

# Notice of Intent to Certify Sole Source

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**To:** Interested Parties

**From:** Stacy Baldwin  
Agency Procurement Officer

**Date:** January 25, 2016

**Re:** Sole Source Certification Number **SS5008** for **Visual ICE Cryotherapy System and Needles**

**Contact Email Address:** [solesource@umc.edu](mailto:solesource@umc.edu)

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## Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5008** for **Visual ICE Cryotherapy System and Needles**, please be advised that UMMC intends to award the purchase of the **Visual ICE Cryotherapy System and Needles** to **Galil Medical, Inc.** as the sole source provider of the Visual ICE Cryotherapy System and Needles.

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

<b>Task</b>	<b>Date</b>
First Advertisement Date	January 25, 2016
Second Advertisement Date	February 1, 2016

Response Deadline from Objectors	February 11, 2016, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before March 24, 2016

## Project Details

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

The University of Mississippi Medical Center (UMMC) seeks to purchase the Visual ICE Cryotherapy System and Needles.

The Visual Ice Cryoablation system is used for the cryoablative destruction of tissue in percutaneous minimally invasive procedures through fourteen (14) and seventeen (17) gauge needles without the need of helium.

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

The system incorporates i-Flow® Technology, a proprietary software algorithm that optimizes performance of each Galil Medical needle, eliminating any usage of helium and offering less argon usage of 20-30%, depending on the cryoneedle utilized. These proprietary features eliminate set-up time and space, completely eliminates the use of helium which is an expensive, diminishing resource, and offers FastThaw™ functionality which reduces thaw time during the procedure by 60%. This Visual Ice System controls the use of i-Thaw® needles to actively thaw ice without the use of helium and the use of needles with CX features to perform FastThaw without helium or perform track ablation to minimize the potential for track seeding. Real-time temperature monitoring, through thermal sensors connected to the system, enables procedural control to protect critical anatomy.

These unique features, help with treating renal cell cancers and other bone and liver tumors. It helps with better targeting the tumors, less bleeding which means less complications, and precise timing that helps shorten treatment time. This system will decrease the likelihood for residual tumor formation, specifically with kidney tumors. A vast majority of the oncology patients treated at UMMC suffer from renal or metastatic bone cancers. This system will provide our oncology patients with a minimally invasive option for treating their cancer and a good prognostic outcome for our oncology patient population.

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

Galil Medical is the only company that manufactures, sales, and distributes the Visual ICE Cryotherapy system and proprietary needles with needle track ablation/cautery (CX) and helium free i-Thaw® capabilities. See supporting letter from **Galil Medical**, Attachment A.

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

This system will be placed in Interventional Radiology with a minimum number of disposables to be purchased. The price of the disposables covers the cost of the systems placement. The estimated amount to be expended for the purchase of the **Visual ICE Cryotherapy System and Needles** is \$65,000.

**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 this system and the associated needles. 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 **Visual ICE Cryotherapy System and Needles** (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 **Galil Medical, 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, February 11, 2016, at 3:00 p.m. (Central Time) to [solesource@umc.edu](mailto:solesource@umc.edu). Responses may be delivered via email to [solesource@umc.edu](mailto: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](mailto:solesource@umc.edu).

Attachment A: Vendor Correspondence

Attachment B: Objection Certification

"Attachment A"



November 11, 2015

UMMC - University of Mississippi Medical Center  
Attention: Andrea Williford  
2500 N State Street  
Jackson, MS 39216

Dear Ms. Williford,

This letter is to confirm that the Visual-ICE® Cryoablation System is a sole source product, manufactured, sold and distributed exclusively by Galil Medical and its authorized distributors. No other company makes a similar or competing product that offers the features of the Galil Medical cryoablation products that include needle track ablation (CX) and helium free **i-Thaw**® capabilities. These proprietary features eliminate set-up time and space, eliminate the use of helium which is an expensive, diminishing resource, and offers FastThaw™ functionality which also reduces thaw time during the procedure.

Please feel free to contact me with any additional questions.

Sincerely,

*Lisa Hayden*

Lisa Hayden  
Vice President, Global Reimbursement,  
Chief Compliance Officer



1-877-639-2796 option #4  
Direct Office Line – 651-287-5126  
Fax – 651-287-5125  
[lisa.hayden@galilmedical.com](mailto:lisa.hayden@galilmedical.com)

Attachment B

**SUBMITTED IN RESPONSE TO  
Sole Source Certification No. SS5008  
Accepted until February 11, 2016, 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