

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval (J&A)
For
Other Than Full and Open Competition (>\$150K)**

Acquisition Plan Action ID: VA247-17-AP-6231

1. **Contracting Activity:** Department of Veterans Affairs, VISN 07, WJB Dorn VA Medical Center, Columbia, South Carolina; 544-17-4-069-4652 – HTA ProCerva Procedure Sets
2. **Nature and/or Description of the Action Being Processed:** HTA Procerva Procedure Sets. Used to circulate heated saline throughout the uterus in order to ablate the lining of the uterine walls, also known as the endometrium.

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for HTA Procerva Procedure Sets in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:**
CLIN 1: HTA Procerva Procedure Kits QTY: 8 UI: EA COST:\$7,955.00 TOTAL: \$63,640.00

Period of Performance

Base Year	October 1, 2017 – September 30, 2018	\$63,640.00
Option 1	October 1, 2018 – September 30, 2019	\$63,640.00
Option 2	October 1, 2019 – September 30, 2020	\$63,640.00
Option 3	October 1, 2020 – September 30, 2021	\$63,640.00
Option 4	October 1, 2021 – September 30, 2022	<u>\$63,640.00</u>
		\$318,200.00

4. **Statutory Authority Permitting Other than Full and Open Competition:**
(X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
() (2) Unusual and Compelling Urgency per FAR 6.302-2;
() (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
() (4) International Agreement per FAR 6.302-4
() (5) Authorized or Required by Statute FAR 6.302-5;
() (6) National Security per FAR 6.302-6;
() (7) Public Interest per FAR 6.302-7;

FAR13.5 Simplified Procedures for Certain Commercial Items: The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

Only One Responsible Source (FAR 6.302-1) – Genesys ProCerva Procedure Sheath provides redundant protection to help gain and maintain a cervical seal, and Seal integrity Check verifies seal before procedure initiation. This is the only system that uses heated saline to ablate. This product is specific to the Genesys HTA System machine that is used for this procedure. The Genesys HTA System is already in use in the facility. There are no alternative procedure kits that will work with this system. Boston Scientific has submitted a signed letter on company letterhead that states that they are the only manufacturer of both the Genesys HTA System machine and procedure kits. Furthermore, this product is not offered through Boston Scientific's system of small business distributors, as also stated in their letter. This product is proprietary to Boston Scientific, and no other brand or distributor exists. The use of brand name descriptions is essential to the Government's requirement, thereby precluding consideration of a product manufactured by another company.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:

An Intent to Sole Source shall be posted via FBO in order to provide other potential offerors the opportunity to indicate that they are able to meet the needs of this requirement. A signed proprietary letter has been submitted by Boston Scientific and competition is not anticipated.

7. Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:

The anticipated cost for this requirement is considered fair and reasonable in comparison to previous purchases made for this exact product. This requirement was previously awarded under a single stand-alone contract in November 2015 under contract VA247-16-C-0096 at a cost of \$6,990.00 per box.

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:

Although the Boston Scientific did submit a propriety letter stating that they are the sole manufacturer and distributor of these sets, and that no other sets are compatible with the Genesys HTA ProCerva system, market research was conducted for this requirement. An internet search of GSA Advantage, Google and Bing was conducted to determine whether other offerors of this product existed, and none were found. A search of the current Med-Surg Prime Vendor listing was also completed with no results found. Finally, three separate searches were completed through Vendor Information Pages (VIP) for potential SDVOSB and VOSB offerors. The first VIP search was for keyword "Genesys", with no results found. The second search was for keyword "ProCerva", with no results found. And the final search was for NAICS code 339112 - Surgical and Medical Instrument Manufacturing; which returned 229 matches, however given that this is a proprietary item, these potential offerors are not permitted to offer this product.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition: This technology is proprietary to Boston Scientific and they are the sole manufacturer and distributor for this product line.

