

**JUSTIFICATION AND APPROVAL
FOR OTHER THAN FULL AND OPEN COMPETITION**

1. Contracting Activity: Department of Veterans Affairs (VA)
Office of Procurement, Acquisition and Logistics
Strategic Acquisition Center
10300 Spotsylvania Avenue, Suite 400
Fredericksburg, VA 22408

2. Description of Action: The proposed action is for a firm-fixed-price (FFP) Indefinite Delivery Indefinite Quantity (IDIQ) contract to a single source, Alcon Laboratories, Inc. (Alcon), (Large Business Manufacturer), 6201 S Freeway, TC-25 Fort Worth, TX 76134. Veterans Health Administration (VHA) has a need for Intraocular Lens (IOLs) implants based upon clinician's determination of medical necessity for use during medical or surgical services and/or procedures at the Veterans Affairs Medical Centers (VAMCs) throughout the United States and its territories. The objective is to streamline Veteran Affairs (VA) procurement of IOLs nationwide, ensure availability, and to enhance the quality of the care VA provides to Veterans while maximizing efficiency and government buying power. The estimated value of this acquisition is \$67,399,114.00 for a five year period.

3. Description of Supplies or Services: The proposed action is to acquire an array of (see table 1 and 2 below), IOLs such as Posterior and Anterior Chamber Lens to treat conditions such as visually significant cataracts, anisometropia, phacomorphic glaucoma, traumatic cataracts and/or anterior segment reconstruction and secondary IOL implantation in aphakia. Alcon is the sole manufacturer of following type of AcrySof® IOLs: Posterior Chamber Lens (Foldable Aspheric Design) with Chromophore (one piece), Transclerally Sutured Posterior Chamber Lens-All PMMA Material, Posterior Chamber Toric Lens (Foldable) with Chromophores (three pieces), and Posterior Chamber Lens (foldable aspheric design) with chromophores (three pieces) (see table 1 below). Additionally, Alcon has proprietary, trademarked IOLs which meet the minimum technical requirements (MTR) of this acquisition (see below table 2).

TABLE 1

IOLS SOLELY MANUFACTURED BY ALCON		
IOL Description	Alcon's Product	Part No.
Posterior Chamber Lens (Foldable Aspheric Design) with	AcrySof® IQ Monofocal IOL	SN60WF

Chromophore (one piece)		
Transclerally Sutured Posterior Chamber Lens-All PMMA Material	Single Piece PMMA IOLs	CZ70BD
Foldable Posterior Chamber Toric Lens with Chromophores	AcrySof® IQ Toric IOLs	SN6AT3, SN6AT4, SN6AT5, SN6AT6, SN6AT7, SN6AT8, SN6AT9
Posterior Chamber Lens (foldable aspheric design) w Chromophores (three pieces)	ACRYSOF® MultiPiece - Posterior Convex IOL & EXPAND®	MN60AC, MN60MA

TABLE 2

ALCON TRADEMARK IOL (MEET MTRS)		
IOL Description	Alcon's Product	Part No.
Posterior Chamber Lens (Foldable) Aspheric Design – One Piece	AcrySof® IQ Monofocal IOL	SN60WF
Posterior Chamber Lens (Foldable) Aspheric Design w/Chromophore – One Piece	UltraSert™ Pre-loaded IOL	AU00T0
Posterior Chamber Lens (Foldable) Aspheric Design w/Chromophore – One Piece	UltraSert™ Pre-loaded IOL	AU00T0 DEL SYS w/ SN60WF
Posterior Chamber Lens (Foldable) – Three Piece	ACRYSOF® MultiPiece - Posterior Convex IOL & EXPAND®	MA50BM
Posterior Chamber Lens (Foldable Aspheric Design) – Three Pieces	ACRYSOF® MultiPiece IOLs & ACRYSOF® MultiPiece - Posterior Convex IOL & EXPAND®	MN60AC, MN60MA
Anterior Chamber Lens – One Piece PMMA	Anterior-Chamber PMMA Single-Piece	MTA3U0, MTA4U0, MTA5U0
Posterior Chamber Lens (Foldable Micro-Incision Capability)	ACRYSOF® Single-Piece IOLs, ACRYSOF® IQ IOLS, AcrySof® IQ Toric IOLs, UltraSert™ Pre-loaded IOL	SA60WF, SN60WF, SN6AT3,4,5,6,7,8,9 AU00T0

These supplies will be delivered under “Just-In-Time (JIT)”, “Direct Vendor Delivery (DVD)” and “Consignment” delivery methods. The Contractor will be required to have a sufficient salesforce available for technical assistance and training. The Contractor will also be required to do technology refresh, item addition and deletion as IOLs become obsolete or recalled and new IOLs are developed.

