

JUSTIFICATION FOR SINGLE SOURCE AWARDS IAW [FAR 13.106-1](#)
(OVER MICRO-PURCHASE THRESHOLD(\$3K) BUT NOT EXCEEDING THE SAT (\$150K))

IAW [FAR13.104](#), COs must promote competition to the maximum extent practicable to obtain supplies and services from the source whose offer is the most advantageous to the Government, considering the administrative cost of the purchase. When competition is not practicable, IAW [FAR13.106-1\(b\)](#), COs solicit from a single source for purchases not exceeding the simplified acquisition threshold. COs may solicit from one source if the CO determines that the circumstances of the contract action deem only one source reasonably available (e.g., urgency, exclusive licensing agreements, brand-name or industrial mobilization). IAW [FAR13.106-3\(b\)\(3\)](#), COs are required to include additional statements ***explaining the absence of competition*** (see [13.106-1](#) for brand name purchases) if only one source is solicited and the acquisition does not exceed the simplified acquisition threshold (does not apply to an acquisition of utility services available from only one source) or supporting the award decision if other than price-related factors were considered in selecting the supplier. This template when completed can be used to document single source awards IAW [FAR13.106-3\(b\)\(3\)](#). Note: Statements such as "only known source" or "only source which can meet the required delivery date" are inadequate to support a sole source purchase.

1. ACQUISITION PLAN ACTION ID:

VA248-16-AP-2757

**1A. PROJECT/TASK
No.**

**Lake Nona-
Activation**

1B. ESTIMATED AMOUNT:

2. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES REQUIRED AND THE INTENDED USE:

Orlando Veterans Affairs Medical Center (OVAMC) Interventional Radiology (IR) Department wishes to obtain Viatorr and Viabahn stents from Gore for particular applications, respectively, in the liver and the vascular system.

VBJR061002A	1 VIABAHN, 6X10,GORE PKG: 1 per EA	2	EA
VBJR061502A	2 VIABAHN, 6X15,GORE PKG: 1 per EA	2	EA
VBJR060502A	3 VIABAHN, 6X5, GORE PKG: 1 per EA	2	EA
VBJR071002A	4 VIABAHN, 7X10,GORE PKG: 1 per EA	2	EA
VBJR071502A	5 VIABAHN, 7X15,GORE PKG: 1 per EA	2	EA
VBJR070502A	6 VIABAHN, 7X5, GORE PKG: 1 per EA	2	EA
PTB107275	7 VIATORR, 10X7,GORE PKG: 1 per EA	2	EA
PTB106275	8 VIATORR, 10X6,GORE PKG: 1 per EA	2	EA
PTB108275	9 VIATORR, 10X8,GORE PKG: 1 per EA	2	EA

3. UNIQUE CHARACTERISTICS THAT LIMIT AVAILABILITY TO ONLY ONE SOURCE, WITH THE REASON NO OTHER SUPPLIES OR SERVICES CAN BE USED:

The Viatorr stent has patent-protected design modifications for use in creation of transjugular intrahepatic portosystemic shunts (TIPS). The Viatorr system has a covered stent portion to allow for decreased tissue ingrowth specifically in liver applications, along with an uncovered portion to allow for fixed point anchoring and portal nutrient flow. This covered/uncovered stent design on a hard-anchoring stent body that passes through a hepatic tract is patent protected and unique in the stent market. The TIPS procedure cannot be effectively accomplished without the device.

The Viabahn stent system is similarly unique in its design in that it has a covalently bonded heparin on the luminal aspect of the graft material, which allows bound drug to interact with the blood pool. The stent has structural features which allow it to be extremely conformable to a tortuous vessel anatomy. This design is patent protected and unique in the market. It is important to note that this device is not a first line therapy for disease based on its cost, however in the comparatively rare cases where the stent is required, no viable substitute is available.

The TIPS procedure is used in critically ill patients or patients who have longstanding severe liver disease as a means of preventing an acute fatal event. While any stent system can be used for the procedure, only the Viatorr design has the support of the IR community in general and of the 3 IR physicians at OVAMC. If the Viatorr device is not stocked on our shelves, then any TIPS care will be sent outside of OVAMC at a cost of roughly \$50,000 per procedure. Purchasing the TIPS stent and keeping these procedures in house therefore represents a significant cost savings to VA despite its high price. The devices are the Academic medical center industry standard for the their respective angiographic procedures, with concurrence from all three practitioners in the OVAMC IR department, based on their cumulative experience of 15 years at seven different medical facilities.

4. REASON THAT SUGGESTED SOURCE IS THE ONLY SOURCE, WHICH CAN PROVIDE THE SUPPLIES OR SERVICES:

The above described stent system modifications are patent protected and unique in the market. While their use is relatively rare, when there is an indication for their use, no substitute is available.

Similarly, in refractory or tortuous SFA atherosclerotic lesions, if a Viabahn stent is not available, VA IR would have to decline the case and send to Non-VA Care, again creating a significantly greater out-of-facility cost to VA.

5. DESCRIPTION OF MARKET RESEARCH CONDUCTED AND RESULTS OR STATEMENT WHY IT WAS NOT CONDUCTED:

Market researched NAC and GSA Schedule for under Viabahn and Viatorr and zero results. Secondly, internet researched under same titles including Peripheral Vascular Disease (PVD) and received one result however, unable to confirm if they are a distributor of these products. Also emailed Manufacturer inquiring if they have any authorized small business distributors and unable to confirm at this time.

6. Contracting Officer's Certification: *Purchase is approved in accordance with FAR13.106-1(b). I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief. Note: COs are required to make a determination of price reasonableness IAW FAR 13.106-3. See the [Commercial Supply and Service SOP for Price Reasonableness templates](#).*

Signature: _____

Date: 3/24/2016

Name: Sherita Glanton

Title: Contract Specialist

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