

DEPARTMENT OF VETERANS AFFAIRS

**Justification for Single Source Awards IAW [FAR 13.106-1](#)
For
Over Micro-Purchase Threshold but Not Exceeding the SAT (\$150K)**

Acquisition Plan Action ID: VA257-18-AP-3376

1. **Contracting Activity:** Department of Veterans Affairs, VISN 17, Network Contracting Activity is responsible for the proposed contracting action on behalf of South Texas Veterans Health Care Center, Audie L. Murphy VA Hospital, under purchase request 671-18-2-055-4694.
2. **Brief Description of Supplies/ Services required and the intended use/Estimated Amount:** The Surgical Service at the Audie L. Murphy VA Hospital is requesting a contract, on a sole source basis, to Covidien for the purchase of a VenaSeal System, 5-pack. The VenaSeal closure system is the only FDA-approved non-tumescent, non-thermal, non-sclerosant procedure that uses a proprietary medical adhesive delivered endovenously to close the vein. This unique approach eliminates the risk of nerve injury when treating the small saphenous vein, which is a risk sometimes associated with certain thermal-based procedures. Clinical studies have demonstrated that the procedure is safe and effective. The procedure is administered without the use of tumescent anesthesia, avoiding patient discomfort associated with multiple needle sticks. The estimated cost of this procurement is \$29,900.00 to \$37,375.00.
3. **Unique characteristics that limit availability to only one source, with the reason no other supplies or services can be used:** The VenaSeal closure system is the only FDA-approved product used to seal veins without the use of thermal ablation. There are no other vendors or distributors that can provide a product like Venaseal. Furthermore, correspondence revealed that this requirement can only be fulfilled by Covidien as they are the sole manufacturer and distributor for this product.
4. **Description of market research conducted and results or statement why it was not conducted:** Market research was conducted IAW VHAPM 810.001 utilizing keyword search of “venaseal”, under NAICS code 339113. Market research revealed 0 possible SDVOSB/VOSBs were returned from VIP (see Attachment 1) under the NAICS. There were 0 possible SDVOSB and 0 VOSB from the Dynamic Small Business Search (see Attachment 2). Therefore, a competitive set-aside is not possible for SDVOSB/VOSBS for this requirement.

Covidien DBA/Medtronic provided a sole source letter, dated 12/07/2017, that they were the Sole source manufacturer of the VenaSeal Closure System, and that this product is only available through them. There are no other items on the market that are FDA approved for office/ clinic use to treat diseased veins.

5. **Contracting Officer's Certification:** *Purchase is approved in accordance with FAR13.106-1(b). 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.*

VHAPM Part 813.106 Simplified Acquisition Procedures: Soliciting from a Single Source
Attachment 1: Single Source Justification for SAP under \$150K

Jon M. Parrocha
Contracting Officer

02/14/2018
Date