Under the “JIT” delivery method, VAMCs will call the respective Alcon sales representative when surgery is scheduled to discuss the case, make a product selection from Alcon’s product line. VAMCs will then 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, VAMCs 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, a facility that uses a significant volume of Alcon procedural packages can request that prosthetic implant appliances be consigned to their facility. Under this method the respective contract vehicle will be used as an ordering method only. A Consignment Agreement will be established, in accordance with VHA Consignment Policy, between the local facility and Alcon to cover any loss or damage of the consigned inventory. The facility would pay only for the “procedural packages” that are used.

Rep Availability: The Contractor must have representatives that can be on-site at VAMC to provide technical assistance as needed. Representatives must be available to be on location to provide technical assistance within 10 – 15 days (scheduled) and telephone technical support for urgent inquiries within 1-2 hours.

Training: The Contractor must make available to the VA the same education material provided to their commercial customer e.g. practice materials/videos/manuals and frequency of training.

Technology Refresh: The contractor shall propose to the Government as stated below improved and/or replacement products within the contracted product line as appropriate new industry technologies emerge and/or products become obsolete during the term of the contract.

Further, the contractor shall ensure that all submissions offered are within scope and state-of-the-art. All improved and/or replacement products shall contain the manufacturer's commercial warranty.

Terminology is defined below:

"State-of-the-art" is defined as the most recently designed components approved by the Food and Drug Administration (FDA) and are announced for marketing purposes.

"Improved items" are defined as items that have qualities that simplify or improve a previous version or contain new and/or emergent technology.

"Replacement products" are defined as product(s) that replace another product(s) with the same functionality, but, will no longer be in production.

The contractor shall ensure that all improved and/or replacement products meet American with Disabilities Act (ADA) and Health Information Portability and Accountability Act (HIPAA) Federal requirements. The contractor shall ensure that all new submissions are approved in accordance with the pre-market notification under the FDA 510K process and labeled appropriately for IOLs.

The contractor shall submit the following information in writing to the CO, CS and COR for review and approval:

- (1) A complete modification request form (provided by the CS after award) includes a list of specific contracted item(s) and/or new submissions to be added in the Attachment 3 - Excel Price-Cost Schedule;
- (2) Product literature for the item(s);
- (3) A detailed description of the differences or benefits of products refreshed as compared to the item(s) being discontinued or added;
- (4) Proper identification of any product requirements and/or procedures related to those product(s) proposed;
- (5) FDA approval (if applicable);
- (6) Provide historical sales to VA by item(s) (if applicable), if applicable; and
- (7) Copy of commercial warranty; and a
- (8) Revised Product listing.

Additions: In addition to the IOLs Implants that are included in the initial award, the Government may add IOL Implants to the contract that meet the scope, outlined paragraph 3, and which are determined to have a fair and reasonable price. New additions will not be accepted during the 1st twelve months after contract award. The Contractor may request addition of new

IOLs Implants as outlined by the Contracting Officer. The Contracting Officer will make a scope determination prior to approving any modifications. Upon receipt of a complete package as outlined above, the CO will review the proposed new addition product(s), and, as deemed appropriate, consult with clinicians, the Prosthetics Sensory Aid Service (PSAS), and the Project Management Office (PMO). In addition, the contractor may be asked to give an oral presentation to support its proposed new addition products. The CO will make a scope determination, and, if appropriate, approve the inclusion of the proposed new addition products into the contract.

If the proposed new addition product(s) are approved for inclusion in the contract, the CO will conduct price negotiations with the contractor, if deemed necessary, and make a fair and reasonable price determination. Once the price of the proposed new addition product(s) are determined to be fair and reasonable, the new product(s) will be added to the contract via a bilateral modification.

Administration of Additions: Any requested additions must be approved by the Contracting Officer and PSAS before they may be offered under the contract. Additionally, other than cost or pricing data must be provided that supports the offered pricing. The items requested will go through the same evaluation procedures as items under the initial proposal evaluation. Approval of addition requests shall be implemented by issuance of a contract modification.

Deletions: At any time during the contract performance, the Government may elect to delete any item(s) at no cost to the Government. Also, at any point during contract performance the Contractor may submit a request to delete items from the contract based on the items being obsolete, unavailable, out of production or superseded. All deletions from the contract shall be at no cost to the Government.

