DRAFT DOCUMENT

STATEMENT OF WORK

1. CONTRACT TITLE: Custom Surgical Procedure Trays IDIQ for the VA Asheville Medical Center

2. BACKGROUND

   Provide for a Custom Sterile Procedure Pack Program for the production and delivery of individualized custom procedure packs to be utilized by the VA Asheville Medical Center (Charles George VA Medical Center) in Asheville, North Carolina. 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. All aspects of pack assembly, packaging and sterilization must adhere to the quality control standards set by the FDA.

3. SCOPE

   The Contractor shall provide all labor, materials, transportation, equipment and supervision, in compliance with federal, state and local regulations, to provide a Custom Sterile Procedure Pack program for the Charles George Medical Center.

4. IMPLEMENTATION PERIOD

   4.1. Implementation Plan: The contractor shall submit a plan to the Contracting Officer (CO) and Facility Point of Contact (Facility POC) outlining how it intends to implement the Custom Sterile Procedure Pack program within 30 calendar days after receipt of award notification. If the initial plan is disapproved, the contractor shall provide corrected plans, using the same time period above, until approved by the Contracting Officer.

   4.2. During the implementation period, the contractor shall validate pack configuration to ensure compliance with facility specifications. Validation shall consist of, but not be limited to the following tasks:

      4.2.1. Configuration of components from Contract/Solicitation Attachment A – Pack Contents List.
      4.2.2. Production of First Article Packs shall be required at the request of the Facility Point of Contact (Facility POC).
      4.2.3. Delivery of first articles for testing and approval. Production of approved packs upon confirmation from the Facility POC and Contracting Officer (CO).

5. TRANSITION PLAN

   The Charles George Medical Center may have current inventory that will have to be exhausted prior to placement of orders. The contractor shall have sufficient inventory to begin performance on day one (1) of the ordering period (period of performance). The Contractor shall provide copies of the standard operating procedures governing batch control, product tracing, component manufacturing lot numbering, and written policies and/or procedures on component recalls within 30 days of contract award and within two weeks of any pack conversion.

6. ORDERING

Upon validation of pack configuration of components and after approval of any required first article testing, a delivery order will be issued to initiate pack manufacture and delivery. A separate delivery order for the initial transition custom pack orders and for each subsequent order will be provided to the contractor.

7. ORDERING PROCEDURES

7.1. Delivery 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.

7.2. Delivery Orders shall contain at a minimum the following information:
- 7.2.1. Date of order;
- 7.2.2. Contract Number and Order Number;
- 7.2.3. CLIN, Description, Quantity, Unit Price, and Total Amount;
- 7.2.4. Delivery or performance Schedule; and
- 7.2.5. Place of Delivery or Performance (Including Consignee)

7.3. Delivery orders under this contract may either be for specified delivery, or fully-funded standing orders to cover deliveries under a specified period. Upon receiving a delivery order or request for delivery from the Facility POC (on an active Standing Delivery Order), the Contractor shall deliver within five (5) calendar days for standard deliveries and within twenty-four (24) hours for emergency deliveries, unless otherwise stated in the delivery order.

7.4. The Contractor shall have full-time representation to receive orders. The Government shall place delivery orders to the following: **(Offeror to complete)**

(a)	Contact Person:	_____
(b)	Telephone Number:	_____
(c)	Fax Number:	_____
(d)	Department:	_____
(e)	Address:	_____
		_____
		_____

7.5. In accordance with contract clause FAR 52.216-19, Order Limitations, if the Contractor does not wish to provide deliveries requested on a delivery order, which are below the minimum order amount or above the maximum order amount as specified herein they shall submit in writing within twenty-four (24) hours of receipt of the delivery order, an explanation of non-intent.

7.6. Under this contract, facility needs may require flexibilities to place daily, weekly, monthly, quarterly, annual, or other interval orders upon facility conversion to be delivered at specified dates. Once placed, the ordering frequency may need to change at any time for orders to be delivered within the contractually required timeframes. The Government requires a supplier that can be flexible in meeting the changing needs of the Government. The scenarios are not all inclusive of the Government's needs, but are representative of the flexibilities necessary.

8. PRODUCTION AND SUPPLY

8.1. The Government requires the Contractor to undertake production of such quantities of the product as are necessary to reasonably assure the Government of an uninterrupted supply of the product based upon an anticipated monthly usage. The Government may not obligate funds for product in inventory or production whenever the contract is terminated. The Contractor shall complete component pack changes within thirty (30) days. Due to the possible need for changes, the Government shall be obligated to only a thirty (30) day supply of packs manufactured at the time of the change acceptance and not exceeding the current fiscal obligation time period. In the event the Government terminates the contract, the Government will not be held responsible to procure the additional inventory. In the event of component changes in any pack, the Government agrees to purchase up to a maximum thirty (30) day usage of the current pack composition before the new pack composition is shipped.

