

PROCUREMENT OF SURGICAL IMPLANTS UNDER 38 U.S.C. 8123

1. REASON FOR ISSUE: To authorize Veterans Health Administration (VHA) to exercise limited use of Title 38 United States Code (U.S.C.) 8123 to execute alternative procedures for the purchase of surgical implants.

2. SUMMARY OF CONTENT: This directive establishes policy and responsibilities for managing the procurement of surgical implants under 38 U.S.C. 8123. Further, this directive defines limitations on the use of the authority when purchasing surgical implants.

3. RELATED ISSUES: VHA Directive 1048, Prosthetic and Sensory Aids Service Specific Purpose Funding, dated July 30, 2014, or subsequent policy. VHA Directive 1081, Procurement Process for Individual Prosthetic Appliances and Sensory Aids Devices Above the Micro-Purchase Threshold, dated March 25, 2014, or subsequent policy.

4. RESPONSIBLE OFFICE: The Office of VHA Prosthetic and Sensory Aids Service and the Office of VHA Procurement and Logistics are responsible for the content of this directive. Questions may be referred to <mailto:vhapsasadmin@VA.gov>.

5. RESCISSION: None.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of October 2023. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

Richard A. Stone, M.D.
Executive in Charge

NOTE: All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

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PROCUREMENT OF SURGICAL IMPLANTS UNDER 38 U.S.C. 8123

1. PURPOSE

This Veterans Health Administration (VHA) directive establishes policy, procedures, and responsibilities to use Title 38 United States Code (U.S.C.) 8123 authority for the procurement of surgical implants, without regard to any other provision of law.

NOTE: 38 U.S.C. 8123 authority will not be used to order surgical implants for inventory or to procure non-implant prosthetic appliances and sensory aids devices. See VHA Directive 1081, *Procurement Process for Individual Prosthetic Appliances and Sensory Aids Devices Above the Micro-Purchase Threshold*, dated March 25, 2014. This directive does not address responsibilities for management of surgical implantable devices.

2. BACKGROUND

a. On October 5, 2017, the Secretary of VA delegated section 8123 authority to the Under Secretary for Health (see Appendix A). This authority allows VHA to procure prosthetic appliances and necessary related services without regard to any other provision of law, including those requirements and limitations in the VA Acquisition Regulations (VAAR), 48 CFR parts 801 through 899, and Federal Acquisition Regulations (FAR), 48 CFR parts 1 through 99. Thus, the authority established in section 8123 precludes the application of any conflicting requirements imposed on VA by Federal procurement statutes or regulations.

b. Pursuant to this delegation of authority, responsible officials are expected to ensure procurement of surgical implants in VHA is efficient, effective, and provides timely access to quality patient care. Officials will develop detailed processes and documented internal controls that minimize risk to the surgical implant procurement process under the section 8123 authority. As compliance issues or new risks are identified, responsible officials will be accountable for implementing effective corrective actions or additional processes and internal controls.

3. DEFINITIONS

a. **Specialty Service.** For purposes of this directive, Specialty Service means any service with responsibility for prescribing and implanting surgical implants, specifically Cardiac Surgery, Thoracic Surgery, General Surgery, Gynecology, Neurosurgery, Ophthalmology, Orthopedic Surgery, Otolaryngology, Plastic Surgery, Podiatry, Urology, Vascular Surgery, Cardiology, Dental, Dermatology, Gastrointestinal, Interventional Pain, Interventional Radiology, Pulmonary, Women's Health Specialty Services.

b. **Specialty Service Personnel.** For purposes of this directive, Specialty Service personnel are any employees responsible for supporting the provision of care, to support a Prescribing Specialty Clinician, or to support administrative functions of an implanting Specialty Service.

c. **Consigned Surgical Implant.** A consigned surgical implant is provided for a specified period of time in which the contractor provides an item/s for Government use and the surgical implant contractor receives reimbursement only if and when the item is used by the Government. Surgical implant consignment may only be established under a surgical implant contract and by a Contracting Officer. This definition is also subject to 48 CFR 816.770, the Veterans Affairs Acquisition Regulation definition of Consignment agreements.

