

Department of Veteran Affairs
VA Pittsburgh Healthcare System (VAPHS)
CUSTOM STERILE PROCEDURE PACKS

I. PURPOSE

Provide for a Custom Sterile Procedure Pack Program for the production and delivery of individualized custom procedure packs to be utilized by the Department of Veteran Affairs, VA Pittsburgh Healthcare System (VAPHS), University Drive C, Pittsburgh, PA 15240. The Custom Sterile Procedure Pack Program will include pack assembly/manufacture, sterilization, quality assurance, and packaging, contractor electronic communication ordering reporting, and delivery. Orders will be made for the custom trays as identified in Contract/Solicitation Attachment A – Pack Contents.

II. SCOPE

The Contractor shall provide all labor, materials, transportation, in compliance with federal, state and local regulations, to provide a Custom Sterile Procedure Pack program for the VAPHS.

III. TERM OF AGREEMENT

This will be a single award, firm-fixed price contract for a period of 51 months, if options are exercised. VAPHS intends to establish the period of performance from 07/01/2018 through 09/30/2022.

IV. SPECIFICATIONS

All components must meet the following industry standards in accordance with the below:

All aspects of pack assembly, packaging and sterilization must adhere to the quality control standards set by the FDA. All specifications for the sterilization process shall meet or exceed the current standards for Association for Advancement of Medical Instrumentation (AAMI); International Association of Healthcare Central Service Material Management (IAHCSMM). The Contractor shall follow current ISO (International Organization for Standardization) for Sterilization of health care product and any other applicable industry standard listed within this statement of work.

V. ORDERING

Upon validation of pack configuration of components and after approval of any required first article testing, an order will be issued to initiate pack manufacture and delivery.

ORDERING PROCEDURES:

PERSON'S AUTHORIZED TO PLACE ORDERS:

The following Government staff members are authorized to place orders under this contract:

1. To Be Determined
2. To Be Determined

(1) Orders shall be issued by facsimile or electronic commerce methods, and only by the Contracting Officer or his/her authorized VA representative for the CLIN Series outlined in the schedule of items identified in the awarded contract.

(2) Orders shall contain at a minimum the following information:

- (a) Date of order;
- (b) CLIN, Description, Quantity, Unit Price, and Total Amount;
- (c) Delivery

(3) Upon receiving an order, the Contractor shall deliver within three (3) calendar days for standard deliveries and within twenty-four (24) hours for emergency deliveries, unless otherwise stated in the delivery order. VAPHS Warehouse opens at 7:00am each morning, Monday-Friday (except for federal holidays). Contractor shall consult with COR regarding special deliveries on holidays, if acceptable to the facility and its need for product.

VI. CHANGES TO COMPOSITION/COMPONENTS OF PROCEDURE TRAYS.

A. Changes to Composition/Components of Procedure Trays.

(1.) The VAPHS may change individual component parts of the tray/pack after thirty (30) days of usage due to technology changes or advancements. The contractor will meet quarterly (every three (3) months) with the COR to discuss changes as needed. **Changes shall not be accepted by the Contractor by any other facility employee other than the Contracting Officer (CO) or Contracting Officer Representative (COR).** The Contractor shall be requested to consider all component part changes and provide a price estimate of each item to be changed. The price proposal will include price plus an estimate for credit for deleted items. Changes will be made by contract modification/supplemental agreement.

- a.) All parties shall agree to changes and must be acknowledge by written correspondence. Items must be identified by an item number, description, quantity and cost.

b.) Substitutions of items shall not be made without prior approval, in writing by the contractor and COR.

- B. The Contractor's Quality Assurance shall verify changes and ensure the product meets the Government specification. When additions or deletions occur, the Contractor shall provide the Contracting Officer/COR with the costs of each individual component added or deleted at the time of the change or before written authorization by the Contracting Officer.
- C. It is reasonable to expect usage and/or requirements may change during the contract period. The Government reserves the right to negotiate with the Contractor to add and/or delete item(s) to pack components.
- D. If for any reason the Contractor is unable to deliver the agreed upon packs, the contractor will provide (12) hour notice to the COR. The contractor will find an alternative source and initiate a backup plan.

