

**DEPARTMENT OF VETERANS AFFAIRS**

**Class - Justification and Approval (J&A)  
For  
Other Than Full and Open Competition (>\$150K)**

**VA260-15-AP-3697**

**1. Contracting Activity:**

Department of Veterans Affairs, VISN 20  
NCO 20 Contracting  
Prosthetics Procurement Team  
5115 NE 82<sup>nd</sup> Ave, Vancouver WA 98662

Contract Specialist: Darren Campbell  
360-852-9853  
Darren.campbell2@va.gov

**2. Nature and/or Description of the Action Being Processed:**

The Prosthetics department of VISN 20 has an immediate need for blanket purchase / consignment agreement with Abbott Vascular who supplies implantable medical stents that are not available from any mandatory sources or on any National Use Contracts.

Blanket Purchase Agreement with consignment and Just-In-Time (JIT) language will be established with the vendor who provides the items prescribed by VA Clinicians, and paid for with Prosthetic Funds. The term of this consignment will be for a one year period.

**3. Description of Supplies/Services Required to Meet the Agency's Needs:**

The Contractor shall deliver the Abbott Vascular Stents to the VA Portland Health Care System's Interventional Radiology Laboratory 100-2d-118 located at 3710 SW U.S. Veterans Hospital Road, Portland, Oregon under a Purchase Order. These stents are;

- Balloon and self-expanding stent system
- Cobalt Chromium stents
- Multi-link design
- Strong and highly flexible stents that conforms to tortuous anatomies
- Indicated for treatment of atherosclerotic iliac artery lesions
- Indicated for reference vessel diameters greater than or equal to 5.0mm and less than or equal to 11mm and lengths up to 50mm.
- FDA approved for the superficial femoral artery
- Indicated to improve luminal diameter in the treatment of patients with symptomatic de novo or restenotic native lesions or occlusions of the SFA and/or proximal popliteal artery.
- indicated for superficial femoral artery vessels diameters of 4,0 to 6,5 mm and lesion lengths up to 140mm.

Vendor: Abbott Vascular  
 3650 Mansell Rd.  
 Alpharetta, GA 30022  
 800-227-9902

**Proposed Consigned Inventory List – Peripheral & Carotid Intervention items (Stents)**

<b>Abbott Vascular Stent Consignment List – Portland VA Medical Center – Account #27253</b>					
Product	Size	Catalog Number	Quantity	Cost Ea.	Extended Cost
<b>OMNILINK ELITE VASCULAR .035 80cm Catheter Length</b>					
Omnilink elite	6x12x80	1012622-12	2	\$1,100.00	\$2,200.00
Omnilink elite	6x16x80	1012622-16	2	\$1,100.00	\$2,200.00
Omnilink elite	6x19x80	1012622-19	2	\$1,100.00	\$2,200.00
Omnilink elite	6x29x80	1012622-29	2	\$1,100.00	\$2,200.00
Omnilink elite	6x39x80	1012622-39	2	\$1,100.00	\$2,200.00
Omnilink elite	6x59x80	1012622-59	2	\$1,100.00	\$2,200.00
Omnilink elite	7x12x80	1012623-12	2	\$1,100.00	\$2,200.00
Omnilink elite	7x16x80	1012623-16	2	\$1,100.00	\$2,200.00
Omnilink elite	7x19x80	1012623-19	2	\$1,100.00	\$2,200.00
Omnilink elite	7x29x80	1012623-29	2	\$1,100.00	\$2,200.00
Omnilink elite	7x39x80	1012623-39	2	\$1,100.00	\$2,200.00
Omnilink elite	7x59x80	1012623-59	2	\$1,100.00	\$2,200.00
Omnilink elite	8x19x80	1012624-19	2	\$1,100.00	\$2,200.00
Omnilink elite	8x29x80	1012624-29	2	\$1,100.00	\$2,200.00
Omnilink elite	8x39x80	1012624-39	2	\$1,100.00	\$2,200.00
Omnilink elite	8x59x80	1012624-59	2	\$1,100.00	\$2,200.00
Omnilink elite	9x19x80	1012625-29	2	\$1,100.00	\$2,200.00
Omnilink elite	9x29x80	1012625-29	2	\$1,100.00	\$2,200.00
Omnilink elite	9x39x80	1012625-39	2	\$1,100.00	\$2,200.00
Omnilink elite	9x59x80	1012625-59	2	\$1,100.00	\$2,200.00
Omnilink elite	10x19x80	1012626-29		\$1,100.00	
Omnilink elite	10x29x80	1012626-29	2	\$1,100.00	\$2,200.00
Omnilink elite	10x39x80	1012626-39	2	\$1,100.00	\$2,200.00
Omnilink elite	10x59x80	1012626-59	2	\$1,100.00	\$2,200.00
<b>Total # of OMNILINK ELITE 80cm</b>			<b>46</b>		<b>\$50,600.00</b>
<b>OMNILINK ELITE VASCULAR .035 135cm Catheter Length</b>					
Omnilink elite	6x12x135	1012629-12			
Omnilink elite	6x16x135	1012629-16			
Omnilink elite	6x19x135	1012629-19			
Omnilink elite	6x29x135	1012629-29			
Omnilink elite	6x39x135	1012629-39			
Omnilink elite	6x59x135	1012629-59			

