

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval (J&A)
For
Other Than Full and Open Competition (>\$150K)**

1. Contracting Activity:

Department of Veterans Affairs, Great Lakes Acquisition Center – Network Contracting Office 12
115 South 84th Street, Milwaukee, WI 53214

2. Nature and/or Description of the Action Being Processed:

2237#: 578-16-1-969-0053

To minimize the risk to our veterans and to continue positive outcomes with how the laryngoscope blade is maneuvered in the posterior pharynx and the epiglottis is manipulated to allow for successfully visualization of the glottis opening tracheal intubation, the Edward Hines, Jr. VA Medical Center is requesting the replacement and upgrade to their current GlideScope system. Additionally, this is an effort to standardize the facility and the VISN. A new firm-fixed price, open market contract will result from this SDVOSB sole source procurement.

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

Video laryngoscopy is a form of indirect laryngoscopy in which the clinician does not directly view the larynx. Instead, visualization of the larynx is performed with fiber optic or digital laryngoscope inserted transnasally or transorally.

The current units at the Hines VA Medical Center are no longer supported by the manufacturer. The facility is requesting to procure 17 GlideScope Titanium Systems with accessories. Additionally, the Hines VA requires Onsite Training (in Operating Room setting) with this procurement. Training of 32 clinical staff should be completed within 2 weeks.

Total contract value: \$394,325.00.

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

- (X) (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):

The GlideScope video laryngoscope (Verathon) has been designed for targeting difficult airway management. This indication was tested and found to be highly effective because the main issue, as expected, was the anterior location of the larynx placing this out of the direct laryngoscope line of sight view. The active physical heating of the viewing lens area enabled the device to resist fogging and bloody contamination. It is suggested using the video device in place of a direct laryngoscope in normal airway management because of the regular occurrence of failed laryngoscopy, which is defined as failure to visualize the glottis throughout the act of intubation well enough to execute the procedure with certainty. Failing to intubate and secure an airway is the number 1 cause of preventable anesthesia death.

The GlideScope Low Profile Video Laryngoscope Blades are the only device in the industry that is designed with a unique blade angle, for all patient sizes, specifically for difficult airway management

The GlideScope Titanium and Single Use Blades are the only blades in the industry that have same profile in both single use and reusable options, so this will accommodate staff familiarity in the outlying areas that do not have quick cleaning capability in ED/RT.

The design of these blades/accessories has improved durability with:

- Reusable (unique to GlideScope specifically):
 - One piece design (vs existing fleet has two molds sealed together)
 - Titanium material with stainless steel connector (vs plastic blade and plastic connector or stainless steel that can bend)
 - No cap is required for cleaning
 - Same profile as Single Use
- Single Use:
 - Cable with a titanium smart connector which connects into a single-use disposable blade
 - Video/Camera are integrated into the disposable blade
 - Meeting infection control standards as the whole blade and handle are discarded (vs just the blade portion)
 - Same profile as Reusable

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

Although Verathon is the sole manufacturer of GlideScope equipment, they have small business distributors. Verathon was able to provide a Woman-Owned Small Business and a Service-Disabled Veteran-Owned Small Business. The decision was made to procure this equipment through the Veterans First Contracting Program using 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.

An intent to sole source IAW FAR 6.302-1 - Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements and IAW Public Law (PL) 109-461 – Veterans First Contracting Program, was published to FBO.gov on 21 December 2015. Only one response was received, see number 10.

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

Prices will be determined fair and reasonable based on market research, comparison of the proposed prices with prices found reasonable on previous purchases via FBO.gov, and the Independent Government Estimate.

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

Sources: NAC MedSurg Catalog, GSA Advantage, FBO.gov, Manufacturer's Website, Customer Service Rep via Telephone

Market research indicates this exact item is not available on a mandatory NAC Contract (Schedule 65). There is no functionally equivalent videolaryngoscope available on NAC. Verathon is currently working with the National Acquisition Center to modify Verathon's existing FSS schedule to include this GlideScope.

This exact equipment is also not available on GSA Contract.

FBO.gov research yielded both sole source to Verathon and sole source to a WOSB results.

Upon contacting Verathon in regards to authorized distributors, Verathon was able to provide a letter stating Tosa Trio, LLC was their only authorized SDVOSB distributor to VISN 12.

Tosa Trio, LLC is registered with SBA and VetBiz as a SDVOSB under NAICS Code: 334510.

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

Hines VA is a leader in the VA in out of OR airway management. In 2014, Hines VA anesthesia staff performed 63% (86 out of 136) of non-OR intubation. Hines VA anesthesia staff used a GlideScope, 71 times (83% of total). Hines VA anesthesia staff had zero failures when using the GlideScope in 2014. In 2013, Hines VA anesthesia staffer performed 56% (98 out of 175). The GlideScope was used in 88% (86 out of 98) of these intubations.

In the OR, GlideScope videolaryngoscopy is used 50-75% of the time for endotracheal intubation. The anesthesia staff at Hines VA strongly believes the routine use of GlideScope video laryngoscopy allows for prompt and safe endotracheal intubation. The staff concur that the Hines VA routine use of GlideScope video laryngoscopy significantly improves patient safety regarding endotracheal intubation.

Additionally, by standardizing to these two products throughout the facility, not only will all accessories connect to the same monitor, but the end user will have the same experience if they use reusable or single use.

This is in the best value of the Government, because Hines VA Medical Center suites are stocked with Verathon GlideScope equipment. VHA Directive 2009-031 requires standardization. When compatibility of new equipment is required by existing equipment, only the compatible equipment can be obtained. It would not be cost effective for the government to replace all existing Verathon equipment for the sole purpose of purchasing a different brand of equipment, which would also exhaust a lot of time for re-training. It would also not be in the best interest of the government to maintain two different systems, as this leaves room for confusion and error. Purchasing compatible equipment allows staff to be better attentive to patient care. Hines VA Medical Center has had

tremendous success using the GlideScope for airway management. It is in the best interest of Hines VA and the Veterans we care for to continue using this specific product.

Furthermore, the other facilities within VISN 12 have been outfitted with GlideScope to expand standardization VISN-wide:

- William S. Middleton VAMC – Madison, WI
- Jesse Brown VAMC – Chicago, IL
- Capt. James A. Lovell FHCC - North Chicago, IL
- Oscar G. Johnson VAMC – Iron Mt, MI
- Clement J. Zablocki VAMC – Milwaukee, WI
- Tomah VAMC – Tomah, WI

Verathon is also providing a trade-in value of \$82,000.00 on existing, outdated equipment, if returned by 31 December 2015, for an overall award amount of \$327,873.00.

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

One response was received from a Woman-Owned Small-Business (WOSB) distributor of Verathon. Clarification was made regarding the Veterans First Contracting Program using Public Law (PL) 109-461 which requires the Veterans Affairs (VA) to increase contracting and subcontracting opportunities for Service Disabled Veteran-Owned Small Business and Veteran-Owned Small Businesses. WOSB information retained for future WOSB or SB set-aside procurements involving Verathon equipment.

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:

It is recommended that Verathon be contacted for a list of Small Business distributors for future GlideScope procurements.

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.

12/21/2015

Emi Cummings
Program Specialist – Surgery Service Line
Edward Hines Jr, VAH

Date

13. Approvals in accordance with the [VHAPM, Volume 6, Chapter VI: OFOC SOP](#).

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

12/21/2015

Alea Barnes
Branch Chief - Equipment

Date

Great Lakes Acquisition Center

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

Christine Hansen
NCO12 Director of Contracting
Great Lakes Acquisition Center

12/21/2015

Date