

Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: October 12, 2015

Re: Sole Source Certification Number SS0012 for AtriCure Cardiac Ablation System single use commodities

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number SS0012 for AtriCure Cardiac Ablation System single use commodities, please be advised that UMMC intends to award the purchase of the AtriCure Cardiac Ablation System single use commodities to Atricure, Inc. as the sole source provider of the AtriCure Cardiac Ablation System single use commodities.

UMMC issues this notice in accordance with Mississippi state law, policy, and procedures for sole source procurements.

Sole Source Criteria

1. Where the compatibility of equipment, accessories, or replacement parts is the paramount consideration (and manufacturer is the sole supplier).
2. Where a sole supplier's item is needed for trial use or testing.
3. Where a sole supplier's item is to be required when no other item will service the needs of UMMC.

Schedule

Task	Date
First Advertisement Date	October 12, 2015
Second Advertisement Date	October 19 2015

Response Deadline from Objectors	October 26, 2015, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before October 27, 2015

Project Details

1. Describe the commodity that the agency is seeking to procure:

The University of Mississippi Medical Center (UMMC) seeks to purchase the AtriCure CryoICE devices, as they are the only devices that effectively work with the AtriCure Cardiac Surgical Ablation System that UMMC currently owns and are intended for use in the cryosurgical treatment of cardiac arrhythmias. The system freezes the targeted heart tissue which causes an inflammatory response (cryonecrosis) to block the irregular cardiac electrical conduction pathway that causes the fibrillation.

2. Explain why the commodity is the only one (1) that can meet the needs of the agency:

AtriCure Synergy OLL2/OSL2 clamps are approved to ablate cardiac tissue for the treatment of persistent Atrial Fibrillation or long-standing persistent Atrial Fibrillation in patients who are undergoing open concomitant CABG and/or valve replacement or repair. AtriCure Synergy Access and Synergy EMR2/EML2 clamps are cleared for cardiac tissue ablation. The AtriCure Isolator multifunctional pen and Isolator linear pen are cleared to both diagnose cardiac arrhythmias and ablate cardiac tissue. ACC2 and cryoICE BOX devices, manufactured by AtriCure, are cleared for the treatment of cardiac arrhythmias when used with cryo1 and cryoICE. The AtriClip LAA Exclusion System is indicated for the occlusion of the left atrial appendage, under direct visualization, in conjunction with other open cardiac surgical procedures. The disposable malleable cryoablation probes used with the CryoICE Box permit a higher heat absorption allowing for temperatures along the length of the probe to be maintained more consistently.

3. Explain why the source is the only person or entity that can provide the required commodity:

AtriCure is the only company that manufactures the cryoICE products. The AtriCure malleable probes, pens and clamps are the only items that will work with the AtriCure Cardiac Surgical Ablation system already owned by UMMC. If other accessories, transducers or cables are used out of accordance with the system, damage to the patient and/or equipment could occur through increased emissions. AtriCure clamps, cryoablation probes and pens are only available through AtriCure and are not available from any other distributors. See supporting letter from Atricure, Inc., Attachment A.

4. Explain why the amount to be expended for the commodity is reasonable:

Based on the historical usage, and anticipated growth, UMMC is asking for approval for \$100,000 spend. This amount is within the expected price range for these products.

5. Describe the efforts that the agency went through to obtain the best possible price for the commodity:

Through market intelligence, UMMC was able to negotiate best pricing for these products. All applicable discounts were explored and applied.

Submission Instructions and Format of Response from Objecting Parties

Interested parties who have reason to believe that the Atricure, Inc. Cardiac Ablation System single use commodities (hereafter, "Products") should not be certified as a sole source should provide information in the Vendor Form for the State to use in determining whether or not to proceed with awarding the sole source to Atricure, Inc. The Vendor Form may be found at <http://www.dfa.state.ms.us/Purchasing/documents/ObjectiontoSoleSourceDetermination.pdf>.

Objections must include the certification in Attachment B.

Comments will be accepted at any time prior to Thursday, October 26, 2015, at 3:00 p.m. (Central Time) to solesource@umc.edu. Responses may be delivered via email to solesource@umc.edu. UMMC WILL NOT BE RESPONSIBLE FOR DELAYS IN THE DELIVERY OF RESPONSES. It is solely the responsibility of the Interested Parties that responses reach UMMC on time. Responses received after the deadline and responses that lack all required information will be rejected. UMMC reserves the right to inspect Interested Party's commodity for comparison purposes.

If you have any questions concerning the information above or if we can be of further assistance, please contact solesource@umc.edu.

Attachment A: Vendor Correspondence

Attachment B: Objection Certification

Sole Source Letter

This letter is to provide notification that AtriCure, Inc. is the sole source provider of the following devices.

Part Number: A000163
Description: MAX1

Part Number: A000195
Description: MID1

Part Number: A000362
Description: OLL2

Part Number: A000452
Description: EMR2

Part Number: A000467
Description: EML2

Part Number: A000475
Description: MCR1

Part Number: A000683
Description: CRYO2

The above devices are intended for use solely with the AtriCure Ablation system (ASU/ASB).

Part Number: A000019 (ASU)
Description: AtriCure ablation and sensing unit
Part Number: A000435 (ASB)
Description: AtriCure switch matrix accessory

The use of accessories, transducers and cables other than those specified in accordance with the instructions or supplied by AtriCure, may result in increased emissions or decreased immunity of the equipment.

The ASU should only be used with approved AtriCure brand Handpieces.

As a result of our investment in innovation, we have created a portfolio of our intellectual property rights that include:

- Patented Technology
- Trademarks
- Copyrights



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Attachment B

**SUBMITTED IN RESPONSE TO
Sole Source Certification No. SS0011
Accepted until October 26, 2015, at 3:00 p.m.**

I certify that the information contained in this objection is true and accurate to the best of my knowledge. I understand that UMMC will investigate all statements made in this objection and that any false or misleading information provided may result in adverse action.

Objector Name
Objector's title

Date