Omnilink elite	7x12x135	1012630-12			
Omnilink elite	7x16x135	1012630-16			
Omnilink elite	7x19x135	1012630-19			
Omnilink elite	7x29x135	1012630-29			
Omnilink elite	7x39x135	1012630-39			
Omnilink elite	7x59x135	1012630-59			
Omnilink elite	8x19x135	1012631-19	2	\$1,100.00	\$2,200.00
Omnilink elite	8x29x135	1012631-29	2	\$1,100.00	\$2,200.00
Omnilink elite	8x39x135	1012631-39		\$1,100.00	
Omnilink elite	8x59x135	1012631-59		\$1,100.00	
Omnilink elite	9x19x135	1012632-19	2	\$1,100.00	\$2,200.00
Omnilink elite	9x29x135	1012632-29	2	\$1,100.00	\$2,200.00
Omnilink elite	9x39x135	1012632-39		\$1,100.00	
Omnilink elite	9x59x135	1012632-59		\$1,100.00	
Omnilink elite	10x19x80	1012626-19		\$1,100.00	
Omnilink elite	10x29x80	1012626-29		\$1,100.00	
Omnilink elite	10x39x80	1012626-39		\$1,100.00	
Omnilink elite	10x59x80	1012626-59		\$1,100.00	
<b>Total # of OMNILINK ELITE 135cm</b>			<b>8</b>		<b>\$17,600.00</b>
<b>SUPERA PERIPHERAL STENT SYSTEM</b>					
Supera Peripheral stent	4.5x20x120	s-45-020-120-p6		\$1,750.00	
Supera Peripheral stent	4.5x30x120	s-45-030-120-p6		\$1,750.00	
Supera Peripheral stent	4.5x40x120	S-45-040-120-P6		\$1,750.00	
Supera Peripheral stent	4.5x60x120	s-45-060-120-p6		\$1,750.00	
Supera Peripheral stent	4.5x80x120	s-45-080-120-p6	3	\$1,750.00	\$5,250.00
Supera Peripheral stent	4.5x100x120	s-45-100-120-p6	3	\$1,750.00	\$5,250.00
Supera Peripheral stent	4.5x120x120	s-45-120-120-p6	3	\$1,750.00	\$5,250.00
Supera Peripheral stent	5.5x20x120	s-55-020-120-p6		\$1,750.00	
Supera Peripheral stent	5.5x30x120	s-55-030-120-p6		\$1,750.00	
Supera Peripheral stent	5.5x40x120	s-55-040-120-p6		\$1,750.00	
Supera Peripheral stent	5.5x60x120	s-55-060-120-p6		\$1,750.00	
Supera Peripheral stent	5.5x80x120	s-55-080-120-p6	3	\$1,750.00	\$5,250.00
Supera Peripheral stent	5.5x100x120	s-55-100-120-p6	3	\$1,750.00	\$5,250.00
Supera Peripheral stent	5.5x120x120	s-55-120-120-p6	3	\$1,750.00	\$5,250.00
Supera Peripheral stent	5.5x150x120	s-55-150-120-p6	3	\$1,750.00	\$5,250.00
Supera Peripheral stent	6.5x20x120	s-65-20-120-p6		\$1,750.00	
Supera Peripheral stent	6.5x30x120	s-65-30-120-p6		\$1,750.00	
Supera Peripheral stent	6.5x40x120	s-65-40-120-p6		\$1,750.00	
Supera Peripheral stent	6.5x60x120	s-65-60-120-p6		\$1,750.00	
Supera Peripheral stent	6.5x80x120	s-65-80-120-p6	2	\$1,750.00	\$3,500.00
Supera Peripheral stent	6.5x100x120	s-65-100-120-p6	2	\$1,750.00	\$3,500.00

