

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: VA252-18-AP-5917

1. Contracting Activity:

Department of Veterans Affairs
VISN 12
Jesse Brown VA Medical Center
537-18-3-969-0288

2. Brief Description of Supplies/ Services required and the intended use/Estimated Amount:

The Surgical Service (Operating Room) Department at the Jesse Brown VA Medical Center located in Chicago, IL has the requirement for Vitrectomy and 3D Visualization Systems. This is a new requirement that will be pursued as a fixed firm price single source purchase order on the open market to a Veteran-Owned Small Business (VOSB) distributor utilizing the Veterans First Contracting Program IAW Public Law (PL) 109-461 which requires the Veterans Affairs (VA) to increase contracting and subcontracting opportunities for Service-Disabled Veteran-Owned Small Businesses (SDVOSBs) and VOSBs.

<u>Line Item</u>	<u>Item Number</u>	<u>Description</u>	<u>Qty</u>	<u>Unit</u>	<u>Unit Cost</u>	<u>Total Cost</u>
0001	8065751550	CONSTELLATION LXT	1	EA		
0002	8065752987	ALCON KEELER LIO HEADSET	1	EA		
0003	8065750888	CONSTELLATION FRAGMENTATION HP	2	EA		
0004	8065750469	INFINITI OZIL TORSIONAL PHACO HANDPIECE	2	EA		
0005	8065830001	NGENUITY 4K OLED SYS	1	EA		
Total Price:						

3. Unique characteristics that limit availability to only one source, with the reason no other supplies or services can be used:

The Surgical Service (Operating Room) Department at the Jesse Brown VA Medical Center located in Chicago, IL has the requirement for Vitrectomy and 3D Visualization Systems. The Ophthalmology Section of Surgical Service is requesting a replacement of its vitrector that is used in the Operating Room. This machine is used to perform procedures called vitrectomy, which is exclusively performed

by highly specialized, fellowship trained ophthalmologists who have performed a two-year vitreoretinal fellowship after completing a general ophthalmology residency program. The vitrector will be used solely within the Jesse Brown VA Medical Center operating room and may be located in any operating room which has an air supply and microscope.

Alcon Laboratories, Inc. is the only company that can provide 3D technology (NGENUITY system) for ophthalmic surgery and it is designed specifically to be used in conjunction with the Constellation system vitrector. No other companies have access to this technology. The NGENUITY 3D "heads-up" viewing system has been developed to assist vitreoretinal surgeons improve surgical outcomes and facilitate teaching. This new video system allows all participants of the surgical team to experience "the surgeon's view" that is typically afforded exclusively to the surgeon when he/she is viewing a stereoscopic image through the microscope binoculars. By allowing others to view the field, this results in more engagement, collaboration and teaching with the entire surgical team. The Constellation settings and menus are overlaid onto the viewing screen giving the surgeon real-time data as to the vitrector's settings and other vital diagnostic information. In addition, this system also assists anterior segment and cataract surgeons in teaching residents and fellows who may be staffing their cases. Veterans' outcomes and the staff's teaching mission will be best served with integrating the most comprehensive, complete and engaging teaching environment possible (3D stereoscopic viewing for all) for residents and surgical staff.

In addition to 3D viewing, the Alcon vitrector has a unique feature called "IOP-controlled infusion", which means the machine continuously monitors the intraocular pressure during vitrectomy surgery and continuously adjusts the infusion to maintain a constant intraocular pressure, despite the height of the patient in comparison to the machine. This allows for better control of intraocular pressure and improved flow through the cutter. Additionally, the Constellation continuously monitors the volume of fluid infused into the eye and has a 50-ml reservoir available when the infusion bottle empties. This is a great safety factor which give the nursing staff time to reload the bottle before it completely empties. Again, a competitive vitrector does not have this feature. The Alcon Constellation machine also has the capability of autonomously dispensing gas into a syringe which a competitive vitrector cannot perform. There are three significant advantages to this capability. First, the surgeon does not need to leave the surgical field to withdraw gas from the stock cylinder tank, and prepare the dilution him-/her-self. This will help reduce surgical time and reduce risk for operator error. Second, there is less risk of wasting gas as the machine precisely measures and flushes the tubing system to minimize waste and reduce operator error. Many times, a full tank may have been wasted (at \$1,250.00 per tank) because of failure to close the valve after use. With the machine dispensing the gas, it eliminates the potential for this costly error. Lastly, the Constellation offers the smallest gauge surgical instruments in the industry. The 27-gauge vitrectomy surgery offered by Alcon may eliminate the need for sutures in surgery, reduce healing time, and reduce patient discomfort. The smallest gauge of vitrector for a competitive product is 25-gauge.

Finally, the Jesse Brown VA Medical Center owns 1) the current Alcon Accurus vitrector; 2) an Alcon Infinity phacoemulsification surgical unit; and 3) an Alcon LenSx femtosecond laser. The Infinity and LenSx are used for anterior segment and cataract surgery. From a logistics, procurement, and business perspective, the transition from the Alcon Accurus to Constellation would be seamless for all parties. The transition to the Alcon Constellation would be most seamless as the Jesse Brown VA Medical Center affiliates (NMH and UIC), residents and fellows are most familiar with its programming, software, hardware, and set-up. The Alcon Constellation is the newest surgical

platform supported by Alcon, and as such would allow Veterans to be served by the latest, most cutting-edge technology on the market today.

4. Description of market research conducted and results or statement why it was not conducted:

The IGCE for this request is [REDACTED] and is therefore subject to the Non-Manufacturer Rule. The Non-Manufacturer Rule, whose threshold of \$150,000.00, allows a firm that is not a manufacturer to qualify as a small business on a supply contract set-aside for small business if it supplies the product of a small business made in the United States (15 USC § 637(a)(17); 13 CFR § 121.406). However, the NAICS code for this procurement is 339112 (Surgical and Medical Instrument Manufacturing) and the employee size standard is 1,000. The FSC is 6540 (Ophthalmic Instruments, Equipment, and Supplies). The NAICS code, NAICS Description, and FSC code are not listed on the Small Business Administration's Class Waiver List dated 1/1/2015. Therefore, a set-aside cannot be sought, including set-asides for VOSBs and SDVOSBs.

In addition to the Market Research and justification above, the Contracting Officer (CO) contacted the manufacturer, Alcon Laboratories, Inc., to determine if it uses and VOSBs or SDVOSBs to distribute its products and specifically the Constellation LXT and NGENUITY systems. The manufacturer replied indicating one VOSB.

It is determined this procurement will be fulfilled via open market single source to O.R. Elder, Inc. (DUNS: 068219476) utilizing the Veterans First Contracting Program IAW Public Law (PL) 109-461 which requires the Veterans Affairs (VA) to increase contracting and subcontracting opportunities for Service-Disabled Veteran-Owned Small Businesses and Veteran-Owned Small Businesses.

Purchase is approved pursuant to 38 U.S.C. 8127(b) and in accordance with VAAR 813.106-70(b)

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.*

Name: _____
Contracting Officer