

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA257-17-AP-10434

- 1. Contracting Activity:** Department of Veterans Affairs, Network Contracting Office 17, Dallas VA Medical Center – Nuclear Medicine.
- 2. Nature and/or Description of the Action Being Processed:** The Nuclear Medicine is requesting a new firm-fixed price contract for the purchase of Sir-Spheres Y90 Resin microspheres. This product is to ensure that we have Y-90 resin microspheres are available for Selective Internal Radiation Therapy (SIRT) for the treatment of liver tumors.
- 3. Description of Supplies/Services Required to Meet the Agency's Needs:**
Bead embolization product. Yellow Label Color, Size 100-3001Jm, Volume 2mL beads. The beads must be able to be combined with cancer- killing chemotherapeutic agents and then delivered to the blood vessels.

Part Number	Description	Unit Issue	Quantity	Unit Cost	Extended Cost
SIR-Y001	SIR S-Spheres Microspheres(included is one delivery set, one vial, one vial holder and shipping	EA	10	\$16,000.00	\$160,000.00
Total:					\$160,000.00

The total estimated cost of the procurement is \$160,000.00 per the Independent Government Cost Estimate provided by the requesting service.

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

(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):

SIR-Spheres are a highly specialized source. The SIRT procedure enables high doses of radiation to be targeted to liver tumors by using the tumor's blood supply. Healthy liver tissue derives up to 90% of its blood supply from the portal vein with only a small amount of the blood supply being derived from the hepatic artery. In contrast, liver tumors derive up to 90% of their blood supply from the hepatic artery since they need a profuse supply of highly oxygenated blood.

The hepatic artery therefore provides an ideal channel to deliver targeted treatment to the tumor. SIR-Spheres® Y-90 resin microspheres consist of biocompatible polymer resin microspheres of a median diameter of 32.5 microns (range between 20 and 60 microns) loaded with yttrium-90 (beta radiation penetrating an average of 2.5 mm in tissue to destroy tumor cells). The resin microspheres are small enough to become lodged in the arterioles within the growing rim of the tumor but are too large to pass through the capillaries and into the venous system. Since yttrium-90 has a half-life of 64.1 hours, most of the radiation (94%) is delivered to the tumor over 11 days. Per the memo attached, SIRTex Medical, Inc. is the sole manufacturer and supplier of the SIR-Spheres in the United States.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable: Only SIRTex Medical Inc. is capable to provide the supplies required by the agency. A copy of this J & A and a Notice of Intent will be made public via FBO for 30 days for any parties that would like to express their interest in this acquisition.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable: In accordance with FAR 13.106-3(a)(2)(ii), based on a comparison of the proposed price with prices found reasonable on previous purchases, the proposed price is deemed fair and reasonable. Unit prices for the SIR-Spheres are consistent with previous years prices. The Department of Army awarded contract for 1 @ \$16,000.00 contract W81K0012A0013. The Qty for this transaction is 10 for \$160,000 so price is determined fair and reasonable. Defense Agency Purchase 6 for \$96,000.00 contract HT001416A0115 average price is \$16,000.00. Vendor provided proprietary letter as the only provider of this type of Microscope.

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted: Research was conducted on 11/6/2017 using key words of product Number resulted in GSA and did not find this on FSS schedule or any other contract. searched FPDS found this was purchased for the Army see above contracts in section 7. Customer also noted that this was purchased under VA259-17-P-2423 sole source as of 01/18/2017. Vendor provided a letter stating they were they are proprietary of this product.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition:
SIRTex Medical, Inc. is the sole manufacturer in the United States of America. (Sole Source Memo attached)

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

SIRTex Medical Inc.

OFOC SOP Revision 06

Original Date: 03/22/11

Revision 06 Date: 08/30/2017

