

## Justification for Other than Full and Open Competition

1. Contracting Activity: Department of Veterans Affairs (VA)  
Office of Acquisition Operations  
Strategic Acquisition Center (SAC)  
10300 Spotsylvania Avenue, Suite 400  
Fredericksburg, VA 22408
2. Description of the Action: The proposed action is for a firm-fixed-price Blanket Purchase Agreement to a single source, Cook Medical, Incorporated (Other than Small Business), 1025 W. Acuff Road 1025, Bloomington, IN 47404-9295. Veterans Health Administration (VHA) has 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 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 under "Just-In-Time (JIT)," "Direct Vendor Delivery (DVD)," and "Consignment" delivery methods.

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

Under the "DVD" method, MTF's may order product in advance of a scheduled surgery or purchase replacement inventory on an "as needed" basis. Under this method all items are packaged for shipment to the delivery point cited on the purchase order. Under the "Consignment" method, an MTF that uses a significant volume of Cook Medical "procedural packages" can request that the stent products be consigned to their facility. Under this method the respective contract vehicle will be used as an ordering method only.

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

The period of performance for this agreement will be for a base period of 1-year with four 1-year option periods. The estimated value of this acquisition is \$44,419,460.90. This estimate is based on 5 years of historical pricing and a vendor specific spend analysis for the required implants on a national basis with Cook Medical, Inc.

4. Statutory Authority: The statutory requirement to comply with 38 U.S.C. §§ 8127 – 8128 and implemented under VA Acquisition Regulation (VAAR) subpart 819.70, as a result of the June 16, 2016, decision of the U.S. Supreme Court in *Kingdomware Technologies, Inc. v. United States (Kingdomware)* has been addressed. Based upon the proprietary nature of these implants, two or more service-disabled Veteran-owned small businesses (SDVOSB) are not available. The statutory authority permitting other than full and open competition is 38 U.S.C. Section 8123 and 41 U.S.C. 253(c)(5) and implemented by the FAR 6.302-5(a)(2)(i) and VAAR 806.302-5(b)(1), Authorized by Statute.

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

6. Efforts to Obtain Competition: Utilizing the authority in 38 U.S.C. 8123 and 41 U.S.C. 253(c)(5), it is appropriate to award this acquisition to Cook Medical, Inc., 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 FedBizOpps on or around August 4, 2016. In addition, this justification will be published with the solicitation in accordance with FAR 6.305(c).

7. Determination of Fair and Reasonable Cost: As the Contracting Officer, I hereby determine that the anticipated cost to the Government will be fair and reasonable. The prices provided by Cook Medical will be compared to historical pricing of the previous contract actions and comparable prices on the commercial price list that was previously negotiated. A pre-negotiation price objective ranging from 5% - 20% will be utilized in that additional price discounts will be sought when negotiating the final price list prior to establishment of the agreement.

8. Market Research: Market research was conducted with implant manufacturers, and it revealed that each manufacturer's implants and surgical procedures are unique and proprietary. A physician's decision to use a particular manufacturer's implant is based on “physician determination of medical necessity/experience.” Using a particular manufacturer's orthopedic 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 product for the duration of their career. In addition, instrumentation sets and auxiliary products are distributed by the manufacturer since they are an essential part of the “procedural package” and required at the time of surgery. This provides the physician with all necessary products needed to complete the surgery.

9. Any Other Facts Supporting this Justification: A physician's decision to use a particular manufacturer's implants is based on the technical characteristics of the implant that is 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. In the prosthetic implant industry, product selection is based on "physician determination of medical necessity/experience;" whereby, other factors that would normally affect the decision to purchase an item, such as price and delivery, are not considered when ordering. Once trained and comfortable with a particular manufacturer's implants, the physician will likely use that manufacturer's products for the duration of their career.

In addition to the implants used during surgeries, there are auxiliary products and instrumentation sets (such as drill bits, saw blades, bone cement, etc.) that are a proprietary part of the "procedural package" since they are necessary for implant surgery. MTFs use the instrumentation sets during surgeries and return the instrumentation sets to Cook after surgery. This arrangement allows the customer to forgo the capital expense of purchasing these instruments.

Some MTFs purchase their instrumentation sets for various other implant surgeries so they are readily available on their shelves for emergency surgeries; however, purchase may not be prudent in all cases. The choice of purchasing any type surgical instruments will be made by the individual MTF.

There are auxiliary products (i.e. guide wire, bone cement, etc.) that are available from other sources; however, Cook distributes proprietary auxiliary products and instrumentation sets since they are essential for implantation of Cook implants and needed at the scheduled time of the surgery. These products are considered auxiliary to the overall cost of the acquisition but are an essential part of the "procedural package."

There are no other manufacturers or distributors other than Cook who can provide VA hospitals with the complete "procedural package" for surgery with a representative available onsite, if needed, to answer questions on Cook implant products. The Cook sales representatives are experts on the vendor's product and are 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: None

11. Actions to Increase Competition: At this time there are no other actions that can be taken to increase competition. The requirement for Cook Medical, Inc., products and related services are based on physician determination of medical necessity/experience.