Supera Peripheral stent	6.5x120x120	s-65-120-120-p6	2	\$1,750.00	\$3,500.00
Supera Peripheral stent	6.5x150x120	s-65-150-120-p6		\$1,750.00	
<b>Total # of Supera Peripheral Stents</b>			<b>27</b>		<b>\$47,250.00</b>
<b>Total # of Consigned Items</b>			<b>81</b>	<b>Replacement Value</b>	<b>\$115,450.00</b>

Peripheral & Carotid Intervention items (Stents) from the proposed vendor are not available on their Multi VISN BOA, VA797N-D-004 or their NAC Contract, V797D-40222. The total replacement cost for all proposed consigned items is \$115,450.00. The annual spend for these items, per the IGCE is \$210k for the Portland VAMC over the life of an agreement. All individual purchases are under micro and paid by Government purchase card using Prosthetics funds.

Vendor pricing is based on establish VA discounted prices.

#### **4. Statutory Authority Permitting Other than Full and Open Competition:**

(38 U.S.C. 8123) The Secretary may procure prosthetic appliances and necessary services required in the fitting, supplying, and training and use of prosthetic appliances by purchase, manufacture, contract, or in such other manner as the Secretary may determine to be proper, without regard to any other provision of law.

- ( ) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- ( ) (2) Unusual and Compelling Urgency per FAR 6.302-2;
- ( ) (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- ( ) (4) International Agreement per FAR 6.302-4
- (X) (5) Authorized or Required by Statute FAR 6.302-5;
- ( ) (6) National Security per FAR 6.302-6;
- ( ) (7) Public Interest per FAR 6.302-7;

IAW with VHA Directive 1081, the authority for this J&A is; FAR 6.302-5, VAAR 806.302-5(b)(1): Authorized or required by statute (38 U.S.C. Section 8123): These prosthetic items/sensory aids are not available for purchase on an existing contract and will be purchased on an open-market basis because the patient's medical need cannot be met through the use of a required source of supply or service and there is medical justification to support the need.

#### **5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):**

The purpose of establishing blanket purchase agreements for consigned or Just-In-Time (JIT) inventory is to prevent the use of unusual and compelling urgency justifications for these items the VISN 20 facilities use on a daily basis for surgical procedures. The proposed vendor on this J&A has an FSS and/or National use Contracts for many of their commonly used items and more specifically,

items designated for Prosthetics use. This justification is for those unique items that are not on their mandatory use contract but still prescribed and used by VISN 20 Clinicians for surgical procedures.

The 8123 authority is specific to Prosthetics and all of these items are implantable surgical devices prescribed by a Clinician to meet the immediate need of a patient, assigned HCPCS code under the Center for Medicare & Medicaid Services and paid for by government purchase cards using Prosthetics fund control points. Any failure to meet that need may result in physical injury to the patient, medical liability to the agency and would adversely impact the mission and objective of VHA.

The purpose of the resulting Blanket Purchase Agreements for consignments is to provide advance planning by ensuring the devices are immediately available for use when needed and prevent unauthorized commitments leading to ratifications.

**6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:**

Due to the uniqueness of the items listed in this J&A, the NCO has requested that the facility Chief responsible for prescribing these items, inform the Contracting Officer of which supplies they wish to have on consignment and/or Just in Time agreements. The Contracting Officer provided the Clinicians with a list of all known and available vendors and their contracted items. Informing the facilities of what is currently available on contract from mandatory sources is the best way for the NCO can ensure offers will be solicited from potential mandatory sources. This is applicable rational used by the NAC in establishing National Use Contracts IAW FAR Part 16.505(b)(2)(i)(A) & (i)(B). Beyond providing the Clinicians with the information there is little the NCO can do to promote competition for Physician Preference Items. There are limited number of vendors capable of supplying these specialized devices, all are known to the Clinicians and the Prosthetics Procurement Teams and therefore, the function of soliciting sources would not provide a benefit to the acquisition.

