

**DEPARTMENT OF VETERANS AFFAIRS**

**Justification for Single Source Awards IAW [FAR 13.106-1](#)  
For  
Over Micro-Purchase Threshold but Not Exceeding the SAT (\$250K)**

**Acquisition Plan Action ID: [36C257-18-AP-0469](#)**

- 1. Contracting Activity:** Department of Department of Veterans Affairs, VISN 17, Network Contracting Officer in San Antonio is purchasing on behalf of Dallas VA Medical Center, under request (2237) number 549-18-3-081-5062.
- 2. Brief Description of Supplies/ Services required and the intended use/Estimated Amount:** Initial stock for drill bits, k-wires, and other disposable items used during ortho trauma cases. The estimated value of the proposed action is \$24,662.38.
- 3. Unique characteristics that limit availability to only one source, with the reason no other supplies or services can be used:** The Trauma and Fracture Division of the Department of Veterans Affairs, Dallas VA provides management of emergency fractures, there is a total of 4 Doctors conducting this procedures on an emergency basis working along Smith & Nephew for the last 10 years, no other Vendor are willing to conduct business with the VA. There is an average of 60 to 70 cases of trauma cases are seen per year by the division. The spectrum of cases treated ranges from patients with a single fracture to those suffering from multiple, life-threatening musculoskeletal injuries. Due to the nature of trauma cases, our orthopedists share strong working relationships with the departments of Plastic Surgery, Neurosurgery, and Vascular Surgery. State-of-the-art techniques are used in the treatment of associated injuries to nerves and blood vessels and incidents involving soft tissue loss. Additionally, significant attention is given to comprehensive evaluation and care of geriatric patients with hip fractures, as well as coordinated care of patients with all types of fractures. Late reconstructive procedures are commonly performed on such conditions as non-unions, malunions, and osteomyelitis. Currently the Vendor provides necessary non-stock items during the procedure and turns in a Bill -Only invoice for items used during the procedure. We want to have all necessary items is stock and in our inventory to put a stop to the Bill-Only invoice process. Items listed in the package are the items needed for any type of emergency trauma procedure.

Surgeons at this facility only use Smith & Nephew implants and instruments, disposable items are needed for the cases. Below is a list of the salient characteristics for the requested items:

The essential physical and functional features of the material or service required are listed below for Smith & Nephew Implants and disposable items. The characteristics are essential to the Government's requirements and to the Dallas VA. They are features that are identified in the specifications as a mandatory requirement that a proposed "equal" product or material must possess for the bid to be considered responsive to the Dallas VA. Smith & Nephew has been providing class leading trauma products for many years. Our fixation products consist of both

internal and external devices, as well as other products such as various fixation and ortho-biological materials used in the stabilization of severe fractures and deformity correction procedures.

Trauma implant systems Among the principal internal fixation products are the [TRIGEN<sup>o</sup> Intramedullary Nailing system](#), [TRIGEN META-NAIL](#) with expanded fixation and technique options, [TRIGEN INTERTAN<sup>o</sup> Intertrochanteric Antegrade nails for hip fractures](#), [TRIGEN SURESHOT<sup>o</sup> Distal Targeting System for Intramedullary Nailing](#) and [PERI-LOC<sup>o</sup> Periarticular Locked Plating](#) system which offers a comprehensive family of fracture specific plate and screw products for the upper and lower extremities. For external fixation and limb restoration, Orthopedics offers the [TAYLOR SPATIAL FRAME<sup>o</sup> Circular Fixation System](#) and [JET-X<sup>o</sup> BAR Unilateral Fixator](#). Smith & Nephew is a world leader in joint replacement systems for knees, hips and shoulders. Whether through extending the life and functionality of implants, improving operating room efficiency, or promoting faster healing and other clinical outcomes, our innovations differentiate us and provide solutions to active patients seeking to regain their quality of life while enhancing economic value for all of our customers. Smith & Nephew implants include **hip, knee and shoulder joints** as well as **ancillary products** such as **bone cement**.

