

Justification for Other than Full and Open Competition

1. Contracting Activity: Department of Veterans Affairs (VA)

Office of Procurement,
Acquisition and Logistics
Strategic Acquisitions Center (SAC)
10300 Spotsylvania Avenue,
Suite 400
Fredericksburg, VA 22408

2. Description of the Action: The proposed action is to establish a firm fixed price Indefinite Delivery Indefinite Quantity (IDIQ) single award sole source contract for Cook Medical, LLC (Cook Medical). Cook Medical a large business, located at 750 Daniels Way, Bloomington, IN 47404-9120. Veterans' Health Administration (VHA) has a need for Prosthetics Implant Appliances based upon a physician's determination of medical necessity for use during surgical services and/or procedures at Veterans Affairs Medical Centers (VAMCs) throughout the United States and its territories. The objective is to ensure availability of Cook Medical implants for nationwide usage and to enhance the quality of care we provide to our Veterans, Leverage spend and maximize efficiency.

3. Description of Supplies/Services: The supplies to be acquired are various types of prosthetic appliances such as cardiac implants: stents including auxiliary products and instrumentation sets. Delivery method will include: Normal, Expedited, Just-In-Time (JIT) Delivery, and Consignment.

In 2016, 20 Top vendors were identified for award of a Prosthetic Implant Appliances contract under authority 38 U.S.C. § 8123. Cook Medical was one of the original Top 20 vendors solicited but did not receive an award in FY 2017. Before award it was found that Cook Medical items were pending FDA approval. Cook Medical are no longer pending FDA approval.

The period of performance (POP) for this requirement will be for a 3-month base with two 1-year option periods. The POP is in conjunction with the end of the original Top 18 Prosthetic awards which ends December 31, 2021. The estimated value of this acquisition is \$44,419,460.91. The estimate is based on 3-month base and two (2) option years of historical pricing and a vendor specific spend analysis for the required implants on a national basis with Cook Medical.

Under "Normal Delivery" the facilities shall contact contractors at a minimum five (5) days prior to the anticipated date of surgery. The required Instrumentations trays shall be delivered to the local Sterilize Procedure Department to go through the

sterilization process to allow adequate time for facilities to have the instruments properly cleaned and sterilized.

Under the "JIT" delivery method, the VAMC will call the respective Cook Medical sales representative when a surgery is scheduled to discuss the case, make a product selection from Cook Medical product line and inform the sales representative of the surgery date and time. The sales representative will transport the implants, instrumentation sets, auxiliary products and back-up components necessary for surgery to the designated site at the scheduled time.

Under the "Consignment" method, a facility can request prosthetic implant appliances be consigned to their facility. Under this method the respective contract vehicle will be used as an ordering method only. The consignment agreement will be established under the awarded contract by a contracting officer and in accordance with Veterans Administration Acquisition Regulation (VAAR) 816.770 Consignment Agreements.

A Memorandum of Understanding (MOU) will be established, in accordance with Veterans Health Administration (VHA) Consignment Policy, between the local VAMC and Cook Medical to cover any loss or damage to the consigned inventory. The VAMC would pay only for the "procedural packages" that are used.

The contractor shall be responsible for providing a VA specific catalog system that will allow streamlined ordering for the Prosthetics and Sensory Aids Services (PSAS) and appointed Ordering Officers. All products shall be Food and Drug Administration (FDA) approved.

4. Statutory Authority: The statutory authority permitting other than full and open competition is 38 U.S.C. § 8123 and 41 U.S.C 3304(a)(5), as implemented by the FAR 6.302-5(a)(2)(i) and VAAR 806.302-5(b)(1). In accordance with 38 U.S.C. § 8123, "The Secretary may procure prosthetic appliances and necessary services required in the fitting, supplying, and training and use of prosthetic appliances by purchase, manufacture, contract, or in such other manner as the Secretary may determine to be proper, without regard to any other provision of law."

5. Rationale Supporting the Use of the Authority Cited Above:

In support of the authority cited above, the products offered by Cook Medical were determined necessary by a team of VA Subject Matter Experts (SME), including technical prosthetics, and sensory aid specialists, as well as representatives for patient safety and from veteran service organizations. In addition, the prescribing physician will provide the necessary clinical evidence to support the medical need for specialized equipment for the Veteran who is eligible, referred, and approved by VACO in use of Cook Medical products.

6. Efforts to Obtain Competition: Utilizing the authority in 38 U.S.C. § 8123 and 41 U.S.C. 3304(a)(5), it is appropriate to award this acquisition to Cook Medical, without regard to any other provisions of law, to include full and open competition. As required by FAR 5.2, this action will be synopsisized through FedBizOps on or around August 12, 2019. In addition, this justification will be published with the solicitation, in accordance with FAR 6.305(a).

7. Determination of Fair and Reasonable Cost: Price reasonableness will be conducted in accordance with 41 U.S.C. 3501 and FAR 15.403-1(c)(3)(ii)(B), "Commercial Items", which states that in order to make this determination, the contracting officer may request the offeror to submit prices paid for the same or similar commercial items under comparable terms and conditions by both Government and commercial customers. As the Contracting Officer, I hereby determine that the anticipated cost to the Government will be fair and reasonable based on the use of price analysis techniques in accordance with FAR 15.404-1(b). Additionally, price discounts will be sought.