8.2. Changes to Composition/Components of Procedure Trays

8.2.1. The Charles George Medical Center may change individual component parts of the tray/pack after an initial thirty (30) days of usage. Pricing and recommended requested changes will be forwarded to the Contractor by the Facility POC. The Contractor shall be required 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. In accordance with FAR clause 52.212-4(d), changes may be made only by written agreement of the parties. Only the Contracting Officer has the authority to make changes to the contract. Changes will be made by contract modification/supplemental agreement.

8.2.2. A Pack Change Worksheet shall be utilized for all pack changes. The change form shall include all of the components, quantity and manufacturer detail for the affected pack, including added items and subtracted items. The format of this form is at the discretion of the contractor, to be approved after award or at time of use.

8.2.3. The sales representative (or equivalent) shall supply the Facility POC with the completed change form. With the agreement of the two parties, each shall sign the change form.

8.2.4. The signed change form shall be forwarded to the Contracting Officer for approval.

8.2.5. Once approved by the Contracting Officer, the Contracting Officer shall issue a contract modification/supplemental agreement; the change shall be submitted to the Contractor for the next production run of that pack.

8.2.6. The Contractor shall provide the facility with an electronic inventory report each month, which details: the number of packs on order, the current forecast, the three month average usage, the six month average usage, the number of packs per case, and the cost of the pack. Trends must be communicated between the sales representative and the Facility POC with a mutual determination to adjust inventory levels.

8.2.7. The arrangement of the component parts in the tray/pack shall be coordinated by both the designees and the Facility POC. This coordination shall be prior to production by the Contractor.

8.2.8. Substitutions of items shall not be made without prior approval, in writing, to the Facility POC and approved by the Contracting Officer via contract modification.

8.2.9. 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 with the costs of each individual component added or deleted at the time of the change or before written authorization by the Contracting Officer.

8.2.10. 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.

8.2.11. If for any reason the Contractor is unable to deliver the agreed upon packs, the contractor will provide (12) hour notice to the Facility POC. The contractor will find an alternative source and initiate a backup plan.

8.3. Contractor shall list in the spaces below the name(s) and address(s) of customer service department(s) with whom the Government will place orders. The customer service department(s) and points of contact shall also be available to act/respond in regard to pack conversions, backorder issues, additions/deletions for pack components, and site visits.

Customer Service Points of Contact
Company Name: Address: Phone No.: Fax No.: Contact Name: Email:

Company Name: Address: Phone No.: Fax No.: Contact Name: Email:

9. DELIVERY REQUIREMENTS

9.1. All deliveries are FOB Destination to the Charles George Medical Center. 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 (or "constructive placement" as defined in carrier tariffs) of the supplies to the destination. If motor carrier (including "piggyback") is used, supplies shall be delivered to truck tailgate at the unloading platform of the consignee, except when the supplies delivered meet the requirements of Item 568 of the National Motor Freight Classification for "heavy or bulky freight." When supplies meeting the requirements of the referenced Item 568 are delivered, unloading (including movement to the tailgate) shall be performed by the consignee, with

assistance from the truck driver, if requested. If the contractor uses freight forwarded for less than carload shipments, the contractor shall ensure that the carrier will furnish tailgate delivery, when required, if transfer to truck is required to complete delivery to consignee.

9.2. Pack deliveries shall be made within five (5) calendar days after receipt of order (ARO).

9.3. The contractor shall maintain, at a minimum, a 97% fill rate for all orders. Fill rates are calculated as described below. The contractor shall furnish fill rate reports quarterly to the contracting officer and the contracting officer shall independently verify the contractor's fill rate based on utilization data.

9.4. Fill-Rate Calculation. The contractor shall individually calculate the fill rate on a quarterly basis, based only on those packs ordered by the medical center, for which the contractor has been authorized to deliver. The Fill-Rate Level will be calculated as follows:

9.5. Fill Rate = Packs accepted by the Government / (Total Packs ordered – Contractual Exceptions)

10. PACKAGING

10.1. 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, except where authorized by the Facility POC.

10.2. 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 Facility POC. 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 Facility POC 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. Delivery of short-dated products may be approved as situations arise.

10.3. 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.

