

DEPARTMENT OF VETERANS AFFAIRS

**Justification for Brand Name Awards IAW [FAR 13.106-1](#)
For
Over Micro-Purchase Threshold but Not Exceeding the SAT (\$250K)**

Acquisition Plan Action ID: [36C248-18-AP-3985](#)

1. Contracting Activity: Department of Veterans Affairs, VISN 08, Orlando VA Healthcare System

Department of Veteran Affairs
Orlando VA Healthcare System
13800 Veterans Way
Orlando, Florida 32827

675-18-4-2205-0125

2. Brief Description of Supplies/ Services required and the intended use/Estimated Amount:

The Graftmaster RX Coronary Stents System is necessary for percutaneous coronary artery interventions. The equipment is imperative to the treatment of obstructive coronary artery disease as well as the day to day operations of a cardiac catheterization lab. The surgical procedure will limit free perforations, defined as free contrast extravasation into the membrane enclosing the heart (pericardium) in native coronary vessels or saphenous vein bypass grafts that are less than or equal to 2.75 mm in diameter. The fully functioning catheterization lab is an integral service to the functioning of our hospital and the delay in our ability to perform coronary interventions will further delay the increase in complexity of our surgical service, inpatient hospital, and emergency room.

Cost: \$43, 110.00

- 1012581-16 Graftmaster Coronary Stent Graft System 3.50mm x 16mm/Rapid-Exchange
- 1012582-26 Graftmaster Coronary Stent Graft System 4.00mm x 26mm/Rapid-Exchange
- 1012582-16 Graftmaster Coronary Stent Graft System 4.00mm x 16mm/Rapid-Exchange
- 1012581-26 Graftmaster Coronary Stent Graft System 3.50mm x 26mm/Rapid-Exchange
- 1012582-26 Graftmaster Coronary Stent Graft System 3.50mm x 26mm/Rapid-Exchange
- 1012581-26 Graftmaster Coronary Stent Graft System 3.50mm x 26mm/Rapid-Exchange

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

The Graftmaster RX Coronary Stent System is proprietary to Abbott Laboratories Inc. Not all the Equipment is interchangeable or equivalent. Graftmaster RX Coronary Stents are regulated and approved for commercial use by USFDA under a Humanitarian Device Exception. The Graftmaster RX Coronary Stent Graft System is composed of the following:

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

- Stent Material; Stainless Steel 316L
- Graft Material; Expandable Polytetrafluoroethylene (ePTFE) sandwiched between two Identical stents
- Double Wall Thickness (mm); 0.52
- Balloon Material; Semi Compliant
- Shaft Size (F); 2.0 – 2.7
- Minimum Deployment Pressure (ATM); 16
- Minimum Guide Wire (in); 0.014
- Usable Length (cm); 143
- Maximum Stent Graft Expansion (mm); 5.5
- Minimum Guide Catheter (in)/F; 0.068/less than or equal to 6/7
- Crimped Stent Profile (in); 0.064, 0.068
- Tip Entry Profile; 0.024
- Average Crossing Profile (in); 0.064, 0.068

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

No market research was conducted by the service. In calling Abbott Laboratories Inc, they stated that the following vendors were authorized distributors; Marathon Medical, and Veterans Healthcare Supply Solutions. Searches were conducted on the following; GSA eLibrary/Advantage, and SAC. The items were not found, which was verified by Abbott Representative. Mr. Joseph also indicated that all items would be shipped directly from Abbott's Warehouse. VIP search was conducted using keyword search for Graftmaster Coronary Stents. Beacon Medical Group Inc. was the only vendor that showed under that search. E-mail was sent for market research purposes. No response was received. In searching FPDS, Abbott was the only listed vendor to have sold the product under 25K between 2012 – 2018. Based on the above market research, will post FBO as SDVOSB Set-Aside using LPTA and J&A Brand Name.

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.*

Debra Matthews
Contracting Officer

09-18-2018

Date