8. Market Research: Based on the market research conducted through internet searches, government database queries, GSA e-library searches and reviews of other market research conducted it is determined that Cook Medical prosthetic implant appliances, are available in the commercial market and meets the agency's requirements. Cook Medical Prosthetic implant appliances are not available through VA FSS and there is no reasonable expectation that two or more SDVOSB, VOSB or SB are capable of providing Cook Medical prosthetic implant appliances. Cook Medical is the sole manufacturer and distributor of the Cook Medical Products.

9. Any Other Facts Supporting this Justification: In the prosthetic implant industry, product selection is based on "physician preference/experience;" whereby, other factors that would normally affect the decision to purchase an item, such as price and delivery, are not considered when ordering. A physician's decision to use a particular manufacturer's implants is based on the technical characteristics of the implants that are expected to produce a higher quality of life for the patient or achieve certain therapeutic results. The use of a particular manufacturer's implants requires highly specialized training on the part of the physician. Once trained and comfortable with a particular manufacturer's implants, the physician will likely use that manufacturer's products for the duration of his career.

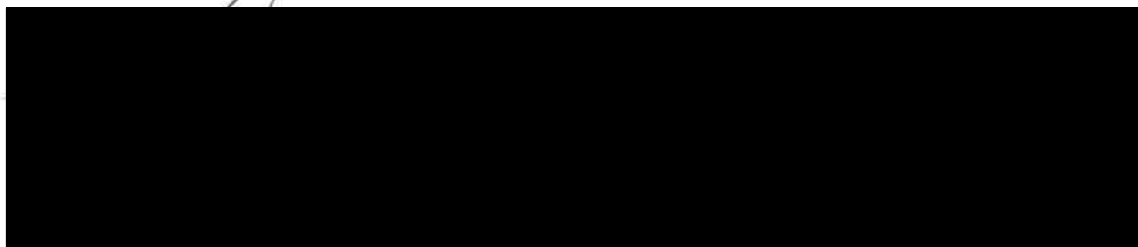
In addition to the implants used during surgeries, there are auxiliary products and/or instrumentation sets (such as drill bits, saw blades, bone cement, etc.) that are part of the "procedural package" necessary for implant surgery as well. The auxiliary products and/or instrumentation sets are used during surgeries and returned to Cook Medical after surgery. Payment is only rendered for products and/or instruments required for surgery. This arrangement allows the customer to forgo the capital expense of purchasing these instruments. The choice of purchasing any type of surgical instruments will be made by the individual VAMC.

There are no other manufactures or distributors other than Cook Medical who can provide VA hospitals with the complete "procedural package" for surgery with a representative available onsite, if needed, to answer questions on Cook Medical implant products. The Cook Medical sales representative is an expert on the vendor's product and is a vital part of helping to ensure that the patient is getting the necessary treatment.

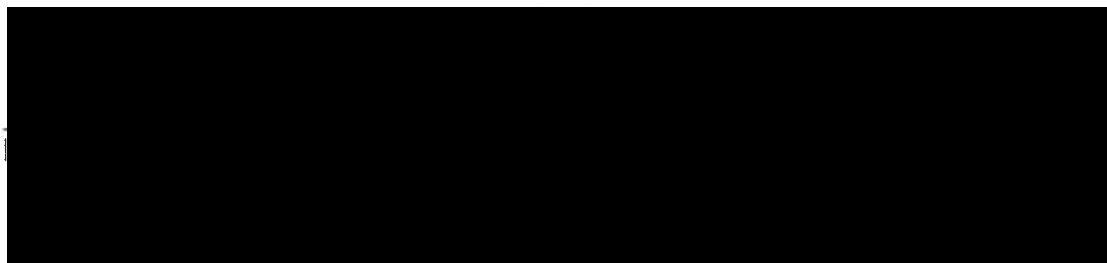
10. A Listing of the Sources, if any, that Expressed, in Writing, an Interest in the Acquisition: No sources expressed in writing an interest in this acquisition.

11. Actions to Increase Competition: At this time there are no other actions that can be taken to increase competition under authority 38 U.S.C. § 8123 and 41 U.S.C. 3304(a)(5). The requirement for Cook Medical, Inc., products and related services are based on physician determination of medical necessity and experience.

12. Technical and Requirements Certifications: I certify that the supporting data under my cognizance, which are included in this justification, are accurate and complete to the best of my knowledge.



13. Determination of Best Value/Procuring Contracting Officer Certification: I hereby determine that the proposed contract action is in the best interest of the agency and will be fair and reasonable based on the use of price evaluation techniques in accordance with FAR 15.404-1(b)(2). Additionally, I certify that this justification is accurate and complete to the best of my knowledge and belief.



Approval

Based on the foregoing justification, I hereby approve the acquisition of Prosthetic Implants Appliances, to Cook Medical LLC in the estimated amount of \$44,419,460.91, on an, other than full and open competition basis, pursuant to the statutory authority cited in paragraph 4 above, subject to availability of funds, and provided that the services and commodities herein described have otherwise been authorized for this acquisition.

