

DEPARTMENT OF VETERANS AFFAIRS
Justification and Approval
For
Other Than Full and Open Competition
MEDRAD Angiojet Ultra Thrombectomy System

1. **Contracting Activity:** Department of Veterans Affairs, Great Lakes Acquisition Center, NCO 12, 115 S. 84th Street, Milwaukee, WI 53214 on behalf of Jesse Brown VA Hospital, 820 S. Damen Avenue, Chicago, IL 60612. This is a justification for other than full and open competition. The purchase request number is 537-12-3-969-0255.
2. **Nature and/or Description of the Action Being Processed:** Justification and approval for other than full and open competition for a one-time buy of MEDRAD Angiojet Ultra Thrombectomy System that jets high speed saline to create a negative pressure zone to extract clots in the heart vessels, on a sole source basis to MEDRAD Interventional, Inc.

Thrombectomy is the removal of a thrombus from a blood vessel, performed as emergency surgery to restore circulation to the affected part. Anticoagulant therapy may begin before surgery. An arteriogram is done to locate the thrombus. During surgery a longitudinal incision is made into the blood vessel, and the clot is removed. After surgery the blood pressure is maintained close to its preoperative level because a decrease would predispose to further clotting.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The Angiojet Ultra Thrombectomy System consists of a highly maneuverable, clean set-up prompts and a fast system preparation time.
 - Patented Cross-stream technology for enhanced thrombus removal
 - Full range of catheters for coronary, peripheral and AV access applications
 - Advanced control system the automates set-up and monitors operation
 - System self configures for each catheter model
 - Automates the set-up of Power Pulse delivery

The Ultra Thrombectomy System is manufactured and distributed by MEDRAD Interventional, Inc. The estimated cost of the system is \$31277.61.

4. **Statutory Authority Permitting Other than Full and Open Competition:** This instrument is being procured under the authority of FAR 6.302-1, 41 U.S.C. 253(c) (1). Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements.
5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):**
Thrombectomy is the surgical removal of a blood clot (thrombus) from a blood vessel. The unique characteristic that differentiates, the MEDRAD, AngioJet Ultra Thrombectomy System is the only FDA-cleared endovascular treatment option that actually removes a thrombus associated with DVT from the body. This procedure quickly restores blood flow and resolves symptoms within minutes. MEDRAD Interventional's intellectual property position makes it unlikely that competitive products will be offered through other sources. It would not be practical or cost effective to purchase other than the recommended Ultra Thrombectomy System in order to meet VA mission requirements. AngioJet is a trademark of MEDRAD, Inc.

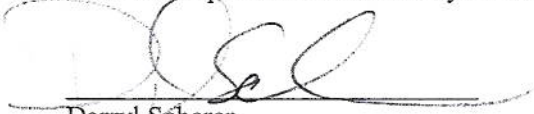
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Market research indicates the Angiojet Ultra Thrombectomy System is distributed exclusively by MEDRAD Interventional, Inc. The manufacture does not maintain a third party distribution system in the United States.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** MEDRAD Interventional, Inc. lists the system publically at \$31,277.61 and have sold to other VA's at that price (Kansas: VA2551210215, South Carolina: VA247-12-Q-0427 and Arizona: VA25610RQ0258).
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** An Internet search of Thrombectomy revealed MEDRAD Interventional as the only source. Researched Angiojet and Thrombectomy and found four FEDBIZ postings all sole sourced to MEDRAD. Researched GSA E-Library with no results. Researched Small Business Administration (SBA) using the NAICS code 334510, found 1273 matching profiles, refined search criteria with NAICS code and keyword Thrombectomy with no results. Researched SBA NAICS code and the keyword of Angiojet with no results. Researched SBA for the keyword of Thrombectomy with no results. Vetbiz had no results with keyword Thrombectomy.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** None
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** No other vendors exist for the Angiojet Ultra Thrombectomy System.
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:**
The VA Cardiology department will continue to monitor technology to provide the best and state-of-the-art thrombectomy treatments available.
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.


Bernadette Speiser
Cardiology
Jesse Brown VA Hospital

8-21-12
Date

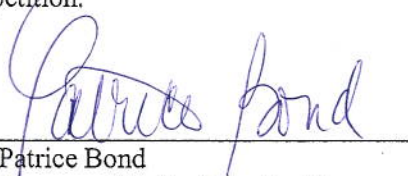
13. **Approvals in accordance with FAR 6.304**

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


Darryl Scherer
Contracting Officer
NCO 12

8-21-2012
Date

- b. **Team Manager:** I certify the justification meets requirements for other than full and open competition.

A handwritten signature in blue ink, appearing to read "Patrice Bond", is written over a horizontal line.

Patrice Bond
Manager, Medical Sharing Team
NCO 12

8/21/2012

Date