VII. DELIVERY REQUIREMENTS

- A. All deliveries are FOB Destination to the VAPHS. Supplies shall be delivered to the destination warehouse unloading platform, or receiving dock, at the expense of the Contractor, except in the case of certain emergency orders. The Government shall not be liable for any delivery, storage, demurrage, accessorial, or other charges involved before the actual delivery. The contractor shall ensure that the carrier will furnish tailgate delivery, when required, if transfer to truck is required to complete delivery.
- B. Upon receipt of an order, for approved manufactured and ready for distribution packs, required deliveries of such packs shall be made within three (3) days. Each order will state the quantity of packs required, delivery date, and delivery and billing address. It is possible that the contracting office will issue one delivery order for the year, with actual deliveries to be specified by authorized staff at the VAPHS.
- C. Emergency deliveries, if required, must be delivered within 24 hours, and must be available on Federal Holidays and weekends. Emergency deliveries may be subject to additional shipping costs, unless the emergency is due to a vendor backorder.

VIII. PACKAGING

- A. Unless otherwise specified in the statement of work, the product shall be packed in substantial containers of the type, size and kind commonly used within the industry for this purpose. The container(s) will be constructed as to ensure acceptance and safe delivery by common carriers to the point of delivery designated by each facility. Items must be packaged adequately to prevent deterioration and damage during shipping, handling and storage. All packs must be clearly labeled on the outside covering if they contain latex products. **However, all products should be totally latex free.**

Each pack shall have a label specifying the manufactured date and sterilization date of the pack and the expiration date of any dated products. This label, located inside of each pack, shall also contain an itemized listing of all components, as well as any missing items that were approved to be left out by the VA. Pack contents list must contain item, quantity, and country of origin information. Color coded packs, or some sort of visual cue to distinguish between pack types must be available upon request by the COR at no additional charge. Expiration dating of all custom sterile procedure packs delivered

under this program shall have a minimal shelf life of 12 months remaining upon delivery to the Government. Prior written approval by the facility COR is required before delivery of short dated products.

- (1) Each pack shall also have a separate label on the outside of the pack that includes the ordering station number and station specified pack name.
- (2) All outer shipping packages shall contain the complete contract number and delivery order number in addition to the shipping address.
- (3) Package content quality is the responsibility of the contractor, including items affixed to the outside of the pack (piggyback) and distributed as a part of the pack. Any pack determined to be defective (e.g. contains expired components, sterility has been compromised, etc.), through no fault of the Government, shall be returned to the Contractor at the Contractor's expense. Full credit or replacement shall be made to the Government.

IX. MANUFACTURING

A. ASSEMBLY AND STERILIZATION

The contractor shall ensure an individual lot number for each custom sterile procedure pack is assigned for clear tracking of all packs. The packing list shall include the manufacturer and lot number of each component item to ensure traceability. The contractor shall meet the following assembly and sterilization requirements:

- (1) The contractor shall validate the sterilization process, with the Association for Advancement of Medical Instrumentation (**AAMI**) at a minimum annually.
- (2) All Component debris, sterility tests, and residual tests are to be performed by contractor at contractor's expense.
- (3) The contractor shall guarantee prior to sterilization, the products shall be assembled in secure air controlled rooms, which are accessible only to authorized personnel with proper attire. International Association of Healthcare Central Service Material Management (IAHCSMM) (<https://www.iahcsmm.org>) and Association for the Advancement of Medical Instrumentation (AAMI) (<http://www.aami.org>) provide guidelines for proper attire.
- (4) The Contractor shall follow current **ISO** (International Organization for Standardization) for Sterilization of health care product.
- (5) The contractor shall guarantee all aspects of the assembly, packaging and sterilization must adhere to the quality control standards set by the **FDA**. The

Contractor (all entities in the production process) shall be registered with the FDA.