Smith & Nephew Implants and components have four metals used in most Smith & Nephew implant components. The materials are:

Cobalt-Chromium Alloy (Co-Cr-Mo; ASTM F-1537), Titanium Alloy (Ti-6Al-4V; ASTM F-1472), 316L Stainless Steel (ASTM F-138), and Zirconium Alloy (Zr-2.5Nb; ASTM F-2384). Chemistry limits (in weight percent) for the metals meet these specifications as follows:

**Cobalt-Chrome Alloy (Co-Cr-Mo)**

Carbon 0.14 max  
Chromium 26.0 – 30.0  
Molybdenum 5.0 – 7.0  
Nickel 1.0 max  
Iron 0.75 max  
Silicon 1.0 max  
Manganese 1.0 max  
Nitrogen 0.25 max  
Cobalt Balance

**Titanium (Ti-Alloy)**

Nitrogen 0.05 max  
Carbon 0.08 max  
Hydrogen 0.015 max  
Iron 0.30 max  
Oxygen 0.20 max  
Aluminum 5.5 – 6.75  
Vanadium 3.5 – 4.5  
Yttrium 0.005 max  
Titanium Balance

**316L Stainless Steel**

Carbon 0.030 max  
Manganese 2.00 max  
Phosphorus 0.025 max  
Sulfur 0.010 max  
Silicon 0.75 max  
Chromium 17.00 – 19.00  
Nickel 13.00 – 15.00  
Molybdenum 2.25 – 3.00  
Nitrogen 0.10 max  
Copper 0.50 max  
Iron Balance

**Zirconium Alloy (Zr-Alloy)**

Niobium 2.40 – 2.80  
Oxygen 0.09 – 0.13  
Carbon 0.027 max  
Chromium 0.020 max  
Hafnium 0.010 max  
Hydrogen 0.0025 max  
Iron 0.15 max  
Nitrogen 0.0080 max  
Tin 0.0050 max  
Zirconium Balance

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Attachment 1: Single Source Justification for SAP under the SAT

Titanium Alloy than the medical industry that the metal suppliers also make the medical alloy to this limit (to minimize inventory). These levels are so low that Titanium Alloy is typically considered This physical or functional characteristic of only one product will meet the minimum requirements of the Dallas VA.

Items required for stock:

71065359	1 ITEM ID NO. 109649 TIN, 5MM X 35MM, LONG, HALF, PIN	PKG: 1 per EA
71065559	2 ITEM ID NO. 109650 TIN, 5MM X 55MM, LONG, HALF, PIN	PKG: 1 per EA
71067374	3 ITEM ID NO. 109651 QUICK CLAMP, 10.5MM TO 5MM	PKG: 1 per EA
71067374	4 ITEM ID NO. 109652 QUICK CLAMP, 10.5MM TO 10.5MM	PKG: 1 per EA
71067318	5 ITEM ID NO. 109653 DRILL FOR SH 5MM, HALF PIN	PKG: 1 per EA
71064001	6 ITEM ID NO. 109654 FREEDOM CLAMP, 10.5MM TO 5MM	PKG: 1 per EA
71062350	7 ITEM ID NO. 109655 350MM BAR	PKG: 1 per EA
71062250	8 ITEM ID NO. 109656 250MM BAR	PKG: 1 per EA
71062300	9 ITEM ID NO. 109657 300MM BAR	PKG: 1 per EA
128039	10 ITEM ID NO. 107825 PIN GUIDE 1.3MM DIA 15CML BAYONET TIP	PKG: 6 per PG
71161012	11 ITEM ID NO. 109738 1.25 K-WIRE	PKG: 6 per PG
71161016	12 ITEM ID NO. 73613 PERI LOCK WIRE 1.6MM	PKG: 6 per PG
7116-1020	13 ITEM ID NO. 104332 PERI-LOC K-WIRE 2.0MM	PKG: 6 per PG
71173501	14 ITEM ID NO. 73614 2.0MM DRILL W/QC	PKG: 1 per EA
71173502	15 ITEM ID NO. 107806 DRILL BIT, ORTHOPEDIC, DIAMETER 2.7 MM, LENGTH 4.9 INCH, QUICK CONNECT, STERILE	PKG: 1 per EA
71173503	16 ITEM ID NO. 70390 2.7MM DRILL BIT W/QC	PKG: 1 per BX
71173504	17 ITEM ID NO. 73843 3.5MM SHORT DRILL BIT W/QC	PKG: 1 per EA
71173505	18 ITEM ID NO. 107822 DRILL BIT 3.5MM DIA 7INL QUICK CONNECT DISPOSABLE	PKG: 1 per EA
71173581	19 ITEM ID NO. 107812 2.7MM CANNULATED DRILL BIT - 155MM	PKG: 1 per EA

