

DETERMINATION OF LIMITATION OF SOURCES

1. CONTRACTING ACTIVITY:

Department of Veterans Affairs, Network Contracting Office - NCO 21.

2. DESCRIPTION OF ACTION:

This action limits competition for the acquisition of Impella Set 2.5. The Impella Set 2.5 is a unique percutaneous cardiac assist device that allows the safe performance of high-risk cardiac procedures. Abiomed Inc is the only vendor that makes the Impella devices.

3. DESCRIPTION OF SUPPLIES/SERVICES:

Abiomed Inc is the only supplier of this item that safe performance of high-risk cardiac procedures. Impella can provide, without the need for trans-septal puncture and large bore venous cannulas, a level of support for the left ventricle that is unmatched by anything else on the market at 2.5 liters of forward flow per minute. An intra-aortic balloon pump cannot provide comparable hemodynamic support. Tandem heart is somewhat comparable, but requires large venous cannulas, trans-septal puncture and cannulation, and a larger team of trained personnel. The VA does not have those resources available.

The VA employ's Impella both for extremely high risk patients who are too sick to get CABG surgery and PCI (stenting) without Impella would be too high risk as well. Impella in these cases can make the case safe and the VA has had numerous success stories using it in this mode. The VA has also used it as a salvage device to try to salvage the life of patients who are with ongoing cardiac arrest or shock due to acute heart failure. No other available device can provide the level of support required for this with comparable speed except ECMO, which requires a perfusion team and a dedicated cardiopulmonary bypass circuit.

4. AUTHORITY CITED:

FAR 13.106(b)(1), only one source is reasonably available because the item is manufactured by Abiomed Inc.

5. REASON FOR AUTHORITY CITED:

The authority cited in paragraph 4 must be used because Abiomed Inc. is the only supplier of the Impella. The Impella can provide a level of support for the left ventricle that is unmatched by anything else on the market at 2.5 liters of forward flow per minute.

6. EFFORTS MADE FOR SOLICITING FROM OTHER VENDORS:

Synopsis is not required in accordance with FAR 5.101(a)(1) in that the proposed contract action is below the threshold.

FAR 6.305 (d) (1) The justifications shall be made publically available at the Government Point of Entry (GPE) www.fedbizopps.gov; must remain for a minimum of 30 days.

7. FAIR AND REASONABLE COST DETERMINATION:

The Contracting Officer has determined that the anticipated price will be determined to be fair and reasonable. A Price Negotiation Memorandum (PNM) will detail how the Government has determined that the anticipated costs will be fair and reasonable.

As this item has been determined to be commercial, cost or pricing data will not be required. Pricing techniques such as described in FAR 15.404-1 (b)(2), will be used to establish price fairness and reasonableness.

8. MARKET RESEARCH:

Market Research was conducted by searching and reviewing FBO, FPDS, and eCMS. It was determined that this product is only available from one source Abiomed Inc and no other suppliers will satisfy agency requirements. The GSA website was also reviewed for existing vendors that provided the stated requirements. It was determined that the product was not available on GSA.

9. SUPPORTING FACTS:

Abiomed Inc. is the only vendor that can supply the Impella Set 2.5.

Any supporting data that is the responsibility of technical or requirements personnel (*e.g.*, verifying the Government's minimum needs or requirements or other rationale for limited sources) and which form a basis for the justification have been certified as complete and accurate by the technical or requirements personnel. The evidence for this is the "Technical Data to Support a Restricted Competition" in the contract file.

10. LISTING OF SOURCES:

Abiomed Inc
22 Cherry Hill Dr.
Danvers, MA 01923-2575
Mr. Joseph Narcisse (925) 548-3666

11. STATEMENT OF ACTIONS:

The justification will be made publicly available at the GPE. Any contractors with a similar product can contract the Contracting Specialist for more information.

12. CONTRACTING OFFICER CERTIFICATION:

I hereby certify that this justification is accurate and complete to the best of my knowledge and belief.

Jaime Kelley
Contract Specialist

12/10/2012
Date

Recommend: Approval / Disapproval

Claire Ursino

Claire Ursino
Contracting Officer

12-10-12

Date