate tool for the removal for that hardware. Surgery time is very expensive at a minimum of \$10.00 per minute. Another cost of prolonged surgery time is the medical risks for the patient. These risks can lead to complications which can be detrimental to the health and well being of our Veteran patients and costly to the facility.

In researching this purchase, I requested quotes from two other vendors. The quote I received from Stryker Orthopedics for a screw removal set. They have two versions with one containing more instruments than the other. The quote they sent was for the basic set but it was embedded into a listing of the larger set with pricing. The total price for the second set which contains 63 items is \$67532.00 which includes two modular trays to hold the instruments. If you subtract these trays the price is \$55032.00. If you apply a 27% discount which the vendor applied to the instruments quoted the total price would be \$40173.36 which is 40% higher than the quote for the Synthes Screw Removal System.

Additionally in looking at an Innomed Screw Removal Set, which included 30 instruments rather than the 60 in the Synthes Screw Removal System, there is a difference in the pricing for each set. However you are not comparing two like sets. There are also some pricing discrepancies between similar items

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such as the Universal Driver Handle for the Innomed set is listed as \$840.00 and the Synthes Handle is priced at \$491.00. There are also some differences in the sizing of the instruments. On the Innomed set the Cruciform Shafts are listed as large, small and mini whereas in the Synthes System the sizes are listed by size (1.5mm/2.0, 1.3mm & 1.0mm). There are also some differences in the sizing of the hollow reamers. After reviewing both quotes, the Innomed Set is not a comprehensive screw removal system like the Synthes instrument set and with the sizing differences; a measurement is more accurate than a general description of large, small and mini. This demonstrates that the Synthes Screw Removal System in more comprehensive has fair and reasonable pricing and is designed with more accurate sizing.

**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. The Synthes Screw Removal Set is compatible with all our Orthopedic Trauma Implants used at the Birmingham VA Medical Center. Approximately 90% of our trauma implants are Synthes. During the market research there is only one other comprehensive surgical hardware removal system available. It is the Shukla Medical Xtract-All which is designed for the removal on intramedullary rods and the screws and bolt that keep them in place. These intramedullary (IM) nails are placed in the long bones (Femur, Tibia, Humerus and, etc) to maintain the alignment and reduction of a fracture. Once the fracture is healed the hardware may become painful or migrate to a location that causes injury to the patient. In these instances the IM nails must be removed. This system in conjunction with the Synthes Screw Removal System would provide a full range of hardware removal instrumentation. But separately they address two entirely different types of orthopedic implants.

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

The Synthes Screw Removal Set is also compatible with bone screws manufactured by other vendors. Any implantation of bone hardware is a race between bone growth and metal fatigue to failure which may result in broken hardware. This set allows for the removal of any such items. American Medical Depot is the only distributor of the Synthes Screw Removal System.

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

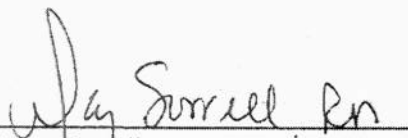
"Material Integration, Inc" --responded to the RFI – Notice of Intent to Sole Source. However several attempts through e-mail and phone were made to contact this vendor with no response. The phone number they provided has been disconnected.

**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:**

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This is a onetime purchase of this instrumentation. Therefore, no actions to remove barriers for future competition are planned since these instruments will be used repeatedly after sterilization for many years to come.

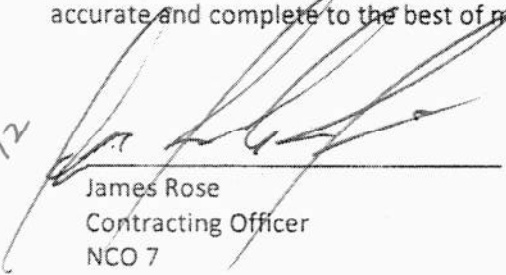
12. Requirements Certification: I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

  
Mary Sorrell  
Nurse Manager  
Birmingham VA Medical Center

4/23/12  
Date


13. Approvals in accordance with FAR 6.304

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

RRJ  
4-27-12  
  
James Rose  
Contracting Officer  
NCO 7

4/27/12  
Date

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

  
Deborah F. Mattingly  
Network Contract Manager  
NCO

27 April 2012  
Date