This IDIQ contract will have a 5-year ordering period. The IGCE for this effort is \$67,399,114.00 for 5 years. The Independent Government Cost Estimate (IGCE) was derived from previous procurement history using an extrapolation of VA sales data from FY 2014-17 for IOLs procured by Veteran Affairs Medical Centers (VAMCs). The estimated price was derived from the 2017 sales price to the VA. Each year was escalated by 7% from the previous year. This escalation accounts for an anticipated 5% increase in quantity based on historical data as well as an anticipated increase in the Veteran population. The total estimated amount was escalated by an additional 2% to account for new products that could be added through the new add process.

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 48 Code of Federal Regulation (C.F.R.), Federal Acquisition Regulation

(FAR) § 6.302-5(a)(2)(i), Veterans Affairs Acquisition Regulation (VAAR) § 806.302-5(b)(1), Authorized by Statute. 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 Use of Authority Cited Above: The cited authority ensures the nationwide availability and consistency of IOLs so that clinicians have the flexibility, upon consultation with patients, to order appropriate implants with minimal interruption to the provision of individualized patient care. A specific implant determination is based upon the clinician assessments of the individual patient's medical needs and anatomy. As a result of the consultation between the clinician and patient, a determination is made as to the type and brand of implant required for favorable medical outcome of the patient. Clinicians also consider the patient level of comfort, preference, lifestyle, quality of life, and whether an IOL has been implanted in the other eye. This decision is also based on the clinician's training and experience utilizing the specified IOLs.

This consultation is important as it negates surgical risks during placement or removal of the prosthetic lens, prevents infections, and reduces implant failure risks. Based on a clinician's evaluation of patients' needs, the clinician or clinical team submits a request for brand name specific prosthetic implant that will achieve favorable treatment outcome for the individual patient. Every implant purchased from Alcon is based on the clinician's determination of the most clinically appropriate implant for the individual patient. Until a patient is in the operating room, the clinician is not always able to determine the exact implant to be inserted. Therefore, multiple implants may be ordered to deliver proper individualized patient care. Alcon provides and manufactures patented and/or trademarked implants that are unique to this company and are essential to patient care within VA. Alcon trademark prosthetic IOLs implants are proprietary and provided to the United States Government through direct sales.

6. Efforts to Obtain Competition: 38 U.S.C. § 8123 authorizes VA to obtain prosthetic appliances in such manner determined to be proper without regard to any other provision of law, including the full and open competition requirements of 41 U.S.C. § 3301, as implemented by FAR Part 6. Use of the authority conferred under 38 U.S.C. § 8123 streamlines VA's procurement of IOLs nationwide and ensures the availability of state of the art IOLs for the nation's Veterans. Accordingly, as authorized by 38 U.S.C. § 8123 and 41 U.S.C. § 3304(a)(5), it is appropriate to award this acquisition to Alcon, without regard to the competition requirements of 41 U.S.C. § 3301, as implemented by FAR Part 6. A notice of intent to sole source will be synopsisized on the Government Point of Entry (GPE) at

<http://www.fedbizopps.gov>. Any proposal received shall be consider and evaluated to determine if it is capable of meeting Agency needs.

7. Determination of Fair and Reasonable Cost: As the Contracting Officer, I hereby determine the anticipated cost of the Government will be fair and reasonable. Pricing will be evaluated in accordance with FAR 15.404-1(b)(2)(ii). The Government will compare the proposed prices to historical prices paid for the same or similar items by developing a "Target Price Range" as a valid basis for comparison. This "Target Price Range" will be based on VA sales data from FY 2014 to FY 2017 and will account for all differing (if any) terms and conditions of the acquisition, quantities, and market and economic factors. The contracting officer reserves the right to open discussions / hold negotiations with the contractor if its pricing falls outside of the "Target Price Range." Award will not be made unless a determination of fair and reasonable prices can be made.
8. Market Research: Market research revealed three capable sources could provide IOLs as outlined in the Government's requirement: Alcon, Bausch & Lomb, and Abbott Medical Optics (AMO). Alcon's patented, trademarked IOL implants are proprietary, and not available from another manufacturer in the commercial marketplace. Alcon also does not authorize distributors of their products. A clinician 's decision to use a particular manufacturer's implant is based on the " clinician 's determination of medical necessity, the experience of the clinician, and their expectation of specific treatment outcomes and patient care. "In conducting the market research products sources were reviewed in accordance FAR 8.002(a), Priorities for use of Government supply sources. The following sources were reviewed: agency inventory, excess from other agency, Federal Prison Industry, Procurement list, wholesale supply sources, GSA, National Acquisition Center (NAC) Contract Catalog Search Tool, Interagency Contract Directory, VIP Vetbiz, and an RFI was issued on Fedbizopps (FBO), and current Strategic Acquisition Contracts (SAC) on the National Strategic Source Listing (NSSL). AMO currently has a VA National contract for its IOLs, which does not expire until 11/30/2021. As such, the Strategic Acquisition Center will proceed to issue two (2) sole source IDIQ contracts - to Alcon and Bausch & Lomb respectively, to replace contracts (for proprietary intraocular lens products) that are set to expire on 6/28/2018.

