

Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: December 7, 2015

Re: Sole Source Certification Number **SS5001** for **Vascular Solutions Catheters and associated disposables**

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5001** for **Vascular Solutions Catheters and associated disposables**, please be advised that UMMC intends to award the purchase of the **Langston Dual Lumen Catheter, the Guideliner Catheter, the Venture Catheter, the Twin-Pass Dual Access Catheter, and the SmartNeedle System** to **Vascular Solutions** as the sole source provider of the **Vascular Solutions Catheters and associated disposables**.

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	December 7, 2015
Second Advertisement Date	December 14, 2015
Response Deadline from Objectors	December 17, 2015, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before December 18, 2015

Project Details

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

The Adult Cardiac Catheterization Lab, a division of University Heart, at the University of Mississippi Medical Center, is requesting the purchase and continued use of Vascular Solutions catheters and associated disposables. The list of commodities includes the Langston Dual Lumen Catheter, the Guideliner Catheter, the Venture Catheter, the Twin-Pass Dual Access Catheter, and the SmartNeedle System. These commodities provide unique services to the cardiovascular diagnostic and interventional cases throughout University Heart.

The Langston dual lumen catheter is the only dual lumen pigtail catheter on the market. Each lumen will allow you to measure the pressures of the heart simultaneously across the aortic valve which is extremely important when looking at aortic stenosis and capturing the pressure on the same heartbeat. This allows our clinicians to measure pressures simultaneously without having to gain a second arterial access on our patients.

The Guideliner catheter is a guide extension catheter that offers several different sizes ranging from 5fr-8fr. The larger size guideliner is used here at UMMC for coronary vessels known to be chronically occluded. These cases require an 8fr Guideliner to provide adequate back up and guide support. The GuideLiner is unique in that it is made out of coil and less likely to kink, but still offers flexibility, which makes it less likely to dissect the coronary vessel.

The Venture is the only deflectable tip coronary catheter on the market that can steer a .014 guidewire and sub-select vessels in the heart. This feature allows the advancement of guidewires into tortuous coronary vessels and branches.

The Twin-Pass Dual Access catheter is the only dual lumen coronary catheter with such a low profile allowing the physician to deliver intra-arterial medications to distal vessels. Also, the catheter allows the physician to exchange wires which is especially important when the physician needs to exchange from a short guidewire to a long guidewire.

The Smart Needle is the only needle on the market that has a Doppler probe inside of the needle that aids the clinician in distinguishing between arterial and venous vessels. The smart needle is particularly useful in patients with difficult access and risk factors such as morbid obesity. The needle portion of the smart needle is disposable and detachable, but the device itself is not disposable.

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

University Heart, a part of Cardiovascular Services at The University of Mississippi Medical Center (UMMC), has initiated an Adult Congenital Heart Program and Valve Center. The procedural component of these programs involves diagnosing valve disease and structural heart disease processes. We are performing interventional procedures such as Transcatheter Aortic Valve Replacement (TAVR), Chronic Total Occlusion (CTO) reversal of coronary arteries, and limb salvage for peripheral vascular disease (PVD). These catheters and needle are essential for verifying whether our patients are candidates for these procedures.

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

Vascular Solutions is the manufacturer and sole distributor of these products. See supporting letter from **Vascular Solutions**, Attachment A.

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

The estimated amount to be expended is for the purchase of the **Vascular Solutions Catheters and associated disposables** is \$80,000. 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 **Langston Dual Lumen Catheter, the Guideliner Catheter, the Venture Catheter, the Twin-Pass Dual Access Catheter, and the SmartNeedle System** (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 **Vascular Solutions**. 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, December 17, 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

"Attachment A"



September 22, 2015

University of Mississippi Medical Center
2500 North State Street
Jackson, MS 39216
Account Number: 220466

This letter is in reference to your request about the following products: Venture, GuideLiner, Twin-Pass, SmartNeedle, and Langston. Vascular Solutions is the manufacturer and sole distributor of these products. Each of these products has unique characteristics that set them apart from other products on the market. Below are brief descriptions as to what makes them unique:

Venture: Venture is the only deflectable tip catheter for guidewire delivery in challenging anatomy.

GuideLiner: The GuideLiner is used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices. GuideLiner V3 has a unique half-pipe that minimizes device/collar interaction by directing and aligning devices through the collar transition.

Twin-Pass: The Twin-Pass has a unique dual lumen design that provides independent access lumens to the distal vessel for delivery of a second guidewire, contrast, or medication.

SmartNeedle: The SmartNeedle is the only needle that provides continuous auditory feedback to help locate and access the artery or vein quickly.

Langston: The Langston catheter is the only dual lumen catheter that will measure simultaneous pressure across the aortic valve.

If you have any questions on the above information, please let me know.

Best Regards,

A handwritten signature in cursive script that reads "Susan Christian".

Susan Christian
Vice President of Sales Operations

cc: Jacob Breehne, Account Manager
Charles Judice, Gulf States Regional Director

P138-15 Product

Attachment B

**SUBMITTED IN RESPONSE TO
Sole Source Certification No. SS5001
Accepted until December 17, 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