- (6) In accordance with the Executive Order 13514 dated October 5, 2009. The Contractor should consider earth friendly solutions, and provide a program that supports green purchasing. Contractor should provide a recycling program for re-useable items that are salvageable and recommend green product components when available.
- (7) The Contractor shall not provide re-sterilization of any single use product for resale to the VA.
- (8) The Contractor shall have in-house sterilization capability or have, the ability to provide sterilization services at all times. The in-house or contract sterilization partners shall be ISO9001:2000 (International Organization for Standardization) certified and undergo routine FDA inspections.
- (9) The contractor shall inspect all component products and also check for damage and short dates.
- (10) The Contractor shall have continual maintenance performed on all sterilizing equipment.
- (11) The contractor shall provide quality assurance staff which shall include personnel familiar with operating room procedures, infection control practices, aseptic techniques and sterilization methods.
- (12) The contractor shall ensure that all individual components within the pack are **TAA** compliant unless otherwise authorized by the CO to place orders from a non-TAA compliant country.

B. COMPONENT PARTS

- (1) Components that are listed as **DO NOT SUBSTITUTE** are due to the requirements of the specific medical center staff or instruments currently being used in the operating room or other circumstances. The substitution or changing of these specific items after award would require the changing of instruments or equipment in order to utilize the substitute of an alternative item. Should an equal product be substituted in lieu of that specified, the product line must specify which item is equal and substituted for which item and be approved by the medical center prior to substitution. If no substitution of an equal product is offered, it will be presumed the offeror will provide the pack as specified.
- (2) Items that are subject to substitution -All substitutions shall be clearly identified with country of origin, and shall be **TAA** compliant.
- (3) All component items required for the tray/pack are to be provided by the Contractor. All component packaging will be removed from outer packaging

to reduce steps in the operating/procedure room, unless otherwise required by the customer or the component manufacturer.

- (4) All packs are to use hard plastic base trays and components parts to reduce **ETO** (Ethylene Oxide) residue and eliminate possible particulate contamination from Styrofoam. Biodegradable trays that have the same affect are acceptable. ETO tape/indicator is to be affixed to the outer wrap and tray where applicable. All custom packs should be sterilized in an approved packaging material with a plastic dust cover. Custom packs material must allow the sterilization of the contents, maintain sterility, and provide a way to remove the contents without contamination. Plastic dust covers should be sealed with a method of sealing which results in a complete seal that is tamper evident and allows for ease of aseptic presentation. Accessories used to secure custom packs should be chosen to allow penetration of the sterilization process, avoid constriction of the package and maintain package integrity.
- (5) Requirements for gowns and drapes shall meet the following criteria:
 - (a) Materials shall be of a soft, memory-free type that precludes shifting of drapes.
 - (b) Material shall be non-abrasive and free of toxic ingredients, non-fast dyes and noxious odors.
 - (c) Materials shall be non-glare and of a color that minimizes distortion from reflected light.
 - (d) Gowns shall fit and allow freedom of movement. Gowns shall have stockinet cuffs, raglan sleeves and welded or stitched seams.
 - (e) Gowns and drapes shall maintain an environment appropriate to body temperatures.

When substitutions are necessary and approved for surgical gowns and drapes, quantitative data must be available to show that the materials for surgical gowns and drapes provide an effective barrier to microbes. The materials must meet the American Society for Testing and Materials (ASTM) requirements for barrier protection, including blood borne pathogens, microbial challenge, as well as hydrostatic pressure with resistance to tears, abrasion and stains. All materials must be lint-free and meet or exceed the requirements of the National Fire Protection Regulations for flammability in Part 1610 of the Code of Federal Regulations.

- (6) The materials for cloth towels must meet the American Society for Testing and Materials (**ASTM**) requirements for barrier protection, including blood borne pathogens, microbial challenge, as well as hydrostatic pressure with resistance to tears, abrasion and stains. All materials must be lint-free and meet or exceed the requirements of the National Fire Protection Regulations for flammability in Part 1610 of the Code of Federal Regulations. When substitutions are necessary and approved for cloth towels, x-ray detectable or not, they are to be absorbent, disposable or towels made of 100% cotton, and pre-washed.
- (7) All components must be **Latex Free** unless specified otherwise by the using facility. All packs must be clearly labeled on the outside covering if they

contain latex products. All products containing latex must also be clearly labeled individually as containing latex.

