

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A)

For

Other Than Full and Open Competition (>\$150K)

1. **Contracting Activity:** Department of Veterans Affairs, VISN 1, Contracting Office proposes to enter into a contract on the basis of other than full and open competition on behalf of the VA Boston Healthcare System (VA BHS), Jamaica Plain campus.

2. **Nature and/or Description of the Action Being Processed:** This is an emergency order for the Jamaica Plain Surgical Service Eye Clinic to provide sustainment of care for the next three months. An older broken instrument was replaced by a Centurion Vision System. The new system is going online and clinical supplies are needed immediately to provide safe surgical care for OR patients. The requested clinical supplies are necessary to perform retina surgical procedures utilizing the Centurion Vision System at the VA BHS. This system is now being used "as a standard of care" for cataract surgery in tertiary referral centers such as VA BHS. The following disposable items are required for operation of the Centurion, manufactured by Alcon Laboratories, Inc. Due to the manufacturer's proprietary technology, the clinical supplies, also manufactured by Alcon are the only supplies that can be used with this instrument. This set up has been shown to have better intraoperative outcomes with less energy exposure to the eye. Implementation will improve patient recovery/outcomes, result in fewer side effects, better satisfaction, lower symptom recurrence rates, and reduction in operating room staff overtime costs due to faster operative procedures and faster recovery time compared to other technology for the same purpose. These clinical supplies are needed immediately in order to utilize the Centurion Vision System during OR procedures in order to avoid further delays to Veterans' care and allow the VA BHS the ability to perform these beneficial surgical procedures upon receipt.

3. Description of Supplies/Services Required to Meet the Agency's Needs:

REF#	DESCRIPTION	U/P	QTY REQUESTED
170.72	ULTRAFLOW 45 DEGREE ANGLED TIP 3MM	BX	18
337.84	25G BACKFLUSH	BX	2
337.92	25G PLUS PIC	BX	2
339.21	25G DIATHERMY PROBE	BX	10
617.92	20/25 GAUGE ADAPTER	BX	1
618.6	ASPHERIC MACULAR LENS	BX	2
65080094	BAG,BSS 500ML PLUS,CENTURION	BX	30
8065149530	25G SOFT TIP CANNULA	BX	10
8065183150	SOLUTION,OPHTHALMIC,VISCOELASTIC SYSTEM, DUOVISIC	BX	185

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8065741082	PACK,SURGICAL,ULTRASOUND INFINITY OPHTHALMIC,STERILE	BX	6
8065750157	KIT,VITRECTOMY,INFINITI,21GA,ANT,ACCURUS PROBE,STER	CS	12
8065750159	KIT,PHACO,SPARE PARTS,IRRIGATION SLEEVE TEST,0.9MM	BX	13
8065750837	23 GAUGE PROBE VIRECTOMY CONSTELLATION	BX	1
8065750917	TUBING,AUXILLIARY ASPIRATION	BX	2
8065750978	25G STRAIGHT LASER PROBE RFID	BX	2
8065750991	23GA STRAIGHT RFID LASER PROBE	BX	7
8065751014	CONSTELLATION AUTO GAS FILL	BX	8
8065751113	23G CURVED FLEXTIP RFID LASER PROBE	BX	7
8065751114	25G FLEX TIP LASER PROBE RFID	BX	6
8065751576	23G ILLUMINATED MEMBRANE PICK	BX	1
8065751577	ILLUMINATED CHANDELIER	BX	3
8065751586	25G VALVED 4MM CANNULA	BX	2
8065751593	25G ILLUMINATED LASER CURVED	BX	2
8065751657	KIT,VITRECTOMY,23 GAUGE,RETINAL, VALVED ENTRY	BX	2
8065751782	25G VALVED 6MM CANNULA	BX	2
8065751800	23G VALVED 6MM CANNULA	BX	1
8065752146	3.0MM POLYMER 1/A COAXIAL CONICAL CURVED TIP	BX	145
8065752918	ACTIVE IRRIGATION,FMS PACK,CENTURION	BX	10
8065912501	BLADE,OPHTHALMIC,MVR,25 GAUGE,FOR SMALL INCISIONS	BX	3
8065977757	HANDPIECE,IOL DELIVERY,FOR MONARCH II,A CARTRIDGES	BX	10
8065977758	MONARCH II IOL DELIVERY SYSTEM "B" CARTRIDGES	BX	10
8065977762	ALCON SURGICAL INC. MONARCH III C"CARTRIDGES	BX	95
8065977763	HANDPIECE,IOL DELIVERY,FOR MONARCH III,BLUE	BX	10
705.13P	FORCEPS,SURGICAL,GRIESHABER REVOLUTION	BX	2
705.43P	25G PLUS END GRASPING FORCEPS	BX	2
705.44P	25G PLUS ILM FORCEPS	BX	2