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71173588	20 ITEM ID NO. 107810 DRILL BIT 2MM DIA 6.1INL QUICK CONNECT STERILE	PKG: 1 per EA
71177134	21 ITEM ID NO. 109830 5.00MM CANNULATED DRILL BIT	PKG: 1 per EA
71177135	22 ITEM ID NO. 109831 5.5MM CANNULATED, DRILL, BIT	PKG: 1 per EA
71177201	23 ITEM ID NO. 109832 3.2MM X 300MM THR GUIDE PIN	PKG: 6 per PG
71177202	24 ITEM ID NO. 106832 3.2MM, DRILL, BIT	PKG: 1 per EA
71631035	25 ITEM ID NO. 104156 SMITH & NEPHEW STERIL DRILL 6.4MM	PKG: 1 per EA
71631110	26 ITEM ID NO. 51687 PILOT DRILL 4.0MM HCPC: SI406	PKG: 1 per EA
71631121	27 ITEM ID NO. 104572 DRILL BIT, ORTHOPEDIC, PILOT, DIAMETER 4MM, LENGTH 333 MM, AO CONNECTOR	PKG: 1 per EA
71631123	28 ITEM ID NO. 73098 4.0MM SHORT AO PILOT DRILL	PKG: 1 per EA
71631320	29 ITEM ID NO. 107827 TRIGEN DISPOSABLE EXTRACTOR	PKG: 1 per EA
71631428	30 ITEM ID NO. 109833 META-TAN COMP, SCREW, DRILL	PKG: 1 per EA
71631432	31 ITEM ID NO. 109834 META-TAN LAG, SCREW, DRILL	PKG: 1 per EA
71631436	32 ITEM ID NO. 104552 PIN, GUIDE, 3.2MM X 343MM	PKG: 1 per EA
71631448	33 ITEM ID NO. 109835 META-TAN COMP, SCREW, STARTER, DRILL	PKG: 1 per EA
71631626	34 ITEM ID NO. 41572 GUIDE ROD BALL TIP 3.0MM X 1000MM HCPC: SI404	PKG: 1 per EA
71674034	35 ITEM ID NO. 106837 7.0, COMPRESSION, DRILL	PKG: 1 per EA
71674540	36 ITEM ID NO. 106835 LAG, SCREW, DRILL, BIT	PKG: 1 per EA
71674570	37 ITEM ID NO. 106836 7.0, COMPRESSION, DRILL	PKG: 1 per EA
71751136	38 ITEM ID NO. 62289 3.2MM TROCAR HCPC: SI304	PKG: 1 per EA
71751146	39 ITEM ID NO. 62290 2.0MM GRAD BALL TIP GD ROD HCPC: SI304	PKG: 1 per BX
71751147	40 ITEM ID NO. 62291 3.2MM TIP THREADED GD PIN HCPC: SI304	PKG: 1 per BX
71751148	41 ITEM ID NO. 62292 3.2MM SHORT GRAD BRAD PT DRILL	

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HCPC: SI304

PKG: 1 per BX

71751149 42 ITEM ID NO. 62293 3.2MM LONG GRAD BRAD PT DRILL

HCPC: SI304

PKG: 1 per BX

- 4. Description of market research conducted and results or statement why it was not conducted:** A keyword search for “clamp” was conducted on VIP, and the search resulted in 1 matches from SDVOSB/VOSB, under NAICS code 339112. However, this vendor did not sell the required item.

A part search for the most expensive item on the list 109654 and keyword “Freedom Clamp” was searched on GSA Advantage, resulting in no items found on GSA Advantage.

A search of SBA Dynamic Small Business Search utilizing the key word search for “clamp” was conducted on DSBS. The search resulted in 0 matches from SDVOSB, and 1 matches from VOSB, under NAICS code 339112.

A search of FPDS-NG utilizing the key word search for “Smith & Nephew” was conducted and the result showed these items have been purchased before under contract 36C25018P3915. This recent award was made sole source after the posted Notice of Intent, received no small business responses.

Based on market research above, it is the recommendation that the requirement be solicited as a sole-source award to Smith & Nephew, Incorporated for an estimated amount of \$24K, to meet the needs of this requirement. **Only Smith & Nephew Vendor can provide needed items.**

- 5. Contracting Officer's Certification:** *Purchase is approved in accordance with FAR13.106-1(b). I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.*

Michael J. Tusinger  
Contracting Officer

Date: 12 September 2018