C. UNAVAILABILITY OF COMPONENT PARTS

Should a component part become unavailable which will temporarily or permanently delay the production of the pack(s), the Contractor shall immediately notify the (COR) and the Contracting Officer by telephone (with written notice to follow within five (5) calendar days) of the situation and the anticipated length of delay.

At a minimum, the unavailability notification shall include the following information:

- (1) Complete item description, (product and lot number) and/or identification
- (2) Contract and Delivery Order
- (3) Reason for unavailability
- (4) If a direct recall was issued, the contractor shall include the manufacturer disposition instructions and level of recall.

Recalls: In accordance with the **Safe Medical Device Act**, (SMDA) the Contractor shall have a documentation system for component product traceability and lot number recordings for product recalls. The Contracting Officer and Contracting Officer Representatives (COR) must be notified immediately by telephone (with written notice to follow within five (5) calendar days) if affected by a product recall. The contractor shall also provide a method of identifying affected packs on the shelf such as a brightly colored sticker or other visual identifier within 24 hours so that VA may mark the existing pack identifying the recalled component(s). Vendor existing inventory will be marked using the same method provided to VA staff. If the recalled component is unavailable for further production of the custom sterile procedure pack(s), no substitutions will be made by the Contractor without written authorization of the CO. Pack conversions in the result of a recall shall adhere to the same timelines for change out as all other pack conversions.

The contractor shall notify the COR and the Contracting Officer of any Manufacturer Backorder (MBO). The status clearly states the reason for any unavailability of component parts due to MBO and shall indicate the length of time for replenishment by product supplier. The government retains the right to investigate the backorder situation to determine the cause of the backorder and to provide assistance to the Custom Sterile Procedure Pack contractor and the participating customers during the MBO period.

No deletions or substitutions will be made without written authorization from the Contracting Officer or delegated representative. If the component will be out of stock for a prolonged period of time and the using service chooses to have the pack assembled without the product, written authorization must be given by the Contracting Officer or COR. The cost of the pack must be adjusted to reflect the change. In addition, the content listing will clearly identify any missing items approved to be left out by the VA.

X. PERFORMANCE STANDARDS

- A. The contractor is responsible for performance of ALL terms and conditions of the contract. CORs will provide contract progress reports quarterly to the CO reflecting performance on this plan and all other aspects of the contract.

XI. QUALITY ASSURANCE

- A. The Custom Sterile Procedure Pack manufacturing facilities must be registered and in good standing with The FDA and ISO9001:2000 certified **ISO**, **CEN** (European Committee for Standardization), **AAMI** (Association of the Advancement of Medical Instrumentation), and **AORN** (Association of Operating Room Nurses) are other Industry standards that must be met. Per FAR 25.4, Trade Agreements, each end product is certified as a U.S.-made, designated country, Caribbean Basin country, or **NAFTA** country (Canada or Mexico) end product.
- B. “Quality System Program” to prevent non-conformances at all product/service stages from design through distribution must be utilized. It is designed to comply with the requirements of **ISO9001:2000** , 21 CFR 820 (Code of Federal Regulations), **EN 46001** , and United States regulations regarding the sales and distribution of medical products. At a minimum ISO9001:2000 Certification must be available at time of proposal submission, and continuously maintained throughout the duration of the contract.
- C. The Custom Sterile Procedure Pack program must provide certain measures in the manufacturing of the kits.
 - (1) Product specifications including video images, bills of material, biological evaluations, component specification, and identification of critical design and process parameters. These include how the parameter is to be met.
 - (2) Production process specifications, including the appropriate equipment specification, production methods, production procedures, compatibility of the design with current systems and equipment.
 - (3) Quality assurance procedures and specifications, i.e., quality plan, including quality assurance checks used and the quality testing apparatus, fixtures, resources, skills, subjective standards and documentation used.
 - (4) Packaging and labeling specifications, including methods and processes used.
 - (5) Sterilization requirements and methods.
 - (6) Testing requirements and methods.