d. **Surgical Implant.** Surgical implant means any biological or non-biological material which is manufactured or processed to be placed into a surgically or naturally formed cavity on the human body; is covered with tissue, has the potential to be covered with tissue, or is permanently embedded in tissue. Surgical implants are implanted by Surgeons and Specialty Services including: Cardiac Surgery, Thoracic Surgery, General Surgery, Gynecology, Neurosurgery, Ophthalmology, Orthopedic Surgery, Otolaryngology, Plastic Surgery, Podiatry, Urology, Vascular Surgery, Cardiology, Dental, Dermatology, Gastrointestinal, Interventional Pain, Interventional Radiology, Pulmonary, Women's Health Specialty Services.

e. **Surgical Implant Coordinator:** A VA employee responsible for duties related to surgical implant management and utilization depending on the needs of the facility Specialty Service. Surgical Implant Coordinators are considered Specialty Service Personnel (see above) regardless of organizational alignment in a Specialty Service, Logistics Service, or PSAS.

f. **Prescribing Specialty Clinician.** For purposes of this directive, Prescribing Specialty Clinician means a clinician responsible for the treatment plan and directing which surgical implant is used during a procedure for an individual Veteran's treatment.

g. **Prescription.** For purposes of this directive, prescription means the treatment plan developed for a Veteran by the Prescribing Specialty Clinician.

h. **PSAS Personnel.** Prosthetics purchasing agents in series GS-1105 or prosthetics representatives in series GS-0672 working in a facility Prosthetics and Sensory Aids Service (PSAS) office who have been specifically delegated authority to use a purchase card to pay for surgical implants under this directive. PSAS personnel will have a written delegation on a VA Form 0242, Government wide Purchase Card Certification, [VA Form 0242](#) (This is an internal VA Web site that is not available to the public). The VA Form 0242 will be annotated for "Implants under 8123". This delegation is limited to payments for consigned surgical implants and surgical implants available on established surgical implant contracts with established prices at any value and for open-market surgical implants valued at or below the micro-purchase threshold.

4. POLICY

a. It is VHA policy to utilize the authority of 38 U.S.C. 8123 to optimize the procurement process for surgical implants to provide Veterans with timely access to care. This policy limits the use of 38 U.S.C. 8123 authority to surgical implants (and associated surgical implant expendables) that must be purchased, or used under

consignment, once a Prescribing Specialty Clinician has determined the patient-specific need.

(1) Prescribing Specialty Clinicians and Specialty Service personnel are authorized to verbally request delivery of surgical implants, or use of consigned surgical implants for routine, urgent, or emergency procedures directly from surgical implant contract holders, surgical implant manufacturers, and authorized distributors.

(2) Prescribing Specialty Clinicians have authority to purchase surgical implants by their action of implanting surgical implants. **Note:** *No written delegation of contracting authority is required.*

b. After a surgical implant is implanted by the Prescribing Specialty Clinician during a patient procedure, the following personnel are authorized to document and pay for the orders using the government purchase card as specified below:

(1) PSAS personnel for open-market surgical implants valued at or below the micro-purchase threshold, consigned surgical implants at any value, and surgical implants on established contracts at any value.

(2) Logistics personnel for associated surgical implant expendables funded with Logistics funds up to the micro-purchase threshold.

(3) Network Contracting Officers for open market surgical implants valued over the micro-purchase threshold funded with Prosthetic funding and for associated surgical implant expendables valued over the micro-purchase threshold funded with Logistics funding.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall compliance with this directive.

b. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management is responsible for:

(1) Communicating the contents of this directive to each VISN Director.

