**Solicitation Number:** **FY19-001**

**Notice Type:** Special Notice

**Synopsis:** **May 01, 2019**

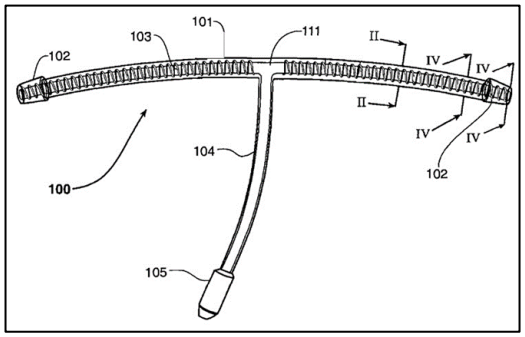
DEPARTMENT OF THE AIR FORCE
AIR FORCE MEDICAL SERVICE
NOTICE OF INTENT

The Air Force Medical Service intends to negotiate on a sole source basis (IAW FAR 13.106-1(b)(2)) with *your company* as the contract manufacturer to manufacture a set number of medical-grade vascular shunt sets that meet pre-determine design specifications and use government-owned established production molds and materials, including, but not limited to:

1. Raw materials, including partial product, packaging and labeling material and guidance for generating additional compliant materials, etc.
2. Documentation, including the Design History File (DHF) with specifications, drawings, work instructions, etc. and draft protocols for construction, cleaning, inspection, packaging, and labeling of the shunt kits.

The sponsor for the submission to the US Food and Drug Administration (FDA) will be the United States Air Force Medical Service (AFMS).

The contractor will provide an ISO 13485 or ISO 9001, FDA Registered, current Good Manufacturing Practice (cGMP) certified facility, and finished product in accordance FDA regulations.




The 5.5 mm shunts will be generated in two lengths: a 50 millimeter and 300 millimeter (shown). Each shunt will be packaged in a medical-grade, hermetically-sealed pouch and labeled. One pouch of each sized shunt will placed in another medical grade pouch, sealed, and labeled as a trauma-specific vascular injury shunt kit with the indications for use (IFU), lot number, and other pertinent information. Ten kits will be packaged to a box with 4 boxes to a shipping container. A total of approximately 500 trauma shunt kits (~1000 shunts) will be generated with this effort, but additional shunts of both sizes will be required for advanced aging, various testing, and quality assurance prior to the construction of the vascular shunt kits. In addition, the 500 kits will be produced in multiple lots, with an initial lot of 50 kits that will be representative articles for inclusion into the 510(k) premarket submission package that will be submitted by the AFMS to the FDA.

The expected period of performance from award of contract to providing the 500 vascular shunt kits is expected to be 12 months, but is negotiable.

The contractor shall be an Original Equipment Manufacturer (OEM) for the proposed class II sterile medical device such that OEM warranty and service are provided and maintained by the

OEM. All licensing, warranty and service associated with the class II sterile medical device shall be in accordance with the OEM terms and conditions.

This acquisition is being conducted under simplified acquisition procedures FAR 13.106-1(b)(2) - Simplified Procedures for the acquisition of supplies and services exceeding the simplified acquisition threshold. The intended procurement will be classified under North America Industry Classification System (NAICS) 541715 (Medical Development Services), 339113 (Surgical Implant Manufacturing), and 446199 (Medical Equipment and Supplies).

Parties interested in responding to this notice will need to submit technical data sufficient to determine capability in accepting a medical device Technology Transfer, transitioning from advanced prototype / finished medical device to providing the same product, a FDA-approved class II sterile peripheral vascular prosthesis (silicone shunt), and estimate of the total program costs and period of performance (preliminary schedule).

All capability statements received by the closing date of this synopsis will be considered by the Government. A determination by the Government not to compete based on responses to this notice is solely within the discretion of the Government. Information received will be considered solely for the purpose of determining whether to conduct a competitive procurement.

Capability statements, cost estimate, and shall be submitted by email only as an Adobe PDF attachment to:

Tom Gardner
Vice President
MHRF
Mobile: 210 347 4962
Email: tgardner@militaryhealthresearch.org

Reference number FY19-001