

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: 36C776-19-AP-1750

Contracting Activity: Department of Veterans Affairs, Program Contracting Activity Central

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

Veteran Affairs Nebraska-Western Iowa Healthcare System (VANWIHS) has a requirement to purchase a Vitreoretinal Ophthalmic Surgical System with an authorized vendor to supply and deliver the item(s) identified below. The Estimated Amount of the requirement is [REDACTED]

| CLIN | Item Number | Item Description | Quantity |
|------|-------------|---|----------|
| 0001 | M5518-V | Alcon Constellation LXT / 8065753048 | 1 |
| 0002 | | Constellation Fragmentation HP / 8065750888 | 1 |
| 0003 | | Passive DR Filter / 8065751051 | 2 |
| 0004 | | Alcon Keeler LIO Headset / 8065752987 | 1 |
| 0005 | | Installation | 1 |
| 0006 | | Training | 1 |

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

Vitreotomy or vitreous surgery can treat a number of conditions. Surgery is indicated only when these 4 conditions are met:

- The findings are causing or threatening vision loss
- The severity of the condition or natural history make spontaneous or non-surgical healing unlikely
- The potential benefits outweigh the potential risks of surgery
- The patient understands the risks and benefits of treatment, as well as alternatives

The goals of surgery are:

- To treat the pathology (abnormal condition) causing visual loss
- To reduce the likelihood of recurrence
- To minimize the risk of complications

The Alcon CONSTELLATION Vision System is an ophthalmic microsurgical system that is indicated for both anterior segment (i.e., phacoemulsification and removal of cataracts) and posterior segment (i.e.,

vitreoretinal) ophthalmic surgery. The PUREPOINT Laser is indicated for use in photocoagulation of both anterior and posterior segments of the eye including:

- Retinal photocoagulation, panretinal photocoagulation and intravitreal endophotocoagulation of vascular and structural abnormalities of the retina and choroid including: Proliferative and nonproliferative retinopathy (including diabetic); choroidal neovascularization secondary to age-related macular degeneration; retinal tears and detachments; macular edema, retinopathy of prematurity; choroidal neovascularization; leaking microaneurysms.
- Iridotomy/Iridectomy for treatment of chronic/primary open angle glaucoma, acute angle closure glaucoma and refractory glaucoma.
- Trabeculoplasty for treatment of chronic/primary open angle glaucoma and refractory glaucoma.
- And other laser treatments including: internal sclerostomy; lattice degeneration; central and branch retinal vein occlusion; suturelysis; vascular and pigment skin lesions

The Alcon system 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 vitreoretinal system does not have this feature. The Alcon Constellation machine has the capability of autonomously dispensing gas into a syringe which a competitive vitrector cannot perform. There are three significant advantages to this capability:

- The surgeon does not need to leave the surgical field to withdraw gas from the stock cylinder tank, and prepare the dilution themselves. This will help reduce surgical time and reduce risk for operator error.
- 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 because of failure to close the valve after use. With the machine dispensing the gas, it eliminates the potential for this costly error.
- The Alcon Constellation system 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.

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

Medical Surgical Prime Vendor (MSPV) Contracts: A search was conducted on the National Acquisition Center’s MedSurg Catalog search located at <http://www.va.gov/nac/MedSurg/List> for a list of nationally awarded contractors and/or prime vendor contracts. The MSPV for Omaha is Kreisers, LLC. (<https://www.va.gov/opal/sac/mspvng.asp>) A search using Kreisers, LLC is not available. MSPV is not an appropriate source at this time.

SDVOSB/VOSB Sources via VetBiz (VIP): In Accordance with VAAR Subpart 819.7004, 819.7005, 819.7006 - <https://www.vip.vetbiz.va.gov/>. A search on Vetbiz.gov was conducted in an attempt to locate Service-Disabled-Veteran-Owned-Small-Business (SDVOSB) and Veteran-Owned-Small Business (VOSB) concerns utilizing NAICS code 339112 (this search provided 306 results). From these results, all vendors were contacted via email (Attachments Email - VIP). One (1) SDVOSB, O.R. Elder Inc responded as being able to meet this requirement and has been identified on the table below.

FBO Intent to Sole Source Notice - 36A77619Q0116: An Intent to Sole Source Notice was published to Federal Business Opportunities (FBO) on May 2, 2019 (Attachment – S03 - FBO – 36A77619Q0116). Zero (0) vendors responded as being able to meet this requirement.

Alcon Laboratories, Inc: Alcon Laboratories, Inc was contacted via email asking if they had authorized distributors. Alcon stated O.R. Elder, Inc (SDVOSB) is the designated authorized distributor to the VA. (Attachment – Alcon – Authorized Distributors).

Gray Market: Per VHA specific requirements set forth in VHAPM Part 813.106-1/2, the VHA aims to prevent the sale of “gray market goods,” defined as goods sold through unauthorized channels in direct competition with authorized distributors. This procurement is for new OEM medical supplies, medical equipment and/or services contracts for maintenance of medical equipment (i.e. replacement parts) for VA Medical Centers. No remanufactures or gray market items will be acceptable.

MARKET RESEARCH FINDINGS:

| Vendor | DUNS | Socioeconomic Category | Alcon Authorized Brand Name Distributor |
|-------------------------|-----------|------------------------|---|
| O.R. Elder, Inc | 068219476 | SDVOSB | Yes |
| Alcon Laboratories, Inc | 008018525 | Other than Small | OEM |

Contracting Officer's Certification: I hereby approve the acquisition of the items contained within this J&A 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.

