

PURPOSE: To ensure standardization of the submission process for all prosthetic appliances and sensory aids over the micro-purchase threshold; the document below is required to be completed and uploaded into the Electronic Contract Management System (eCMS) **Planning Module**. For access to the eCMS Planning Module, please contact the Network Contracting Office (NCO) eCMS Coordinator. Select from the following links to identify a local/regional eCMS/Application Coordinator: [SAO West](#), [SAO East](#), [SAO Central](#).

This procurement request document is designed to be a complete compilation of all information required by the NCO to process the requested prosthetic item(s)/service(s). **NOTE:** Patient consults are **prohibited** in eCMS and ALL Patient Health Information MUST be redacted from all documents before uploading into the eCMS Planning Module.

A. Contact Information: Prosthetics Point of Contact

Reset Form

eMail:

francine.price@va.gov

B. Item Information: Accounting and Appropriation Data

Funding Amount as Verified by POC

\$32,500.00

Station Code

618

BOC & Fund Control Point

2692 / 912 (MEDICAL)

Detailed Description of Item/Aid

TRANSCATHER AORTIC VALVE REPLACEMENT (TAVR)

Consult/Reference* Identification

*IEN 668# plus station identifier (e.g. Veteran's Last Initial and last 4 digits of the Veteran's SSN (for filtering purposes))

PROS V23 618 UNU "BILL & REPLACE" 6182918086 (MI) TAVR

C. Detailed Procurement Information: Provide the following information

List any [Mandatory Sources](#) (these are referred to as National Committed Use Contracts). Add Waiver req't if not used.

N/A

NOTE: Per [VHA Handbook 1761-1](#) these would require [waivers](#) if the standardized contracts are not used.

List any [Federal Supply Schedule \(FSS\) National or Local Contract Numbers](#) utilized

OPEN MARKET

Vendor Name

EDWARDS LIFESCIENCES

Vendor Point of Contact Info Name

CUSTOMER SERVICE

VISTA/IFCAP Vendor #

33804

Fax Number, Phone Number, or eMail Address to Send Documents for POC above

PH: 800-424-3278 / FAX: 800-422-9329

Date Item/Service Required

Mar 29, 2016

Delivery Information

Other

Delivery Address (If "Other")

UNU

"BILL & REPLACE" NEED ON OF BEFORE 3/30/2016

Payment Only?

No

Consult Type

New

Consult Date

Mar 24, 2016

Quote Date

Mar 24, 2016

PO Line Items/HCPSC Location

Appear on Following Page

Purchase Order Line Item Information

<input type="button" value="+"/> <input type="button" value="-"/>	Item	TRANSCATHER AORTIC VALVE REPLACEMENT (TAVR)	HCPC	SB185	Price	32,500	Quantity	1
BOC/Billing Item No.		2692 / 34313		Serial Number		4914226		

D. eCMS Procurement Package Completion Instructions: Verify each item by checking the adjacent box.

Patient Information MUST be redacted prior to loading into [eCMS Planning Module](#).

- ☐ Verify item is **FDA Approved** (for Open Market Purchases for [biologics](#) and [medical devices](#))
- ☒ Verify all **Patient Information** is **redacted**
- ☒ Verify **Consults** are **not loaded** into eCMS to prevent unauthorized disclosure of Patient Information
- ☒ Verify Supporting Documentation is provided within [eCMS Planning Module](#):
 - ☐ Vendor Quote(s)
 - ☒ Implantation Form(s)
 - ☐ Serial/Item Identification Number(s)
 - ☒ Other Information, as needed

E. Justification & Approval (J&A):

Check ONE of the Following

- ☒ <150k: Add Open Market J&A to Procurement Request
- ☐ FSS: Add FSS J&A to Procurement Request
- ☐ NO J&A is required
- ☐ ≥150k: [Add J&A](#) to Procurement Request

A Justification and Approval Document is required when a Sole Source is requested due to Emergency/Urgent and Compelling circumstances where only One Source can provide the item or service, or for USC 8123 Requests.

Is this an EMERGENCY Procurement? Yes ☐ No ☒

Surgical Implant

1. Nature and/or Description of the Action Being Approved:

The J&A is to support the award of a contract or purchase order on a sole source basis for the purchase of surgical implants from a single source per medical determination of need.

2. Description of Supplies/Services Required to Meet the Agency's Needs:

Surgically implanted products are specified by the clinical team to meet the unique and comprehensive needs of each Veteran with an identified medical indication.

3. Statutory Authority Permitting Other than Full and Open Competition: Include narrative for ONLY ONE item below.

Toggle check box selections to add or remove narrative text in 4 below.

- ☐ Urgent or compelling request for prosthetic appliance or sensory aid from an **FSS** Vendor per [FAR 8.405-6\(a\)\(1\)\(i\)\(A\)](#)
- ☐ Sole Source request for prosthetic appliance or sensory aid from an **FSS** Vendor per [FAR 8.405-6\(a\)\(1\)\(i\)\(B\)](#)
- ☒ Single Source (only one responsible source and no other supplies or services will satisfy the requested prosthetic item/sensory aid), per [FAR 13.106-1\(b\)\(1\)](#).
- ☐ Urgency (emergency request for prosthetic item/sensory aid where delay in the award would cause patient harm and there is medical justification to support the need) per [FAR 13.106-1\(b\)\(1\)](#).
- ☐ Exception to Fair Opportunity per [FAR 16.505\(b\)\(2\)\(i\)\(B\)](#). This language applies to, and is contained in, the National Contracts for Pacemaker/ICD/Implantable Loop Recorders awarded by the NAC.
- ☐ Title [38 U.S.C. 8123](#) and [41 U.S.C. 253\(c\)\(5\)](#) (Authorized or Required by Statute [FAR 6.302-5](#) and [VAAR 806.302-5\(b\)](#))

4. Demonstration that the Contractor's Unique Qualifications or Nature of the Procurement Requires the Use of the Authority Cited Above (Applicability of Authority):

The prescribed item will be purchased from the Vendor identified because they are able to meet the Veteran's immediate need. The item was prescribed by the Veteran's attending Physician who has the authority to prescribe the method of treatment to best satisfy the medical condition of his/her patient. The physician has determined this item as the best device to treat the patient's medical condition and functional limitations. Substituting another device other than that specifically prescribed is beyond the role, competency, and professional functions of the Contract Specialist and would be detrimental to the treatment of the Veteran patient.

5. Requirements Certification:

I certify that the requirement outlined in this justification is a Bona Fide Need and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

Prescriber -or-
Requestor

Ready to Sign? Click here!

Print Form

Emergency eMail

6. Approvals in Accordance with VHA PM Volume Six, Chapter VI:

Contracting Officer's Certification (required): I certify that the foregoing justification is accurate and complete to the best of my knowledge and the order represents the best value to the government.

Contracting
Officer

Director of Contracting/Designee: I certify the justification meets requirements for other than full and open competition.

DoC -or-
Designee