

**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. PURCHASE REQUEST OR REQUISITION NUMBER:**

523-18-1-7811-0009

**1A. PROJECT/TASK  
NUMBER**

None

**1B. ESTIMATED AMOUNT:**

\$51,025.00

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

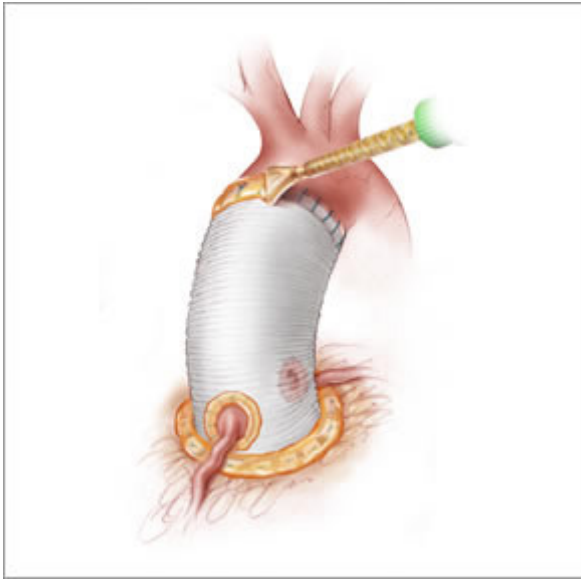
BioGlue's two components, purified bovine serum albumin (BSA) and glutaraldehyde, are dispensed by a controlled delivery system. Once dispensed, the two components are fully mixed within the applicator tip. BioGlue, upon application to the tissue at the repair site, creates a flexible mechanical seal independent of the body's clotting mechanisms.

BioGlue begins to polymerize within 20 to 30 seconds and reaches full strength within two minutes.

BioGlue also adheres to synthetic graft materials through mechanical bonding within the interstices of the graft matrix.

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

BioGlue is indicated for use as an adjunct to standard methods of achieving hemostasis (such as sutures and staples) in adult patients in open surgical repair of large vessels (such as aorta, femoral and carotid arteries).



**CE (product certification) Mark Approval**

BioGlue has been awarded three CE marks for its use in:

- Cardiac and Vascular repair
- Pulmonary repair
- Soft tissue repair

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

BioGlue is indicated for use as an adjunct to standard methods of surgical repair (such as sutures, staples, electrocautery, and/or patches) to bond, seal, and/or reinforce soft tissue. BioGlue may also be applied alone to seal and/or reinforce damaged parenchyma when other ligature or conventional procedures are ineffective or impractical. Indicated soft tissues include: Cardiac, Vascular, Pulmonary, Genitourinary, Alimentary (esophageal, gastrointestinal, and colorectal), Abdominal tissues (pancreatic, splenic, hepatic, biliary)

Additionally, BioGlue is used in the fixation of surgical meshes in hernia repair.

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

The Bioglue has been used in the OR for many years the continued use helps improve the performance in the prevention of blood loss. It is also very effective in the recovery time in patient care due to the patient receiving less blood transfusion while be admitted.

6. *I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.*

**Requestor:**

PKI Digital Signature	MELISSA D. Williams 288038	Digitally signed by MELISSA D. Williams 288038 DN: dc=gov, dc=va, o=internal, ou=people, 0.9.2342.19200300.100.1.1=melissa.williams@va.g ov, cn=MELISSA D. Williams 288038 Date: 2017.08.29 05:32:34 -04'00'	Phone:	857-203-6133
			Date:	8/29/17

**Date:** 08/29/2017

**Name:** Melissa Williams

**Title:** Inventory Management Specialist

**Facility:** Boston Healthcare System VISN 1

**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.*

**Signature:** \_\_\_\_\_

**Date:** 10/3/2017

**Name:** Julie A. Lemire

**Title:** Contracting Officer

**Facility:** NCO1 – Manchester VAMC