

DEPARTMENT OF VETERANS AFFAIRS

**Justification for Single Source Awards IAW [FAR 13.106-1](#)
For
Over Micro-Purchase Threshold but Not Exceeding the SAT (\$250K)**

Acquisition Plan Action ID: 36C263-18-AP-2864

1. **Contracting Activity:** Department of Veterans Affairs, VISN 23, Iowa City, IA Medical Center
2237: 636-19-1-4051-0001
2. **Brief Description of Supplies/ Services required and the intended use/Estimated Amount:** Trans-Carotid Artery Revascularization procedure is designed to protect the brain from most sizes and types of embolic debris when introducing interventional devices into the carotid artery. Small emboli, not large enough to cause a major stroke, can still cause a minor brain infarction and impact cognitive function.
Trans-Carotid Artery Revascularization is a surgically inspired procedure and is designed to mimic the arterial access and safeguards of surgery. In carotid artery surgery, the arteries are clamped above and below the blockage to block blood flow and prevent plaque from traveling to the brain during treatment. Similarly, the SILK ROAD MEDICAL ENROUTE Trans-Carotid Neuroprotection System isolates the blockage from forward blood flow during stent placement by reversing blood flow away from the brain. Because the flow reversal method does not rely on a distally placed filter to capture emboli before they reach the brain, it collects both small and large debris.
3. **Unique characteristics that limit availability to only one source, with the reason no other supplies or services can be used:** SILK ROAD MEDICAL is the only manufacturer of this type of product that provides stenting for the carotid artery that isolates the diseased portion of the artery to prevent plaque traveling to the brain and causing a stroke. This is a minimally invasive procedure that causes less stress to the patient's cardiovascular system, reducing the risk of intraoperative cardiovascular events. If this system is not purchased, either a standard carotid endarterectomy will need to be performed with increased risk to the patient, or the patient will be fee based out to a facility that has this system available.

A veteran is scheduled for surgery using this device for October 18, 2018.

4. **Description of market research conducted and results or statement why it was not conducted:**
See market research report uploaded in file for details.

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 [S19 Open Market \(FAR13\) Award Documentation Form with Abstract](#) to document price reasonableness.*

Name

09/21/2018

Date

VHAPM Part 813.106 Simplified Acquisition Procedures: Soliciting from a Single Source
Attachment 1: Single Source Justification for SAP under the SAT