

**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:

SHARON.BROWN9@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

Detailed Description of Item/Aid

TAVR VALVE KIT

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 URGENT 81245 TAVR VALVE KIT DOS: 05/12/16

**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

N/A

Vendor Name

EDWARDS LIFESCIENCE

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

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

Date Item/Service Required

May 16, 2016

Delivery Information

Other

Delivery Address (If "Other")

URGENT; DELIVER TO 2R-101 ON 05/16/16

Payment Only?

No

Consult Type

New

Consult Date

May 13, 2016

Quote Date

May 13, 2016

PO Line Items/HCPSC Location

Appear on Following Page

**Purchase Order Line Item Information**

<input type="button" value="+"/> <input type="button" value="-"/>	Item	26MM TAVR VALVE KIT 9600TFX	HCPC	SB185	Price	32,500	Quantity	1
BOC/Billing Item No.		2692/34313		Serial Number		4904013		

**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
- ☐ NO J&A is required
- ☐ FSS: Add FSS J&A to Procurement Request
- ☐ ≥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 ☐

**Emergency/Urgent Requests:** An e-mail with subject line "Emergency" is to be transmitted to notify the NCO Prosthetics Manager of the emergency request by PSAS. PSAS should verify receipt of the order by the Prosthetics Team Lead and that action is being taken. All emergencies shall be received by Procurement no later than 2:00 PM for same day action. Any emergencies that arrive after the 2:00 PM same day cutoff will be executed by 10:00 AM the following business day. In the event no confirmation is received by 2:30 PM the PSAS requestor shall notify the NCO PSAS email Group.

**Time Zones:** For same day processing through distributors in varying time zones, be cognizant of time differences; emergency orders placed in Pacific time zones that require processing through VA offices located in Eastern time zones are to be placed with Procurement Activity prior to 11AM Pacific time for same day processing.

[Create Emergency eMail](#)

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

Sharon E Brown-Robinson  
381457

Digitally signed by Sharon E Brown-Robinson 381457  
DN: dc=gov, dc=va, o=internal, ou=people,  
0.9.2342.19200300.100.1.1=sharon.brown9@va.gov, cn=Sharon E Brown-  
Robinson 381457  
Date: 2016.05.13 10:04:13 -05'00'

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

Deborah S. McGee  
256794

Digitally signed by Deborah S. McGee 256794  
DN: dc=gov, dc=va, o=internal, ou=people,  
0.9.2342.19200300.100.1.1=deborah.mcgee@va.gov,  
cn=Deborah S. McGee 256794  
Date: 2016.05.13 11:57:23 -05'00'

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

DoC -or-  
Designee

Robert A. Johnson 220249

Digitally signed by Robert A. Johnson 220249  
DN: dc=gov, dc=va, o=internal, ou=people,  
0.9.2342.19200300.100.1.1=robert.johnson3@va.gov, cn=Robert  
A. Johnson 220249  
Date: 2016.05.13 11:58:58 -05'00'

**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:

john.lachance@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

912

Detailed Description of Item/Aid

URGENT PAY & REPLACE, 26MM TAVR VALVE KIT, DOS 5/12/16. SHORT NOTICE CASE, NO INITIAL

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))

6182900790-89

**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.

NA

*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

NA

Vendor Name

EDWARDS LIFESCIENCES LLC

Vendor Point of Contact Info Name

CUSTOMER SERVICE/DELORIS

VISTA/IFCAP Vendor #

33804

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

800-422-9329/800-424-3278

Date Item/Service Required

May 16, 2016

Delivery Information

Other

Delivery Address (If "Other")

ST618 RM 2R/102 ATTN: KIM/LYNN. PRICING/AVAILABILITY CONFIRMED WITH CUST SERV/DELORIS. SHORT NOTICE CASE. NO INTIAL. ROBERT ALERTED. THANKS.

Payment Only?

No

Consult Type

Replace

Consult Date

May 13, 2016

Quote Date

May 13, 2016

PO Line Items/HCPSC Location

Appear on Following Page

**Purchase Order Line Item Information**

<input type="button" value="+"/> <input type="button" value="-"/>	Item	26MM TAVR VALVE KIT	HCPC	SB185	Price	32,500	Quantity	1
BOC/Billing Item No.		20999		Serial Number		9600TFX (KIT REORDER #9600CM26A)/4932171		

**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
- ☐ NO J&A is required
- ☐ FSS: Add FSS J&A to Procurement Request
- ☐ ≥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 ☐

**Emergency/Urgent Requests:** An e-mail with subject line "Emergency" is to be transmitted to notify the NCO Prosthetics Manager of the emergency request by PSAS. PSAS should verify receipt of the order by the Prosthetics Team Lead and that action is being taken. All emergencies shall be received by Procurement no later than 2:00 PM for same day action. Any emergencies that arrive after the 2:00 PM same day cutoff will be executed by 10:00 AM the following business day. In the event no confirmation is received by 2:30 PM the PSAS requestor shall notify the NCO PSAS email Group.

**Time Zones:** For same day processing through distributors in varying time zones, be cognizant of time differences; emergency orders placed in Pacific time zones that require processing through VA offices located in Eastern time zones are to be placed with Procurement Activity prior to 11AM Pacific time for same day processing.

[Create Emergency eMail](#)

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 represents a compelling urgency in order to ensure the patient's physical well-being. The item described will be purchased from the Vendor identified because they are able to meet the Veteran's immediate need. Failure to meet the immediate need may result in physically injury to the patient, medical liability to the agency, and would adversely impact the mission and objectives of the VHA.

**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

John E. LaChance 224831

Digitally signed by John E. LaChance 224831  
DN: dc=gov, dc=va, o=internal, ou=people,  
0.9.2342.19200300.100.1.1=john.lachance@va.gov, cn=John E. LaChance  
224831  
Date: 2016.05.13 10:49:37 -05'00'

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

Deborah S. McGee  
256794

Digitally signed by Deborah S. McGee 256794  
DN: dc=gov, dc=va, o=internal, ou=people,  
0.9.2342.19200300.100.1.1=deborah.mcgee@va.gov,  
cn=Deborah S. McGee 256794  
Date: 2016.05.13 11:56:55 -05'00'

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

DoC -or-  
Designee

Robert A. Johnson 220249

Digitally signed by Robert A. Johnson 220249  
DN: dc=gov, dc=va, o=internal, ou=people,  
0.9.2342.19200300.100.1.1=robert.johnson3@va.gov, cn=Robert  
A. Johnson 220249  
Date: 2016.05.13 12:00:51 -05'00'