The Government may, at its option and expense, request an unrelated third party to inspect the packs provided by the Contractor. The Contractor shall repair, at the Contractor’s cost, any faults or omissions discovered by the inspection of the third party within fifteen (15) days when notified by the COR.

The Government may, at its option and expense, inspect the contractor’s manufacturing and distribution centers at least annually, within five working days upon request by the COR.

XII. FURNISHED ITEMS AND SERVICES

- A. The Government shall not provide the facilities, equipment, materials, or any products under this contract.

- B.** The Contractor shall furnish and provide everything required to perform this contract in accordance with all of its terms.

XIII. ABBREVIATIONS/DEFINITIONS

AAMI:	Association for Advancement of Medical Instrumentation
AORN:	Association of Operating Room Nurses
ASTM:	American Society for Testing and Materials
CEN:	European Committee for Standardization
CFR:	Code of Federal Regulations
CO:	Contract Officer
COR:	Contracting Officer Representative(s)
EN 46001:	European Nations Quality Standards
ETO:	Ethylene Oxide
FAR:	Federal Acquisition Regulation
FDA:	Food and Drug Administration
GS1:	Global Standards 1
HF:	High Frequency
ISO:	International Organization for Standardization
MBO	Manufacturers Back Order
MSDS	Material Safety Data Sheet
NAFTA:	North American Free Trade Agreement
PO:	Purchase Order
PHT/DEHP	Phthalates and Di(2-ethylhexyl)phthalate
RFID:	Radio Frequency Identification
SMDA	Safe Medical Device Act
TAA:	Trade Agreements Act
UHF:	Ultra High Frequency
VA:	Department of Veterans of Affairs

Component	A component is an item or set of items in a pack, used in a procedure for the benefit of the patient or clinician. Components are not defined as material required, while maintaining the integrity of the package.
Contractual Exceptions	Packs not shipped due to manufacturer's backorder, manufacturer's recall, manufacture's discontinued items. Packs for which delivery is excusable as set forth in FAR 52.212-4(f).
Custom Sterile Procedure Pack Program	Custom pack programs are designed to develop individualized procedure packs to save on operating room start-up times, cut down on the time between patients, and generally create standard practices that result in hospital effectiveness, efficiency and charge/cost capture.
Fill Rate	Rate in which ordered products are delivered within contracted delivery time. The calculation for fill rate will be (Items Delivered/Items Ordered). The fill rate is applicable to all approved full production custom sterile procedure packs.

First Article Pack	As defined by the FAR, a First Article means a preproduction model, initial production sample, test sample, first lot, pilot lot, or pilot models. First article packs shall be at no cost to the Government.
Manufacturer Back Order (MBO)	A physical order placed by the Custom Sterile Procedure Pack contractor to a product supplier and which is not shipped to the Custom Sterile Procedure Pack Contractor from the product supplier within thirty days.
New Pack	A brand new pack that is required of the facility that is newly configured.
Pack Conversion	A reconfiguration of an existing pack.
Piggyback	Component part that is affixed to the outside of the custom sterile procedure pack due to the inability to include it inside the pack (i.e. unique sterilization requirements).
Radio-frequency identification (RFID)	The wireless use of electromagnetic fields to transfer data, for the purposes of automatically identifying and tracking tags attached to objects. The tags contain electronically stored information. Some tags are powered by electromagnetic induction from magnetic fields produced near the reader. Some types collect energy from the interrogating radio waves and act as a passive transponder. Two primary frequencies are used within the VA. They are 13.56 MHz High Frequency (HF) and 433 MHz Ultra High Frequency (UHF).
Short Dated Product	Any product delivered with an expiration date less than twelve months from date of delivery.
Packs Totally Filled	Includes an order for which all packs ordered were delivered
Packs Partially Filled	Includes any packs where the quantity delivered is less than quantity ordered.