DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval
For
Other Than Full and Open Competition

1. **Contracting Activity:** The agency responsible for this acquisition is: The Department of Veterans Affairs, VISN 21, VANCHCS, 150 Muir Road, Martinez, CA 94553. The Contracting Officer for this procurement is Angela Oppenheimer. The Department of Veteran Affairs proposes to enter into a contract on the basis of other than full and open competition for [redacted]. Purchase Request Number is 654-12-1-133-0660. Flair Stents for the Reno VA

2. **Nature and/or Description of the Action Being Processed:** This is a new procurement and the contract contemplated will be firm fixed price to Bard Peripheral Vascular, P. O. Box 1740, Tempe, AZ 85281.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The procurement is to provide the only endovascular flair stent graft currently approved by the FDA for the VASNHCS Cath Lab at a cost of $26,495.00.

4. **Statutory Authority Permitting Other than Full and Open Competition:** 41 USC §253(c) (1), as implemented by FAR 6.302.1

   (X) (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
   ( ) (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;

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 contractor, Bard Peripheral Vascular, is currently the only FDA-approved maker of endovascular FLAIR stents in the U.S. market. These stents are used in fistulas and will increase the life of certain fistulas. According to the FDA's website under "Recently-Approved Devices", "FLAIR Endovascular Stent Graft – P060002)":

   > The FLAIR Endovascular Stent Graft is used to treat a stenosis, a narrowing or blockage, which has developed at the connection of a vein and an arteriovenous (A-V) access graft, known as the venous anastomosis. An A-V access graft acts as an artificial blood vessel that can be used repeatedly to draw blood with a needle during hemodialysis. The FLAIR Endovascular Stent Graft is a flexible, self-expanding tube made of a ePTFE (expanded polytetrafluoroethylene) and a metallic support structure known as a stent, which holds the device open within the vein and A-V access graft. The stent graft is compressed into the end of a long, thin, tube-like device called a delivery catheter so that it can be implanted in the body. The Bard FLAIR Endovascular Stent Graft is the first endovascular system approved to treat a stenosis at the venous anastomoses of an A-V access graft.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable** No additional effort was made to solicit other sources for these stents. Based on market research, Bard is the only maker of stents producing a fluted stent for A-V fistula work.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The FLAIR endovascular stent is used instead of two other treatment options (balloon

angioplasty alone to open the narrowed segment or blockage in the A-V access graft; or surgery to remove the blockage.) The FLAIR stent graft maintains the patency of dialysis access grafts more effectively than balloon angioplasty alone and is the only implant approved by the U.S. FDA for use in the treatment of stenoses at the venous anastomosis of ePTFE or other synthetic arteriovenous access grafts. Since the FLAIR stent is unique, it does not currently have a direct competitor in the market that makes a comparable endovascular stent graft that is also FDA-approved. However, pricing of FLAIR stents are comparable to other types of stents used in various other cardiovascular surgical procedures.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** FAR Part 10 directs that market research be conducted on each acquisition appropriate to the circumstances. Market research was conducted and is filed in the eCMS briefcase under P02.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** The FLAIR Endovascular Stent Graft is used after balloon inflation is performed to open the narrowed segment in the A-V access graft. The delivery catheter containing the endovascular graft is inserted into the A-V access graft and placed across the narrowed segment that has just been opened with the balloon. The endovascular graft is then released and self-expands so that it is pressing against the A-V access and blood vessel to keep the area open. The FLAIR Endovascular Stent Graft can be used to support or hold open a narrowed or blocked area at the connection of the A-V access graft and natural blood vessel. The FLAIR endovascular stents are used instead of two other treatment options: 1) balloon angioplasty alone to open the narrowed segment or blockage in the A-V access graft; or 2) surgery to remove the blockage. Use of the FLAIR Endovascular Stent Graft will restore blood flow at the venous anastomosis of an A-V access graft and keep the area open longer compared to treatment with balloon angioplasty alone.

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

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:** Bard is the only vendor that makes this type of product. However, for future orders, the market will be scanned for consideration of other FDA-approved competitors.

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.

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Recommend for Approval,

Angela M Oppenheimer — 4/24/12

ANGELA OPPENHEIMER
Contracting Officer

Date

Approved / Disapproved,

D Neal — 4/24/12

DON NEAL
Supply Team Manager

Date