(2) Confirming that each VISN has, and utilizes on an ongoing basis, a means for ensuring the terms of this directive are fulfilled in all the VA medical facilities of the VISN.

c. **VHA National Director, Prosthetic and Sensory Aids Service (PSAS) and VHA Chief Procurement and Logistics Officer (P&LO).** VHA National Director, PSAS and Chief, P&LO are responsible for:

(1) Publishing on PSAS SharePoint site, <https://vaww.infoshare.va.gov/sites/prosthetics/default.aspx>, business process guidelines, standard operating procedures, internal controls, or any other type of

instruction to implement the authority pursuant to 38 U.S.C. 8123 to purchase surgical implants. **NOTE:** *This is an internal VA Web site that is not available to the public.*

(2) Maintaining auditable records to document purchases, invoices, and payment for surgical implants.

(3) Ensuring maximum availability of volume pricing arrangements with suppliers.

(4) Optimizing the surgical implant supply chain to minimize the need for just-in-time procurement.

(5) Developing a communication plan to suppliers, industry associations, and Veteran Service Organizations about the use of 38 U.S.C. 8123.

(6) Developing and communicating to appropriate VA entities internal controls to monitor adherence to this directive.

d. **Network Contracting Officers.** Network Contracting Officers are responsible for utilizing the PSAS's GUI interface and the government purchase card to document and pay for open market surgical implant orders over the micro-purchase threshold submitted by PSAS personnel in accordance with this directive, and to document and pay for associated surgical implant expendables submitted by Logistics personnel in accordance with this directive.

e. **Veteran Integrated Service Network (VISN) Director.** The VISN Director is responsible for ensuring that all Specialty Service, PSAS, and Logistics Service within facilities and the VISN comply with this directive.

f. **VA Medical Center Director.** The VA medical facility Director is responsible for ensuring facility compliance with this directive.

g. **Specialty Service Leadership.** Specialty Service leadership are responsible for:

(1) Implementing and communicating internal controls to monitor the adherence to this directive.

(2) Determining whether to dedicate a Surgical Implant Coordinator to perform some or all of the responsibilities assigned to Specialty Service personnel. Specialty Service Leadership are encouraged to work with their local medical facility leadership to request and assign surgical implant coordinators, as appropriate.

h. **Prescribing Specialty Clinicians.** Prescribing Specialty Clinicians, or Specialty Service personnel at the direction of the Prescribing Specialty Clinician, are responsible for:

(1) Recording each prescription in charts, notes, or a surgery request under the individual Veteran's name prior to implantation.

(2) Entering a post-procedural surgical implant consult in Computerized Patient Record System (CPRS) within 2 business days after the surgery. The consult must include:

- (a) Date surgical implant was requested from vendor;
- (b) Date of surgery;
- (c) Vendor name;
- (d) Type of procedure;
- (e) Name of surgical implant(s) used and quantity;
- (f) Serial/lot number(s); and
- (g) Wasted surgical implants.

i. **Specialty Service Personnel.** At the direction of the Prescribing Specialty Clinician, Specialty Service personnel are responsible for:

(1) Verbally requesting either delivery or consigned surgical implants for routine, urgent, or emergency procedures directly from surgical implant contract holders, surgical implant manufacturers, and authorized distributors. The request for delivery must be medically necessary and documented by a prescription in CPRS. ***NOTE: The Prescribing Specialty Clinician has the authority to select which surgical implant is medically necessary. The implantation of the surgical implants by a Prescribing Specialty Clinician is an authorized obligation.***

(2) Requesting only surgical implants which are approved by the Federal Drug Administration. ***NOTE: Grey market surgical implants are prohibited.***

(3) Requiring vendors to submit invoices within 24 hours after surgery and to submit separate invoices for surgical implants to PSAS, and associated surgical implant expendables to Logistics.

NOTE: All payments for surgical implants will be processed by PSAS or Contracting personnel and for associated surgical implant expendables, Logistics Service personnel.

j. **Prosthetic and Sensory Aids Service (PSAS) Personnel.** PSAS personnel are responsible for:

(1) Confirming receipt of and comparing the actionable post-procedural surgical implant consult and invoices/proof of delivery to ensure that the payment amount is complete and accurate, and cooperating with Specialty Service personnel or vendors if additional information is required

(2) Complying with established scorecard performance measures for purchase order timeliness.

