

JUSTIFICATION FOR SINGLE SOURCE AWARDS IAW FAR 13.106-1
(OVER MICRO-PURCHASE THRESHOLD(\$3K) BUT NOT EXCEEDING THE SAT (\$150K))

IAW [FAR13.104](#), COs must promote competition to the maximum extent practicable to obtain supplies and services from the source whose offer is the most advantageous to the Government, considering the administrative cost of the purchase. When competition is not practicable, IAW [FAR13.106-1\(b\)](#), COs solicit from a single source for purchases not exceeding the simplified acquisition threshold. COs may solicit from one source if the CO determines that the circumstances of the contract action deem only one source reasonably available (e.g., urgency, exclusive licensing agreements, brand-name or industrial mobilization). IAW [FAR13.106-3\(b\)\(3\)](#), COs are required to include additional statements **explaining the absence of competition** (see [13.106-1](#) for brand name purchases) if only one source is solicited and the acquisition does not exceed the simplified acquisition threshold (does not apply to an acquisition of utility services available from only one source) or supporting the award decision if other than price-related factors were considered in selecting the supplier. This template when completed can be used to document single source awards IAW [FAR13.106-3\(b\)\(3\)](#). Note: Statements such as "only known source" or "only source which can meet the required delivery date" are inadequate to support a sole source purchase.

1. PURCHASE REQUEST OR REQUISITION NUMBER:

580-18-3-047-0139

**1A. PROJECT/TASK
NUMBER**

1B. ESTIMATED AMOUNT:

2. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES REQUIRED AND THE INTENDED USE:

The Michael E. DeBakey VA Medical Center (MEDVAMC) is requesting to purchase a stocking order comprised of different Mitek Sports implantable items. These implantable products will be used in all Orthopedic Sports Medicine cases, specifically for different types of shoulder cases.

3. UNIQUE CHARACTERISTICS THAT LIMIT AVAILABILITY TO ONLY ONE SOURCE, WITH THE REASON NO OTHER SUPPLIES OR SERVICES CAN BE USED:

This single use digital flexible ureteroscope uses proprietary technology and improves consistent readings and decreases turnover time needed for processing in SPS.

4. REASON THAT SUGGESTED SOURCE IS THE ONLY SOURCE, WHICH CAN PROVIDE THE SUPPLIES OR SERVICES:

The MEDVAMC currently uses these implantable products for all shoulder cases. However, we are currently purchasing them on a case-by-case basis. We are experiencing delays in paying the vendor and product turn around. We do anywhere between 5-10 cases per week that require these products; therefore, we need to have stock available at the hospital always. These Mitek products are required due to the technique the MEDVAMC Orthopedic surgeons are trained on and prefer. Each different anchor system has salient characteristics.

- **Healix Advance Anchors:** Anchor is built upon the historical performance of the HEALIX ANCHOR™ Instrument and dual thread technology. It has increased anchor torque strength for harder bone applications, and ensures better anchor performance upon insertion. The new multi-thread design enhances speed and ease of use for faster anchor advancement into the bone and with only bone preparation with most bone qualities. The family of anchors has also been expanded to allow greater versatility with addressing the patient's repair needs and the surgeon's corresponding surgical technique. Multiple anchor sizes and suture loading configurations enable versatility with fixation and suture spanning across the rotator cuff.
- **Fastin RC Dual Channeled Anchor:** Threaded with ORTHOCORD® Suture, offers an

advantageous high-strength solution to surgeons who perform both arthroscopic and open rotator cuff procedures.