10.4. All outer shipping packages shall contain the complete contract number and delivery order number in addition to the shipping address.

10.5. Package content quality is the responsibility of the prime 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.

10.6. The Veterans Health Administration is currently implementing Real Time Location Services (RTLS) throughout its Medical Centers nationwide. One component of the RTLS project includes cardiac catheterization lab supplies using RFID smart cabinets. The purpose is to track those high cost items for increased supply chain visibility and track invasive supplies using a unique device identifier to associate those supplies to a patient through a direct link with our Cart-CL documentation software. The application and use of RFID may expand beyond the CATH lab in future years. Cabinets currently in use include those manufactured by WaveMark, Solstice, and Terso. Where RFID Tags are specified, tags shall be Global Standards 1 (GS1) compliant and must be available in both UHF and HF technologies, as specified by the Charles George Medical Center. Tags will be placed either on specified components or the packs, at the discretion of the ordering facility.

11. MANUFACTURING

11.1. STERILIZATION AND ASSEMBLY

11.1.1. 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:

11.1.2. The contractor shall validate the sterilization process, with the Association for Advancement of Medical Instrumentation (AAMI) at a minimum annually. The Contractor shall send the validation to the Contracting Officer within 30 days of annual inspection completion.

11.1.3. All Component debris, sterility tests, and residual tests are to be performed by contract laboratories at contractor's expense.

11.1.4. 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.

11.1.5. The Contractor shall follow current ISO (International Organization for Standardization) for Sterilization of health care product.

11.1.6. 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.

11.1.7. 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.

11.1.8. The Contractor shall not provide re-sterilization of any single use product for resale to the VA.

11.1.9. 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.

11.1.10. The contractor shall inspect all component products and also check for damage and short dates.

11.1.11. The Contractor shall have continual maintenance performed on all sterilizing equipment.

11.1.12. 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. TRAY/BUNDLE CONSTRUCTION

12.1. 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.

12.2. 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.

13. NONAVAILITILIY OF COMPONENT PARTS

13.1. Should a component part become unavailable which will temporarily or permanently delay the production of the pack(s), the Contractor shall immediately notify the Facility POC 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.

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

13.1.1.1. Complete item description, (product and lot number) and/or identification

13.1.1.2. Contract and Delivery Order

13.1.1.3. Reason for unavailability

13.1.1.4. If a direct recall was issued, the contractor shall include the manufacturer disposition instructions and level of recall.

13.2. 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 Facility POC 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.

13.3. The contractor shall notify the Facility POC 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.

13.4. 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 Facility POC. 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.

14. QUALITY ASSURANCE

14.1. 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.

14.2. "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.

14.3. 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 Facility POC.

14.4. 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 Facility POC.

15. DELIVERABLES

The following table summarizes the deliverables outlined in this Statement of Work.

Document Title	**SOW Section**	**Format**	**Frequency**
Transition Plan	SOW Section 5	Contractor's discretion	Within 30 calendar days after contract award.
AAMI Sterilization Annual Inspection Certificate	SOW Section 11	AAMI's format	Within 30 calendar days after annual inspection completion.

16. PERFORMANCE MEASURES

The following table summarizes the means by which contractor performance will be measured during the ordering period of the base IDIQ contract. Measures will be used to assess performance prior to exercising options and may be used in the submission of CPARS evaluations.

Title	Description	Metric	Note:
Order Fill-Rate	The contractor shall make delivery, on all orders under this contract, within the terms of SOW Section 8.	97% fill-rate	See SOW Section 8 for the method of calculation. Fill-Rate may be calculated at any time to verify if performance problems exist, but will likely be conducted once, annually, prior to option exercise.
Order Accuracy	The contractor shall make accurate deliveries. Accuracy is defined as delivering the correct types and quantities of bundles, as ordered.	97% accuracy of all delivered items.	This metric will be calculated as: Accurate items/(Total items delivered - Contractual Exceptions). This metric may be calculated at any time to verify if performance problems exist, but will likely be conducted once, annually, prior to option exercise.
Pack Contents Accuracy	A bundle that is missing a required component(s), by type or quantity, will be considered one inaccurate item within the ordered inventory.	97% accuracy of all delivered surgical packs.	This metric will be calculated as: Perfect Bundles/(Total bundles delivered - Contractual Exceptions). This metric may be calculated at any time to verify if performance problems exist, but will likely be conducted once, annually, prior to option exercise.

17. GOVERNMENT-FURNISHED EQUIPMENT AND PROPERTY

No Government-furnished equipment or property is provided under this contract.