(3) For surgical implants on established contracts, including consigned surgical implants, reviewing and confirming invoice prices by matching prices against contracted prices before issuing a purchase order, and disputing and correcting non-matching prices before issuing a purchase order to authorize payment.

(4) Utilizing the GUI interface and government purchase card to document and pay for all orders made by Specialty Service personnel for open-market surgical implants valued up to the micro-purchase threshold, and to document and pay for contract surgical implants at any value.

(5) Submitting an Acquisition Plan to the Network Contracting Office for all open market surgical implant orders over the micro-purchase threshold. Warranted Contracting Officers are authorized to document and pay for market surgical implant orders over the micro-purchase threshold funded with Prosthetic funding. Network Contracting Officers will assure prices are fair and reasonable before payment.

(6) Completing a purchase order with the PSAS Vista GUI package/APAT for surgical implants, closing out the consult; and sending a copy of the purchase order to the vendor for payment.

(7) Reconciling purchase card transactions in accordance with established timelines and VA Financial Policy Volume XVI – Charge Card Programs. Closing out individual patient purchase card charges within the Prosthetic's reconciliation menu and reconciling with the authorized bank.

(8) PSAS personnel who are purchase card approving officials will ensure surgical implant payments are proper and in accordance with purchase card policy.

k. **Logistics Personnel.** Logistics Personnel are responsible for:

(1) Utilizing the government purchase card to document and pay for all associated surgical implant expendables funded with Logistics funds up to the micro-purchase threshold in accordance with VA Financial Policy Volume XVI – Charge Card Programs.

(2) Confirming receipt of and comparing invoices/proof of delivery to ensure that the payment amount is complete and accurate and matches existing contract prices, when applicable and cooperating with Specialty Service personnel or vendors if additional information is required.

(3) Reconciling purchase card transactions in accordance with established timelines and policy. Closing out individual patient purchase card charges within the purchase card order reconciliation menu and reconciling with the authorized bank.

(4) Logistics personnel who are purchase card approving officials will ensure associated surgical implant expendable payments are proper and in accordance with purchase card policy.

(5) Submitting an Acquisition Plan to the Network Contracting Office for all invoices over the micro-purchase limit. Network Contracting Officers are authorized to document

and pay for associated surgical implant expendable submitted by Logistics in accordance with this directive.

6. DEVELOPMENT OF VHA BUSINESS PROCESSES (SEE APPENDIX B)

The VHA business processes developed in accordance with this directive must adhere to the following when procuring surgical implants:

a. Improve internal controls, streamline administrative processes, and optimize spending by prioritizing utilization of contracts for surgical implants that leverage volume pricing with high-volume suppliers.

b. Optimally use the expertise and time of Specialty Service personnel, PSAS personnel and Contracting Officers.

c. Utilize the requirements of VHA Directive 1048, Prosthetic and Sensory Aids Service Specific Purpose Funding, dated July 30, 2014, to serve as written assurance of funds for obligations made by authorized Prescribing Specialty Clinicians.

7. TRAINING REQUIREMENTS

VHA National Director, Prosthetic and Sensory Aids Service (PSAS) and VHA Chief Procurement and Logistics Officer (P&LO) are responsible for providing training to Prescribing Specialty Clinician, Specialty Service personnel, PSAS personnel, Logistics personnel, and Network Contracting Officers who have a role in the procurement of surgical implants in accordance with directive about the limitations on authority and how to order, document, and pay for surgical implants and associated surgical implant expendables. Additionally, all purchase card holders paying under the authority of this directive are required to meet the training requirements specified in Volume XVI, VA Charge Card Program, Chapter 1A, Administrative Actions for Government Purchase Cards, Appendix A, Government Purchase Card Training Requirements.

