

Chapter VI: Other Than Full and Open Competition (OFOC) SOP
Attachment 4: Single Source Justification for SAP under \$150K

JUSTIFICATION FOR SINGLE SOURCE AWARDS IAW FAR 13.106-1
(OVER MICRO-PURCHASE THRESHOLD(\$3K) BUT NOT EXCEEDING THE SAT (\$150K))

IAW [FAR13.104](#), COs must promote competition to the maximum extent practicable to obtain supplies and services from the source whose offer is the most advantageous to the Government, considering the administrative cost of the purchase. When competition is not practicable, IAW [FAR13.106-1\(b\)](#), COs solicit from a single source for purchases not exceeding the simplified acquisition threshold. COs may solicit from one source if the CO determines that the circumstances of the contract action deem only one source reasonably available (e.g., urgency, exclusive licensing agreements, brand-name or industrial mobilization). IAW [FAR13.106-3\(b\)\(3\)](#), COs are required to include additional statements **explaining the absence of competition** (see [13.106-1](#) for brand name purchases) if only one source is solicited and the acquisition does not exceed the simplified acquisition threshold (does not apply to an acquisition of utility services available from only one source) or supporting the award decision if other than price-related factors were considered in selecting the supplier. This template when completed can be used to document single source awards IAW [FAR13.106-3\(b\)\(3\)](#). Note: Statements such as "only known source" or "only source which can meet the required delivery date" are inadequate to support a sole source purchase.

1. PURCHASE REQUEST OR REQUISITION NUMBER:

2237 (589-16-1-4802-0356)

**1A. PROJECT/TASK
NUMBER**

1B. ESTIMATED AMOUNT:

\$122,200.00

2. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES REQUIRED AND THE INTENDED USE:

This procurement is for (Medtronic) Drug Eluting Peripheral Balloons coated with Paclitaxel used for patient procedures, performed by the Interventional Cardiologist and Vascular Surgeons at the Wichita, KS Veterans Affairs Medical Center. The Balloons reopen arteries located in the upper leg, specifically the superficial femoral and popliteal arteries, when they have been narrowed or blocked by plaque. Once deployed in the artery, the balloon delivers a proven, safe and effective dose of the anti-restenotic drug paclitaxel to the artery walls. The drug aims to prevent the artery from narrowing again by minimizing scar tissue formation. This unique request is for immediate Drug Eluting Peripheral Balloons coated with Paclitaxel required for surgery and to replenish the GIP levels until the permanent Delivery Order Contract is established which will effectively support the Cardiovascular Lab for veteran patients surgeries once awarded. The items must be FDA approved for use in the superficial femoral and popliteal arteries. Medtronic is the sole manufacturer/distributor for these types of items required by the physician to use which helps prevent limb amputations and was determined cost effective for the VA.

3. UNIQUE CHARACTERISTICS THAT LIMIT AVAILABILITY TO ONLY ONE SOURCE, WITH THE REASON NO OTHER SUPPLIES OR SERVICES CAN BE USED:

Market research conducted concluded Medtronic is the only manufacture for this unique procurement and can only provide these Drug Eluting Peripheral Balloons coated with Paclitaxel. The Medtronic balloons come in lengths up to 120cm. Also, due to the exceptional proficiently level of the physician's success when treating patients with these items the physicians experienced no compromising incident. The use of these Drug Eluting Peripheral Balloons coated with Paclitaxel provide not only better outcome of surgeries but also decreases procedure time. When using these Drug Eluting Peripheral Balloons coated with Paclitaxel, the need for repeated procedures are greatly reduced, thus resulting in cost savings for the VA and prevent the patient from having to undergo multiple procedures for the same problem.

4. REASON THAT SUGGESTED SOURCE IS THE ONLY SOURCE, WHICH CAN PROVIDE THE SUPPLIES OR SERVICES:

Medtronic is the only manufacture and distributor for these Drug Eluting Peripheral Balloons coated with Paclitaxel requested for patient procedures and GIP that satisfy the requirements. Medtronic's balloons come in the longest lengths. They are coated with the FreePac™ coating solution, which is a proprietary coating with a nominal drug dose density of 3.5 µg of paclitaxel per mm2 of the expanded balloon surface. The FreePac™ coating contains a hydrophilic excipient (urea) which facilitates the release and transfer of the active pharmaceutical ingredient (paclitaxel) into the arterial vessel wall.

5. DESCRIPTION OF MARKET RESEARCH CONDUCTED AND RESULTS OR STATEMENT WHY IT WAS NOT CONDUCTED:

Market research was done, also past contracts was sole source and deemed pricing was deemed fair and reasonable.

6. 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.*

Signature: _____

Date: 26 Oct 15

Name: Donald Hannah
Title: Contracting Officer
Facility: Wichita, VAMC