

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition (>\$150K to \$650K)

VA260-16-A-0054

1. Contracting Activity:

Department of Veterans Affairs, VISN 20
NCO 20 Contracting
Prosthetics Procurement Team
5115 NE 82nd 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 Bard Peripheral Vascular, Inc. who supplies Lutonix drug-coated balloon catheters as implantable medical devices 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.

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

The Contractor shall deliver the Lutonix drug-coated balloon catheters to the VA Puget Sound Health Care System's Interventional Radiology Division Building 100- room 2d117 located at 1660 S. Columbia Way, Seattle Washington 98108, under a no cost purchase order. The devices are used in surgical procedures when deemed necessary by the attending VA Clinicians.

4. Proposed Consigned Inventory List – Bio-inductive rotator cuff kits

Product	Size	Catalog Number	PAR Level
Bard Lutonix Balloon	.035 130cm 4x40	LX35130440	1
Bard Lutonix Balloon	.035 130cm4x60	LX35130460	1
Bard Lutonix Balloon	.035 130cm4x80	LX35130480	1
Bard Lutonix Balloon	.035 130cm 4x100	LX351304100	1
Bard Lutonix Balloon	.035 130cm4x120	LX351304120	
Bard Lutonix Balloon	.035 130cm4x150	LX351304150	
Bard Lutonix Balloon	.035 130cm5x40	LX35130540	1
Bard Lutonix Balloon	.035 130cm 5x60	LX35130560	1
Bard Lutonix Balloon	.035 130cm5x80	LX35130580	1
Bard Lutonix Balloon	.035 130cm5x100	LX351305100	1
Bard Lutonix Balloon	.035 130cm5x120	LX351305120	
Bard Lutonix Balloon	.035 130cm5x150	LX351305150	
Bard Lutonix Balloon	.035 130cm6x40	LX35130640	1
Bard Lutonix Balloon	.035 130cm 6x60	LX35130660	1
Bard Lutonix Balloon	.035 130cm6x80	LX35130680	1
Bard Lutonix Balloon	.035 130cm6x100	LX351306100	
Bard Lutonix Balloon	.035 130cm6x120	LX351306120	
Bard Lutonix Balloon	.035 130cm6x150	LX351306150	
Bard Lutonix Balloon	.035 130cm7x40	LX35130740	1
Bard Lutonix Balloon	.035 130cm7x60	LX35130760	1
Total Number of Inventory Items			13

These non-biological balloon catheters from the proposed vendor are not available from mandatory sources such as FSS or National Use Contracts. The total replacement cost for all proposed consigned items is \$23,400.00. The estimated spend for these items; per the IGCE is \$222,980.00 over the life of the agreement. All individual purchases will be made using the clinical consult process and sent to appropriate NCO 20 contracting department for purchase to replace the used inventory. Payment will be made with the Government purchase card using Prosthetics funds.

5. 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 41 U.S.C. 3304(a)(5) and 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 where there is medical justification to support the need.

**Medical justification is supported in the consult placed by the VA clinician.*

REFERENCES:

- a. 38 U.S.C. Section 8123.
- b. VHA Directive 1081, March 25, 2014
- c. VHA Directive 1173, Prosthetic and Sensory Aids Service.
- d. VHA Handbook 1173.1, Eligibility.
- e. VHA Procurement Manual, Revision 04: 10/07/2015

6. 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 does not have an FSS and/or National use Contracts with the Government for these specific items which are used for surgical implant procedures. This justification is for these unique items that are not available on mandatory use contract or from mandatory sources but will be 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 or VA specific codes and paid for by government purchase cards using prosthetics funds. 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 Agreement for consignment of stock is to provide advance planning by ensuring the devices are immediately available for use when needed and prevent unauthorized commitments leading to ratifications.

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

Bard's Lutonix Catheters are drug coated balloon PTA catheters indicated for improving luminal diameter for the treatment of obstructive de novo or non-stented restenotic lesions in native femoropopliteal arteries.

Due to the uniqueness of the items being requested, establishing a sole source consignment agreement is the only appropriate method in order to obtain the inventory needed for surgical procedures. Because these items are proprietary and only sold by the company through local representatives, the function of soliciting sources would not provide a benefit to the acquisition.

In accordance with FAR 5.202, the contract actions in 806.302-5 do not require synopsising.

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

Through negotiations for another station agreement, the contractor has agreed to offer a discount off their list price for these catheters. The discount ranges from 10% to 15% depending on size. By having this consignment agreement in place it will ensure a consistent discounted savings over the life of the agreement and eliminate unauthorized commitments for these specialized catheters.

It is the CO's determination that a discount offered to the VA is fair and reasonable thus making this agreement to be in the best interest of the Government.

9. 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 market research to determine that the items listed in this J&A are not available from contracted sources. The contractor confirmed they do not have these items available on any government contract and further research, primarily conducted using the NAC Med/Surg catalog and the GSA eLibrary confirmed that these products can only be purchased through Bard Peripheral Vascular on the open market.

In accordance with FAR 5.202, the contract actions in 806.302-5 do not require synopsising.

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

No other facts are needed to support this

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

Bard Peripheral Vascular, Inc.
Wade Nedved
Northwest District Manager
303-718-1471
Wade.Nedved@crbard.com

12. 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:

Bard's Lutonix Catheters are drug coated balloon PTA catheters indicated for improving luminal diameter for the treatment of obstructive de novo or non-stented restenotic lesions in native femoropopliteal arteries.

This type of medical device is considered high-cost and high-quality 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).

In this case, Bard's has a proprietary technology and by their own omission, there are no other medical device companies small or disadvantaged that can provide this specific surgical device. Therefore, the optimal option was to negotiate a discount with the Bard who is the only vendor capable of providing the Lutonix Catheters to the VA. Until such time as other companies develop and make available this type of technology, Bard Peripheral Vascular, Inc. is the only vendor capable of supplying these items which are a sole source physician preference item in the truest sense of the term.

In accordance with FAR 5.202, the contract actions in 806.302-5 do not require synopsis.

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>

- 13. 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.
(This signature is the requestor's supervisor, fund control point official, chief of service, someone with responsibility and accountability)

Teri Kautzman
Radiology Technician
VAPSHCS

Date

- 14. Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP.** *This part if filled out by Contracting Staff as part of the Justification*

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

Darren Campbell
Contract Specialist
NCO 20 Contracting (Prosthetics)

Date

- a. **Director of Contracting/Designee (Required >\$150K to \$650K):** I certify the justification meets requirements for other than full and open competition.

Stacia M. Nunn
Chief, Division 2 Contracting
Network Contracting Office 20 (NCO 20)

Date:

May 24, 2016