8. RECORDS MANAGEMENT

All records regardless of format (paper, electronic, electronic systems) created by this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. If you have any questions regarding any aspect of records management you should contact your facility Records Manager or your Records Liaison.

9. REFERENCES

a. 38 U.S.C. 8123.

b. 38 CFR 17.150.

c. Secretary of Veterans Affairs Memorandum, Delegation of Authority to Implement 38 United States Code (U.S.C.) 8123, Procurement of Prosthetic Appliances, dated October 5, 2017.

d. VHA Directive 1048, Prosthetic and Sensory Aids Service Specific Purpose Funding, dated July 30, 2014.

e. VA Financial Policy Volume XVI – Charge Card Programs.

**DELEGATION OF AUTHORITY TO IMPLEMENT 38 UNITED STATES CODE (U.S.C.)
8123, PROCUREMENT OF PROSTHETIC APPLIANCES**

**Department of
Veterans Affairs**

Memorandum

Date: **OCT 5 - 2017**

From: **Secretary (00)**

Subj: **Delegation of Authority to Implement 38 United States Code (U.S.C.) § 8123,
Procurement of Prosthetic Appliances (VAIQ 7836622)**

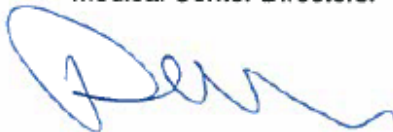
To: **Under Secretary for Health (10)**

1. I delegate authority to the Under Secretary for Health (USH) to act on behalf of the Department of Veterans Affairs (VA) to implement 38 U.S.C. § 8123.
2. **AUTHORITY:** 38 U.S.C. § 8123, "The Secretary may procure prosthetic appliances and necessary services required in the fitting, supplying, and training, and use of prosthetic appliances by purchase, manufacture, contract, or in such other manner as the Secretary may determine to be proper, without regard to any other provision of law."
3. **BACKGROUND:** This delegation promotes streamlined operational business processes to meet Veterans' clinical needs and provide Veterans access to prescribed care, while advancing the procurement of prosthetic appliances and services with efficient business processes outside of the requirements and limitations of VA Acquisition Regulations or Federal Acquisition Regulations.
4. **RESTRICTIONS:** The USH, in consultation with VA Office of Management, will establish efficient business processes under this authority to ensure internal controls on spending and to meet statutory requirements for recording financial obligations. The USH will ensure managers and employees are accountable to follow procedures and internal controls implemented under this authority.
5. **PROVISIONS:** The new business processes may include the following provisions:
 - a. Approval of non-warranted individuals to contact vendors and verbally obligate the Government by requesting prosthetic appliances be provided.
 - b. Approval of non-warranted individuals to establish purchase orders and use purchase cards to pay for such orders without regard to micro-purchase threshold limitations.
 - c. Approval of establishing written obligated purchase card orders and payment to vendors after the product has been used.

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Subj: Delegation of Authority to Implement 38 United States Code (U.S.C.) §
8123, Procurement of Prosthetic Appliances

6. This delegation of authority is effective immediately and will be implemented only after formal concurrence of a new business process document within 60 days of signature. This delegation may not be delegated to Network Directors or Medical Center Directors. This authority will remain in effect until rescinded.

A handwritten signature in blue ink, appearing to read 'D. Shulkin', is positioned above the printed name.

David J. Shulkin, M.D.

PROCUREMENT SURGICAL IMPLANT PROCESS**1. BEFORE A SURGICAL IMPLANT PROCEDURE OCCURS (PRE-PROCEDURE):**

Overview: A surgical implant will be procured (or used from consigned stock) as prescribed by a Prescribing Specialty Clinician for an individual Veteran and at the time needed for a procedure. Only Prescribing Specialty Clinician may decide what surgical implant items will be used. Prescribing Specialty Clinicians are encouraged to use surgical implants available on established contracts at discounted prices. Lists of contracted surgical implants are provided to services by the PSAS. Pre-procedure Actions:

