

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA250-16-AP-4338 / 541-16-4-703-2890

- Contracting Activity:** Department of Veterans Affairs, VISN 10, Louis Stokes Cleveland VA Medical Center
- Nature and/or Description of the Action Being Processed:**
VAMC Cleveland is requesting the Procurement of **Minimally Invasive Cardiac/Valve Surgery Instrumentation**. All instruments requested are listed below. Model numbers and vendors are given for cross reference purposes only. These devices will be used during intraoperative cardiothoracic procedures. We are requesting Open Market Sole source for these instruments since These instruments are used by all minimally invasive cardiothoracic surgery centers that VAMC Cleveland has been in contact with and have gone to visiting and training with. VHA Cleveland Cardiothoracic Surgeons have determined that these instruments provide superior quality for the specific procedures and techniques the medical center intends to use them for as they were adjusted to the purposes of the minimally invasive cardiac surgical procedures – specifically, mini- aortic and mitral valve repair and replacement.
- Description of Supplies/Services Required to Meet the Agency's Needs:**
Geister instrumentation is the only instrument that can supply instrumentation that has flush port through the entire instrument so that it can be properly cleaned in accordance with VHA Directive 1116.

Instrument manufacturer and model numbers are referenced below and must be NAME BRAND.

All items are specific to Geister based on the need to be utilized in highly detailed minimally invasive cardiac surgical procedures.

MODEL #	DESCRIPTION	MANUFACTURER
23-34118	MICS SHOVEL RETRACTOR-LARGE BLADE	GEISTER
23-38034	MICS SHOVEL RETRACTOR-SMALL BLADE	GEISTER
29-1396E2M	ValveGate Mini-Thoracotomy Retractor with hinged arms, 2x2 tubular blades 40 mm x 50 mm and 40 mm x 70 mm. Blades are Fenestrated. Retractor has tunable crossbar (Detachable) for accessories	GEISTER
34-7475	ValveGate™ Suture Catcher fine, 1.8 mm	GEISTER
34-7485	ValveGate™ Nerve Hook	GEISTER
34-7499B	ValveGate flushing adapter, w/snap holder	GEISTER
34-7800	ValveGate Needle Holder Straight w/catch TC 5mm shaft diameter, Standard working length 25cm	GEISTER
34-7800S	ValveGate needle holder str w/catach TC, 17 cm, 5 mm shaft diameter	GEISTER

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34-7802	ValveGate needle holder cvd w/ catch TC 5 mm shaft diameter, standard working length 25 cm	GEISTER
34-7802S	ValveGate Needle Holder cvd. W. catch tc, 17 cm 5mm shaft diameter	GEISTER
34-7806S	ValveGate Mini TC needle holder cvd w/ratchet, 17 cm, 5 mm shaft diameter	GEISTER
34-7824S	ValveGate resano valve grasping forceps, 17 cm 5 mm shaft diameter, strong, jaw for valves	GEISTER
34-7825	ValveGate DeBakey Tissue Fcps Wide 1 x 2 teeth, wide jaw, 2.8 x 11 mm, straight. 5 mm shaft diameter working length 25 cm	GEISTER
34-7825S	ValveGate DeBakey Tissue Fcps wide, 17 cm, 1 x 2 teeth, wide jaw, 2.8 x 11 mm, straight. 5 mm shaft diameter	GEISTER
34-7830S	ValveGate Scissors 15 degree, 17 cm, 5mm shaft diameter.	GEISTER
34-7851	ValveGate Knot pusher 25cm, push to open, short jaw 5 mm shaft diameter	GEISTER
38-7802S	ValveGate PRO Needle Holder Curved. TC w ratchet. 5mm shaft diameter. Standard working length 17 CM for minimally invasive valve surgery	GEISTER
38-7825S	ValveGate PRO DeBakey Tissue Forceps Wide. 1 x2 teeth, wide jaw, 2.8 x 11 mm straight. 5mm shaft diameter, standard working length 17 CM” for minimally invasive valve surgery	GEISTER
77-3605.US	Convertible Plastic Container, 2 levels w/ inserts	GEISTER
77-3620	ValveGate PRO system Tray Basket Container with Filter. Special Tray DIN with Filter to connect 8 instruments 480 x250 x 50 mm, with lid	GEISTER
V10142	Cygnets Aortic Cross Clamp 16 ½”, 66mm, Straight, w/sterilization tray. Rigid shaft enables tunneling and accurate clamp placement. Once properly positioned, the rigid shaft retracts leaving a flexible neck, which can be maneuvered to a location remote of the surgical procedure	GEISTER

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

41 USC §3304(a)(1), as implemented by FAR 6.302-1.

- (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):

a. **Only One Responsible Source (FAR 6.302-1)** – Geister instrumentation are the only instruments that have flush port through the entire instrument so that it can be properly cleaned in accordance with VHA Directive 1116 and National Program Office for Sterile Processing (NPOSP) requirements.

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

FSS and Open Market sources were reviewed. No surgical instruments made for this procedure are available on FSS/GSA. Geister was contacted and the manufacturer only has one US distributor, Vitalitec.

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

It has been determined that the anticipated cost the Government will be fair and reasonable based on prior purchases and the Independent Government Cost Estimate.

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

FSS and Open Market sources were reviewed. No surgical instruments made for this procedure are available on FSS/GSA. The only vendor that provides instrumentation that can be cleaned per National Program office for Sterile Processing (NPOSP) mandates and VHA Directive 1116 is the instrumentation manufactured by Geister and distributed by Vitalitec.

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

Valve Gate Pro line of instrumentation is completely made from surgical stainless steel without any plastic or Aluminum components. The adjustable jaw and handle open per user's preference with promotes less fatigue. The scissors within the set are designed to cut through the hardest calcified tissues while the needle holders firmly grasp and drive even the largest needles. These instruments promote ergonomics by allowing precise anastomosis suturing by finger turning and not by wrist bending. Instruments have a solid construction and have optimized surfaces for maximum durability, wear, and corrosion resistance. Each instrument is color coded for easier identification. Instruments have flush port through the entire instrument so that it can be properly cleaned in accordance with VHA Directive 1116 and National Program Office for Sterile Processing (NPOSP) requirements.

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

VITALITEC INTERNATIONAL INC (Small Business)
DUNS: 121464288 CAGE Code: 4QEK7
10 CORDAGE PK CIR STE 100
PLYMOUTH, MA, 02360-7318, UNITED STATES

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:

SPS continues to review the market for items that can be cleaned via NPOSP mandates and VHA Directive 1116. Once more come to market, these items will be considered.

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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.

Shawn P. Huelsman
Assistant Chief, SPS
Louis Stokes Cleveland VAMC

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

Christopher A. Callihan
Contracting Officer
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- b. **Director of Contracting /Designee (Required over\$150K but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

Connie A McKay
Branch Chief –Supply Team #2
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