

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: [REDACTED]

1. **Contracting Activity:** Department of Veterans Affairs, VISN 4, Corporal Michael J. Crescenzo VA Medical Center (CMC VAMC) located at 3900 Woodland Avenue, Philadelphia PA, 19140.

Purchase Request (VA2237): [REDACTED]

2. **Brief Description of Supplies/ Services required and the intended use/Estimated Amount:** The SAVI SCOUT system and all of its accessories, auxiliaries, and supplies are brand specific. New requirement (No refurbished products will be accepted). The system shall have the following specifications and features including but not limited to:

- System that utilizes a small reflector(s) and radar technology with insignificant MIR bloom that aids the surgeon(s) in locating target tissue during a lumpectomy or surgical biopsy procedure and allows for MRI surgical planning
- Ability to allow for long-term reflector placement and soft tissue use outside of the breast space
- Wire-free product to offer a 60mm detection range and 360 degree detection with +/- 1mm accuracy
- No RFID technology
- Key features of this system enable the providers to detect, localize, and identify the breast tumor(s)
- This is a new requirement that requires brand name only
- All Deliverables shall be delivered preferably within 30 days

Estimated Amount: \$89,395.00

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

IAW with FAR 6.302-1 The SAVI SCOUT® Wire-Free Radar Localization System is only available from one single supplier. Merit Medical Systems, Inc. is the sole manufacturer of the SAVI SCOUT® Wire-Free Radar Localization System, which includes the SCOUT® Console 2.5D and Guide and the SCOUT® Radiology Verification Console described in the Purchase Agreement (collectively, the “System”).

The SAVI SCOUT® System is a medical device that uses a small reflector and radar technology, with insignificant MRI bloom, that aids surgeons in locating target tissue during a lumpectomy or surgical biopsy procedure and allows for MRI surgical planning. Further, the System has been cleared by the U.S. Food and Drug Administration for long-term reflector placement and soft tissue use outside of the breast space.

There are no other surgical guidance systems that are both MRI-compatible and cleared for implantation for more than 30 days. Lastly, the System is the only wire-free product to offer a 60 mm detection range and 360° detection with ±1mm accuracy. Merit Medical owns all the proprietary rights to the System, including all its component parts. In regards to the acquisition, there is no need to compete this procurement among SDVOSBs and VOSBs to achieve a fair and reasonable price Per VA PPM 2016-05 (Revised August 2019) Implementation of the Veterans First Contracting Program.

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

The following market research analysis was conducted:

Vendor Information Pages (VIP): On February 1, 2022, the Contract Specialist searched VIP databases using search criteria, keywords “Savi Scout Console” and NAICS “339112” to determine if two or more verified service-disabled veteran-owned small business (SDVOBs) and veteran-owned small businesses (VOSBs) were available. 13 vendors were identified however zero can satisfy the agency’s needs. Due to the nature of this procurement, Merit Medical is the only manufacturer and sole distributor for this requirement.

Correspondence with the Merit Medical: Merit Medical owns all the proprietary rights to the System, including all its component parts. The SAVI SCOUT® System can be purchased through Merit Medical.

Request for Information (RFIs): On February 3, 2022, the Contract Specialist published the RFI 36C24422Q0255 to Contract Opportunities. As a result, the contracting activity received zero responses.

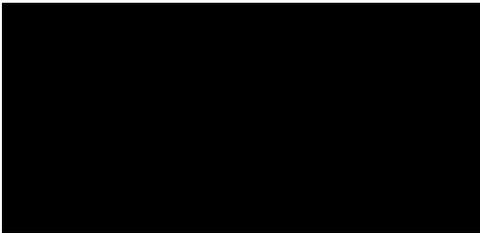
The Savi Scout Radar Localization System was not found on any VHA National Strategic Source Listing. A search on USASpending.gov displayed that prior purchases for the

VHAPG Part 813.106 Simplified Acquisition Procedures: Soliciting from a Single Source
Attachment 1: Single Source Justification for SAP under the SAT

Savi Scout system were open market and awarded to Merit Medical. The nonmanufacturer rule analysis demonstrated that the VA rule of two (for SD/VOSB set-asides) or the SBA rule of two (for Small Business set-asides) cannot be under this acquisition for manufactured products or other supply items.

Based on the Market Research Analysis, the acquisition strategy will be to award Merit Medical (Large Business) on a sole source basis IAW with FAR 6.302-1. This acquisition strategy is the most advantageous to the Government due to a reduced decision cycle and improved delivery of products.

- 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.*



Date