- a. Prescribing Specialty Clinician/Specialty Service/Surgical Implant coordinator determine what surgical implants need to be ordered.
- b. Specialty Service/Surgical Implant Coordinator contacts the vendor to verbally (or by email or other form) to make available to order needed surgical implants and associated surgical implant expendables (if needed) and schedule delivery time/place.
NOTE: *If associated surgical implant expendables are ordered, the Specialty Service/Surgical Implant Coordinator will notify Logistics personnel of items that will required Logistics payment.*
- c. Vendor delivers the requested surgical implant and associated surgical implant expendables.
- d. Specialty Service receives the delivered surgical implants and completes any pre-procedure preparation of the surgical implants such as sterile processing.
- e. Prescribing Specialty Clinician performs the Veteran care using the surgical implants, thereby obligating the government to payment for the items.

2. AFTER IMPLANTATION IS COMPLETE:

Overview: Only PSAS personnel who have submitted a VA Form 0242 annotated for 8123 authority and have received the necessary single purchase limit increase on their card, are authorized to pay for surgical implants on contracts valued above the micro-purchase threshold. Other PSAS personnel may pay for contract or open market surgical implants valued \$10,000 (or current micro-purchase threshold) or under without submitting an 8123-annotated VA Form 0242. Logistics personnel purchase card holders and warranted Contracting Officers are not required to submit an 8123-annotated VA Form 0242. Post-procedure Actions:

- a. Specialty Service personnel submit a CPRS Surgical Implant post-procedure consult to PSAS no more than 2 business days after implantation day.
- b. Vendor submits invoice and sticker sheets, if applicable, to PSAS and submits invoice for associated surgical implant expendables to Logistics, if expendables are used.

c. PSAS personnel match a post-procedure consult in CPRS to a vendor invoice and review for accuracy and completeness. PSAS returns any document for correction or additional information if needed.

(1) PSAS completes purchase card transaction and sends written order record using VA Form 10-2421, Prosthetics Authorization for Items or Services to vendor when the invoice only contains surgical implants available on established contracts or the value is under \$10,000 (or current micro-purchase threshold) for open market surgical implants.

(2) For all others, PSAS prepares and submits a request for surgical implant payment to the Network Contracting Office using an acquisition plan document in the FORCE module.

d. Logistics personnel match a post-procedure consult in CPRS to a vendor invoice and review for accuracy and completeness. Logistics personnel return any document for correction or additional information if needed.

(1) Logistics personnel completes a purchase card transaction and sends a written order using VA-Form 2138, Purchase Card Order to the vendor when the value of the surgical implant expendables invoice is \$10,000 (or current micro-purchase threshold) or under.

(2) For all others, Logistics personnel prepares and submits a request for associated surgical implant expendables payment to the Network Contracting Office using an acquisition plan document in the FORCE module.

e. Network Contracting Officers receive requests for surgical implant or associated surgical implant expendable payment through FORCE. They review the invoice and other documents for accuracy and completeness. They return any document for correction or additional information if needed. A Network Contracting Officer completes a purchase card transaction and sends a written order record using VA Form 10-2421, Prosthetics Authorization for Items or Services to the vendor. For associated surgical implant expendables, use a VA Form 2138, Purchase Card Order.

f. Vendors, after receiving a written order and authorization to charge the purchase card from either PSAS personnel, Logistics personnel, or a Network Contracting Officer, will charge the provided credit card number to receive their payment.

g. Reconciliation of posted Vendor charges is required.

(1) Daily, or as needed, PSAS personnel (cardholder and approving official) will reconcile charged purchase card transactions in GUI and the bank system and close out the consult records in GUI.

(2) Daily, or as needed, Logistics personnel (cardholder and approving official) reconcile earlier purchase card transactions in IFCAP and the bank system.

(3) Daily, or as needed, Network Contracting Officers (cardholders and approving officials) reconcile earlier purchase card transactions in GUI, IFCAP, and the bank system and close out the consult records in GUI.