

**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:**

589-15-3-4802-3405

**1A. PROJECT/TASK  
NUMBER**

N/A

**1B. ESTIMATED AMOUNT:**

\$96,145.50

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

Medtronic Drug Coated IN.PACT Peripheral Balloons.

These are drug coated balloons designed to 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.

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

The Medtronic balloons come in lengths up to 120cm. The excipient that is used on the Medtronic balloon is urea which is hydrophilic and naturally produced in the body and non-toxic. By reducing the need for repeat procedures, the device is also proving to be cost-effective. The Medtronic IN-PACT Balloon Catheter has the best data as evaluated by the Interventional Radiologist and the Cardiovascular Lab Manager in Wichita, KS.

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

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 mm<sup>2</sup> 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:**

A search was conducted on the NAC using the keywords "drug coated balloon" which displayed 70 results. However, they did not meet the requirements listed on the statement of work. A search was conducted on the GSA, SBA, and VetBiz websites using the keywords "balloon coated with paclitaxel" which displayed zero results. A search was conducted on the FPDS website using the keywords "drug coated balloon" which displayed 10 records. The Department of Veterans Affairs awarded all 10 contracts to Medtronic Inc, which is a large business. The Department of Veterans Affairs NCO 19 awarded all 10 contracts to Medtronic Inc, which is a large business. VA259-15-P-2395 and VA259-15-P-2850 were sole source awards.

**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: Yvonne B. Kittling  
902239

Digitally signed by Yvonne B. Kittling 902239  
DN: dc=gov, dc=va, ou=internal, ou=people,  
0.9.2342.19200300.100.1.1=yvonne.kittling@va.gov,  
cn=Yvonne B. Kittling 902239  
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Date: 5/6/2015

Name: Yvonne Kittling  
Title: Contracting Officer  
Facility: NCO 15