Alcon has been determined to be a responsible source with respect to performance. The company is registered and certified in SAM with the NAICS code for this requirement. In addition, the Federal Awardee Performance and Integrity Information System (FAPIS) was reviewed and FAPIS shows no reports for Alcon that would indicate defective pricing, instances of contractor fault or recipient not-qualified, terminations for cause, default or material failure to comply, or non-responsibility of the contractor .

9. Other Facts: Alcon is only source for AcrySof® and other Alcon proprietary IOLs with chromosphere lens, which are lens that undergo a process that imparts a yellow tint to the lens. This an antiquated process, however, there are many Veterans that currently have a chromosphere lens in one eye. Clinicians prefer to have a chromophore lens in the fellow eye to prevent distortion of color or appearance.

Alcon is also the only source for AcrySof® and other Alcon proprietary IOLs with eyelets in the haptic, which is IOL design that provides an opening on the haptic of the IOL for ease when suturing. The eyelets permit sutures to be placed easily at symmetrical points. This design is used for complex procedures. In such procedure, the lack of the eyelets in the haptic could result complications such as: tilting, decentration, and inadvertent slippage of the sutures. To prevent complications, clinician s would utilize IOLs with eyelets in the haptic.

10. Listing of the Sources, if any that Expressed, in Writing, an Interest in the Acquisition: The following table shows all Contractors who responded in writing. The contracting officer has determined that the SDVOSB Contractors: Corps Medical Supply, 1st American Medical Distributors, and Veteran Health Medical Supply, are not capable of meeting requirements as stated in paragraph 3 above. AMO currently has a contract with the SAC which includes the IOLs utilized by VA. Additionally, the SAC anticipates awarding a sole source IDIQ contract to Bausch & Lomb.

Contractor	Bus Size	Manufacturer (M) or Distributor (D)
Alcon	Large	M
AMO	Large	M
Bausch & Lomb	Large	M
Corps Medical Supply	SDVOSB	D (AMO)
1 st American Medical Distributors	SDVOSB	D (B&L)
Veteran Health Medical Supply	SDVOSB	D (AMO)

11. Actions to Increase Competition: Currently, there are no actions that can be undertaken to increase competition. Clinicians have determined that Alcon's IOL implants are necessary to fulfill the Government's requirement. The Government will continue to conduct market research to ascertain if there are changes in the market place which clinicians determine are acceptable to enable future actions to be competed.

12. Technical and Requirements Certification: 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 and belief.

Signature: _____
Rodney Hickson
Deputy Program Manager
Prosthetic & Sensory Aids

Digitally signed by Rodney B Hickson 588545
Date: 2018.04.18 06:33:43 -04'00'

Date: _____

13. Procuring Contracting Officer Certification: I hereby determine that the proposed contract action will represent the best value to the Government and certify that the justification is accurate and complete to the best of my knowledge and belief.

Signature: _____
Joy Garrett-Bey
Contracting Officer

Digitally signed by Joy R. Garrett-Bey
1538064
Date: 2018.05.11 13:35:42 -04'00'

Date: _____

Approval

Based on the preceding justification, I hereby concur with the acquisition of Prosthetic Implants (IOLs) to Alcon in the estimated amount of \$67,399,114.00. Pursuant to the authority cited in 38 U.S.C. § 8123 and 41 U.S.C. § 3304(a)(5), as implemented by the FAR Subpart 6.302-5(a)(2)(i) and VAAR Subpart 806.302-5(b)(1), Authorized or Required by Statute, subject to availability of funds, and provided that the services and commodities herein described have otherwise been authorized for this acquisition.

Signature: _____ Date: _____

Elegear J. Primus
Head of Contracting Activity
Strategic Acquisition Center