This action will be synopsized with an intent to sole source IAW FAR Part 13.105 and FAR Part 5.201.

**7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:**

The proposed Contractor has established pricing for the Department of Veterans Affairs. As verified by the Vendor, the catalog pricing for the Supera product is \$2,995 each and \$2,095 for the Omnilink. The pricing to the VA is \$1,750.00 for the Supera which realizes a 42% discount off catalog prices and the cost for the Omnilink to the VA is \$1,100.00 or a 50% discount. The CO has confirmed that the proper HCPCS code for these stents is; C1876. After review in IFCAP for the procurement history of this code, it shows we have paid as much as the catalog list price from this vendor on several purchases. The pricing offered by the vendor are bases on a consignment basis and not on any type of volume or usage commitment. By having this consignment agreement in place it will ensure a consistent discounted price with an average of 46% savings over the life of the agreement for these specialized Interventional Radiology Stents. It is the CO's determination that a discount of 42% for Supera and 50% for Omnilink is fair and reasonable thus making this agreement to be in the best interest of the Government.

**8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:**

As the Contract Specialist, I conducted extensive market research to determine that the items listed in this J&A are not available from contracted sources. This research was primarily conducted by researching the NAC catalog of the vendors contracted items. It also required personal contact with NAC Contracting Officers as well as the Vendor's contract POC's The Clinicians who desire to have these items on hand and the program office who request them rarely know if it's on contract.

The results of this research clearly shows that these types of items are very specialized, researched and developed by few companies, marketed and sold directly to the facilities through company sales representatives to be used by Clinicians who are either trained specifically in their applications or through experience determine they are the best for their procedures and therefore satisfy the agencies need.

**9. Any Other Facts Supporting the Use of Other than Full and Open Competition:**

No other facts are needed to support this

**10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**

Abbott Vascular  
3650 Mansell Rd. STE 200  
Alpharetta, GA 30022  
Local Rep: Pete Schoen (503) 709-1695

**11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:**

Cardiovascular surgery and interventional cardiology devices are considered high-cost and high-quality medical devices and frequently referred to as physician preference items (PPI's). The Medical Centers rely on the expertise and judgment of their clinicians to prescribe the devices they need for patient care and contracting cannot direct or influence their decision therefore, the devices outlined in this J&A would be considered physicians preference items.

According to an article located in the VA Medical Center Library, there are three principal avenues for the VA Medical Center's purchasing departments to deal with PPIs. The first is to limit the number of vendors for each class of device and then to negotiate on the basis of volume discounts. This is the least optimal choice because it limits the number of vendors thus reducing competition, and hence the willingness to discount prices. The second avenue permits all device firms to sell to the hospital (that is, permits all device sales representatives access to the operating rooms) but imposes a price cap on each class of device, regardless of vendor. This strategy avoids interference with physicians' preferences but risks having the sales representatives substitute low-function for high-function devices. The third avenue is to negotiate a percentage discount off unit prices for all of the devices and associated hardware from each vendor (Robinson, 2008).

Clearly all three approaches have plus and minuses and often the VA uses the latter however one of the ominous barriers to having all vendors participate is the logistics involved in consigning every vendors products within the facility. Furthermore, contracting will always seek discounts and the discounts suppliers are willing to offer are generally based on the volume of devices the facilities use and the relationships established.

Reference: Robinson, J.C. (2008, November). Value-Based Purchasing For Medical Devices. *Health Affairs*, 27(6), 1523-1531. Retrieved from <http://content.healthaffairs.org/content/27/6/1523.full#abstract-1>

- 12. Requirements Certification:** 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.

_____ Name Dr. Lee Hall Title Chief Interventional Radiology Facility Portland VAHCS	_____ 06/04/2015 Date
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**13. Approvals in accordance with the [VHAPM, Volume 6, Chapter VI: OFOC SOP](#).**

- a. **Contracting Officer's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

_____ for Darren Campbell Contract Specialist NCO 20 Contracting	_____ 6/04/2015 Date
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- b. **Director of Contracting /Designee (Required \$150K and above):** I certify the justification meets requirements for other than full and open competition.

_____ Nicholas M. Jenkins Director of Contracting Network COntacting Office 20	_____ 6/8/2015 Date
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