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705.45P	25G PLUS ASYMMETRICAL FORCEPS	BX	2
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Total Value:

4. Statutory Authority Permitting Other than Full and Open Competition:

- (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- (2) Unusual and Compelling Urgency per FAR 6.302-2;
- (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- (4) International Agreement per FAR 6.302-4
- (5) Authorized or Required by Statute FAR 6.302-5;
- (6) National Security per FAR 6.302-6;
- (7) Public Interest per FAR 6.302-7;

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

Alcon Laboratories Inc. clinical supplies are needed to be used in the Operating Room at the VA BHS Jamaica Plains campus with the Centurion Vision System to provide standardized care for Retina surgical patients. Due to the urgent need, the supplies needed for the Centurion Vision System must be procured from the manufacturer, Alcon Laboratories, Inc.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:

A search on the internet was conducted to determine possible vendors authorized to distribute and sell Alcon products. Although CCST and GSA were queried to identify any existing contracts that could meet the government's requirements, the clinical supplies are not available under those vehicles. Due to the immediate need for these clinical supplies, it is necessary to procure them directly from the manufacturer, Alcon Laboratories, Inc.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:

The Contracting Officer will determine that the anticipated price will be fair and reasonable based upon the fact that the pricing provided is the commercial price for these supplies and is consistent with informal quotes received as well as previous purchases.

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:

Market research was conducted to determine if sources could provide the clinical supplies for the Centurion Pack. Due to the urgent need for these supplies, it was determined to be in the best interest of the Government to obtain them directly from the manufacturer, Alcon Laboratories.

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9. Any Other Facts Supporting the Use of Other than Full and Open Competition:

Time and availability of product to be able to provide direct patient care is of the utmost importance in order to ensure Veterans ability to obtain these retina surgical procedures as soon as possible.

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

Alcon Laboratories, Inc. is the sole source provider of the Centurion System and the clinical supply disposables that are used with the system.

11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:

Additional market research will be conducted to determine if there are any small business dealers who can provide the disposable supplies for the Centurion Vision System.

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12. **Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

 Invalid signature

X Cheryl Hayes-Montville

Cheryl Hayes-Montville
Chief, Logistics
Signed by: vhaboshayesc

13.

Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP. This part is filled out by Contracting Staff as part of the Justification

a. **Contracting Officer's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Heather N.

Hampton 225727

Heather Hampton
Supervisor, Supply Branch South Chief
VAMC Manchester, NH

Digitally signed by Heather N. Hampton
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July 10, 2015

Date

b. **QA Review:**

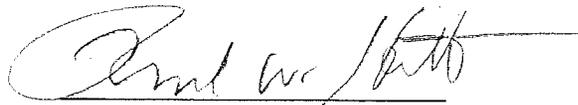
Gary W Dilk 231297

Gary Dilk
Procurement Analyst

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c. **Director of Contracting /Designee (Required \$150K and above):** I certify the justification meets requirements for other than full and open competition.



Ronald Hirtle
DIVISION CHIEF
NCO/PCO 1 Director of Contracting or Designee
VAMC Manchester, NH

Date

14 JUL 15