- Sharp tip
 - Double loaded with suture
 - Independent suture eyelets
 - Smaller inner core and wide, deeper-pitch cancellous thread
- **Lupine BR Anchor:** This system provides surgeons with the flexibility of material, design and procedures. It also provides an instrumentation set that allows for superior access, great visibility and precision in hole placements. In tight anatomic environments, such as shoulder instability procedures, LUPINE® Anchor offers a unique solution for reliable outcomes.
 - BIOCRYL® RAPIDE® Material
 - 43lbs of pull-out strength, which is 30% stronger than Bio-SutureTak®
 - Loop eyelet for excellent suture slideability
 - Orthocord suture that delivers 55lbs of tensile strength and is 45% less stiff than Fiberwire®
 - Minimal drill hole needed on the glenoid, 2.9mm
 - Numerous surgical applications and techniques with the same anchor.
 - Offers great utility to end-user, can be used in MCL/LCL repair, Distal Biceps Repair and many other procedures
 - 4 guide options that allow ease of access to the target pathology; Dove Tail, Fish Mouth, Hybrid and Saw Tooth
- **TRUESPAN™:** The TRUESPAN Meniscal Repair System is intended for use in meniscal repairs and meniscal allograft transplant procedures. It is intended to be used for anchoring the allograft to the meniscal rim during allograft transplant procedures.
 - Features an ergonomic design that is comfortable to hold and a single trigger, allowing use with only one hand! No needle assembly or reloading steps required.
 - Implants and suture are protected by a depth stop and rigid needle while accessing hard to reach locations.
 - Available 0°, 12°, & 24° needles pre-loaded with non-absorbable PEEK or absorbable PLGA implants and partially absorbable 2-0 ORTHOCORD® Suture.
 - Small size needle & implants minimize tissue disruption and 'kickback' during deployment. Repairs with TRUESPAN™ Implants do not leave a knot or hard body on articular surfaces!
- **INTRAFIX™ ADVANCE:** an implant system used for fixation of tissue including ligament, or tendon to bone during cruciate ligament reconstruction.
 - Redesigned implants and instrumentation for greater ease of use and reliability
 - High fixation strength and low displacement¹
 - Sheath protects graft and provides 360° of graft-to-bone compression
 - Available in BIOCRYL RAPIDE® Biocomposite Material and PEEK
 - Simplified implant sizing scheme
- **SPEEDTRAP™:** The implantable suture construct is made of a non-absorbable, flat spine suture composed of ultra-high molecular weight polyethylene (UHMWPE) and a co-braided winding suture composed of either green (D&C Green #6) poly (ethylene terephthalate) (PET) and UHMWPE, or un-dyed PET and UHMWPE. The suture construct is supplied on a disposable, non-implantable, sterile delivery device made of polypropylene.
 - Innovative design provides even distribution and pattern of whipstitches - High strength "winding" suture anchored to flat "spine" suture
 - "Needleless" design compresses the graft, eliminating graft damage from needle pierces
 - High strength suture and construct for graft tensioning
 - Sterile, disposable delivery device
- **MILAGRO® ADVANCE Interference Screw:** utilizes an advanced screw design that offers

exceptional bone engagement and rapid insertion. It comes available in Mitek Sports Medicine proprietary BIOCRYL RAPIDE® Biocomposite Material as well as PEEK Material.

- BIOCRYL RAPIDE Biocomposite Material promotes bony ingrowth at the implant site.
- Inserts approximately 2x faster than traditional interference screws.
- Improved interdigitation of graft threads increases overall fixation strength by 25%.
- Unique Distal-tip requires 83% less effort to achieve bone engagement.
- Ease of bone engagement and lower insertion torque ensure robust insertion into hard bone with minimal torque transmission to soft tissue grafts and tendons
- Available in BIOCRYL RAPIDE Biocomposite Material and PEEK
- **PROFILE™ Interference Screws:** have a rounded atraumatic head and provide excellent fixation with bone-tendon or soft tissue grafts.
 - Titanium construction for robust screw insertion
 - Tapered tip allows easy engagement with bone
 - Polished threads provide a smooth interface with grafts, while reducing insertion torque.

Numerous sizes offered to accommodate each patient's anatomy: 7x20, 7x25, 7x30, 8x20, 8x25, 8x30, 9x20, 9x25, 9x30mm

5. DESCRIPTION OF MARKET RESEARCH CONDUCTED AND RESULTS OR STATEMENT WHY IT WAS NOT CONDUCTED:

An internet search and consult with the Chief of Orthopedic Surgery was conducted and no other vendors were found to have the capability of meeting the agency's need for this specific and specialized equipment.

6. 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.*

Signature: _____

Date: _____

Name: _____

Title: _____

Facility: _____